Are You Ready for a Sterilization Recall?

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

Objectives

- To define a recall
- To review the AAMI recommended protocols for a recall
- To describe the retesting of sterilizers after a recall

Departmental Policies - Where it all starts. Policies define what one must do, for example: "All implantable devices shall be processed with a biological monitor. The devices shall not be released until the result of the BI is known." Departmental Procedures describes the steps that must be followed to comply with the stated policy. The ideal is every reprocessed medical device, especially an implant, should be fully traceable to the patient on whom it was used or on whom it is implanted.

Fact: The possibility of a recall is the reason why so many Sterile Processing Departments perform daily or even every load biological testing. Also, 85% of sterilization process failures are caused by human error, 10% are a result of equipment malfunctions, and 5% relate to utility problems. Therefore, we need to focus on the PROCESS.

What sort of human errors can occur? According to AAMI ST-79 (Comprehensive Guide to Steam Sterilization and Sterility Assurance in Healthcare Facilities (2013):

- Misinterpretation of monitoring tools (printouts)
- Incorrect physical monitors for the load
- Incorrect use of biological vial or Process Challenge Device (PCD)
- Incorrect selection of BI or BI PCD for the load (used wrong test)
- Incorrect placement of BI PCD in the load (e.g., another pack was placed on top of the PCD)

Photo Above – BI PCD not placed flat, or over the drain line as required

- Incorrect incubation of BI
- Misinterpretation of BI result
- Incorrect documentation of BI result
- Incorrect use of Class 5 integrating CI PCD
- Incorrect selection of Chemical indicator PCD for the load
- Misinterpretation of Class 5 integrating CI result
- Incorrect documentation of Class 5 integrating CI result
- Incorrect use of internal CI
- Incorrect selection of internal CI for the load
- Misinterpretation of internal CI result
- Incorrect documentation of internal CI results
- Incorrect storage of any CIs or BIs
- Failure to verify expiration date on test packs or chemical indicators before use
- Failure to match lot control numbers of BI and control vials
- Failure to check physical monitors for functionality before running cycle
- Use of broken media ampoule or ampoule with missing spore strip

- Use of BI PCD or CI PCD that is missing the BI or CI
- Use of defective CI (e.g., a CI that is faded, shows a partial color change because of incorrect storage, or has been previously exposed to the sterilant)
- Selection of incorrect cycle for load contents (containment device or medical device manufacturer's instructions for use not followed)
- Use of inappropriate packaging materials or packaging technique
- Incorrect packaging or containment device for the cycle parameters
- Incorrect preparation of containment device for use (e.g., incorrect filters, valves, or bottom tray)
- Use of a paper–plastic pouch, woven or nonwoven wrapper, or towel in a 270ºF to 275ºF (132ºC to 135ºC) gravity displacement cycle
- Use of a tray that does not allow air removal and steam penetration
- Use of a wrapper that is too large for the application
- Placement of a folded paper–plastic pouch inside another paper–plastic pouch

Photo Above – Incorrect Packaging - Paper-Plastic Pouch Doubled, Inside Pouch Folded Over

- Placement of a paper–plastic pouch inside a wrapped set or containment device without verification of adequate air removal and steam penetration by product testing
- Incorrect placement of basins in set (i.e., basins are not aligned in the same direction)
- Failure to use non-linting absorbent material between nested basins

- Preparation of textile packs that are too dense to sterilize with the cycle parameters chosen
- Inadequate preconditioning of packaging materials (i.e., not holding package materials at 68ºF to 73ºF (20ºC to 23ºC) for 2 hours before use)
- Incorrect Loading of Sterilizer
- Stacking of containment devices if not recommended by manufacturer
- Stacking of perforated instrument trays
- Incorrect placement of instrument trays (i.e., not laying instrument trays flat or parallel to the shelf)
- Incorrect placement of paper–plastic pouches (e.g., placing pouches flat instead of on edge; not allowing sufficient space between pouches; not placing pouches with plastic sides facing one direction)

