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Expiration Dating

LEARNING OBJECTIVES

1. Define the terms used in the expiration date process
2. Describe how an expiration date is determined
3. Discuss event-related sterility dating
4. Discuss packaging materials' impact on event-related sterility and identify staff responsibility in maintaining package

WITH THE ADVENT OF THE EVENT-RELATED STERILITY PROCESS, the healthcare industry began removing expiration dates from its products. In recent years, however, due to changing requirements from the US Food and Drug Administration (FDA), the industry has once again begun seeing expiration dates return on products. This lesson will discuss the expiration date process and how it affects the Central Service (CS) department.

OBJECTIVE 1: DEFINE THE TERMS USED IN THE EXPIRATION DATE PROCESS

There are several terms used in the expiration dating process that are important for a CS technician to understand. "Event-related sterility" is one such term. Event-related sterility means an item is sterile until an event occurs to make the sterility of the product questionable (e.g., dropping the item on the floor, moisture detected on the packaging, or an item reaching its expiration date). An expiration date is defined as the date after which a product should not be used because of an expected decline in quality or effectiveness.

CS professionals may have noticed that many products contain a manufacture date rather than an expiration date. These

two dates should not be confused.

Simply put, a manufacture date is the date in which the product was made or came into being. The Association for the Advancement of Medical Instrumentation (AAMI) states that "if a product contains a material that degrades over time, the product should be labeled with an expiration date that takes the degradation into account." This includes the barrier protection capabilities of packaging materials. Some items have a manufacture date printed on the box that states the item can be used until a certain amount of time (e.g., two years) after the product's manufacture date. To address the barrier protection capabilities of some packaging materials, the products' instructions for use (IFU) may state the amount of time (after sterilization) the items packaged inside can be used before needing to be

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Example of product packaging with manufacture date and expiration date

reprocessed.

According to the FDA, shelf life is the term or period during which a commodity remains suitable for its intended use. An expiration date is the termination of shelf life, after which a percentage of the commodity (e.g., medical devices) may no longer function as intended. In other words, a product's shelf life generally means the length of time one can expect a product to look and act as expected, and to stay safe for use.

Regardless of which term is used, a product should no longer be used and must be removed from service when the final date is reached.

OBJECTIVE 2: DISCUSS HOW AN EXPIRATION DATE IS DETERMINED

An expiration date frequently comes from stability studies using pre- and post-sterilized samples in an accelerated and/or real-time aging process to determine an expiration date for a packaged item. Accelerated aging is conducted by simulating the period claimed for product expiration (e.g., one year, two years, etc.). Simulation is achieved by varying

temperature and humidity levels and exposing the package to the conditions with which it is expected to survive during its shelf life.

Real-time aging programs provide the best data to determine shelf life of aging materials. This test is conducted by placing a test item on a shelf and allowing it to be exposed to normal storage conditions. This testing will establish the item's accurate expiration date; however, real-time dating isn't always feasible because products can become obsolete in a short period of time. This is why manufacturers use accelerated dating (although it is important to note that accelerated aging data is only accepted until real-time data is available).

OBJECTIVE 3: DISCUSS EVENT-RELATED STERILITY DATING

In the 1980s, the idea of time-related sterility was challenged (the concept that items were contaminated by events was written in an article by educator and speaker Dan Mayworm); thus, the term "event-related sterility" (ERS) was coined. ANSI/AAMI ST79, Section 10.3.3, states

that contents of a packaged sterile item are sterile unless the package is opened or damaged. Therefore, the package must be carefully checked before a product is used.

While most facilities have adopted ERS, some still use time-related expiration. Whichever is used, The Joint Commission (TJC) requires policies and procedures for either protocol to be consistently applied throughout the facility.

ERS is based on the premise that the shelf life of a packaged sterile item is dependent upon the quality of packaging materials, storage conditions, the condition during transport and the amount of handling of a packaged sterile item. Reaching an expiration date; exposure to dust; temperature and humidity fluctuations; a missing sterility indicator; and the presence of moisture, tears, holes and broken seals are examples of events that can compromise the integrity of a package. Post-sterilization barrier properties of the packaging materials used are another important event.

The Association of periOperative Registered Nurses (AORN) advises that



facilities practicing ERS should adopt a protocol to ensure oldest items are used first, based on the sterilization date marked on each item. Items should be routinely inventoried and rotated so that items with the oldest sterilization date are used first. AORN also recommends sterile items that are unused for more than a year be evaluated to determine whether they should be maintained in a sterile state.

