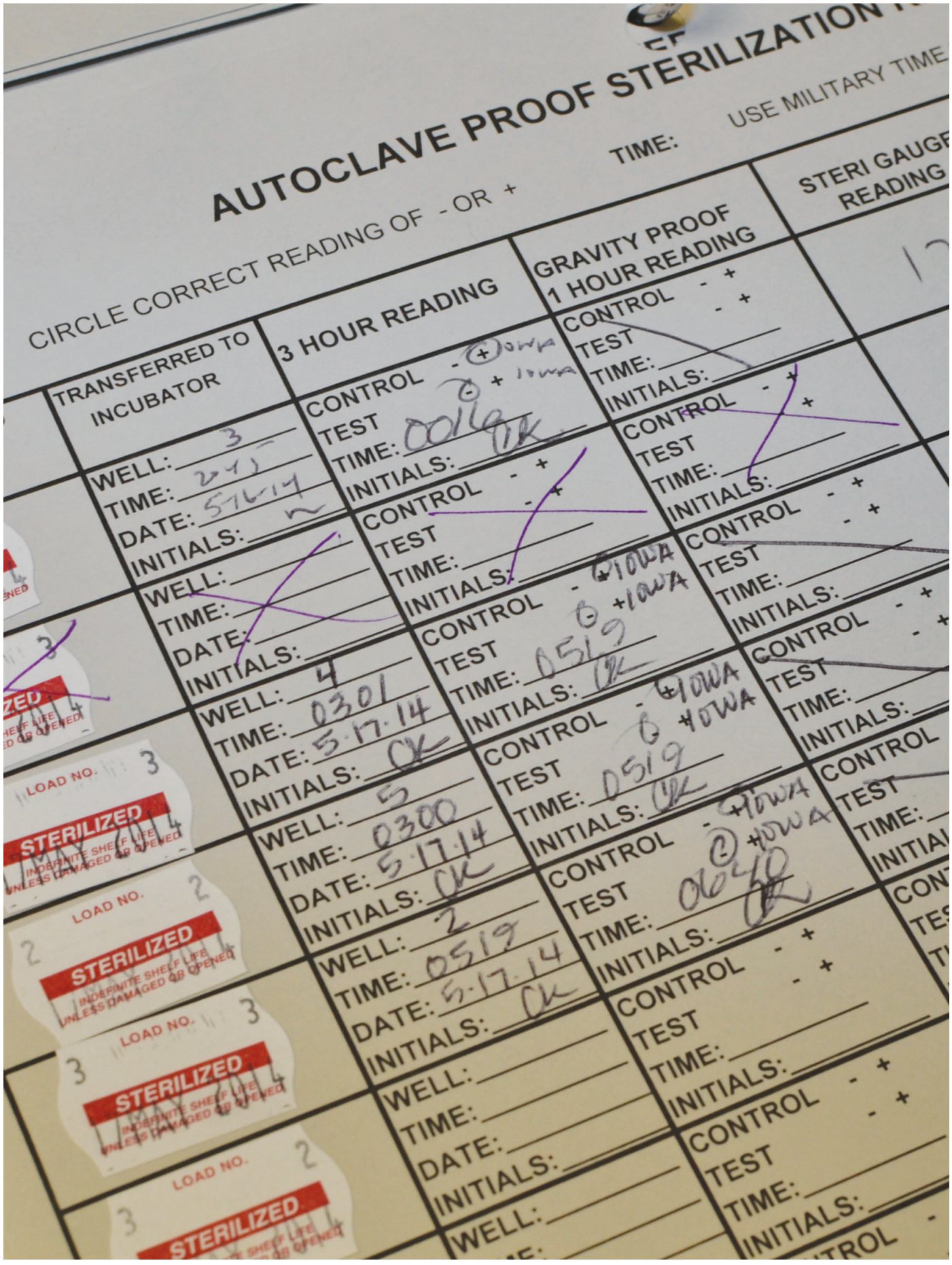
AUTOCLAVE PROOF STERILIZATION
TIME:
USE MILITARY TIME
CIRCLE CORRECT READING OF - OR +
TRANSFERRED TO INCUBATOR
3 HOUR READING
GRAVITY PROOF 1 HOUR READING
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CONTROL
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TIME:
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IOWA
OK
LOAD NO.
STERILIZED
INDEFINITE SHELF LIFE UNLESS DAMAGED OR OPENED

