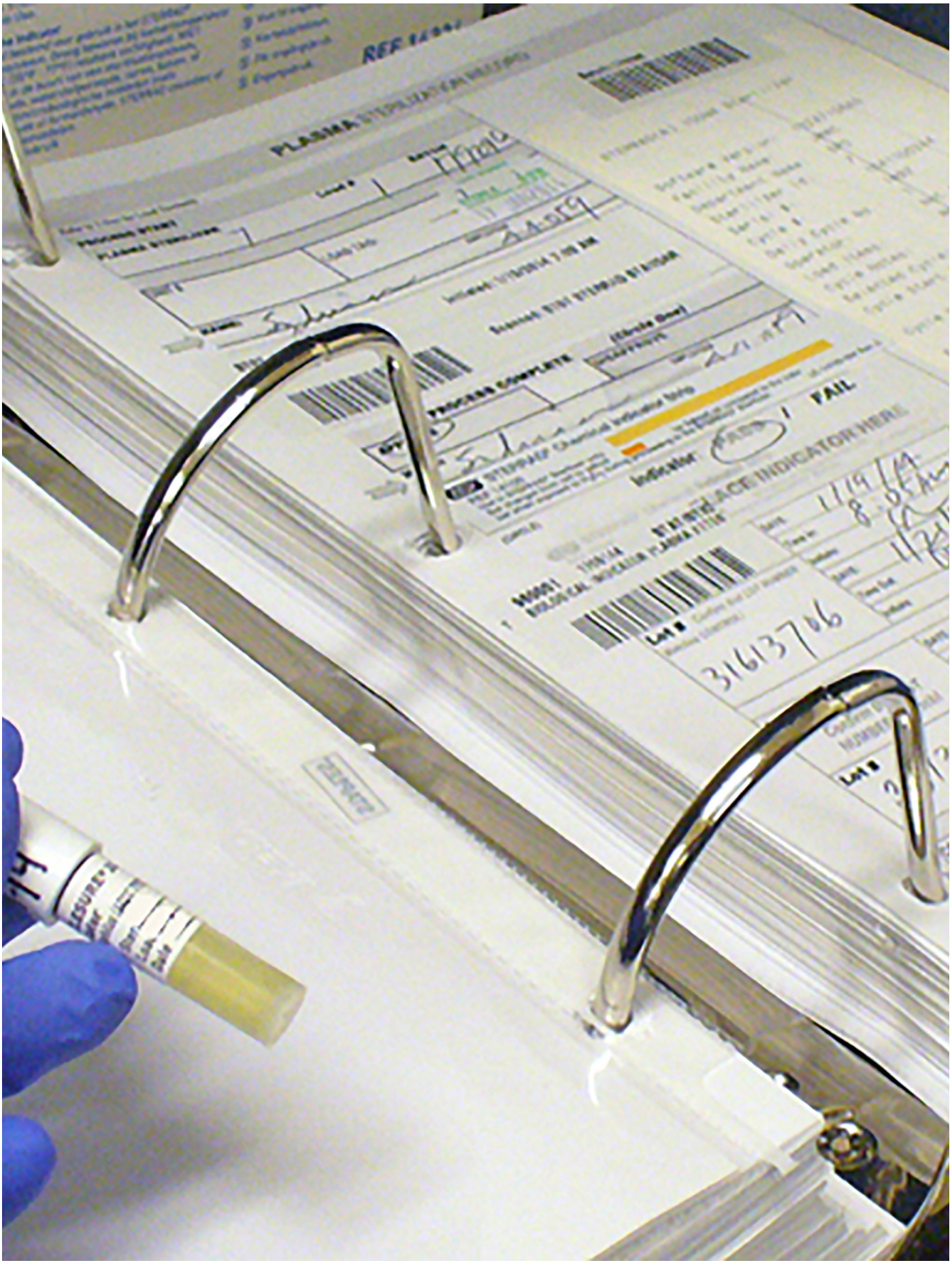
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# Understanding Sterilization Recalls

