HEALTHCARE PURCHASING NEWS

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LEARNING OBJECTIVES

1. *List eight types of expiration dates commonly used in medical device reprocessing and preparation*
2. *Identify ways to manage expiration dating in sterile processing departments*
3. *Discuss expiration dating activities to help keep departments ready for regulatory surveys*

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Expiration dating in the SPD

by Michele McKinley and Tammy Gentry

Is this expired? It seems like the question should be an easy one to answer by looking at the label of any time-sensitive item in a sterile processing department (SPD). But what if the labeled expiration date isn't the one you need to follow? Many items in the SPD are labeled with expiration dates, but some require new expiration dates once a bottle is opened. Others receive expiration dating after they have gone through a process. Still others must be determined from a combination of items that have different individual expiration dates. In order to be sure that all sterile processing functions are safe and compliant with product instructions, department policies, and regulatory standards, it's important to understand which expiration dates should be followed and where to find them.

Expiration dating purposes and terms

Expiration dates inform users when an item is no longer acceptable to use safely. What makes an item unsafe depends on the type of item. For example, one common item used in SPDs is microbicidal chemistries such as sterilants and disinfectants. As they age, the active ingredients in these formulations can lose their ability to kill or inactivate microorganisms over time. The expiration dates printed on sterilants and disinfectants help prevent staff from using a microbicidal chemistry that is ineffective.

Products that use active biological components can also lose potency over time. One example is enzymes in cleaning chemistry formulations, which can decline and lose effectiveness against their targeted soils. Another example is bacterial endospores in biological indicators, which can weaken or die as they age. Without strong bacterial spores to challenge the sterilizer, the sterilization process may test as "acceptable" but actually be failing to deliver the required kill level, resulting in potential undetected infectious material remaining on the devices after the sterilization process completes.

Many expiration dates are assigned at the time of production by the manufacturer. There are also dates assigned by the sterile processing technician, either when the item is opened or after it has been processed. Technicians must understand when expiration dates are assigned, which are their responsibility, and where they can find the expiration date for every item in the department. Identifying expiration dates requires an understanding of the types and terms for all relevant expiration dates.

- *Expiration or expiry date:* This date is assigned at the time of manufacture. Typically, it is the last day the item

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can be used. The majority of expiration dates include the month, day, and year. However, a few may still have only the month and year printed on the labeling. The instructions for use should state whether it is the first day or last day of the month. These include:

- *Hang time:* Hang time refers to the number of days that a reprocessed endoscope can be stored after drying before it's reused.
- *Open bottle dating:* This refers to the practice of assigning a new expiration date based upon the first opening of a bottle. This date gives the maximum time that an item is stable after the bottle is opened and the contents are exposed to air. Water test strips, high level disinfection test strips and some cleaning chemistries have defined open bottle dating rules. Open-bottle dating does not extend the labeled expiration date of the item; it often shortens the usage time of the contents.
- *Period after opening (PAO) date:* similar to open bottle dating, this is the amount of time that an item remains safe for human use after opening. Although PAO is typically used for cosmetics, it is occasionally seen in instrument processing areas.
- *Post-sterilization shelf life:* This refers to the length of time after a sterilization process that the sterilized item can be safely used. This dating is independent of product expiration dating. Sterilization pouches are a great example. When manufactured, sterilization pouches are assigned an expiration date. This date is related to the pouch's ability to seal and the chemical indicator's performance in the sterilization process. Once the sterilization pouch is used in a sterilization process, the pouch expiration date is no longer valid, and the post-sterilization shelf life date is followed. This date is based upon the ability of the pouch to protect the sterile contents from microbial invasion and the stability of the chemical indicators after they have been sterilized.
- *Shelf life:* This is the time frame within which an item remains fit for use. The shelf life is used to define the expiration date. It can be used to assign the expiration date at time of manufacture, at package opening, or after a process. Labels and instructions for use may include directions based on shelf life such as "stable for two years from date of manufacture" and "use within six months of first opening the bottle."
- *Event-related shelf life/expiration:* This indicates that the item is fit for use until a specified event makes the item unfit. This type of expiration dating is used primarily with sterilized packages of surgical instrumentation. Items are safe for use until an event that can potentially allow microorganisms to enter the package and reach the sterilized items occurs. Tears in wraps, popped pouch seals, and evidence of moisture are examples of events that could allow microorganisms to enter the package.
- *Endpoint stability:* This refers to the timeframe during which a visible test result will remain unchanged. This relates to chemical indicator strips and other test strips that have a visible test result that is interpreted. Although this is not an expiration date, it is often considered in the assignment of expiration dates for sterilized packages that contain chemical indicator strips.

