Sterilization & Infection Control

What is role of the Class 6 indicator?

With a new type of sterilization monitor, the Class 6 emulating indicator, on the market, managers are asking how the new device fits into their sterilization quality assurance programs.

Two companies recently had Class 6 indicators cleared by the Food and Drug Administration for sale in the US: Steris Corp of Mentor, Ohio (Verify SixCess brand), and Steritec Products of Castle Rock, Colorado (Emugraph brand).

Managers will need to be armed with knowledge to sort out the new information and differing opinions.

A different approach

Class 6 indicators use a different approach than biological indicators (BIs), which have been used for years in sterilization monitoring. BIs are defined as having 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.

In contrast, Class 6 indicators use a chemical ink formulated to change abruptly when the indicator reaches the “stated value(s)” for that sterilization cycle. The “stated values” correspond to critical variables the sterilizer manufacturer has defined for the sterilization process.

A Class 6 indicator, for example, can be set to have a stated value of 4 minutes at 270°F (132°C), the standard dynamic air removal steam sterilization cycle, notes Lon Bruso, vice president of Steritec Products. Thus, when this Class 6 indicator shows a pass result, it means the indicator was exposed to conditions that met those parameters.

Whether that is equivalent to a sterility assurance level (SAL) of $10^{-6}$ is a question. By definition, an SAL is based on the chance that a given number of microorganisms will remain viable after being subjected to a sterilization process. Chemical indicators do not contain microorganisms.

In another difference, Class 6 indicators are designed and validated for specific sterilization cycles. In general, a different Class 6 indicator is needed for each type of cycle to be monitored. This also means Class 6 indicators can be designed to monitor the longer times needed for extended cycles, which have become more common with large, complex instrument sets. Stocking a larger number of indicators might be a challenge for managers because staff would have to be educated about the need to match the right indicator with the right cycle.

Class 5 and Class 6 indicators

How do Class 6 indicators differ from Class 5 chemical indicators (CIs), which have been on the market for some time?
Both are covered in the Association for the Advancement of Medical Instrumentation (AAMI) manufacturer standard for chemical indicators (ANSI/AAMI/ISO 11140-1:2005). The standard defines classes of indicators and performance requirements and/or test methods for CIs.

Under the standard, the response of Class 5 CIs is required to correlate to a BI at 3 times and temperatures. The response of Class 6 indicators is not required to correlate to a BI. That is an advantage or a disadvantage, depending on your point of view.

Steris says Class 6 indicators have an advantage, giving the example of a 270°F sterilization cycle, which has several variations: 3 minutes for metal or nonporous items (no lumens) in a flash sterilization cycle, 4 minutes for wrapped items in a prevacuum cycle, 10 minutes for metal items with lumens in a flash gravity cycle, and 15 minutes for a wrapped item in a gravity cycle. A Class 5 indicator, which is timed to match a BI, can indicate that 2 minutes of steam have been delivered but can’t indicate that for 3, 4, 10, or 15 minutes. A Class 6 indicator could be matched to each cycle.

On the other hand, 3M, which sells BIs and Class 5 indicators, maintains that Class 5 indicators have an advantage because, in mimicking BIs, they can detect types of sterilization process failures, such as air-steam mixtures and inadequate air removal, not detected by physical monitors or other types of CIs, including the Class 6.

3M refers to AAMI’s steam sterilization standard for health care facilities (ANSI/AAMI ST79:2006 and A1:2008), which states, “Biological monitoring provides the only direct measure of the lethality of a sterilization cycle.” Martha Young, MS, CSPT, senior technical service specialist for 3M adds: “Neither Class 5 nor Class 6 CIs contain spores and thus do not directly measure the lethality of a sterilization process.”

She adds: “Both sterilizer manufacturers and medical device manufacturers use BIs to validate their sterilizers and devices to ensure there is sufficient lethality to produce the desired sterility assurance level (SAL) for the device, typically 10^-6. CIs cannot be used to determine the SAL.”

Role in sterilization monitoring?

What role would Class 6 indicators play in current sterilization monitoring? Professional guidelines do not yet address this question, and opinions differ.

Bruso of Steritec Products says Class 6 indicators can monitor that the sterilization process met conditions beyond the 2 minutes where BIs are typically killed, as in the full 4-minute 270°F steam cycle.

But Chuck Hughes of SPS Medical, an independent lab that conducts validation testing for sterilizer and medical device manufacturers, questions whether that higher degree of resistance means a Class 6 indicator is better than a BI. SPS Medical also makes BIs and Class 5 indicators.

“I would throw out the question: ‘Do we need something more resistant than the BI or Class 5 indicators, which are cleared by the FDA as equal to a BI?’” Hughes says.

He notes that 1 to 2 minutes of saturated steam is what is needed to kill the most resistant microorganisms, as presented by a BI. He says the 4-minute cycle actually is 100% overkill beyond what is needed to kill a BI, which is a requirement of the FDA.