BY DAVID JAGROSSE, CRCST, CHL

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**LEARNING OBJECTIVES**

1. Identify what can go wrong when sterilizing products
2. Explain what is involved in a recall, per current guidelines
3. Describe how to minimize or eliminate a recall

Creating the title for this article was fun and challenging as there were so many ways to try and capture this topic. While not quite an outline of the objectives for the article, it does follow a a pattern that will help Sterile Processing (SP) professionals deal with sterilization failures and any resulting recalls. The intent of this lesson is to offer all the essential ingredients for a facility to create the best path forward with the SP team. There is nothing fun about performing a recall; however, by acting in a proactive manner, SP technicians will always be better prepared when the real task presents itself. Think of the disaster preparedness drills often performed within healthcare facilities. Technicians can be excited in knowing they are ready to handle whatever a hectic day in the life of Sterile Processing department (SPD) may entail.

With any process developed, it is important to ensure that the department is guided by the Big Three: critical thinking, best practices and current guidelines. This lesson delves into sterilization recalls and offers guidance for achieving the best possible end results, while always keeping patient safety at the very forefront. Similar to other efforts in the SPD, it is important to take a multidisciplinary approach and perform a risk assessment to evaluate the current state of the recall policy. Do you have one? How old is it? When was it last updated? Perhaps it dates back to the older technology when biological monitoring was 48 hours and recalls were much larger endeavors that involved many more devices than what the current rapid read technology offers.

In either case, doing this (and reviewing all the processes on a regular basis) forms a good foundation for a quality system of improvement in the department. To delve further into this topic, obtain ANSI/AAMI ST90:2017, *Processing of health care products—Quality management systems for processing in health care facilities.*

## Objective 1: Identify what can go wrong when sterilizing products

Let's consider what it takes to ensure a robust system is in place for sterilization recalls within the SPD. Perhaps start by asking, "What could possibly go wrong?" The simple answer: many

things can go wrong, but there's no need to panic. Sterilization is a science, and this is why these processes are monitored. In monitoring processes, technicians look for certain critical elements to come together, so load release can occur. These will be discussed later in this lesson.

The Association for the Advancement of Medical Instrumentation (AAMI) develops standards for the healthcare profession, and the organization has some specific guidance on this topic. To be specific, the document this lesson will review is ANSI/AAMI ST79:2017 with Amendments A1, A2, AA3, A4:2020, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities.* Monitoring was mentioned previously, so it is important to review that first to help ensure a robust monitoring system is in place to detect failures in real time or shortly thereafter. The longer it takes to detect a problem, the more risk there will be in potentially releasing devices that could be used on patients.

Section 13 of ANSI/AAMI ST79 addresses monitoring of mechanical cleaning equipment; product identification and traceability; physical, chemical and biological monitoring of steam sterilization cycles; residual air (Bowie-Dick type) testing of dynamic-air-removal sterilizers; periodic product quality assurance; product recalls; and related quality control measures.

While recalls can occur in any modality of sterilization (such as ethylene oxide, low-temperature hydrogen peroxide, or others), steam sterilization will be the focus of this lesson. The processes and information reviewed here can also be applied to the other sterilization modalities, but within their own parameters of monitoring.

For steam sterilization, look at the process monitoring tools used and their corresponding frequencies of use. Generally speaking, physical indicators, biological indicators (BIs) and chemical indicators (CIs) are used to monitor critical sterilization parameters. When this trinity of monitoring comes together and passes successfully, the sterile goods can be released from the load or cycle.

ANSI/AAMI ST79 tables 2 and 3 as well as section 13.5.3.2 (Using biological indicators) indicate thefrequency of use of these products for steam sterilization.

- Physical: Every sterilizer cycle printout verified post-cycle.
- Chemical: Indicators in every package and external process indicators. Bowie-Dick test daily.
- Biological: At least weekly, but preferably every day the sterilizer is in use.