CRCST SELF-STUDY LESSON PLAN
Lesson No. CRCST 172 (Technical Continuing Education - TCE)

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The Science of Speed – Today's Rapid Readout BIs

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LEARNING OBJECTIVES
1. Describe the design and function of biological indicators
2. Understand how rapid readout biological indicator systems work
3. Discuss the recommended uses of biological indicators for sterilization monitoring

Biological indicators (BIs) are an important part of a quality control system for hospital sterilization processes. Information about the quality of the sterilization process supplied by BIs, when combined with the information from physical monitors and chemical indicators, provides the basis for the decision on whether to release the medical devices for use on patients.

Objective 1: Describe the design and function of biological indicators

BIs are defined as a test system containing viable microorganisms providing a defined resistance to a specified sterilization process.[1] A key point in this definition is "viable microorganisms," as BIs are the only sterilization monitoring tools that directly test the effect of the sterilization process on microorganisms.

When discussing BIs, it's important to gain a better understanding of microbiology. A few types of bacteria have developed the ability to change from an active, growing cell (vegetative cell) to a highly-protected, dormant cell (spore), and back again, depending on their environment. The spore itself is like a seed; it is dormant (or "sleeping"), has a highly protective dry shell, and is capable of withstanding extreme conditions for prolonged periods of time. If the spore senses that conditions will now support life, it goes through a series of biological "start-up" steps (called activation and germination) to once again become a regular, active bacterial cell. BIs use the spore form of Bacillus bacteria because of the toughness of these spores and the challenge they present to the sterilization process. The spores in all BIs require incubation, during which time the spores are exposed to the growth media and the BI is heated to the optimum temperature for spore outgrowth. Any surviving spores will activate and germinate to become vegetative cells, and then these cells will begin to grow, which means they will replicate (one becomes two, two become four, etc.).

The incubation time for a BI is the amount of time that the BI must be incubated before a decision can be made that the sterilized BI is negative (i.e., the spores are all dead) and the test is complete. If a control BI turns positive, it has completed its "task" of providing

The international BI performance standards state that the reference incubation time for a BI is seven days.1 This incubation time was established in the early days of BIs and was based on the technology available at that time. An incubation period of seven days is not at all practical in today's healthcare environment; therefore, for BIs, there was a need for speed.

information on the quality of the BI system (in the case of a positive control) or of the sterilization process itself (a positive test BI indicates a sterilization process failure). If a BI turns positive, the BI test will end at that point and appropriate action will be taken. But how long must a BI be incubated before it can be decided it is truly "negative" and the test can be ended? This timeframe is called the incubation time.

The international BI performance standards state that the reference incubation time for a BI is seven days.[1] This incubation time was established in the early days of BIs and was based on the technology available at that time. An incubation period of seven days is not at all practical in today's healthcare environment; therefore, for BIs, there was a need for speed.

Objective 2: Understand how rapid readout biological indicator systems work

Early BIs were simple spore strips, where the spores were applied to a small paper strip that was enclosed in an envelope, which allowed sterilant penetration while protecting the spore strip from outside contamination. After the sterilization process, the strips were transferred to a test tube containing the growth medium. The test tubes were then incubated at the proper temperature for up to seven days. To determine whether the BI was positive or negative, the user needed to look for a "signal" from the spores that they were alive (positive BI) or dead (negative BI).

The original signal used to determine a positive or negative result was the development of cloudiness in the test tube. If the spore strip placed in the test tube had any viable spores, the surviving spores would convert to vegetative cells and begin to grow. Over time, the number of cells in the test tube would increase to the point where the number of cells in the tube was high enough to scatter light passing though the test tube, making the medium appear cloudy. This process required a significant amount of incubation time (up to seven days) to allow the spores to germinate and enough cells to grow to make the media cloudy.

