

Event Related Sterility - What's It All About, Anyway?

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

A number of years ago, many healthcare professionals began challenging procedures. Why do we do things a certain way and is there a better, and more economical way to do it? With the constraints on healthcare costs today, it is essential that we need to do things smarter and more efficiently. We need to question all our practices by asking, "Why do we do things this way?"

One example is re-processing outdated items. For years, this was a major task for sterile processing personnel. Yet there was little we could do to change this.

The theory of "no expiration dates" was first proposed in the 1980's. The question is "At what point in a day with a stated expiration date, does a package expire? It is at midnight? At noon?" No one knew.

The concept of Event Related Sterility assumes a package will remain sterile unless the integrity of the package becomes compromised. This makes sense. Bacteria are hitchhikers—they cannot move on their own—and need a vehicle to be transported (i.e. hands, fluid).

However, healthcare personnel, traditionally, are reluctant to change. The original shelf life studies performed by the Centers for Disease Control (CDC) were based upon packaging used in the 70's. That study revealed that a package could become contaminated in as little as three days. But the packaging used when that study was performed was muslin! The CDC has not referred to expiration dating since the mid 1980's. However, in healthcare we like to keep "status quo".

The packaging materials used in the past were the best we had back then. For example:

—1920-1960..we used muslin

—1960's...Dennison paper (first disposable paper wrap) became available

—1960's.. The first non-woven wraps available

—1970-80..Peel pouches, rigid containers became available

During this time the Joint Commission for the Accreditation of Healthcare Organizations (JCAHO) required that sterile processing place an expiration date on items. However, the JCAHO removed this from their standard in 1990. JCAHO now states, "written policies for addressing the shelf life of all stored sterile items". The Association for the Advancement of Medical Instrumentation (AAMI) and the Association of peri-Operative Registered

Nurses (AORN) recognize event related sterility. In addition, the packaging materials used today are cleared by the Food and Drug Administration (FDA) which has classified packaging materials as a Class II Medical Devices.

Sterility maintenance is a big responsibility yet it is difficult to control sterility maintenance outside the Sterile Processing/CS Department. Many Sterile Processing Departments do not feel comfortable with this process. However, the benefits to an Event Related Dating policy outweigh the risks, if the program is implemented and monitored correctly.

To begin, look at the problem. Perform an investigation and collect data regarding how many packages are returned for re-processing due to outdates or damage. After the data is collected, the data should be analyzed the data

The problem with time related sterility dating is that the policy calls for placement of an expiration date indicating when items can no longer be used. We are also required to have policies for all conditions for handling and storage of sterile items. Many items we receive from outside manufacturers still have an expiration date on them but this is based upon materials that may break down over time. It is costly to reprocess outdates. It is also difficult to determine the best dating policy for your facility. Some organizations (AORN) suggest performing studies using potential events (e.g. dropped package). It is important to perform a cost benefit analysis. What does it cost your facility for time (labor), materials and services (steam, ETO) to re-sterilize items? How are items being handled and transported in your facility? Are they transported by volunteers? Transporters? Sterile Processing staff?

An event is anything which can cause contamination. Contamination occurs by:

- Poor barrier quality of the packaging materials (e.g. muslin)
- Microbial challenge (how "dirty/soiled" is the environment?)
- Events themselves (e.g. placing a package on a wet table).

The major events which compromise sterility include:

λMicrobes- types and quantity

λLocation - where items are stored or transported

λTemperature- microbes love temperatures around 98.67°F. The maximum temperature for the sterile storage area is 75 deg. F.

λAir movement - some microbes travel in air currents. Stagnant air permits microbes to congregate. The recommended air movement in Sterile Storage is 4 air exchanges per hour with positive pressure (clear air in).

λHumidity - high humidity levels (above 70%) should be avoided; packaging integrity can be adversely affected. Humidity levels should not fall below 30% in this area.

λTraffic - the more people in the sterile storage area. The greater potential for contaminates.

λOpening the package - if aseptic technique is not used, the package contents can become contaminated upon opening!

λ Handling/transport (dropping or compressing)

—Visual evidence of compromise; be suspect if an item appear to have tears or holes in the package, rupture of the package seals, broken closures or missing locks from rigid containers, evidence of moisture (wetness) or crushed packages.

Remember, microbes don't have watches---they get into packs based upon EVENTS! Most often we put them there! So, what conditions are needed to PREVENT events?

The recommended storage conditions include keeping items at least eight to ten inches off the floor. This is to permit Housekeeping to clean under the shelves without splashing the sterile product. Supplies should be kept at least 18" from sprinkler heads (this is a fire code), and two inches from an outside wall. Packages should not be cradled or crushed in the arms or while in storage. They should not be stored where they can become wet.

