Steam sterilization failure investigation: A systematic line of attack

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Any day in the sterile processing environment can be challenging, but add a suspected sterilization failure to the scenario and a challenging day can become even more frustrating. Depending on the time of day the suspected failure is discovered, and the circumstances surrounding it, getting to the bottom of the situation can be a critical time-sensitive endeavor, especially if it is necessary to recall previously sterilized items.

Sterilization failures can be detected at any time during reprocessing or just prior to the use of a medical device. They may be identified at any of the following stages of the process: when a pack is opened and the internal chemical indicator shows an inconclusive result; if a biological indicator test shows growth; if there is moisture on or in the device packaging (wet packs); during the review of cycle parameters after a sterilization cycle; or when failed chemical indicators are discovered within the sterilizer load.

Steam sterilization failures can be the result of a number of factors: a sterilizer can fail to operate properly; chemical, enzymatic, and biological sterilization monitoring devices can perform improperly or poorly; a wet pack or load can occur; or operator error may cause a failure. It is critical to have a well-planned, systematic approach in place to address any of these potential situations, since they can occur at any time.

There are five basic factors to investigate whenever there is a suspected sterilization failure:

1. Equipment failures occur when decontamination or sterilization equipment is malfunctioning. These malfunctions can involve components of the equipment or the utilities that supply the equipment.
2. Process failures occur when processes that should take place prior to sterilization are not properly completed. Examples include: organic residue on devices that is not removed by automated washing equipment; detergents or other chemicals that are not adequately removed from reusable wrap material during laundering; or improperly functioning valves or filters in rigid sterilization containers that can compromise sterilization.
3. Human error is the most frequent cause of sterilization failures. Although there are many ways in which human error can play a part, the most common errors are failing to set appropriate sterilization parameters, overloading or improperly loading the sterilizer, and failing to initiate the cycle once the sterilizer has been loaded.
4. Procedural errors occur when improper departmental procedures are being used. An example of a procedural error is processing a device according to a departmental procedure that dictates a four-minute sterilization exposure at 270°F, when the device manufacturer’s instructions indicate that a longer exposure time is required.
5. Environmental failures occur when environmental conditions cause a sterilized device to become contaminated following sterilization. For example, when a fully loaded cart is removed from a sterilizer cycle, it is placed directly under an air conditioning vent, an environmental condition that establishes that the device can cause wet packs, which may compromise the integrity of the load.

The investigation

Regardless of the perceived cause of a suspected sterilization failure, all five of these factors must be investigated and ruled out to confirm that all problems have been identified. The logical, step-by-step order of this investigation process can help ensure a thorough solution.

Step 1: Determine the extent of the failure

Identify and quarantine the suspected load and temporarily remove the affected sterilizer from service. Determine the extent of the suspected failure by investigating whether this is a single event within a single pack, a complete sterilization load failure, or a failure of multiple loads. Example 1: A pack opened in the O.R. reveals an inconclusive result on the internal chemical indicator. The load is identified and the processed packs are retrieved and quarantined if possible. Open other packages to check their internal indicators.
Step 2: Investigate what caused the failure

For each affected load, investigate all five factors, beginning with the easiest, which is equipment performance.

a) Review the sterilizer printout tape or graph recorder to determine if the appropriate sterilization parameters were met. Review all other biological or chemical monitors used in routine monitoring of the sterilizer, since these products are designed to detect a variety of parameters and performance levels vary greatly from product to product.

b) Review the results of the daily air removal test (Bowie-Dick test) to ensure that it was successful.

c) Review preventive or repair maintenance records for the equipment in question to determine if there have been any recent performance changes such as a frequently failing component, a change in utilities (steam supply), or work being performed during the cycle.

If an equipment failure is determined as a result of this evaluation, the sterilizer must be repaired and all processed items must be repackaged and sterilized.

If a major sterilization repair is conducted, three consecutive Bowie-Dick tests and three consecutive biological indicator (BI) tests must be processed in the sterilizer. If the results of all three Bowie-Dick tests and BI tests are negative, the sterilizer can be returned to service. BIs should be incubated appropriately to assess spore growth.

If BI test packs are the only internal load control monitoring being used, then items from all loads since the last negative BI test load should be recalled. If class 5 integrator test packs are used, then all items from all loads since the last negative class 5 integrator test pack result should be recalled.