Photo Above – Paper Plastic pouches not in separator and tucked between packs

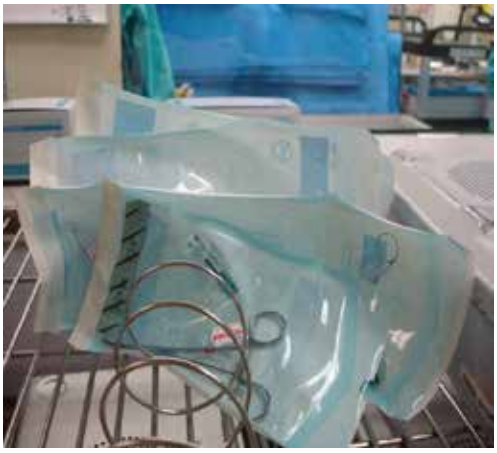


Photo Above – Paper-Plastic pouches in pouch separator

– Incorrect Loading of Sterilizer

Photos Above – Incorrect Loading of Steam Sterilizer

Photo Above - Correct Loading of Steam Sterilizer

- Incorrect placement of basins (i.e., not placing basins on their sides so that water can drain)
- Incorrect placement of textile packs (i.e., not placing them on edge)
- Placement of packages too close together, impeding air removal and sterilant penetration in the load

EQUIPMENT 10% - UTILITY 5% Failures – can be caused by:

- Poor steam quality or quantity
- Wet steam
- Improper insulation of steam lines
- Malfunction of trap in steam line or no trap in steam line
- Malfunction of drain check valve or no drain check valve
- Steam contact with a cold load
- Too much water in steam produced at boiler
- Superheated steam
- Improper heat-up of chamber
- Desiccated packaging materials (e.g., towels)
- Steam pressure too low for the temperature

- Excessive reduction of steam pressure too close to sterilizer
- Faulty steam control valve or pressure reducer control valve
- Variations in steam pressure because of clogged filter, poorly engineered piping, or excessive demands
- Out-of-calibration pressure gauges and controllers
- Clogged steam lines and steam supply strainer
- Clogged chamber drain line, strainer, or chamber drain screen
- Malfunction of valves
- Incomplete Air Removal
- Inadequate vacuum or vacuum depth or other air removal system
- Clogged chamber drain line, strainer, or chamber drain screen
- Clogged vent lines
- Leak in the door gasket or in other areas of chamber
- Plugged, faulty or incorrectly adjusted control valves
- Incomplete Air Removal
- Low steam pressure
- High water temperature
- Inadequate water supply pressure
- Clogged water supply strainer
- Trapping of air by the load
- Incorrect cycle parameters for the load
- Inadequate Cycle Temperature
- Out-of-calibration temperature gauge
- Long heat-up time for large loads (i.e., heat lag)

- Clogged chamber drain line, strainer, or chamber drain screen
- Inadequate Cycle Temperature
- Variations in steam pressure because of clogged filter, poorly engineered piping, or excessive demands on steam supply
- Presence of non-condensable gases in steam line and load
- Inadequate steam supply pressure
- Clogged steam supply strainer
- Insufficient Time @ Temperature
- Out-of-calibration control timer
- Inappropriate cycle parameters for the load being processed
- Come-up time of less than 1.5 minutes in a 270ºF to 275ºF (132ºC to 135ºC) gravity-displacement cycle
- Oversized load

Identification - Each item or package intended for use as a sterile product should be labeled with a lot identifier. This is also referred to as a lot control label (sticker). At a minimum, the lot control label should contain the:

- Sterilizer number
- date of sterilization (month, day, year)
- Sterilization load number

Lot identification enables personnel to retrieve items in the event of a recall and to trace problems to their source. Depending on the dating system used at your facility, there are two types of labels; a label that permits an expiration date (if you date your items) or a label that has an event-related statement (no expiration date). When using the lot control label it is important that all the information is clear (not smudged or not legible). Without clear information, items may not be able to be retrieved.

Photo Above – Lot Control Label for Event Related Dating

Manufacturer's Recall - Sometimes a manufacturer must recall a product because of a problem. Healthcare facilities are notified and the item is identified by

- Name
- Catalog number
- Lot number

The healthcare facility is responsible for locating the item, retrieving the item and documentation of the process.