Upon completion of any cycle, regardless of modality, these critical parameters must be inspected to ensure they were met. This should occur before items are released to the patient, but this is not always the case (with the exception being implant devices, which must be quarantined). If parameters are not met, a recall will be needed, along with work to ensure items are not used on patients. If items were in fact used, the SPD must be able to identify what was used and on whom.

## Objective 2: Explain what is involved in a recall per current guidelines

In the world of sterilization recalls, certain scenarios can lead to much later detection of sterilization failures and subsequent load recalls (dependent upon the policy the facility develops). They include:

- Incubation times of the BIs and the frequency of use
- Wet packs (identified inside or outside the department)
- CI failure identified outside of the department

Once a process failure is detected, technicians should start by referencing the department policies and procedures. Robust policies and procedures should be in place, backed by equally robust staff training and ongoing competency assurance (remember, you're a quality processing factory). The following offers some guidance for developing those policies.

- Policies should be developed in collaboration with the potential medical departments involved (it's not just the Operating Room) and, of course, the infection prevention and risk management departments.
- Do no harm. Keep the policy patient focused. As with everything SP professionals do, patient safety is the end goal. Items must be recalled as soon as possible before patient use. If items are used on a patient, the team should develop a procedure to determine if and how patients will be notified.

Preparing for these scenarios in advance makes a stressful and challenging situation more manageable and provides clarity as to which actions are taken and who is responsible for them. *Note: ANSI/AAMI ST79 also provides a decision tree for tracking down CI and BI failures and physical monitoring devices. See Figure 10.*

It is also critical that the department policy identifies who oversees the recall process. There should be a designated person to facilitate the process. The process to follow regarding *what* needs to be recalled and *how* the potentially affected areas should implement the recall should be clear. If the recall is large enough, there may be a need for all

hands on deck, involving all members of the department and potentially even others from outside the department.

Let's take a look at ANSI/AAMI ST79 section 13.7.5.2: *Recall of items processed by the health care facility*. This section states that the department should establish written policies and procedures covering the recall of items that have been processed and issued or stored. Collaboration with other departments such as Infection and Risk Management should be used to develop the department policies and procedures. This section also discusses reasons for instituting a recall, recall responsibility, department notification and recall documentation. These documents typically offer a rationale or further explanation of what the standard is targeting. For this section, it states that it is important to note that the policy should indicate what to do with the equipment that was used in the event of a failure (such as taking the unit out of service, etc.). The team should develop possible scenarios to guide them through the notification process.

Let's further review direct guidance from AAMI ST79 to ensure all points in the recall process are addressed. Section 13.7.5.2.2, *Recall procedure if processed items are suspected to be nonsterile,* discusses retrieval of items from the last negative BI, communication to affected departments, and lot numbers. Required record keeping and actions when the recall order is received (destruction or return of affected items) is also addressed in this section.

There is also direct guidance for the actual recall report. ANSI/AAMI ST79:2017 13.7.5.2.3 states that the recall report should include the reason for the recall, any biological test results, and corrective action taken. The standard also discusses identification of all products that need to be recalled and what was done with the retrieved recalled items.

## Objective 3: Describe how to minimize or eliminate a recall

Now that we have covered monitoring failures and the need for creating robust policies and procedures for recalling the goods (and the associated reporting related to those recalls), let's discuss how to prevent them from happening. Preventive action on both staff and equipment is the key: the goal is to be proactive versus reactive.

For staff, there are two important aspects related to this: staff training and staff proficiency. Regular training and staff observation can help ensure best practices and adherence to policies, procedures and the most current instructions for use (IFU). Staff proficiency can be monitored, and plans should be in place to ensure competency. This is all part of a good quality management system.

***Leak testing.*** Sterilizers require leak testing according to the IFU/owner's manual recommendations and whenever a problem is detected or suspected.