Now you must investigate the entire sterilization process, beginning with cleaning.

a) Verify that the washing equipment is working properly (spray arms aren’t obstructed and water heating element isn’t malfunctioning, for example).

b) Verify that the washing equipment monitoring devices are functioning correctly.

c) Ensure that all cleaning chemistries used in the washers are appropriate for the equipment and the devices being processed, and that they are being dispensed correctly.

Ensure that sterility assurance products (indicators, integrators) are performing as intended.

a) Verify that all products are within their manufactured expiration date and have been stored properly.

b) Verify that BI growth is the indicator organism by sending the positive BI to the facility lab for a presumptive identification (gram-stain) of the microorganisms present on the BI (following the BI manufacturer’s instructions).

**NOTE:** If the gram-stain results show no gram-positive or gram-variable rods resembling bacillus species, the indicator should be considered contaminated during handling and processing. In this case, recalled items can be redistributed without reprocessing, and the sterilizer can be returned to service. All inconclusive gram-stain results should be treated as if they are the indicator organism.

Ensure that packaging or barrier systems are functioning properly.

a) Inspect rigid sterilization containers to ensure that components such as valves and filter mechanisms are functioning properly.

b) Inspect reusable wraps to ensure that detergent or chemical residue has been adequately removed during the laundering process.

c) Ensure that all disposable and reusable sterilization wrap or pouches have been stored in an appropriate temperature and humidity-controlled environment to prevent excessive drying, which can result in super-humid conditions during sterilization.

**Human error** is unfortunately a common contributor to sterilization failures and can be relatively easy to detect during the failure investigation process.

a) Verify that the correct sterilization parameters were selected for the items that were sterilized (gravity-displacement vs. prevacuum sterilization, sterilization exposure time, sterilization temperature, dry time, etc.).

b) Ensure that the cycle was actually initiated by the operator by comparing the cycle sequence from the printout tape or graph recorder against the number of loads documented in the sterilization load log.

c) If a wet load has occurred, ensure that the sterilizer load contents were not placed in the sterilizer or on the sterilizer loading cart incorrectly. Ensure that the sterilizer was not overloaded. Inspect individual packages to rule out improper assembly or the inclusion of contents that may hold water and prevent drainage, i.e., small basins, silicone mats without adequate drainage holes, non-absorbent tray liners, etc.

d) If sterilization failure is due to human error, all load contents must be repackaged and sterilized correctly. However, no equipment repairs are necessary and the sterilizer can be returned to service.

**Procedural errors** can be an elusive source of sterilization failures because they occur when staff members believe they are performing a task correctly when in fact they are not.

a) Review the hospital’s written procedures and compare with the sterilizer and device manufacturer’s instructions.

b) Ensure that the procedure being performed is the most current procedure for that set/device.

c) If the sterilization failure is due to a procedural error, all affected devices must be repackaged and sterilized according to the most current procedures and parameters, and hospital written procedures must be revised. However, items and equipment sterilized using the correct parameters are not affected.

Example 1: A complex set of specialty instruments contained in a multi-layered tray is sterilized using cycle parameters specified in the hospital procedures (four-minute sterilization exposure at 270°F, with a 30-minute dry time), instead of the 10-minute exposure recommended by the set/device manufacturer.

Occasionally the environment can play a role in suspected sterilization failures.

a) Verify that the sterilization cart or sterilized items were not placed near an air conditioning vent immediately after being removed from the sterilizer.

b) Observe the area where the affected items were cooling for external sources of moisture, such as a ceiling leak, a sink, or water fountain.

c) If an environmental cause is determined, all items must be repackaged and sterilized.

d) This type of suspected failure does not require sterilizer service and the equipment should be placed back in service.

Example 2: A ceiling leak above sterilized packages results in wet packages.

**Step 3: Recalls**

Although we have listed this as a step, in reality recalls occur throughout the investigational process as affected items are identified.

If good quality assurance processes are in place, most suspected or real sterilization failures are detected during the three tests described above. If failures persist, additional steps should be taken.

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Urges should be identified in the sterile processing area before items are distributed for use. If a recall of processed items is necessary, the Association for the Advancement of Medical Instrumentation recommends the following process:

"A 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.
d) Designate the person(s) responsible for reporting on the execution of a recall order.

