

Recalls

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****This in-service has been Approved by the CBSPD for 1 CEU.**

We have all had to deal with recalls of one kind or another. It might have been related to items sterilized in our own departments or with commercially sterilized items. Regardless of the source, we must take immediate action to account for all of the affected lot numbers.

Frequently, within our own departments, the need to recall items is due to a positive biological indicator (BI). The purpose of the BI is to challenge the sterilization process. The test indicators validate that sterilizing conditions were attained by killing the spores in the test pack. When a positive BI is noted, the first step is to review all mechanical and chemical monitoring records since the last negative BI. Only 10% of positive BI's are due to equipment failure. Review the sterilization printout carefully to be sure there were no inaccuracies. Before beginning the recall process, look at the following carefully. These are all possible causes of a positive BI:

- Was there inadequate sterilization time?
- Was the exposure time set correctly for the temperature?
- Review how the sets were prepared, packaged, labeled, and loaded into the sterilizer.
- Was the test pack improperly processed?
- Review the actual processes performed by the staff to determine if the positive was caused by the operator. 85% of most sterilization errors are caused by the operator.
- Is it possible that the load was never started and the contents were never processed?
- Was the correct BI used?
- Was the control and the BI from the same lot?
- Was the BI contaminated with microorganisms not originally in the BI?
- Was the incubation faulty?

Recalls due to positive biological indicators require all items from cycles sterilized back to the last negative biological indicator results in the affected sterilizer be retrieved. The first thing a staff member needs to do is notify the appropriate supervisor or their designee of situations that may warrant a recall such as a positive biological indicator, a failed mechanical indicator, an unacceptable internal or external chemical indicator or any situation that indicates that a load was not adequately processed. The supervisor or designee would then make the decision to implement a recall based on the facilities policies and procedures.

Recall procedures are established to expedite the retrieval of processed items that have been determined to be suspect, immediately quarantine the sterilizer and notify physicians or departments that may have received the suspect items. Once a recall has been deemed necessary, notification of physicians and departments should be the beginning of the recall process and subsequent to needed documentation. The information used in the documentation could include but is not limited to:

- Supervisor or designee initiating and or authorizing the recall
- The individual responsible for documenting the results of the recall
- Reason for the recall
- Time and date of the suspect cycle
- Description of the load contents with reference given to the Lot and load control numbers.
- The results of the print out or graph depending on your sterilization unit.

All medical devices processed in that specific sterilization unit since the last negative BI are considered non-sterile. It is of utmost importance to accurately assign lot numbers and record items to be sterilized within our own departments because this is the record to be used to identify all items from affected cycles. Once all items have been identified they are to be located and retrieved. All must be completely reprocessed. A single positive BI does not indicate a sterilizer malfunction if mechanical and chemical indicators are acceptable and appear to be functioning properly. A second BI should be immediately processed while holding the suspect items in quarantine. If you would like to know if the BI was contaminated and human error caused the positive, the positive BI can be sent to the lab for identification of the specific microorganism. If it is different than the microorganism in the BI you have confirmed that the BI has been contaminated and the positive was caused by human error.

When there is evidence of a sterilization failure the Infection Control Department should be notified to follow-up if any of the suspect medical devices were used on patients and consult with the physicians that came in contact with the suspect medical devices.

Notify your sterilizer service representative for assistance in determining the sterilization failure. The combined results of mechanical, chemical and biological monitoring should determine the success of any changes made or become obvious if the sterilizer continues to malfunction. Once the cause has been noted, arrange to have the unit serviced or repaired. After the corrections have been made, a vacuum steam sterilizer must be re-validated with three consecutive negative biological monitors in three consecutive cycles, followed by three consecutive dynamic air removal tests. Each type of cycle (gravity and pre-vacuum) must be tested and all test results negative before the sterilizer is put back into use.

For table top sterilizers designed to be used with multiple types of modes or cycles (e.g., 270°F to 274°F [132°C to 135°C], unwrapped instruments; 270°F to 274°F [132°C to 135°C], wrapped instruments or peel pouches; 250°F [121°C], wrapped packs; 250°F [121°C], liquids), then each sterilization mode or cycle should be routinely tested with a

BI PCD. The unit is not to be used until the results of these tests are acceptable. Once the sterilizer is determined to be functioning properly it can be put back into routine use. It is important to keep records. This includes the time/date of the cycle, sterilizer identification, packaging materials, location of the BI, results of the test and the control, and the name of the person conducting and reading the test.

It has been shown that the prevention of recall situations is frequent biological monitoring and quarantine. Increased biological monitoring can contribute to the reduction in healthcare acquired infections (HAI's), cost reduction in decreased reprocessing and liability, and will promote the confidence needed for good work flow in CS/SPD. Some facilities feel it is clinically and operationally more effective to monitor every load with a biological monitor than it is to deal with the costs associated with recall, HAI's and litigation.