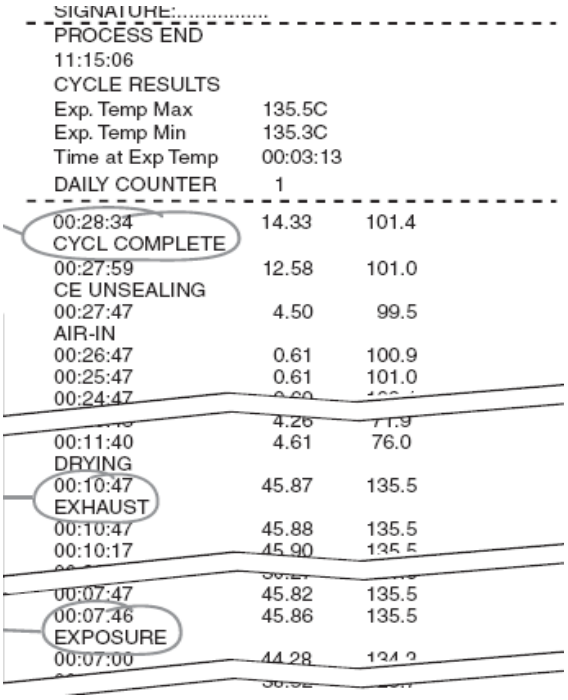
Equipment Recall - Recalled medical devices and/or patient care equipment should be removed from service immediately.

Policies and Procedures – Your department's Policy on Recall should clearly identify all the steps to take including:

- Circumstances for issuing a recall order
- Designate the person authorized to issue a recall order
- Designate the person responsible for reporting on the execution of a recall order.

A recall order should be in writing and should identify by sterilization lot number the items to be recalled. Identify the persons or departments that are to be notified and specify the action they are to take.

A Sterilization Recall at Your Facility – The first thing to do is to check the mechanical monitors which include recorders, displays, digital printouts, gauges, etc. Were they checked? Do you know how to interpret them? If not, you should request an inservice so you understand how to correctly interpret them. The AAMI standard is that sterilizer operators should review the printout at the end of the cycle and if all parameters were met, initial the printout (chart). You should not be signing a chart or printout if you do not understand what you are signing.


SIGNATURE:.....
PROCESS END
11:15:06
CYCLE RESULTS
Exp. Temp Max 135.5C
Exp. Temp Min 135.3C
Time at Exp Temp 00:03:13
DAILY COUNTER 1
00:28:34 14.33 101.4
CYCL COMPLETE
00:27:59 12.58 101.0
CE UNSEALING
00:27:47 4.50 99.5
AIR-IN
00:26:47 0.61 100.9
00:25:47 0.61 101.0
00:11:40 4.61 76.0
DRYING
00:10:47 45.87 135.5
EXHAUST
00:10:47 45.88 135.5
00:07:47 45.82 135.5
00:07:46 45.86 135.5
EXPOSURE

We perform biological monitoring using spores specific to the sterilization process. AAMI recommends BI's should be used within PCD's for routine sterilizer efficacy monitoring at least weekly, preferably every day that the sterilizer is in use. In addition, a BI should be used with any load containing implants. In addition, it is recommended to perform qualification testing of the sterilizer after installation, relocation, malfunctions, major repairs and process failures. Biological testing provides the only direct measure of the lethality of the sterilization process.

It is important to follow the BI manufacturer's instructions for use including storage, expiration date, how to activate the BI vial, incubation, interpretation of results, use of a control vial and length of incubation for final reading. Non-compliance could result in a false positive result or an inaccurate BI test.

Sterilization Records – Sterilization records can be subpoenaed in a court of law therefore they must be accurate, complete and legible. For each sterilization cycle record you should document:

- The lot number for the cycle
- Specific contents of the load (do not use general terms such as "24 OR peel packs") because this does not indicate what was inside the packages.
- Exposure time and temperature as set on the sterilizer
- Name or initials of the operator
- Results of biological testing (if included in the load)