"A recall order should
a) Be communicated to affected departments and followed by a written order.
b) Identify by sterilization lot number the products to be recalled.
c) Identify the persons or departments to whom the order is addressed.
d) Require the recording, in terms of kind and quantity, of the products obtained in the recall.
e) Specify the action to be taken by the persons receiving the order (e.g., destruction or return of product).

"A report of a recall order should
a) Identify the circumstances that prompted the recall order.
b) Specify the corrective action(s) taken to prevent a recurrence.
c) State, in terms of the total number of products intended to be recalled, the percentage of products actually included in the recall.
d) Provide verification that the recalled items were reprocessed or destroyed, as appropriate.

"Rationale:
To ensure patient safety and compliance with the user facility reporting requirements of the Safe Medical Devices Act of 1990, the healthcare facility should establish recall procedures to expedite the retrieval of processed items that are suspected to be nonsterile and to ensure adequate follow-up actions such as the quarantine of the sterilizer, notification of physicians and affected clinical departments, and surveillance of patients." (ANSI/AAMI – ST46:2002, 7.9, p. 55)

Step 4: Corrective action
Once the cause has been determined, actions must be taken to correct and prevent future sterilization failures. In addition, these actions must be reviewed at a later date to confirm that preventative measures were successful.

Conclusion
The most efficient, safe, and economical way to address actual or suspected sterilization failures is to prevent them. First and foremost, sterilization must only be performed by individuals who have been thoroughly trained and have demonstrated competency in the performance of sterilization activities.

All sterilization equipment should be appropriately and routinely maintained by qualified individuals, including routine preventive maintenance. Sterilizer repairs should be performed in a timely manner. The steam source for all steam sterilization equipment must be routinely monitored for steam purity and adequate steam pressure. Sterilizers should be routinely monitored using appropriate air removal, chemical, and biological monitoring products. Routine auditing procedures must also be in place and audits should be conducted on a regular basis.

Because it is not realistic to prevent all sterilization failures, having a decisive failure investigation procedure in place can expedite the time it takes to identify the failure source and help ensure that corrective measures are immediately carried out, and potential patient involvement is minimized.
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CIRCLE THE CORRECT ANSWER

1. A steam sterilization failure is almost always caused by a malfunctioning sterilizer.
   A. True
   B. False

2. Which of the following is not a means to prevent some steam sterilization failures:
   A. Thoroughly training all staff members performing sterilization tasks
   B. Monitoring steam sterilizers on a weekly basis
   C. Ensuring that preventive maintenance is routinely performed on all steam sterilization equipment
   D. Conducting routine process audits in the sterile processing department

3. A wet pack may be caused by:
   A. Sterilization carts placed near air conditioning vents after being removed from the steam sterilizer
   B. Overloading the sterilizer chamber or sterilizer loading cart
   C. Items placed too closely to water sources following sterilization
   D. Items or sets not thoroughly dried prior to packaging and sterilization
   E. Poor steam quality
   F. All of the above

4. The most common cause of a steam sterilization failure is:
   A. A poorly maintained sterilizer
   B. Staff error
   C. Steam supply interruption
   D. Incorrect department procedures

5. A procedural error can occur when a department procedure is followed, but is improper.
   A. True
   B. False

6. Steam sterilization failures may be detected:
   A. During the sterilization cycle
   B. Immediately following the sterilization cycle
   C. When sterilized packages are opened for use
   D. When a biological indicator or chemical process indicator failure is observed
   E. All of the above
   F. None of the above

7. The extent of a recall is determined by the results of:
   A. The previous passing biological indicator test
   B. The previous passing Class 5 integrator challenge pack
   C. The cycle printouts from the previous sterilization cycle
   D. The results of internal chemical indicators within the same sterilization cycle
   E. a and b only
   F. All of the above

8. A sterilizer service call is necessary for all steam sterilization failures.
   A. True
   B. False

9. The easiest of the five elements in the failure investigation process is:
   A. Human error
   B. Environmental factors
   C. Process failure
   D. Procedural error
   E. Equipment failure

10. If a recall of a failed sterilization load is necessary, AAMI recommends:
    A. Notifying all affected departments of the recall
    B. Changing biological indicators
    C. Placing a service call with the sterilizer manufacturer
    D. Recalling only items from the affected sterilization load
    E. Notifying the facility infection control officer so that follow-up surveillance of patients can be conducted
    F. All of the above
    G. a and e only

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