Managing expiration dating

The first step when managing expiration dating is to identify all forms of it used in the department and to document them in policies, procedures, and work instructions as appropriate. Four things should be considered when developing expiration dating documents:

1. Inventory rotation/ first in-first out (FIFO)

Inventory rotation is critical when managing expiration-dated items. Practicing a first in/first out approach ensures that the oldest items are used first. Workstations, local storage cabinets and decentralized storage locations should all be included in the rotation schedule.

Monitor how often each item is rotated through inventory. The longer an item sits in an inventory location, the more likely it is to be moved, handled and exposed to environmental contamination such as dust. If an item is exposed to an event that requires reprocessing and the SPD is unaware, surgical delays can result while replacements are sought and reprocessed.

2. Reconciling expiration dates

When a pack contains more than one item with an expiration date, the pack's label should show the expiration date from the item with the shortest time remaining.

Remember to consider the endpoint stability for any indicators that are inside sterile packages. Chemical indicators (CIs) within sterile packages may give a false fail or false pass result if interpreted after the endpoint stability timeframe has passed. Technicians may need to understand what the result may be and determine, through a risk assessment, the policy for expiration dating of the package to ensure a safe interpretation of the CI before using the sterile items.

Chemical test strips are used to ensure that a disinfectant has the minimum recommended concentration of the active ingredient to obtain disinfection. The result of a test strip cannot be used to extend a disinfectant's open bottle expiration date. Procedures and work instructions should clearly state this.

3. Reprocessing

Items assigned a hang time or expiration date after processing may not be used within the specified hang time. Polices should include instructions for reprocessing expired items and should include which decontamination steps must be repeated. For example, do expired hang time endoscopes require all steps, including leak testing, cleaning, and high level disinfection, for expiration reprocessing?

4. Reconcile event-related and post sterilization shelf life of sterilized items

Event-related expiration dating is commonly used throughout healthcare when labeling sterilized pouches, wrapped items and containers. Observable events include holes and tears in packages, faded external indicators, broken or lifting tape, moisture and spotting, compromised seals, packages showing signs of excessive handling, inappropriate storage and transport, and items dropped on the floor. Other events can happen over time that are not so easy to see, including packaging material degradation, loss of adhesive stickiness, and exposure to environmental bioburden. The manufacturers' post-sterilization shelf life guidance becomes important in these cases. Manufacturers of products such as sterilization wraps must provide a post-sterilization shelf life timeframe so users will know when the effects of time could result in a microbial breach. Each facility should evaluate the vendor-provided post-sterilization shelf life, along with the events that could occur in the facility, to set their policy and procedures for event-related shelf life. A risk assessment may be used to help with this decision.

Expiration dating and regulatory surveys

Credentialing bodies help facilities comply with the requirements of the Center for Medicare and Medicaid Services. Compliance allows a facility to treat individuals taking part in these government

SELF-STUDY TEST ANSWERS: 1. D, 2. D, 3. C, 4. D, 5. A, 6. A, 7. B, 8. B, 9. D, 10. C

programs and obtain payment for the treatment. To qualify, healthcare facilities must pass an initial assessment and then maintain passing results from subsequent inspections and surveys. Sterile processing and endoscope reprocessing activities continue to be a focus of surveyors, with findings that may include expiration dating issues.

"Expired product"

This finding usually involves remote areas that maintain expiration-dated supplies. A few examples: The decontamination area where cleaning solutions are stored beneath sinks, sterile storage areas where bins are used to store peel packs, and product-in-hand sanitization dispensers that are not frequently used.

"Expired indicator strips within sterilized pouches"

In these findings, the expiration date printed on the chemical indicator strip within a sterilized pouch is beyond the indicator's expiration date. The surveyor states that the sterilization pouch should be reprocessed. In this case, it's possible the surveyor may not be knowledgeable about what the chemical indicator's expiration date signifies (the date by which the indicator must be put through a sterilization process). An indicator strip sterilized on the last day of its expiration date will show an expired expiration date within the sterilized pouch the next day but will still be within its endpoint stability shelf life as specified by the chemical indicator's instructions for use. In essence, the chemical reaction or physical change that occurs creates the opportunity for a new expiration date.

When presented with this finding, it is important to share the facility's policies and procedures that address the reconciliation of expiration dates and endpoint stability. Be prepared for the follow-up question, "How do you ensure that the indicator strip is read within the endpoint stability time frame?"