The next technological advancement introduced a color-based pH indicator into the growth media to make the BI signal a color change rather than cloudiness. A pH indicator changes color based on the pH of the solution. Self-contained BIs (SCBIs) utilizing the pH color change system have growth media that is formulated so growing bacteria will change the media pH until the color changes. The optimization of the media in SCBIs and the user's ability to detect the color change signal faster than the cloudiness signal reduced the incubation time from seven days to two or three days. This was much faster and easier than spore strips but still required incubation times that were not optimal for healthcare.

The next major leap in reduction of BI incubation time came from new technology that enabled detection of biological signals from viable spores much earlier in their germination and outgrowth process. Spore activation and germination is a very complex, multi-step process involving many biochemical reactions. Specialized proteins called enzymes act as catalysts that make these reactions happen much more quickly.

Rapid readout BI technology uses a special indicator in the growth medium that reacts with an enzyme that is active in the startup process. This indicator is like the pH indicator system, except that instead of turning color based on a change in acidity, this indicator changes from a non-fluorescent molecule to a fluorescent molecule when it is acted on by the enzyme. Fluorescence means that it will "glow" or emit light at a certain

wavelength that can be detected and measured by BI readers. This technology, coupled with continued improvements of the physical design of rapid BIs and improved sensors and electronics in the readers, have now reduced BI incubation times to less than an hour, and in some cases, less than 30 minutes.

Objective 3: Discuss the recommended uses of biological indicators for sterilization monitoring

One cannot see sterility. This basic fact drives the need for a quality control system that provides information on the quality of a sterilization process, so a decision can be made on whether the processed instruments are safe for patient use.

US standards for the key healthcare sterilization processes [steam, ethylene oxide (EO), and vaporized hydrogen peroxide] all recommend the integrated use of three quality control monitoring tools: physical monitors, chemical indicators (CIs), and BIs.[2,3,4] The information provided by each tool is different. Physical monitors are electronic sensors inside the chamber that provide data such as the temperature or pressure. This data is recorded on a printout that can also be used as a record of the cycle. CIs utilize specially selected chemicals that respond to the effects of the sterilization process. CIs that are used on the outside of packages (Type 1 process indicators) can provide visual evidence that an item has gone through the sterilizer. Remember that process indicators are only designed to indicate exposure to the sterilant; they do not provide evidence that the process was effective. The more sophisticated CIs (Type 5 and Type 6 indicators) that are used inside packages are designed to respond to all the sterilization process variables and provide more information on whether the required process conditions were achieved.

BIs are used to directly measure the effectiveness of the sterilization process by measuring its effect on live microorganisms.

BIs are placed with the load inside of the sterilizer chamber, in the location determined to be the most difficult to sterilize. The typical BI placement location for large steam sterilizers is over the drain; for EO sterilizers, in the center of the load; and for hydrogen peroxide sterilizers, at different chamber locations specific to the sterilizer, cycle and load. The sterilizer manufacturer's instructions should be followed regarding the recommended placement location for the BI in their sterilizer.

BIs are typically placed inside of process challenge devices (PCDs) to have the BI perform as if it was placed inside containers or packages in the load. Reference PCDs that can be constructed in healthcare facilities are described in the standards.[2,3,4] Commercially available PCDs that have been cleared by the US Food and Drug Administration (FDA) with performance equivalent to the reference PCDs are also available. These single-use devices eliminate the need for staff to assemble test packs and are typically more consistent because of automated assembly processes and quality control procedures required of medical device manufacturers.

The recommended frequency of use for BIs in healthcare facilities varies by the sterilization process. For steam, the recommendation is weekly use but, preferably, daily use, for routine efficacy monitoring. Also, a BI should be used to release any load containing an implantable device. Implants loads should always be quarantined until the BI results are available.[2] A BI should be used to monitor every load for EO sterilization processes. Again, any implants should be quarantined until the BI results are available.[3] Finally, for vaporized hydrogen peroxide processes, BIs should be used daily but, preferably, in every load. Vaporized hydrogen peroxide has the same requirement of implant load quarantine until the BI results are available.[4]

As one can see, there is some variability in the current recommended practices regarding BIs' frequency of use. It is interesting to note that this type of variation is not allowed for medical device manufacturers that are supplying sterile, single-use devices to healthcare facilities. National and international standards for medical device manufacturers require the same level of quality control for every sterilization load, regardless of the device, intended use, day of the week, etc.[5,6,7] Reusable medical devices reprocessed in a healthcare facility do not have to meet the same level of consistency as those sterile devices received directly from manufacturers. Many healthcare facilities are now leveraging the significant reductions in BI incubation time to increase their frequency of use of this important QC tool, without negatively affecting their workflow.