AAMI recommends that sterilizers be biologically monitored at least once a week, preferably daily, when normal cycles are used, in each flash sterilization load and in any load containing an implantable device. A positive BI is a significant event. Different sterilization units are validated by different microorganisms. A biological monitor specific to the type of sterilization unit being monitored is necessary. Determine that the correct biological indicator was used. Steam, low temperature gas plasma, and ozone BI's contain *Geobacillus stearothermophilus* (previously *Bacillus stearothermophilus*). *Bacillus atrophaeus* (previously *Bacillus subtilis*) is used to test ethylene oxide and dry heat sterilizers. After processing, the BI's are incubated. If viable spores remain, they will grow creating a positive biological. Biological indicators should be handled and used according to the manufacturers instructions. Biological monitors that test positive are to be discarded as medical waste.

AAMI Recommended Practices clearly state that our healthcare facilities must have written policies and procedures for the recall of medical devices. These policies and procedures are to be developed cooperatively with Infection Control and Risk Management. They are to be documented and all records maintained.

The recall outline recommended by AAMI (*Comprehensive Guide to Steam Sterilization and Sterility Assurance in Healthcare Facilities: ST-79, 2006*) is as follows:

10.11.2

Recall Procedure should

- a) be written
- b) outline the circumstances for issuing a recall order
- c) designate the person(s) authorized to issue a recall order; and
- d) designate the person(s) responsible for reporting on the execution of a recall order

10.11.3

Recall Order should

- e) include all items processed back to the last negative BI; be immediately communicated to affected departments and followed by a written order;
- f) identify by sterilization lot number the products to be recalled;
- g) identify the persons or departments to whom the order is addressed;
- h) require the recording, in terms of kind and quantity, of the products obtained in the recall; and
- i) specify the action to be taken by the persons receiving the order (e.g., destruction or
- j) return of the product)

10.11.4

Recall Report should

- k) identify the circumstances that prompted the recall order
- l) specify the corrective action(s) taken to prevent a recurrence
- m) state, in terms of the total number of products intended to be recalled, the percentage of products actually located in the recall; and
- n) provide verification that the recalled items were reprocessed or destroyed, as appropriate

REFERENCES:

AAMI ST: 79 2006, Comprehensive Guide to Steam sterilization and sterility assurance in healthcare facilities. Section 10.11

The Basics of Sterile Processing, second edition, 2007. Sterile Processing University, LLC, Lebanon, NJ

POST TEST QUESTIONS: Recalls

This in-service is Approved by the CBSPD for 1 CEU. Complete this post test and follow the directions at the end of the test for payment and results.

1. In healthcare facilities CS/SPD departments, who is responsible for initiating a recall due to two consecutive positive biological indicators?
 - A. Infection control
 - B. Risk Management
 - C. Quality Control
 - D. Manager or Designee

2. All medical devices processed in a healthcare facility that are involved in a recall should be
 - A. re-sterilized
 - B. used immediately
 - C. completely reprocessed
 - D. repackaged and re-sterilized

3. Once a sterilization failure has been determined, how far back do you recall medical devices processed in that unit?
 - A. to the last positive biological
 - B. to the last negative biological
 - C. only the items processed that day
 - D. all items reprocessed in the past week

4. Most sterilization errors are usually due to
 - A. poor service
 - B. faulty equipment
 - C. the sterilizer operator
 - D. the type of load processed

5. The control BI and the BI used to monitor the sterilization cycle
 - A. must come from the same lot number
 - B. must be processed at the same time
 - C. must be incubated at different temperatures
 - D. can be from different manufacturers

6. After repairs to a high vacuum steam sterilizer how should it be monitored before putting it back into routine use?
 - A. three consecutive BI's and then three consecutive Dynamic Air Removal Tests
 - B. three intermittent BI's and then three intermittent Dynamic Air Removal Tests
 - C. three BI's and three Dynamic Air Removal Tests run together consecutively
 - D. three BI's and three Dynamic Air Removal Tests run together intermittently

7. AAMI recommends that sterilizers be monitored no less than
 - A. each load
 - B. every day
 - C. once a week
 - D. bi-weekly

 8. Biological monitors that test positive are to be
 - A. discarded as medical waste
 - B. discarded as routine trash
 - C. re-sterilized and then discarded as routine trash
 - D. discarded by the lab after they determine the cause of the positive

 9. *Geobacillus stearothermophilus* (previously *Bacillus stearothermophilus*) is used in the biological monitors to test all of the following sterilizers except
 - A. EtO
 - B. Steam
 - C. Ozone
 - D. Peracetic Acid

 10. Frequent biological monitoring helps in prevention of
 - A. recall situations
 - B. equipment failure
 - C. operator error
 - D. documentation errors
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Directions for Payment and Results

This in-service = \$10

Re-do's = \$10 each

No refunds (all sales are FINAL), prices subject to change.

Payment is accepted in the form of a Credit Card, Facility Check, or Money Order only.
Sorry, no personal checks.

Please see the form on the following page.

Upon passing this in-service, your certificate will be mailed to you within 7-10 business days.

Please fill out the form below and submit it with your payment and the quiz to:

Sterile Processing University, 59 Allerton Road, Lebanon, NJ 08833.

Name: _____

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If you have any questions, please email heidi@spdceus.com

Thank you!