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Supervisory Continuing Education (SCE) lessons provide members with ongoing education focusing on supervisory or management issues. These lessons are designed for CHL re-certification, but can be of value to any CRCST in a management or supervisory role.

LEARNING OBJECTIVES
1. Discuss biological monitoring requirements
2. Explain how biological indicators impact total process time, load capacity and departmental productivity
3. Describe how to balance sterilization productivity with patient and hospital risks

SELECTING BIOLOGICAL INDICATORS TO BALANCE PRODUCTIVITY AND RISK

It’s 3 p.m. on a Sunday afternoon. The city is quiet and you’re standing on the corner, ready to cross the road. The crosswalk signal says, “don’t go,” but you’re sure you can cross the road before that one oncoming car gets to the intersection. Do you wait for the signal to change? Many people wouldn’t. Why waste the time waiting when you can make it across now? In the moment, they forget about various other risks. They could trip and fall over something unseen in the road or drop a cell phone in the crosswalk and be forced to stop to retrieve it. They might not know that a car parked nearby is about to move into the intersection. Most of the time, these events don’t happen, but it only takes one time to cause an avoidable costly tragedy.

Biological indicators (BIs) are the crosswalk signals of sterilization. They guard against the unseen and unexpected events that may result in serious harm to a patient. Often, they are seen as unnecessary and redundant, or as roadblocks that delay the completion of work; however, newer technologies are offering the opportunity to change these perceptions and improve the department’s sterility assurance program.

Objective 1: Discuss biological monitoring requirements
Sterilizing medical instruments to reduce infection risk has been a standard of practice since Ernst von Bergmann issued the first recommendation to steam sterilize surgical instruments in 1885. In the 1970s, Central Service/Sterile Processing (CS/SP) experts gained a better understanding of sterilization process modalities and the functions that can go wrong within them, and biological monitoring became an important addition to the process. Today, every sterilization modality has a sterility assurance requirement that includes biological monitoring. Each requirement is based on the standards for that specific process.

Several different sterilization
The first requirement uses BIs within an appropriate challenge pack or process challenge device (PCD) to qualify sterilizer equipment after installation and before its first use, or to requalify it if it has been relocated, has undergone major repairs, or has had a sterilization failure event. Challenge packs are specifically designed for each modality and, in some cases, for specific cycles.

The second biological monitoring requirement uses PCDs to verify the microbial efficacy of the sterilization equipment when cycles are run. For these tests, the BI challenge packs are placed within a loaded sterilizer chamber. At the end of the cycle, any implant load that contains a BI is not released for use until the BI test result is known.\(^1\)

The frequency of testing depends on the sterilization process (see Table 1).

In addition to requiring different use frequencies, each sterilization modality requires a different type of BI and PCD. Two different bacterial endospores are used to construct BIs for these applications: Geobacillus stearothermophilus for steam and VHP sterilization; and Bacillus atrophaeus for EtO. Each organism has proven resistance to the specified sterilization process. The sterilizer’s ability to kill or deactivate organisms in a load is demonstrated by killing the endospores in the BIs.

Endospores are not visible to the human eye, so confirming their death requires an incubation process that allows the by-products of cellular life to become visible to the human eye or to a special reader. The amount of time required for a positive result (organisms are still alive, so the sterilization process has failed) to be detected depends on several factors, including the endospore

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### Table 1: Frequency of routine biological indicator testing for three common sterilization platforms

<table>
<thead>
<tr>
<th>Sterilization Process</th>
<th>AAMI Standard</th>
<th>Frequency of Load Monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steam</td>
<td>ANSI/AAMI ST79:2017</td>
<td>○ Weekly, preferably daily ○ With every load containing an implantable device</td>
</tr>
<tr>
<td>EtO</td>
<td>ANSI/AAMI ST14:2008</td>
<td>○ Every sterilization cycle</td>
</tr>
<tr>
<td>VHP</td>
<td>ANSI/AAMI ST58:2013</td>
<td>○ Daily, preferably every sterilization cycle ○ With every load containing an implantable device</td>
</tr>
</tbody>
</table>

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### Table 2: Incubation times for currently available biological indicators