"No open-bottle expiration dating"

This finding is usually noted when surveyors are evaluating high level disinfection practices, but it can be found wherever chemistries (including cleaning chemistries) are used. It often occurs in departments where the entire contents of a bottle will be used within a single shift, so team members do not see the need to document an open bottle expiration date on this container. To avoid this finding, it's important to train staff to label all open bottles every time and to audit staff practices to ensure that instructions for use are followed.

Solutions decanted into basins or sinks also fall within this finding category. Basins should be labeled with the appropriate expiration date as defined in the solution's instructions for use. Be aware that some solutions may have different expiration dating rules between decanted solution and solution that is stored in the opened original bottle.

Preparing for the surveyor

While the SPD and team should always be in a state of survey readiness, day-to-day issues can grab people's attention and allow important processes to be missed. Managing expiration-dated items is one of those tasks that can be overlooked. Here are a few tips to help manage expiration dating so that the department will be survey-ready:

- *Establish a regularly scheduled department walk-through*. Inspect all areas that have expiration-dated items to ensure that all are within their pre-expiration periods and that proper inventory rotation is occurring. Remember that time-limited items are not all labeled with a typical expiration date. Examine work areas to look for product labeling, work bin locations, open bottles, basins and any other items that expire. Check inventory rotation in department storage, sterile storage and remote storage areas. Confirm that FIFO is followed.
- *Audit policies, procedures, and work instructions to assure the inclusion of expiration dating in all its forms*. Confirm that staff demonstrates understanding of and competence with expiration dating policies, procedures and work instructions, which are often included in the training and competency testing for product use and department processes. Remember to include any operating room staff with responsibility for evaluating items supplied by sterile processing in your training and competency evaluation.
- *Have justifications written and approved per facility policies for all expiration dates set within the department*. This can include event-related packaging, hang time, and reconciliation of multi-expiration dated items within a single pack. Risk assessments may be necessary to establish facility policy regarding expiration dating. They should be available or included with each justification.

Understanding and competency will optimize expiration dating

Sterile processing technicians must manage and adhere to expiration dates on time-limited items used for medical device reprocessing and preparation. These dates are in place to assure fully effective decontamination and sterilization products and processes. Some are set by the manufacturer, and some are determined within the department. By developing complete and effective written policies, procedures and work instructions for expiration dating, a department can simplify the nuances and complexity of this function. And by providing regular training and competency testing, managers can maintain proper protocols and avoid expiration dating findings during surveys. In the end, it all comes back to supporting optimal patient outcomes, which is the goal of everyone in healthcare.

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CONTINUING EDUCATION TEST • SEPTEMBER 2022

Expiration dating in the SPD

Circle the one correct answer:

1. **Which of the following do not have an expiration date?**
   A. Sterilants and disinfectants
   B. Chemical indicators
   C. Reusable brushes
   D. None of the above

2. **_____ indicates that a sterilized item is fit for use until a specified event makes it unfit for use.**
   A. Expiration date
   B. Shelf life
   C. Endpoint stability
   D. Event-related shelf life

3. **This is assigned at the time of manufacture.**
   A. Shelf life
   B. Endpoint stability
   C. Expiration date
   D. Event-related shelf life

4. **This term refers to the number of days that a processed endoscope can be stored after drying and before use.**
   A. Post-sterilization shelf life
   B. Shelf life
   C. Endpoint stability
   D. Hang time

5. **The timeframe during which an item remains fit for use is its _____**
   A. Shelf life
   B. Endpoint stability
   C. Expiration date
   D. Hang time

6. **Once a sterilization pouch is used in a sterilization process, the pouch expiration date is no longer valid, and the post-sterilization shelf life date is followed.**
   A. TRUE
   B. FALSE

7. **The timeframe in which a visible test result will remain unchanged.**
   A. Shelf life
   B. Endpoint stability
   C. Expiration date
   D. Event-related shelf life

8. **FIFO refers to**
   A. Sterilization order
   B. Inventory rotation
   C. Survey findings
   D. None of the above

9. **To prepare for an audit:**
   A. Establish a regularly scheduled walk-through.
   B. Audit policies, procedures, and work instructions for inclusion of expiration dating in all its forms.
   C. Have justification written and approved per facility policies for expiration dates set within the department.
   D. All of the above.

10. **_____ continue to be a focus of surveyors.**
    A. Staff findings
    B. Washer disinfectors and ultrasonics
    C. Sterile processing and endoscope reprocessing
    D. Ergonomics

CONTINUING EDUCATION TEST SCORING

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