Rapid readout BIs make the quarantine of implantable devices until the BI test result is available much more realistic. Many hospitals have moved to monitoring every sterilization load with BIs, even where the current healthcare standards do not require it, such as for steam and vaporized hydrogen peroxide. The reasons often cited for making this change include assurance of a uniform standard of care for all patients, avoidance of the extra work and expense required in the event of a recall, and reduction of errors in the Sterile Processing department caused by varying requirements for BI monitoring.

BI technology has continued to evolve, with faster detection of the biological signals produced by the bacterial spores that provide the direct challenge to the sterilization process. These technologies have resulted in BIs with incubation times of less than 30 minutes for some sterilization processes. These brief incubation times now make it possible to obtain biological test results in time for optimized instrument workflow, including shorter quarantine periods for implantable devices, and in many facilities, for all instruments.

Conclusion

BI technology has continued to evolve, with faster detection of the biological signals produced by the bacterial spores that provide the direct challenge to the sterilization process. These technologies have resulted in BIs with incubation times of less than 30 minutes for some sterilization processes. These brief incubation times now make it possible to obtain biological test results in time for optimized instrument workflow, including shorter quarantine periods for implantable devices, and in many facilities, for all instruments. These indicators facilitate improved quality control of sterilization processes by enabling increased frequency of biological monitoring.

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CRCST Self-Study Lesson Plan Quiz - The Science of Speed – Today's Rapid Readout BIs

Lesson No. CRCST 172 (Technical Continuing Education - TCE) • Lesson expires May 2023

1. The reference incubation time for a conventional biological indicator is seven days, but rapid readout technology has enabled biological indicators with incubation times of less than:
a. Seven days
b. Five days
c. 24 hours
d. 30 minutes

2. Sterilizer printouts from the electronic sensors in the chamber can prove that a sterilization cycle was effective.
a. True
b. False

3. Which of the following provide a direct measurement of the lethality of the sterilization process?
a. Physical monitors
b. Biological indicators
c. Chemical indicators
d. None of the above

4. Biological indicators with rapid readout technology rely on a biological signal from germinating and replicating spores.
a. True
b. False

5. Biological indicators utilize bacterial spores because spores are difficult to kill and present a significant challenge to the sterilization process.
a. True
b. False

6. The most effective quality control system for healthcare sterilization uses a combination of:
a. Biological indicator and chemical indicators
b. Physical monitors and chemical indicators
c. Biological indicator and physical monitors
d. All the above

7. Chemical indicators on the outside of packages are used to test all the sterilization process parameters and prove that the process was effective.
a. True
b. False

8. Rapid readout biological indicators can make it easier to quarantine implantable devices until the biological indicator test is complete.
a. True
b. False

9. Biological indicator manufacturers' instructions for use are the best reference for where biological indicators and process challenge devices should be placed in the sterilizer chamber.
a. True
b. False

10. For biological monitoring of steam sterilization, ANSI/AAMI ST79 recommends the use of biological indicator process challenge devices with all implant loads at which of the following testing frequencies?
a. Weekly, preferably daily
b. Every load
c. After a weekly leak test
d. ANSI/AAMI ST79 has no recommendations regarding implant loads

11. Biological indicators are placed:
a. On the bottom shelf
b. In the center of the middle shelf
c. In the location most difficult to sterilize
d. On the top shelf

12. What is the proper frequency for biological indicator use?
a. Daily
b. Weekly
c. Every load
d. This determination is based on the sterilization type

13. Ethylene oxide cycles should be monitored with a biological monitor:
a. Weekly
b. Daily
c. Every cycle
d. None of the above

14. Although not required, many healthcare facilities now run a biological indicator:
a. Weekly
b. Daily
c. Only with loads that contain implants
d. Every load

15. Today's biological indicators use which of the following to signal a positive reading?
a. pH indicator
b. Cloudy medium
c. Enzyme
d. All the above

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