

Sterilization & Infection Control

Using biological indicators appropriately

Biological monitoring is the cornerstone of your sterilization quality assurance program. What's the right way to use biological indicators (BIs)? What's their role in load release? And how are they used in conjunction with chemical indicators?

OR Manager posed frequently asked questions to Cynthia Spry, RN, MA, MSN, CNOR, cochair of the working group that recently issued a comprehensive update to the steam sterilization standard from the Association for the Advancement of Medical Instrumentation (AAMI). The new edition of the *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities* (ANSI/AAMI ST79) was published in Fall 2006.

Q What is the difference between a biological and a chemical indicator? Why do we need to use both?

Spry: Sterilization indicators, which are actually quality monitors, provide information to let you know a sterilizer is working as it should be. They also give some assurance that the sterilization process has been appropriate and safe for the patient.

BIs and chemical indicators (CIs) both give important information. A sterilization cycle has certain parameters that must be achieved for sterilization to occur, such as a specific temperature that must be reached for a specific amount of exposure time.

A BI, which contains live organisms with a known resistance to the sterilization process, is the only monitor that measures the lethality of the sterilization process.

In contrast, a CI tests whether one or more parameters within the sterilizer have been met or missed. The easiest example is a Class 1 CI, which simply tells you there's been exposure to the sterilant.

The key concept is that all of these indicators have different purposes—one is not better than the other. CIs give you results immediately. BIs must be incubated to see if the spores germinate and grow, which, depending on the type used, can take a significant amount of time. Most facilities do not have enough instrument inventory to hold their items until the BI incubates. CIs can give some assurance that the items are probably sterile. If all indicators produce the results they are supposed to produce, there is a probability, though it is a high probability, that your items are sterile.

But remember: No matter what happens with these indicators, they do not guarantee that the items in the sterilization load have become sterile. It's the whole process, including decontamination, cleaning, pack preparation, sterilization, and quality monitoring, that determines whether the items in a load will be sterile.

Q What is the difference between using the conventional BI and the early readout BI? I have heard they are now considered equivalent. Is that correct?

Spry: They are both BIs. There is not a special category for early readout BIs. The early readout BI provides a result based on an enzyme reaction and provides results in a relatively short time. The early readout BI also contains spores, and you can choose to incubate it if you want additional information. Users like the early readout BI because the enzyme readout and the fully incubated readout are highly correlated—if one is negative, the other should also be negative.

Sterilization process monitoring recommendations

Routine load release

Nonimplants	Implants
Physical monitoring of cycle	Physical monitoring of cycle
External and internal chemical monitoring of packages	External and internal chemical monitoring of packages
Optional monitoring of the load with a process challenge device (PCD) containing one of the following: <ul style="list-style-type: none"> • a biological indicator (BI) • a BI and a Class 5 integrating indicator • a BI and an enzyme-only indicator • a Class 5 integrating indicator • an enzyme-only indicator. 	Monitoring of every load with: <ul style="list-style-type: none"> • a PCD containing a BI and a Class 5 integrating indicator or • a PCD containing a BI and an enzyme-only indicator.

Note: A process challenge device is an item designed to constitute a defined resistance to a sterilization process and used to assess performance of the process.

Source: Association for the Advancement of Medical Instrumentation. Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities. ANSI/AAMI ST 79: 2006, p 81. Section of Table 7. Reprinted with permission.

For reassurance, most facilities elect to grow out the early readout BI from time to time. It is up to the facility to determine how often to do this. Some do it every time they run a load; others do it occasionally. The AAMI standard is not prescriptive about how often to do this. It's up to the user to confer with the manufacturer to determine how to use the product.

Q What is AAMI's recommendation on using BIs for routine load release?

Spry: You don't have to use a BI for routine load release in a load that doesn't contain an implant—it's optional. AAMI says optional monitoring of a non-implant load includes a PCD (process challenge device) with one of the following:

- a BI
- a BI and a Class 5 integrating indicator
- a BI and an enzyme-only indicator
- a Class 5 integrating indicator
- an enzyme-only indicator.