The quality of packaging material is essential to maintaining sterility. According to the AORN's Recommended Practice on Packaging, "an effective packaging material... should ...provide an adequate barrier to microorganisms or their vehicles". It is important to select packaging material after a review of the manufacturer's technical data describing the barrier performance of the packaging. Does it have good barrier qualities for moisture? Bacteria? Dust? Also review the sterility maintenance studies which should have been performed by independent laboratory.

Look around your department and facility. Some factors to consider include:

- Where are items stored (throughout the facility)? How are they stored?
- Does the staff routinely rotate stock?
- Are items stacked? (Only rigid containers should be stacked).
- Do storage areas have limited access?
- When were the areas last inspected?
- When was the last Inservice given on sterile storage requirements?

You should also be looking at conditions during transport of sterile items. According to JCAHO, "Sterile Supplies should be transported in a covered or enclosed cart with a solid bottom shelf"; "Reusable covers for carts should be cleaned after each use; carts decontaminated and dried prior to use for sterile supplies". Are these practices being followed at your facility? Also look to see if:

- Items are stacked on one another during transport/distribution?
- Sterile supplies are transported or distributed by means which minimize or eliminate the possibility of accidental contamination?
- Packs are not be touched until cool.
- Packs which are dropped on the floor, compressed, torn or wet are considered contaminated and are completely re-processed.
- Supplies are handled carefully; avoid crushing, bending, compressing or puncturing the packaging.
- All persons handling sterile packages know and follow proper practices?

- How many times are items handled after sterilization? How many times is too much?
- The instrument sets are of proper weight?
- Instrument trays are positioned at proper levels in the storage area to facilitate removal?
- The staff is monitored for adherence to proper handling practices?
- Are supplies rotated to ensure the first item in is the first used?

—If you do not have an Event Related Sterility policy and wish to implement one, you need to establish a multi-disciplinary Committee. This Committee should define the goals; review the technical data; review your current practices and develop and implement the initial and ongoing testing. Before implementation, develop a policy that defines how you will label packs (need a statement that is visible stating “this pack will remain sterile until package compromised” or similar statement); the events which would require reprocessing of packs, determine which items which will continue to be dated; define your rotation policy to prevent package damage and defines how you will monitor compliance with the policy.

It is important to develop and implement training programs for all facility personnel because everyone handling sterile packages must be knowledgeable in sterility maintenance concepts. It is also recommended to monitor infection rates before and after implementation of policy (Infection Control plays an important part in this process). Also, the facility should decide how the remaining packs (with expiration dates on them) will be reprocessed once they expire (e.g. place a statement “packages will be reprocessed as they expire”). It is also important to define any exceptions to the policy such as medications; rubber or latex items (e.g. catheters, tubings) and devices purchased from manufacturers.

To some professionals, expiration dating is a “sacred cow” whose time has come to be put to pasture. However, if your MAJOR reason for considering event related sterility is **FINANCIAL..... think again!** If you think that Event Related Sterility will **MAGICALLY** reduce your costs and cut down on re-work....you haven’t analyzed the project thoroughly! The process does work, **however the basic principles of sterility maintenance CANNOT be forgotten....someone must still bear this responsibility!**

If you set up your program correctly and include adequate safeguards, you can achieve the best of both worlds, **improved process performance without sacrificing quality!**

QUESTIONS FOR EVENT RELATED INSERVICE

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. A package becomes compromised
 - A) after 1 hour
 - B) after 5 hours
 - C) immediately after sterilization
 - D) after an event

2. Bacteria are similar to
 - A) transporters
 - B) hitchhikers
 - C) deliverymen
 - D) drivers

3. The original studies performed by the CDC on shelf life were based upon
 - A) Use of dust covers
 - B) Use of rigid containers
 - C) Use of muslin wrappers
 - D) Use of non-woven wrappers

4. The FDA classifies packaging materials as which Class of devices?
 - A) Class I
 - B) Class II
 - C) Class III
 - D) Class IV

5. The main reason a manufacturer places an expiration date on his package is:
 - A) Get the facility to purchase more.
 - B) Eliminate the need to rotate stock.
 - C) Prevent backorders.
 - D) Materials can break down over time

6. A major cause of pack contamination is:
 - A) Quality bacterial barriers
 - B) Quality moisture barriers
 - C) Excessive handling
 - D) Reduced microbial presence.

7. The maximum temperature for a sterile storage area is:
 - A) 65 deg F.
 - B) 70 deg. F.
 - C) 75 deg. F
 - D) 80 deg. F.

8. The maximum humidity level for sterile storage is:
 - A) 80%
 - B) 70%
 - C) 60%
 - D) 50%

9. The minimum humidity level for sterile storage area is:
A) 15%
B) 20%
C) 30%
D) 40%
10. Sterile supplies should be kept:
A) in a open area
B) with heavier sets on top shelves
C) with rigid containers stored on top of wrapped sets
D) with only rigid containers stacked
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Directions for Payment and Results

This in-service = \$10

Re-do's = \$10 each

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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:

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

Thank you!