<table>
<thead>
<tr>
<th>Sterilization Process</th>
<th>Type of BI/Detection System</th>
<th>Final Read Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steam</td>
<td>Traditional BI with pH indicator</td>
<td>24 hours</td>
</tr>
<tr>
<td></td>
<td>Traditional BI with pH indicator and spectrophotometric reader</td>
<td>10 hours</td>
</tr>
<tr>
<td>EtO</td>
<td>Fast acting BI with enzymatic activity detection</td>
<td>20 minutes</td>
</tr>
<tr>
<td></td>
<td>Traditional BI with pH indicator</td>
<td>48 hours</td>
</tr>
<tr>
<td></td>
<td>Fast acting BI with enzymatic activity detection</td>
<td>4 hours</td>
</tr>
<tr>
<td>VHP</td>
<td>Traditional BI with pH indicator</td>
<td>24 hours</td>
</tr>
<tr>
<td></td>
<td>Fast acting BI with enzymatic activity detection</td>
<td>20 minutes</td>
</tr>
</tbody>
</table>
species, the sterilization process, and the detection system being used. The response time can range from 20 minutes to 48 hours (see Table 2).

Regardless of the process used, after the sterilization cycle is completed, the BI must be incubated. Loads containing implants cannot be released for use until incubation is complete and a negative result is documented; thus, the incubation time adds to the total time required to release the load and impacts the total sterilization process time.

**Objective 2: Explain how biological indicators impact total process time, load capacity and departmental productivity**

A sterilization process is segmented into three workflow segments: loading, sterilization and load release. Including a PCD in the load at the beginning of the loading function does not affect the time to load the sterilizer, nor does it change the required sterilization parameters or cycle time; however PCDs containing BIs can lengthen the time required to release the load for storage or use.

To release a sterilization load, three things are examined:

1. **Cycle printout:** Were the cycle parameters achieved and was the correct cycle used?
2. **Visible chemical indicators (CIs):** Are the CI tape, data cards and/or any CI strips visible through the packaging indicating a “passing” result (negative for growth)?
3. **BIs in an implant load:** Are they negative for growth?

The cycle printout takes a minute or two to check. CIs are observed as items from the load are moved out of the sterilizer to storage areas. These steps do not add significant time to the overall process.

BIs are a different story. Before the load containing a BI is released, the BI should be placed in the incubator. For implant loads, the BI must be negative for growth. BI incubation times range from 20 minutes to two days. The choice of BI product can have a significant impact on the time it takes to release each load and ultimately, on the overall productivity of the department.

Although BIs can lead to longer release times, they are not the only cause. Additional conditions may need to be met before a sterilization load is released. For example, steam sterilization yields very hot items, often more than 250°F, so the load must be cooled before it can be released. This can take an hour or more.

![Figure 1: Load release timeline for two BI final read times](Image)

**Figure 1: Load release timeline for two BI final read times**

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**Impact of biological monitoring on load capacity**

Items are placed into sterilizers on shelves or in baskets. The load’s configuration is balanced to allow the maximum quantity of packs to be sterilized in a single cycle. To properly monitor each load, the PCD must be placed in the load, but not
immediately on or under any of the load items. Some PCDs require significant space on a sterilizer shelf, or a specific placement within the sterilizer that prevents that shelf space from being used to hold an item for sterilization. The loss of that sterilization space impacts load volume to differing degrees.

Figure 2 shows the number of packs that four different steam sterilizers can process at one time. They range from 3 packs in a small sterilizer to 25 packs in a floor loading sterilizer. Removing one pack and replacing it with a PCD in a floor-loading sterilizer reduces its instrument load volume by 4%. However, if one pack is replaced by a PCD within the small steam sterilizer, the load volume is reduced by 33%, which is a significant reduction in productivity per load.

Benefits of standardization
If a department’s PCD use frequency was only based on productivity and compliance to guidelines, healthcare facilities would follow the minimum usage recommendations of the standards. However, many infection prevention, risk management and CS/SP teams determine the number of PCDs to use by implementing standardized practices that can minimize costly errors, while also addressing potential risks to patients and hospitals.

