

The Role of Central Service in Infection Prevention



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- Study Guide #12

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Description of Study Guide Topic

This study guide will review important elements and activities of Central Service that affect infection prevention.

The Central Service department is usually responsible for:

- > Pick-up and transport of soiled equipment and instruments from patient care areas to the decontamination area

- > Decontamination of soiled patient care items and equipment, surgical instruments, medical devices and other healthcare equipment

- > Inspection and preparation of items before distribution or further processing

- > Disinfection and/or sterilization of medical devices, surgical instruments and equipment

- > Physical, chemical and biological monitoring of sterilization cycles

- > Sterility maintenance and distribution of the items to other departments

- > Continuous quality process improvement

Overall Purpose of the Study Guide

To review the important functions of Central Service with a focus on the important role this department plays in infection prevention.

Objectives

Upon completion of this independent study, the participant should be able to:

1. Review important work practices related to the preparation of items for terminal sterilization.
2. Describe the methods of monitoring the sterilization process.

Intended Audience

This study guide provides for independent study for those persons who need to improve their understanding of the Central Service department in infection prevention: Central Service managers and technicians, perioperative nurses, surgical technologists, infection preventionists, etc.

Introduction

Although this department has many names, such as SPD, CPD, CSPD, CSD, CSSD and CMS, we will refer to it as Central Service (CS).

How many of you have ever really asked yourselves what role Central Service plays in infection prevention in your healthcare facility? Have you ever visited the department to ask questions and seen exactly what the daily responsibilities are? If you work in the surgical suite, have you ever spent time in Central Service to get a better understanding of the support it provides to your department?

If you are an infection prevention professional, have you ever had to address a problem that involved the CS department? Were you comfortable with your knowledge of how their overall mission affects patient care?

Most departments that are supported by Central Service are not knowledgeable about the complexities of this department's role in infection prevention. It is not due to a lack of interest, but more likely, a lack of time and often a lack of adequate staffing that prevents learning. It is difficult to spare staff for this type of orientation. In spite of the challenges, it is advisable to at least include Central Service in orientations for newly-hired healthcare employees, so that they understand how this department supports their area and many other areas in the healthcare facility. They will learn that CS departments are also tightly staffed, yet have a huge responsibility to support excellence in patient care.

Every person performing tasks in Central Service must keep in mind the ultimate goal - infection prevention. This department's function is to provide products for healthcare that are safe to handle by colleagues and people in other departments and are safe to use in patient care.

Standards and Recommended Practices

All of the tasks performed by Central Service professionals should follow established standards and recommended practices provided by the Association for the Advancement of Medical Instrumentation (AAMI). AAMI is accredited by the American National Standards Institute and is recognized as one of the principal voluntary standards organizations in the United States.

AAMI provides a forum for more than 60 technical committees, subcommittees and working groups that write consensus voluntary standards for medical devices, technical information reports and recommended practices. Its standards documents are respected around the world and are used as models and references nationally and internationally. They are the standards of practice for the United States for decontamination, sterilization and related topics and are referred to by healthcare organizations, state and local departments of health and the Joint Commission (JC). The information is prepared by representatives from:

- > The International Association of Healthcare Central Service Materiel Management – IAHCSSMM (www.iahcsmm.org)
- > The Association of periOperative Registered Nurses – AORN (www.aorn.org)
- > The Association for Professionals in Infection Control and Epidemiology – APIC (www.apic.org)
- > The Certification Board for Sterile Processing AND Distribution – CBSPD – formerly NICHSPDP (www.sterileprocessing.org)
- > Various healthcare product and equipment manufacturers' experts, healthcare professionals, private consultants and the FDA

The AAMI standards are purchased directly from AAMI (www.aami.org) and should be a basis for Central Service policies, procedures and quality process performance requirements.

Similar standards are prepared for Canada by the Canadian Standards Association - CSA International (www.csa.ca). Other countries throughout the world may have their own national standards for practice.

Supportive education references and guidelines are also available from professional organizations. Healthcare device and processing equipment manufacturers provide additional educational materials and seminars.

Central Service management must acknowledge the importance of understanding these standards and using them to implement necessary process quality improvements.

The following information on decontamination can be found in the AAMI document "Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities" (ANSI/AAMI ST 79:2006), where the topic is comprehensively presented.

Pick-up and Transport of Contaminated Items

Central Service management has a responsibility to communicate to their customer departments exactly how they want contaminated items to be prepared for pick-up. The customer might be required to remove visible soil from surgical instruments and equipment with a water dampened sponge. In other cases, heavily soiled items like those from orthopedic surgery, may need to be soaked in an enzyme solution. Strong consideration should be given to using spray gels and foams that keep soil moist on instruments. The advantage of spray gels and foams limits the use of water that adds the risk of splashing and exposure to contamination. In each case, the contaminated items are to be placed in impervious containers to prevent the transporter from direct contact with them and to prevent splash or spill accidents.

