What do we look for daily but don’t really want to find? Positive BIs

by Rose Seavey, RN, MBA, CNOR, ACSP

No one is pleased to see a positive Biological Indicator (BI). When it occurs, it requires a lot of time and effort to take the appropriate steps to determine the cause of the problem.

However, a positive biological indicator is telling you something important. Items in the load may not be sterile and patients may be at risk. The sterilizer, the load, the cycle or operator may be the cause of the problem.

The purpose of biological monitoring is to document the efficacy of specific sterilization cycles. Sterilization process validation documents with a high degree of assurance that a specific process was produced meeting predetermined specifications and quality characteristics. The sterilization cycle is designed to kill all microorganisms by mid-point of the cycle. This is called the overkill cycle, wherein the processes challenged with BIs at sterilization times that are equal to or less than half of the full cycle. Half cycle is used because the exact amount of microbial resistance or numbers of microorganisms on the product(s) are not always known. As a result, the full cycle is considered acceptable when the BIs are killed or numbers of microorganisms on the product(s) are not always known. As a result, the full cycle is considered acceptable when the BIs are killed.

A BI enables the user to determine whether items have been subjected to all of the conditions necessary for sterilization. A positive BI is doing its job – signaling that organisms were able to survive the sterilization process.

The condition of the sterilizer equipment, the skill of the sterilizer operator, and other aspects determining the success or failure of a steam sterilization cycle could vary from one cycle to another.

Condition of sterilizer

In order to detect malfunctions as soon as possible, physical monitoring of the sterilizer is necessary. These displays, digital printouts and/or gages tell us what the sterilization cycle conditions are in real-time. Prior to items being removed from the sterilizer, the operator should review the physical monitors, time, temperature, and pressure recorders to see if they match the desired cycle conditions.

If all of the identified parameters are not met, the department head or designee should be notified. If the problem cannot be corrected immediately, the load should be considered un-sterile and the sterilizer must be removed from service until a service or maintenance person corrects the problem.

While physical monitoring information can be very useful and provides an immediate indication of a problem, it does not necessarily reflect the conditions inside each pack. Mass, density and packaging differences can and do reflect the conditions inside each pack. Mass, density and packaging differences can and do result in a range of heat-up times not reflected in readings. Pressure gauges do not detect steam quality problems or the presence of air. Temperature readings do not indicate superheated steam conditions that can be generated within individual packs. Physical monitoring information provides an important piece of information.
to the sterilizer operator. It should be reviewed as soon as possible but not relied upon solely.

Utilities
When positive BI results are detected, it is easy to overlook the possibility that the problem may be related to changes in the steam or water systems. Fluctuations in steam that result in "hick-ups" in steam quality can result in occasional positive BIs. These can be especially difficult and frustrating to troubleshoot. Likewise, fluctuations in water pressure can occur due to construction or demands when multiple locations are drawing water at the same time. If water pressure falls below a required level because the kitchen and laundry place a demand for water at the same time the Sterile Processing department is using instrument washers, cart washers and multiple sterilizers, it can result in inefficient air removal. The possibility of these types of problems is often overlooked when troubleshooting positive BIs.

When work is performed on the steam or water system, sterilization departments should be notified, even if notification is retroactive due to an emergency repair that was performed at night or over a weekend. This will alert sterilization professionals of potential problems and aid in investigating positive BI results if they occur.

Processing personnel
Personnel assigned to sterilization responsibilities must be qualified to do so. Operating sterilizers is a science and it takes detailed training to know and understand related principles and practices. Operator qualifications should be demonstrated and documented in regard to: 1. Operation of each specific sterilizer system they are responsible for operating, and 2. Principles of sterilization and infection control, to include decontamination, inspection, packaging, sterilization procedures, equipment operation and safety precautions.

The possibility of operator error during preparation and sterilization processing can be reduced with proper orientation, on-the-job training and frequent in-services.

It has been suggested by many that all staff operating sterilizers be certified as a stipulation of employment, or at the very least, become certified by their second year of service.

Load configuration
Procedures describing load contents and placement configurations should be developed and followed. It is important to follow the manufacturer's written instructions carefully because sterilizers differ in design and operation.

As workloads increase over time, it is not uncommon for load sizes to also increase to keep up with the demand. The load capacity of a particular sterilizer design may be exceeded without realizing it and result in occasional positive BIs. Sterilizer manufacturers should provide load capacity specifications.