***Steam quality.*** Is house steam (from the plant boiler) used for the sterilizer? Having the appropriate quality of steam is very important and, again, the AAMI ST79 document offers parameters for steam quality. Steam quality and noncondensable gases can play a major role in both wet packs and sterilizer failures. Being proactive and scheduling regular maintenance according to the equipment IFU/manual is essential.

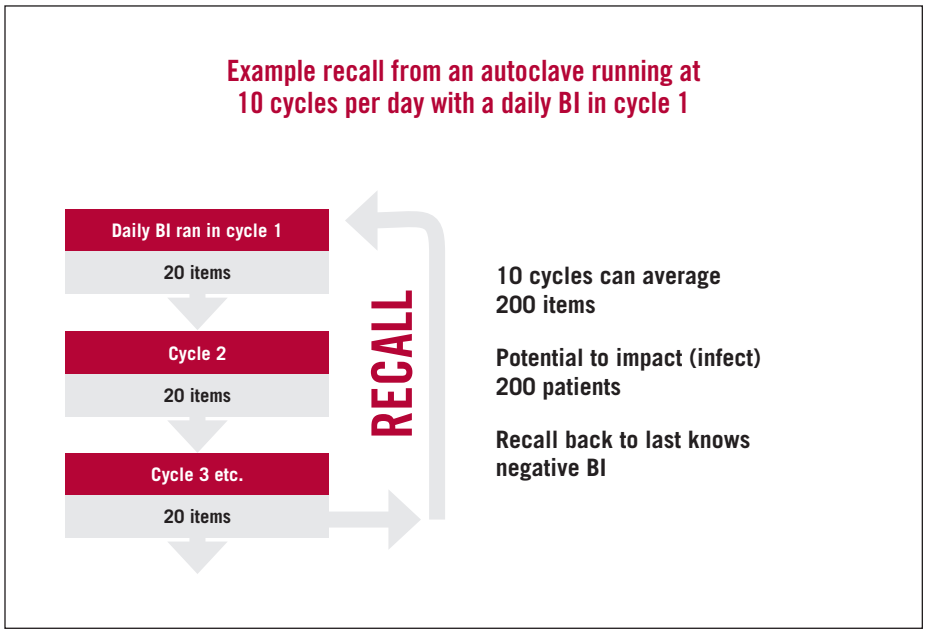
Finally, let's focus again on the process of monitoring devices and the frequency of use. We can look at the minimum requirements and how the department can go above and beyond for safer outcomes. For CIs, which type of indicator is being used? Many reasons can be given to use a Type 5 indicator as there can be early load release for implants, according to the AAMI standard, if the need for this were to occur. Also, the Type 5 indicator is more robust and monitors more critical parameters than a Type 4 indicator.

Some indictors are categorized into two categories: pass/fail and interpretive devices. A pass/fail device is something that may change from white to black. It gives a solid, one-way indication that a parameter was met. Interpretive devices are, at times, more robust in that they measure more parameters and require interpretation by the users. Interpretive devices have the potential to tell the technician more of what is happening during a cycle.

Some facilities use different types of indicators—such as a Type 4 or less within the instrument sets and a more robust Type 5 in a process challenge device (PCD) pack by itself or with a BI indicator. Consistency is key because every patient deserves the highest quality of monitoring across the spectrum. The same can be said for frequency of BI testing.

Finally, to prevent the contamination of goods and reduce the potential for post-cycle wet packs, it is recommended that the department has a digital temperature gun. This equipment enables SP technicians to monitor loads and confirm that the contents are released at the temperatures indicated in the AAMI standards.

Current AAMI standards state that biological testing should be performed "weekly—preferably daily—and with every implant device." ANSI/AAMI ST79:2017, section 13.7.5.2.2, section A, addresses the recall procedure of processed items that are suspected to be nonsterile. It also states that in the event




of a recall, items should be retrieved back to the last negative BI.