User departments should discard all sharps, trash and liquids at the point of use, and keep everything together for transport to the decontamination room. Customer departments have the responsibility to prepare contaminated items exactly as instructed by Central Service so there are no injuries due to sharps, disposable needles or scalpel blades left in an instrument tray. The outside of the impervious plastic bag or rigid container should not be contaminated because safety must prevail for the transporter and others who will handle these containers with bare hands.

The transporter has the responsibility to handle the items carefully to avoid injury, as well as personal and cross contamination.

Decontamination

The Environment

The decontamination room is a restricted area that should be occupied only by the people working there. It should be an area that is separate or with a spatial barrier where contaminated items are carefully decontaminated to render them safe to handle before distribution or further processing.

AAMI standards for the decontamination environment include:

- > adequate space to accommodate the activity that takes place there
- > floors, walls and work surfaces that are easy to clean and dry and disinfect - microorganisms should not be allowed to hide and replicate in this area

- > good general lighting and special lighting over work areas that may include magnifiers with light for better visualization while cleaning fine and delicate instruments
- > excellent ventilation – air under negative pressure (exhausted to the outside) in the decontamination area so that dust, particulates and aerosols do not migrate into clean, sterilization, or storage areas where the air is at positive pressure
- > at least 10 air exchanges per hour
- > temperature at 60-65° F (16-18° C) and relative humidity at 30-60% for worker comfort and to reduce the probability of microbial growth (especially molds) and increased overall bioburden. Temperatures and humidity levels must be logged daily
- > separate hand washing sink that is hands-free and separate from decontamination sinks. Hand washing sink should be near the exit from the department
- > housekeeping and decontamination supplies must be kept separate from those used in clean preparation areas
- > an emergency eyewash and shower

Standard Precautions

Standard Precautions guidelines teach us to assume that all soiled or contaminated items may harbor harmful microorganisms and that we must protect ourselves from direct contact. People with irritated or broken skin should not work in the decontamination area. A policy and procedure should be in place that indicates what measures should be taken to protect the staff member's wound area if decontamination work is unavoidable. Wounds must also be covered when working in clean areas so that any microorganisms from the wound are not spread to work surfaces, clean and sterile products and co-workers. The facility's infection prevention officer should be involved in preparing this policy and procedure.

Personal Protective Equipment - PPE

Wearing PPE is a necessary and mandated infection prevention measure. CS personnel are required to wear PPE, according to the Occupational Safety and Health Administration (OSHA) document "Occupational Exposure to Bloodborne Pathogens Final Rule 29 CFR Part 1910.1030," found in the Code of Federal Regulations. OSHA defines PPE as "specialized clothing or equipment worn by an employee for protection against a hazard. General work clothes (e.g., pants, shirts, blouses) that are not intended to function as protection against a hazard are not considered to be PPE."

Decontamination workers should wear clean, facility-provided uniforms; usually scrub pants and shirt, safe nonskid shoes or boots that can be cleaned and head and facial hair cover. PPE consisting of general purpose liquid-proof long cuffed utility gloves, liquid-resistant shoe covers, gowns and long sleeved aprons or jumpsuits should be worn over this basic scrub attire. A surgical mask and eye protection (safety goggles, full face, or eye shields) are also necessary. Persons working in the decontamination area must inform management if the PPE does not fit them properly or is uncomfortable and if the eye protection distorts their vision, so that accommodations can be made. When the PPE is removed, the basic scrub attire should be inspected for cleanliness. If uniforms are soiled or wet they must be removed and workers should shower or spot

clean themselves and put on clean uniforms.

Although everyone knows that PPE is for their protection, some fail to understand that wearing it and removing it properly also protects other healthcare workers, clean work areas, patients and perhaps their own families. Managers must make it perfectly clear that PPE is not optional. State health departments, JC and OSHA can levy heavy fines for noncompliance in the use of PPE. There can be no tolerance for noncompliance.

Safe Work Practices

Safe work practices simply require common sense. A sensible workflow pattern (dirty to clean) is established and policies and procedures followed to prevent cross contamination in the decontamination environment. Although room layouts and equipment are not always ideal, measures can be taken to do the best with what you have.