The more choices and variations in a process, the higher the probability that an error is made. Missing a PCD test can lead to audit findings from inspectors and accrediting bodies. Fines and the loss of accreditation have a financial impact on the hospital. These potential costs are much greater than the costs associated with standardizing to a higher usage rate. For example, a facility with both VHP and steam sterilizers may choose to standardize their practice to the higher usage requirement of the VHP sterilizer (as shown in Table 1).

Another PCD-related risk has to do with sterilization of implantable devices. Implants are classified as high-risk devices since they are inserted inside the patient, and they are a focus for many agencies during inspections. To prevent accidentally omitting a PCD with a load containing an implantable device, many facilities will test every cycle with a PCD.

Objective 3: Describe how to balance sterilization productivity with patient and hospital risks
When a BI is positive, it indicates that the conditions for sterilization were not achieved within the sterilizer. A high probability exists that the devices within the load are not sterile. A patient exposed to a non-sterile device may become infected. An infection has serious ramifications and may even cause death.

When a positive BI is identified, none of the items in the load can be used. An investigation is completed to determine why it occurred. Part of that investigation is to discover when it happened. If a department is performing daily or weekly PCD tests, there may be several cycles processed between tests. Without a PCD in those loads, it may not be possible to know exactly when the problem started, so all released items from loads processed between the last passing BI and the failing BI must be assumed to be non-sterile. This has a large impact on productivity because now hundreds or even thousands of items must be returned to sterile processing to be reprocessed. This could also lead to device or set shortages and potential surgery and procedure delays.

Note: If appropriate laboratory testing of the positive BI shows a false positive the retrieval of all items may be discontinued and the documentation should reflect the false positive testing.

In addition, patients may have been
exposed to items from these questionable loads. They must be notified and monitored to ensure that they do not become infected as a result and suffer the mental anguish of waiting to see if they become infected.

The decreased productivity and the risk of patient harm from delayed procedures and infections must also be considered. The best practice to eliminate this risk is to test every sterilization load.

FABIs have been shown to improve productivity when departments want to increase the use of PCDs. The greatest improvement in productivity occurs when a facility moves from a traditional BI (24–48 hour read times) to a FABI (four hours or less). Release times are reduced by 88% or more (see Table 3).

FABIs have also decreased the time associated with test result documentation. Many of the newer electronic incubators and growth-detecting readers can communicate to electronic documentation systems. Automation enhances standardization while also decreasing the monitoring workload on technicians. This allows them to proceed with other work in the department.

Conclusion
Every healthcare sterilization process requires a careful balancing of risk and benefit. The more productive a sterile processing department can be every day, the better it can support the surgical department and their patients. But optimal productivity must always include considerations for patient safety and risk management. Monitoring with FABIs may be a solution because provide the opportunity to increase standardization by enabling biological monitoring in every load. FABIs can instill greater confidence in every load release while also minimizing the time impact on productivity. Finally, FABI monitoring in every load eliminates the risk of potential consequences from performing only the minimum required testing, and this can ultimately contribute to better patient care and improved hospital reputation.

REFERENCES
1. Association for the Advancement of Medical Instrumentation. ANSI/AAMI ST79: 2017, 13.3.2 and 13.6.3.
2. Association for the Advancement of Medical Instrumentation. ANSI/AAMI ST79: 2017, 13.7.5.1 d.

<table>
<thead>
<tr>
<th>STERILIZATION PROCESS</th>
<th>TYPICAL TRADITIONAL BI FINAL READ TIMES</th>
<th>TYPICAL FAST ACTING BI FINAL READ TIMES</th>
<th>TIME SAVINGS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steam</td>
<td>24 hours</td>
<td>3 hours</td>
<td>88% (8 times faster)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>20 minutes</td>
<td>98% (72 times faster)</td>
</tr>
<tr>
<td>Eto</td>
<td>48 hours</td>
<td>4 hours</td>
<td>92% (12 times faster)</td>
</tr>
<tr>
<td>VHP</td>
<td>24 hours</td>
<td>20 minutes</td>
<td>98% (72 times faster)</td>
</tr>
</tbody>
</table>

Table 3: Time savings from fast-acting biological indicators