OBJECTIVE 4: DISCUSS PACKAGING MATERIALS' IMPACT ON EVENT-RELATED STERILITY AND IDENTIFY STAFF RESPONSIBILITY IN MAINTAINING PACKAGE INTEGRITY

Due to recent regulatory activities, many are questioning whether ERS is becoming a practice of the past. This is a result of the FDA requiring sterilization manufacturing companies to submit a new 510(k) application to confirm that their sterilization wrap meets all current requirements. As a result of the FDA testing protocols, sterilization packaging manufacturers are implementing expiration dates on some packaging material. Some rigid container manufacturers have also begun to state a time-related expiration date for items sterilized in their systems. It is important to note that packaging expiration dates are considered an "event."

As an example, one major sterilization packaging manufacturer used real-time testing to support a 30-day sterility maintenance claim for their products. After additional testing, they were able to substantiate a claim of one year for some of their specialty wraps that were sterilized using prevacuum systems and ethylene oxide processes.

Although facilities may have adopted ERS protocol for sterility maintenance, manufacturers' expiration dates supersede any ERS protocol; this includes not just the medical device being packaged, but the packaging material as well.

The responsibility for sterility maintenance of sterile supplies belongs to any person who comes in contact with the sterile product. All healthcare professionals should practice proper hand hygiene and follow established procedures for handling sterile packages. Packages should be visually inspected to ensure they are not torn, wet or otherwise compromised. Storage areas should be kept as clean as possible. Packages should be lifted and not dragged from the shelf. All protocols for product cooling should also be followed after each type of sterilization process.

Transport carts and bins should be clean and dry, with no dents or flaws that could damage the packaging materials. Sterile packages should not be stacked when placed on transport carts, case carts and storage carts.

CONCLUSION

Over the years, the practice of expiration dating has been replaced with the process of event-related sterility; however, expiration dates have always been a part of the event-related process. In recent years, manufacturers began performing stability testing on their products to validate the length of time items can remain sterile after processing. It is important for CS technicians to be aware of the length of time items have been validated to remain sterile, and be aware of any events that could compromise the item's sterility. 

RESOURCES

US Food and Drug Administration. Shelf life of Medical Devices. <https://www.fda.gov/downloads/MedicalDevices/.../UCM081366.pdf>

Association for the Advancement of Medical Instrumentation. ANSI/AAMI ST79:2010 & A1:2010 & A2:2011 & A3:2012 & A4:2013, Section 10.3.3. Comprehensive guide to steam sterilization and sterility assurance in health care facilities.

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CRCST Self-Study Lesson Plan Quiz - Expiration Dating

Lesson No. CRCST 157 (Technical Continuing Education - TCE) • Lesson expires November 2020

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1. Event-related sterility means:
 - a. Expiration dates are not necessary
 - b. An item is considered sterile until used
 - c. An item is considered sterile until something happens to compromise that item
 - d. All the above
2. The manufacture date is:
 - a. The date an item expires
 - b. The date an item was made
 - c. The date the manufacturer has determined the product will start to degrade
 - d. Both A and C
3. The time an item remains suitable for use is the definition of:
 - a. Event-related sterility
 - b. Manufacture date
 - c. Shelf life
 - d. Expiration date
4. Expiration dates are developed using:
 - a. US Food and Drug Administration labeling documents
 - b. Association for the Advancement of Medical Instrumentation standards
 - c. Stability studies
 - d. All the above
5. A study that simulates the time period claimed for product expiration is called:
 - a. Accelerated aging
 - b. Event-related sterility
 - c. Expiration dating
 - d. Barrier protection
6. During simulation studies to determine an expiration date, the manufacturer will:
 - a. Vary room temperature
 - b. Vary humidity levels
 - c. Expose packages to conditions that may occur during their shelf life
 - d. All the above
7. According to ANSI/AAMI ST79, event-related sterility means:
 - a. Items should be reprocessed if not used in one year
 - b. Expiration dating does not need to be done
 - c. Facilities should perform accelerating aging studies
 - d. Items are sterile unless the package is opened or damaged
8. When using event-related sterility, items do not need to be rotated.
 - a. True
 - b. False
9. Which of the following is an event that could compromise an item's sterility?
 - a. Storage conditions
 - b. Age of the packaging material
 - c. Post-sterilization barrier properties
 - d. All the above
10. Manufacturers are implementing expiration dating on some wrapping materials, but not on container systems.
 - a. True
 - b. False
11. An expiration date is not part of the event-related sterility protocol because an expiration date is not considered an event.
 - a. True
 - b. False
12. Who bears the responsibility for sterility maintenance?
 - a. Infection Prevention department
 - b. Central Service manager
 - c. Risk Management professionals
 - d. Sterility maintenance is the responsibility of every healthcare professional
13. To help ensure sterility maintenance:
 - a. Good hand hygiene should be practiced
 - b. Packages should be lifted and not dragged from the shelf
 - c. Packaging should be properly cooled after each type of sterilization process
 - d. All the above
14. Visual inspection of sterile packages is part of maintaining package sterility.
 - a. True
 - b. False
15. Sterile trays should be carefully stacked when placing them on transport carts.
 - a. True
 - b. False

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