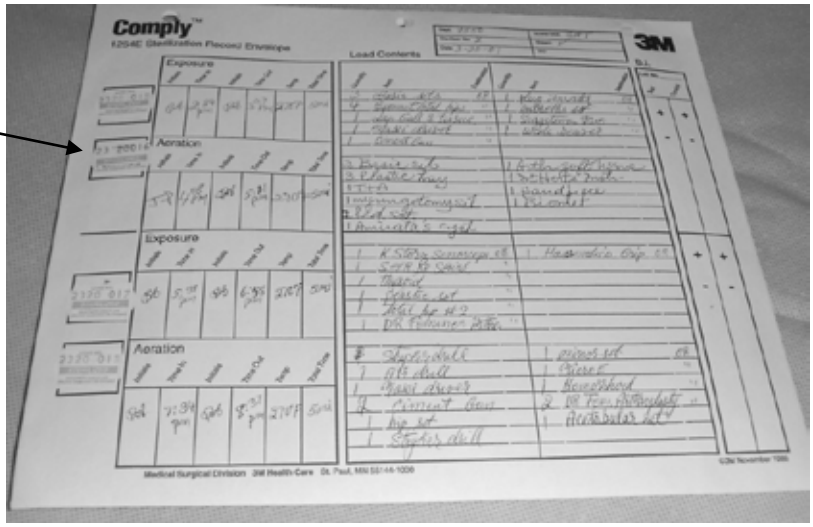


Photo Above – Sterilization Log with Lot Label and contents of each load recorded

In addition, the results of the Bowie-Dick (if applicable) test should be documented on the Sterilization Record and the test sheet saved. If a chemical integrator is included in your PCD, make sure to document the response of the CI in the PCD. The CI can be saved with the sterilization records. Document any reports of inconclusive or non-responsive CI's found later in the load. Make sure all information is written LEGIBLY.

Positive BI Results - When a positive BI occurs, the following actions should be taken

– Notify your supervisor

- Review the sterilizer printout/chart and CI results to verify sterilization parameters. If it is identified that a cycle had the wrong parameters, then rewrap and reprocess the load. No other action is needed.
- Advise the infection control department
- Using the information from the sterilization log and the lot control identification, begin a recall of all items processed in the affected sterilizer back to the last known negative BI.
- Reprocess all the recalled items
- A BI test should be repeated in the next sterilization cycle and the load held until a negative result is obtained

False Positive BIs - To avoid false positive BI's, carefully follow the BI manufacturer's instructions for use. False positive BI's usually occur when the vial is contaminated by improper handling. Sometimes the BI can be sub-cultured in the microbiology lab in your facility. If bacilli are found, it indicates a sterilization failure; if bacilli are not found it usually indicates a false positive. This test can take seven days to get a final result from the lab so most people just consider the load suspect and reprocess the load as a precaution. The lab should try to identify the microorganism so you can determine the cause of the sterilization process failure and correct the problem.

If the problem was sterilization related and/or the repeat BI test is positive, a service call is needed and the sterilizer should not be used until repaired. If a sterilizer has been repaired after a malfunction it should be re-challenged with a BI PCD (qualification testing). AAMI recommends:

- BI & PCD in three consecutive cycles / empty chamber (for non-tabletop sterilizers). If both gravity and pre-vacuum cycles are used, both must be tested with 3 BI tests each. Only the shortest exposure time for each type of cycle needs to be tested.
- Dynamic air removal sterilizers also require a Bowie-Dick test pack be performed in three consecutive cycles after the BI testing is performed.

When all results are satisfactory the sterilizer can be put back into routine use.

Wet Packs - Wet packs should never be used. If the load is questionable for moisture, all items in the load should be recalled as a precaution.

Recall Documentation - Recall records should include:

- How many items from the effected sterilizer were retrieved?
- Which items not retrieved? A list should be provided to Infection Prevention for follow-up with patients.

- The outcome of the BI investigation
- Corrective actions taken to resolve the problem
- Information regarding items used before they could be retrieved

SUMMARY - Positive BIs do happen. We must be prepared and knowledgeable in the process to effectively handle a recall. Documentation of all part of the process is essential. Most important, effective management of a recall will result in less "panic", confusion and frustration.

QUIZ ON RECALLS

Please click on the link below to take the quiz.

https://www.spdceus.com/ceus/recalls_quiz.htm

Good Luck!