Imagine this scenario: Ten cycles have been run in an autoclave that had 20 items in each cycle. That's a total of 200 items. A BI was run both before the items were run as well as the next day; this biological test is positive. Standards tell technicians that items must be recalled to the last known negative BI. That's 200 items and potentially 200 patients, 200 infections or deaths, and 200 lawsuits. *Author's note: This is what I refer to as the "window of liability."" How do we lower that window or even slam it shut? We do so by practicing every load monitoring. In this practice, we run a biological test (preferably a rapid readout device) on every cycle and for every patient.*

## Conclusion

Every SP professional should have the tools, resources and knowledge to develop a robust recall policy with the SPD team and, more importantly, some insight into how to prevent, reduce and promptly detect recalls.This will help close the window of liability and achieve greater patient safety.

### RESOURCES

1. American National Standards Institute/ Association for the Advancement of Medical Instrumentation. ANSI/AAMI ST79:2017 & 2020 amendments, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities.* Available for purchase at www.aami.org.

2. American National Standards Institute/ Association for the Advancement of Medical Instrumentation. ANSI/AAMI ST90:2017, *Processing of health care products—Quality management systems for processing in health care facilities.* Available for purchase at www.aami.org.

# CRCST Self-Study Lesson Plan Quiz
## Understanding Sterilization Recalls

Lesson No. CRCST 180 (Technical Continuing Education - TCE) • Lesson expires September 2024

1. Which organization provides guidance on the sterilization recall process in healthcare settings?
   a. Association of periOperative Registered Nurses (AORN)
   b. U.S. Food and Drug Administration (FDA)
   c. Association for the Advancement of Medical Instrumentation (AAMI)
   d. Occupational Safety and Health Administration (OSHA)

2. Section 13 of ANSI/AAMI ST79:2017 addresses monitoring of:
   a. Mechanical cleaning equipment
   b. Staff competency
   c. Departmental layout and workflow
   d. None of the above

3. Which three monitoring tools are utilized for steam sterilization?
   a. Physical, chemical, biological
   b. Physical, industrial, chemical
   c. Physical, steam, biological
   d. Physical, biological, steam quality

4. A Sterile Processing department should have robust policies and procedures regarding recalls.
   a. True
   b. False

5. Policy is best developed:
   a. By administration
   b. By Sterile Processing technicians
   c. By Risk Management
   d. In collaboration with involved departments

6. When a biological indicator fails:
   a. All involved areas should be notified
   b. Items are recalled back to the last known negative biological result
   c. Patients the items were use on should be identified
   d. All the above

7. Current AAMI standards state minimum biological testing should be performed:
   a. Weekly
   b. Daily
   c. On every load
   d. None of the above

8. According to ANSI/AAMI ST79: 13.7.5.2.3, a report of a recall should:
   a. Identify the circumstances that prompted the recall order
   b. Include documentation of microbiological test results when a positive biological indicator initiated the recall
   c. Specify the corrective action(s) taken to prevent recurrence
   d. All the above

9. The following can help reduce steam sterilization cycle failures and avoid a recall:
   a. Regular and ongoing equipment maintenance, according to the manufacturer's instructions for use
   b. Verification of all recalled items
   c. Following ANSI/AAMI ST90
   d. All the above

10. The more biological tests that are run, the fewer nonsterile medical devices can potentially be used on patients.
    a. True
    b. False

11. When developing a process, one should be guided by:
    a. Long-term departmental practices
    b. Quality issues
    c. Critical thinking
    d. All the above

12. One step in a good quality process is:
    a. Performing a leak test daily
    b. Reviewing processes on a regular basis
    c. Documenting sterilization parameters at least weekly
    d. All the above

13. ANSI/AAMI ST90 is the document that covers:
    a. Steam sterilization
    b. Biological indicator incubation times
    c. How the recall process should be performed
    d. Quality management systems

14. Items in a recall should be:
    a. Reprocessed or destroyed
    b. Accounted for and documented
    c. Communicated to all involved departments
    d. All the above

15. A sterilization printout:
    a. Is an example of a physical monitor
    b. Should be verified weekly
    c. Verifies each item in the load is sterile
    d. All the above

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