

“Sterile Storage” By Paul A. Hess, BSN, RN, CRCST, ACSP – Adapted from a presentation by Richard Blackburn, Director of Materials Management, Clarion Health, Gastonia, NC

Objectives:

1. Identify conditions that will compromise the sterility of a package
2. Describe the proper airflow for sterile storage; define positive pressure

airflow.

3. Name major sources of contamination.
4. State recommended temperature & humidity ranges for sterile storage areas.
5. State why the use of shipping cartons for storage containers is unacceptable
6. Compare advantages and disadvantages of open and closed shelving
7. State required distance from floor, outside wall and ceiling for storage of sterile items, explain the source of the requirements.
8. Define and demonstrate FIFO
9. Demonstrate acceptable methods of handling sterilized items, including stock rotation, inspection transport and outdates.
10. Describe the recall and reporting of defective commercially manufactured products.

The goal of any sterile storage area is to provide an efficient, effective space that ensures the protection of sterile items. The packaging alone does not provide a complete barrier against contamination. Each department must establish policies and procedures for storing and handling of sterile items. Managers must assure that the staff adheres to these policies.

Sterile storage areas must provide conditions for sterile items to not only remain sterile and functional, but must also be available when needed. Three conditions that will compromise packaging and sterility maintenance are: moisture, soil and physical damage.

We need to establish safeguards to maintain package integrity and sterility. These are:

1. *Environmental controls* in the form of temperature maintenance and humidity control. We must minimize airborne contaminants in the form of dust via unfiltered and untreated outside air, air fresheners and insect sprays. A positive pressure airflow where the airflows out into less clean areas helps to prevent contaminants from entering the storage space. Ideally ten air exchanges an hour are recommended. That means that the volume of air being circulated into a storage area is sufficient to be completely changed ten times each hour. The air being sent into the storage area ideally needs a temperature range of 65°F to 72°F with a relative

humidity range between 35 and 75%. It is a good practice to develop a contingency plan within each department on handling extreme changes of temperature and humidity. Always evaluate the circumstances that cause a situation to develop. As an example, a sudden increase in temperature and humidity as can happen during a power failure, will cause it to “rain” within a normally controlled environment. This situation would cause contamination in a very short period of time. Another way that this can happen is if the sterilized package is taken from a controlled environment and transported in an uncontrolled environment, the same contamination will happen. A gradual increase in temperature without an increase in humidity, makes everyone uncomfortable and does not make ideal storage conditions, but will also not produce the type of contamination seen during a sudden change. Sterility maintenance is a matter of the products storage conditions not some arbitrary point in time.

2. *Controlling traffic patterns.* Storage areas ideally need to be located away from general traffic patterns. Limit personnel access to sterile storage areas. Storage areas ideally need to be at or near the point of use. Transport systems that provide for the protection of the sterile package while in transit. Personnel are a source of contamination. Housekeeping personnel must be aware of sterile storage standards and utilize products and techniques that will not contaminate the integrity of the sterile items. Proper attire, good employee hygiene and health are essential to maintain integrity of the storage areas. Storage areas must prevent contamination from containers and transportation vehicles. Use transport containers that have rounded edges and no sharp protrusions.
3. *Storage systems* are two basic types: open or closed. Open shelving is economical, easy to clean, allows easy access to the user and conserves floor space. It does not offer the best protection however. Being open the supplies are subject to passers by and to environmental influences. If you are using open shelving you need to keep items 8” from the floor, 2” from the outside walls, 18” from ceiling fixtures such as sprinklers. You need to provide an impervious barrier between the bottom shelf and the floor. Do not locate a storage shelf unit under uninsulated water pipes or sewer lines. Closed shelving offers better protection against damage and contamination. The drawbacks can be that they are more expensive; the supplies are not easy to access. Closed shelving frequently is used for seldom-used items because of the greater protection that they provide.

