Event Related Shelf Life

The CBSPD has preapproved this in-service. This in-service is valid for five years from December 2005.

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By: Arlene Carlo RN, BSN, CPM, FCSP
Carlo Consulting Company, Inc
Miromar Lakes, FL

Shelf life, when used with respect to a sterilized product, is defined as the period of time during which sterility is presumed to be maintained. Event related shelf life is based on the principle that specific events, not time, are responsible for sterile products becoming contaminated. Events that can compromise a sterile package include tears or holes in the wrapper, rupture of seals or closures, and wetness and compression of packs.

The practice of event related shelf life recognizes that the contents of a sterilized package should remain sterile for an indefinite period of time unless the integrity of the package is compromised. The integrity of the package is the determining factor in establishing sterility of the contents.

Products such as medication and catheters that may degrade over time still require an expiration date. However, the user bears the ultimate responsibility to visually inspect and assess the integrity of all sterile packages before the contents are used.

Evolution

Shelf life studies were conducted in the early 1970's by the Center for Disease Control using 140-thread count muslin cloth, the primary packaging material at the time. Microorganisms were found to penetrate double-wrap muslin in 21-26 days when stored on open shelves. Based on these studies healthcare facilities used a time related shelf life system for items sterilized in the healthcare setting include:

- The Joint Commission on Accreditation of Healthcare Organizations (JCAHO)
- The Association for the Advancement of Medical Instrumentation (AAMI)
- The Association of periOperative Registered Nurses (AORN)
- The American Society for Healthcare Central Service Professionals (ASHCSP)
- The International Association of Healthcare Central Service Materiel Management (IAHCSMM)

Key Factors

An effective event related shelf life system is an integral part of quality patient care and is a cost effective practice. The timely and costly practice of reprocessing sterile outdated packages is eliminated, thereby improving productivity and reducing processing costs.

The quality of the packaging material, the conditions during transport and storage, and the amount of handling all contribute to maintaining sterility. It is essential for a healthcare facility that is considering a change from a time related shelf life system to an event related shelf life system to review these requirements and perform a needs assessment of the supplies that would be needed, as well as the storage conditions and handling practices at the facility.

Packaging material

The critical first factor is the packaging material. Review the characteristics of packaging material being considered for use. Products that are of high quality and performance should be used to provide an effective barrier to microbial penetration and protection against contact contamination during handling.

Storage

The storage conditions play a key role in maintaining sterility. After sterilization, sterile packages should be stored in an area where they will be protected from the environment, i.e., dust, dirt, moisture, and insects. The sterile storage area is best located in a separate enclosed area with limited access. Temperature, humidity, and air exchanges should be controlled and items should be stored 8-10 inches off the floor, 18 inches from the ceiling and 2 inches from an outside wall.

Handling

The number of times a package is handled before use is also an important factor. Sterile packs should be rotated using the FIFO, first in/first out practice to help minimize the number of times the sterile pack is handled while stored. One source, Gruendemann and Mangum, authors of Infection Prevention in Surgical Settings, state that a sterile package should be handled only three times. First, when removing it from the sterilizer cart and placing it on the shelf; second, when placing it on a case cart or supply cart; and third when it is picked up and opened for use.
Implementation

The implementation of an event related shelf life system requires planning and quite a bit of work, followed by ongoing monitoring and periodic auditing of the process.

Essential steps include:

- Establishing written policies and procedures that include preparation of sterile supplies and labeling, storage and handling, supply rotation, and package integrity assessment.
- Presenting a proposal, to change from a time related shelf life system to an event related shelf life system to the infection control committee for approval.
- Ordering supplies needed to implement the new system.
- Educating all staff involved in the change.
- Selecting a date to begin the transition to the new shelf life system.
- Communicating information regarding the change in shelf life protocol to departments using in-house sterilized items.
- Retrieving existing items from the current time related shelf life system.
- Implementing the new protocol for event related shelf life.
- Monitoring the system on an ongoing basis and periodically auditing the process to ensure continuous quality improvement.

Conclusion

The premise that contamination of sterilized packages is event related and not time related is now widely recognized and accepted in healthcare. Implementing and maintaining an effective event related shelf life system in the healthcare facility can enhance sterility assurance, improve productivity and save money.

References:

- Association for the Advancement of Medical Instrumentation, AAMI Standards and Recommended Practices, Steam Sterilization and Sterility Assurance in Health Care, ST46, 2002 Edition
- "Event Related Shelf Life": Position Paper #3, 1996 ASHCSP/IAHCSMM

About the Author

Arlene Carlo, RN, BSN, CPM, FCSP, is a consultant and serves as a clinical specialist and educator for Case Medical, Inc. Arlene is an experienced central service manager, a member of ASHCSP, IAHCSMM, AORN, and AAMI. She served as the ASHCSP chairperson for the ASHCSP/IAHCSMM Position Paper on Event Related Shelf Life and continues to support the central service profession as an author and speaker.
POST TEST: Event Related Shelf Life

1. Event related shelf life is based on the principal that elapsed time is responsible for sterile products becoming contaminated.
   A. True
   B. False

2. No expiration date is routinely assigned in an event related shelf life system.
   A. True
   B. False

3. JCAHO does not recognizes event related shelf life as an alternative to timed outdating for items sterilized in the healthcare facility.
   A. True
   B. False

4. All are true about sterile packaging regulatory requirements except:
   A. Class II medical device
   B. Regulated by AAMI
   C. Regulated by FDA
   D. 510 (k) required

5. Performance standards of packaging material are critical to maintaining sterility.
   A. True
   B. False

6. The integrity of a package is the determining factor in establishing sterility of the contents in an event related shelf life systems.
   A. True
   B. False

7. An event that can compromise a sterile package would include:
   A. Tears or holes in the wrapper
   B. Rupture of seals
   C. Both A and B
   D. None of the above

8. Storage and handling conditions do not effect sterility maintenance.
   A. True
   B. False

9. A proposal to change from a time related shelf life system to an event related system should be presented to _____ for approval.
   A. Finance
   B. Product Standards Committee
   C. Infection Control Committee
   D. Materials Management Committee

10. Implementing an event related sterility system can enhance sterility assurance and provide improvement in productivity but will not provide any cost savings.
    A. True
    B. False

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