For example:

- > Extra supplies that are used in the decontamination process should not be removed for use in other areas of the department. Consider that the drawers, cupboards and open shelves near the decontamination work sink will all be contaminated by aerosolization of soiled cleaning liquids, or by persons accessing items from those areas wearing PPE. If others must access the extra items and there is no clean storage area outside the decontamination room, a closed cupboard might be placed at the door to the area, far away from the sink. It would be labeled “clean storage” to remind everyone not to touch it with soiled hands or gloves
- > Decontamination workers should be careful to limit splashing and subsequent aerosols by avoiding washing and rinsing under running water. Cleaning should be performed under the water level in a sink of cleaning solution, with a second sink of water for rinsing
- > Low-foaming detergents should be used to provide a clear view beneath the water surface. This can reduce the risk of accidents from sharp items
- > PPE should be worn when working with an ultrasonic cleaner to prevent contact from the aerosolization that may occur. Ultrasonic cleaners are operated with lids closed during the cleaning and rinsing process

Decontamination vs Cleaning

Decontamination is a two-step process that begins with thorough cleaning and rinsing. Some items may only need to be cleaned and rinsed, depending on how they are used and what the likelihood of disease transmission is with subsequent uses. The second step, the application of a microbicidal process such as disinfection or sterilization, can be used to further the decontamination process.

Cleaning

Medical devices, surgical instruments, patient care and surgical utensils, as well as other patient care equipment must all be processed according to individual manufacturer’s instructions. Their guidelines for disassembly and the acceptable methods for cleaning, enzyme soak, detergent use, rinsing and drying must be followed. Each device manufacturer must validate the processing guidelines for efficacy. CS personnel must follow the documented instructions precisely. Sometimes hands-on education needs to be provided by

the manufacturer representative to ensure that everyone clearly understands the process. Cleaning can be accomplished manually or mechanically, depending on the manufacturer’s instructions for their product. No matter what method is used to clean items, there are critical factors that must be considered for a favorable outcome:

- > the type and amount of soil - protein soil from blood and body fluids, tissue, feces, urine and sputum; amylase, fats or oils, ointments and lubricants
- > the condition of the soil - moist or dried on the surfaces
- > the choice of a detergent that is compatible with the type and condition of soil, the item to be cleaned and the method of cleaning
- > the water temperature and water quality (degree of hardness) compatible with all of the above
- > the duration of cleaning activity, either manual, mechanical or a combination of both
- > the configuration of the items – opened or disassembled
- > the configuration of trays of instruments for mechanical processing – opened or disassembled, in a tray that is not overloaded so the cleaning activity can reach all surfaces
- > the direction and force of mechanical cleaning activity (wash and rinse waters)

There are several types of automated washer/disinfectors available to CS, some of which incorporate a thermal disinfection phase and/or chemical disinfectant rinses capable of destroying various types of microorganisms. The manufacturers of this equipment provide information regarding the efficacy of the process. Depending on the type of automated system used, the processed items are generally rendered safe to handle. The various types of washing systems include:

- > ultrasonic cleaners (for fine cleaning) to remove soil from cracks, crevices, joints, lumens and other areas that are difficult to clean by other methods
- > utensil washers and cart washers
- > washer/sanitizers and washer/disinfectors
- > pasteurization equipment
- > washer/sterilizers

Some items will only require thorough cleaning and rinsing because they only come in contact with healthy intact skin; others may require further processing that includes a microbicidal process.

Microbicidal Processes

The second step in decontamination is the use of a microbicidal process. This step is designed to provide a particular level of microbial lethality or “kill.” Depending on the level of kill needed, this will be accomplished by a disinfection or sterilization process. This step is necessary when thorough cleaning and rinsing are not enough to adequately decontaminate a medical instrument or device that, because of its design or application for use, is capable of harboring contamination that can present a high risk of disease

transmission to workers or patients.

Some of the automated washing equipment mentioned earlier incorporates these processes. Items that cannot be mechanically processed may undergo manual application of a disinfectant or a separate sterilization cycle to complete decontamination.

The type and level of microbial kill depends on the:

- > bioburden type and population
- > type of antimicrobial agent used
- > concentration of the active ingredients of the liquid disinfectant
- > spectrum of the disinfecting or sterilizing agent's effectiveness
- > exposure time and temperature to the disinfecting or sterilizing agent
- > bioburden resistance
- > presence of any inactivating substances
- > proper use of microbicidal method

CS managers assess their processing needs and choose the decontamination methods that best suit their challenges. They must fully evaluate the options and equipment that are available to them. One method will not be suitable for all circumstances.

Preparation for Terminal Sterilization

Once the decontaminated items reach the clean preparation area, they are considered safe to handle. On this side of the department they are thoroughly inspected for cleanliness and proper working order before being assembled into sets and wrapped or containerized for sterilization.

Preparation for Steam Sterilization

CS staff knows that steam must penetrate all surfaces, therefore all hinged instruments must be open and all multipart instruments must be disassembled, following manufacturer's instructions. This is often a challenge because some customers do not want the instruments disassembled in the sets. If instruments are not prepared properly it is likely that surfaces will not be sterilized. When the users move or remove parts (like the sliding blade on a self retaining retractor, a locked ratchet on a clamp or towel clip, or the tip of a tonsil suction) during a procedure, they are likely to uncover non-sterilized surfaces and risk contaminating the sterile field and putting the patient at risk for an infection.