Though monitoring is optional, it's common practice for facilities to monitor with a BI often. One issue is that if you have a recall, you must go back to your last negative BI. If you haven't done any monitoring with a BI in a while, you may have a lot of loads that you will need to recall. So monitoring more often is better than less often.

Q What is the recommendation for monitoring loads with implants?

Spry: If you have a load with implants, use of a BI is *not* optional. AAMI recommends that every load with an implant be monitored with a PCD containing:

- a BI and a Class 5 integrating indicator or
- a BI and an enzyme-only indicator.

Both AAMI and AORN strongly recommend that you should not release an implant until results of the BI are known.

The benefit of using the Class 5 indicator or an enzyme-only indicator is that you get some information immediately. A Class 5 integrating indicator is a very good tool. I personally think it would be nice to use a Class 5 in every pack because it gives you much more information than a Class 1 indicator. But a Class 5 integrator is more expensive than a Class 1 indicator, so many hospitals use a Class 1 rather than a Class 5 in every pack.

Q What if a surgeon insists on having an implant released before the BI result is known?

Spry: AAMI has very strong wording to say that releasing implants before the BI results are known is unacceptable and should be the exception, not the rule. AAMI recommends developing a guidance defining emergency situations and taking steps to reduce the frequency of these emergencies. If there is an emergency, and an implant must be released before the BI results are known:

- The release should be documented.
- The BI result obtained later should also be documented.
- The documentation should be fully traceable to the patient, for example, by recording the sterilizer load number on the patient chart or recording the patient name on the load record.

AAMI provides a sample form for documenting these exceptions (Annex L). Exceptions should be reviewed to see if there are patterns. Why did this happen? How often does it happen? Is it occurring in a particular specialty or with a particular surgeon? Then look at the patterns to see what needs to be corrected to prevent these situations.

Q Does AAMI define an implant?

Spry: AAMI refers to the Food and Drug Administration's definition, which says an implant is a device placed into a surgically or naturally formed cavity of the human body that is intended to remain there for a period of 30 days or more. By that definition, orthopedic screws would be implants, and processing of these is a major concern of mine. I know not all facilities process screws as if they are implants. I have seen some flash sterilized, which is specifically not recommended for implants.

In some instances, a screw that has been on the table but not used is placed back in the rack, and the rack is flash sterilized without proper decontamination. I think people need to think about their practice in this regard. I would also like to see these screws supplied sterile from the manufacturer. I remember a time when hip prostheses were routinely processed in the hospital. Now they are commercially sterilized. I would like to see the same thing for all plates and screws.

Q What does AAMI recommend for biological testing of steam sterilizers?

Spry: AAMI suggests doing routine sterilizer efficacy monitoring weekly, preferably daily, with a full load, using a PCD containing a BI. The PCD may also contain a CI. In flash sterilizers, monitoring is done in an empty chamber.

Q Can you suggest any tools we can use to help educate the staff about AAMI's monitoring recommendations?

Spry: Get the AAMI ST79 standard and turn to pages 81-82. There you will find Tables 7 and 8, which summarize the monitoring recommendations. These tables tell you specifically what monitoring to do for load release and for efficacy testing of your sterilizers. You'll want to keep them handy for easy reference.

Sterilization today requires a significant knowledge base. It used to be we had

only steam and ethylene oxide. Now we have not only steam but different kinds of steam; we have hydrogen peroxide, gas plasma, and liquid sterilization. Instruments are also much more complex, we know more about infection, and we know the implications of infections with implants.

You should not be operating a sterilizer or processing instruments unless you're clear about what needs to be done and what kind of indicator is appropriate. Users really need to stay on top of this. ❖

The AAMI ST79 standard is available from AAMI at <http://marketplace.aami.org/>. The price is \$200 (\$100 for AAMI members).