“There is no question that you can make a chemical indicator more difficult to pass than a biological indicator,” Hughes says. “But is more resistant
better?” He adds, “The only value I see in that is in monitoring a prion cycle,” which is an extended cycle of 18 minutes at 270° F in a prevacuum sterilizer. Currently, indicators are not available in the US for prion cycles.

He maintains that users looking for the convenience of a CI that is as accurate as a BI but that does not require incubation can use Class 5 indicators, as recommended by AORN and AAMI ST79.

**Monitoring extended cycles**

An area where Class 6 indicators might be helpful is for monitoring sterilization cycles, such as extended cycles of 8 minutes or 20 minutes at 270° F.

“It would be nice to have a Class 6 indicator that is cycle specific for some of these extended cycles,” says Cynthia Spry, RN, MSN, CNOR, an independent consultant.

A drawback is that extended cycles have not been standardized. Under FDA rules, indicators can be released only for currently validated cycle parameters. These are not necessarily the same as some of the manufacturers’ extended cycles.

Manufacturers have been working with the FDA to resolve this issue. AAMI has a new technical information report that addresses extended cycles titled *Process Challenge Devices/Test Packs for Use in Health Care Facilities* (TIR31). The report requests that manufacturers standardize their cycles, which would allow indicators to be developed for those cycles.

“Class 6 emulating indicators lend themselves perfectly to extended cycles,” says Richard Schule, MBA, FCS, FAST, director of clinical education for Steris. “The goal of extended cycles is to lengthen the exposure of complex sets or devices, allowing every surface to contact steam.” He said a Class 6 indicator can demonstrate that the sterilizer achieved these conditions, adding that Class 6 indicators are the “only indicators capable of targeting the specific exposure time requirements for extended cycles.”

Hughes says he does not think Class 6 indicators are necessary for monitoring extended cycles. The issue, he says, is making sure the BIs and Class 5 indicators are in the right locations in the tray; that is, where the steam is least likely to penetrate. The purpose is to verify that all of the tray’s nooks and crannies are exposed to 2 minutes of saturated steam.

The reason for extended cycles, Hughes says, is that when a company is validating a tray for sterilization, the process may take 5 minutes or more to ensure steam has reached all parts of the tray. Under the FDA’s overkill requirements, the cycle must then be doubled to 10 minutes for the FDA to clear the tray for marketing.

Hughes says, in his view, steam penetration can be monitored by locating BIs and Class 5 indicators in the hardest-to-reach areas of the tray.

**Load release**

The burning question is whether Class 6 can be used for the release of sterilizer loads containing implants. Current professional guidelines recommend use of a BI for every load containing an implant, with items quarantined until the BI result is negative. It is also recommended that a Class 5 indicator be used within the BI process challenge device. The guidelines include those from AORN, AAMI (AAMI ST79), and the Centers for Disease Control and Prevention (CDC).

Information from Steris says its Class 6 indicators “may be used to release all loads.” That creates a quandary for OR and central services (CS) managers.
Standards and guidelines

Managers rely on professional guidelines in setting policies for sterilization monitoring. The Joint Commission’s infection control standards (IC.02.02.01) require hospitals to use reprocessing methods “consistent with regulatory and professional standards.”

AORN, AAMI ST79, and the CDC’s newly revised Guideline for Disinfection and Sterilization in Healthcare Facilities do not yet address the Class 6 indicator.

AAMI’s steam sterilization hospital practices working group is waiting for published scientific evidence before providing guidance on the Class 6 in AAMI ST79, says Spry, the working group’s cochair.

To date, independent published research on the Class 6 indicator is lacking.

“A Class 6 emulating indicator is not a BI. They both have application,” Spry says. “The question is, what is the most appropriate use in the US market?” Class 6 indicators have been used in some European countries, most notably in France, where all steam cycles are 18 minutes. Class 6 indicators are available in Europe to match the 18-minute prion cycle.

Like AORN and AAMI ST79, the CDC guideline continues to recommend monitoring with a BI for every load with implants, quarantining the items whenever possible until the BI is negative. The guideline was finished before the Class 6 indicators entered the market.

In a comment to OR Manager, the CDC guideline’s senior author, William Rutala, PhD, MPH, said Class 6 indicators “are not a substitute for a biological indicator.” He added: “No professional organization has recommended the use of Class 6 emulating indicators as a substitute for biological indicators, and there are no data (to include our own data) that demonstrate that a Class 6 indicator mimics a biological indicator at suboptimal sterilization times.” He has completed a study that has not yet been published.

How to proceed?

Until more evidence is available, Spry suggests that managers can use the AORN Recommended Practices for Product Selection in Perioperative Practice Settings as a framework for decision making. The recommended practices outline a general process for product selection.

OR and central service managers interviewed by OR Manager say they are interested in the new Class 6 indicator technology but find the competing claims confusing. They say they would like to see published scientific evidence on the Class 6. They also are waiting for guidance from the professional standards, though these can take years to be updated.

—Pat Patterson

References