General considerations for sterile storage, regardless of the

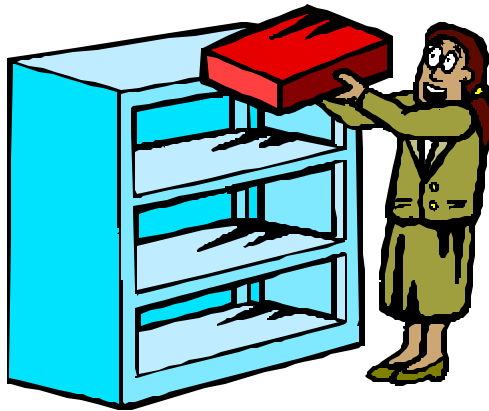
type of storage units include allowing freshly sterilized items to cool properly before storing. Never handle a warm package. If you find it necessary to handle a warm package it must be considered contaminated, the seals need to be broken and the item reprocessed before use. Use a sterility maintenance cover (dust cover), 2 to 3 millimeters thick to enhance the protection for items that you expect to remain idle on a shelf for a prolonged period. Assure that the package is the correct size and is properly sealed. It should fit flush so as not to allow a ballooning of the cover. This will act as a bellows and through handling the organisms on the outer wrap will be forced into the package. It must also be labeled as a maintenance cover so that the end user knows that the package outer wrap is not sterile, that only the contents are sterile. When placing items on the shelf, ensure enough space to easily accommodate the normal inventory level. Do not overcrowd, over stack or compress packages to make them fit.

Proper Inventory Control / Proper handling of sterile items. Develop systems will minimize handling of supplies by staff. You can distribute supplies by loading onto carts, carrying in baskets, totes, etc. Never carry sterile supplies under your arm. The moisture will contaminate the package. Any time you handle a package, check the package integrity. Look for tears in the wrapper, soil, and evidence of water contamination, pinholes. Check that the seals are intact, that the sterilization chemical indicators, if present, have changed to their appropriate color and that the product has not passed its expiration date. If any of the above conditions are not met the item must not be used until reprocessed if possible or discarded if it is a single patient use / disposable item. If it is a single patient use item you may want to consider making the device available to your educators to use as a teaching tool. The product would get some use and the educator would not have to waste a perfectly good product for a demonstration.

Proper inventory control also means that you must have proper housekeeping practices. When cleaning, move from clean areas to dirty. Dust, insects and vermin can be carriers of microorganisms. Clean up all spills immediately. Establish a regular, routine schedule for cleaning. Remember, just because it may be housekeeping's job to clean your department, you are still responsible for it's cleanliness!

Proper inventory control also means stock arrangement and stock rotation. FIFO means **F**irst **I**n, **F**irst **O**ut. Move your stock left to right and back to front. In other words, load your shelves from the left and pull from the right side and load from the back and pull from the front. Stock rotation also means shelf life. The majority of healthcare facilities have adopted the concept of event related sterility for the good that they produce. Simply

stated, a product is sterile until it's not. The most common form of shelf life is an expiration date entered by the manufacturer. This may be a point in time determined by the manufacturer based on the viability of their product after manufacture. In fact, most products bear a statement that the "package is sterile until opened or damaged". In this scenario, an expiration date is based on the products ability to perform rather than it's ability to remain sterile. Shelf life is more a matter of a storage environment than an arbitrary point in time. Outdating supplies is a surveillance that needs to be conducted on a regular basis. Expiration may be stated as a particular calendar date (the milk in your refrigerator is a good example) or a given measure of time after the date of manufacture. A common symbol being used to denote expiration is ⌚. A common symbol being used to show



manufacture date is 🏭. Both symbols would be accompanied by a calendar date. Each facility must have a policy designating your protocols for expiration outdating and supply rotation. A statement that I've heard used is "When in doubt, throw it out." To that I would add reprocess or recycle if possible.

Occasionally a manufacturer, usually based on an adverse event or a quality assurance problem, conducts a recall of its product. The manufacturer will notify the healthcare facility of which products are included by name, catalog number, and lot number, as applicable. These recall notices may be sent to the Purchasing, Materials Management, Biomedical and Risk Management departments. In some instances they must report these occurrences to the Food and Drug Administration.

In conclusion, once packaged and sterilized, an item must be protected from contamination through various methods of environmental control, appropriate shelving, stock rotation, proper handling, inspection and cleanliness.

For Additional Reading

Training Manual for Health Care Central Service Technicians, Fourth Edition, Chapter Eight, 2001
American Society for Healthcare Central Service Professionals of the American Hospital Association.

AORN Recommended Practice: Sterilization, 2004 Standards, Recommended Practices, and Guidelines, Association of Perioperative Nurses, Denver, CO