Items that require the same exposure time/temperature, cycle drying and/or cool down time, may be processed together. Things to consider when loading a sterilizer include: adequate air removal, adequate penetration of steam into each package, and steam evacuation. Items such as basins and trays that may hold water should be positioned in the direction that will allow condensation to be eliminated. Metal items should be placed below textile items. There are specific ways to load a sterilizer relating to load contents. Specific recommendations can be found in AAMI's Steam sterilization and sterility assurance in health care facilities. ANSI/AAMI ST 46, 5.7, 2002p33-34

Cycles
Different cycle conditions may be required for different types of loads. With diverse instrumentation it is becoming more challenging to match cycle conditions to load requirements. Differences in sterilization processes [which includes equipment, utilities such as steam and water, load sizes, loading technique and added packaging] can also all affect required sterilization times. Each time a change is made to contents or packaging, verification testing should be performed to assure that sterilization conditions are being attained. Selecting the correct cycle for the load is becoming more complicated and challenging.

Rigid containers
Various container systems have minimum recommended sterilization times listed. Recommended parameters should be tested with biological and chemical indicators placed inside these containers in the most difficult location to achieve sterilization conditions.

A new products are added to instrument sets or changes are made to packaging, such as the addition of an over-wrap or internal containers, verification testing should be performed to assure that sterilization conditions are being attained inside the pack or container.

Specific container systems may be designed for specific types of cycles. It is important to check with the manufacturer to identify any sterilization limitations that may exist. Drying time recommendations may also be different for various types of containers. Condensate may be sterile while the pack is still in the sterilizer but during handling it can act as a transport mechanism for microbes and result in contamination.

Recall process
The recall process involves decision making responsibilities from a multidisciplinary group of healthcare workers, depending on the extent of the sterilization process.

If a BI tests positive, several steps need to take place. The first step is to report it immediately to the appropriate supervisor and the infection control department. This notification should be placed in writing. The report should include: 1. The time and date of the questionable sterilizer cycle; 2. A description of the sterilizer and load, with reference to the appropriate lot control number; 3. The results of physical and mechanical monitoring and internal chemical indicators (if applicable) as obtained from the user departments; and 4. Any other information that could be useful in determining whether the report is valid or questionable due to human error.

Following a sterilization failure, devices processed in that machine, dating from the sterilization cycle failure to the last negative BI, should not be considered sterile. If possible, these items should be retrieved, and reprocessed.

After the cause of the sterilization failure is determined and corrected, the sterilizer in question must be immediately re-challenged in three consecutive empty-chamber cycles. Until the results of retesting are satisfactory, the performance of the sterilizer must be considered in question.

When there is evidence of a sterilization failure, the infection control officer should be notified, so that follow-up surveillance of patients can be conducted.

Summary
Positive biological indicators, BIs, are something sterilization professionals would prefer not to detect during routine monitoring. A much work as they create, a positive BI that prevents a patient infection is worth its weight in gold. Positive BIs can be the result of many circumstances.
Some are within control and can be prevented, others cannot. Troubleshooting positive BIs can be challenging due to the many potential causes but determining the reason is crucial to protecting patients.

References
1. Association for the Advancement of Medical Instrumentation. Steam sterilization and sterility assurance in health care facilities. ANSI/AAMI ST46, 2002, p50
2. Ibid, p44
3. Ibid, 44
5. Association for the Advancement of Medical Instrumentation. Steam sterilization and sterility assurance in health care facilities. ANSI/AAMI ST46, 2002, p41
6. Ibid, p18
7. Ibid, p50

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Circle the one correct answer

1. A BI demonstrates the ability of the sterilizer to effectively kill microorganisms.
   A. True
   B. False

2. Success or failure of a steam sterilization process does not vary from one cycle to another.
   A. True
   B. False

3. It is not necessary to monitor the function of the sterilizer as they are always reliable.
   A. True
   B. False

4. Changes in the steam, water system or supply can affect the sterilization cycle.
   A. True
   B. False

5. Possibility of operator error during preparation and processing can be reduced with the proper orientation, on-the-job training and in-services.
   A. True
   B. False

6. BIs should be used for verification testing following changes made to contents or packaging.
   A. True
   B. False

7. After detection of a sterilization failure, the sterilizer must be tested in three consecutive empty-chamber cycles.
   A. True
   B. False

8. A positive BI provides important information about the sterilization cycle.
   A. True
   B. False

9. A positive biological indicator means that items in the load have been properly sterilized.
   A. True
   B. False

10. Physical monitoring does not necessarily reflect the conditions inside each pack.
    A. True
    B. False

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