Air is another enemy to steam sterilization so the lumens of catheters, needles and tubings are flushed with distilled, deionized or sterile water (unless the device manufacturer warns against it) just before wrapping and sterilization. The moisture in the lumens facilitates the movement of air out of the lumen as it turns to steam. The CS department does not use tap water because of the possibility of pyrogens that can cause fevers of unknown origin.

Mesh or open instrument trays are perforated for drainage of condensate and are generally lined with an absorbent surgical towel (reusable or disposable). The metal mass is distributed evenly throughout the tray to enable more efficient sterilant penetration

and drying at the end of the sterilization cycle. Rigid sterilization container manufacturers must be consulted before towels are used with their containers. The instrument trays must lay flat on the sterilizer shelf for more efficient air removal, sterilant penetration and contact and drying. Producing dry sets at the end of the cycle is essential for sterility maintenance.

Basin sets are prepared using absorbent surgical towels to separate the nested utensils within the set. The towel separates surfaces for more efficient air removal, sterilant penetration and drying. The utensils in the basin set are all prepared so wrapped sets are placed on edge in the sterilizer shelf and condensate can drain from them.

Textile products and wrappers should all be made of materials that will permit adequate air removal, sterilant penetration and drying. Textile manufacturers are consulted for their validated pack assembly recommendations (pack size and density). The packs are prepared using this information and the OR's pack arrangement requests. Packs wrapped too tight or too dense will likely trap air and may not be sterilized.

CS professionals understand that textiles must not be ironed after laundering to avoid superheating them during steam sterilization. Superheating can deteriorate textiles and prevent steam sterilization from occurring because the steam may become too dry as moisture is penetrating and hydrating the "too dry" textiles.

Textile packs are positioned in the sterilizer so layers of fabric within are perpendicular to the shelf, for ease in air removal, sterilant penetration and evacuation for drying.

Preparation for Ethylene Oxide Sterilization

Ethylene Oxide (EO) sterilization preparation is basically the same as for steam in that everything must be clean and thoroughly dry. Lumens are not flushed with water before sterilization because EO and water form ethylene glycol (antifreeze), an undesirable byproduct that may not be made safe with aeration.

Too many absorbent towels in wrapped trays can absorb too much of the limited moisture available in an EO sterilization cycle. The humidity hydrates microorganisms to enable the EO to penetrate and kill. If there is not enough humidity the sterilization process may be ineffective. CS limits the use of these towels for EO cycles.

Additional low temperature sterilization methods are available to healthcare facilities. CS management must investigate the compatibility for the items they process and follow the manufacturers' instructions carefully to achieve sterilization. Items sterilized by one method can not necessarily be processed by a new method, unless the medical device manufacturer has validated that the process is acceptable and effective for their product.

Packaging Materials for Sterilization

The wrappers (textile and disposable), paper or plastic peel pouches, rigid sterilization container systems and all accessory products used with any sterilization process are evaluated before purchase. The manufacturers of these products must provide validated documentation that their products are compatible for use with the specific sterilization systems and cycles being utilized. CS managers should ascertain that these products will permit air removal, sterilant penetration and evacuation and (in the case of ethylene oxide sterilization), aeration. In addition, packaging products should:

- > be free of toxins and non-fast dyes

- > be low-linting
- > provide an adequate barrier to microorganisms
- > resist tearing and puncturing
- > maintain excellent seal integrity that is tamper-evident
- > enable ease in aseptic presentation
- > be cost effective

The AORN Standards, Recommended Practices, and Guidelines contains a document called "Selection and Use – Packaging Systems" that has been the primary guidance for packaging materials since the 1970s. AAMI also has a standard called "Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities" (ANSI/AAMI ST 79:2006), as well as "Processing of Reusable Surgical Textiles for Use in Health Care Facilities" (AAMI, 2000).

Monitoring Sterilization Quality Control

Monitoring the sterilization process is just as important as properly preparing items for sterilization. It is important to remember that sterilization of items is a probability. In order to achieve sterilization, the instruments, medical devices, textiles, etc., must be properly decontaminated, prepared, wrapped and loaded for sterilization. The sterilizer must also be routinely maintained. The operator must choose the correct sterilization method for the items to be processed, the correct cycle time and temperature and the optimal aeration time for EO-sterilized items.

Physical Monitors

Gauges, chart recorders and computer printouts monitor and record cycle parameters on the varying types and ages of sterilizers being used today. Cycle data must be reviewed at the completion of every cycle and before the next cycle is initiated to see how the sterilizer performed the previous cycle. The printout data should also be checked during the phases of the cycle and when the cycle is complete to see if the sterilization parameters were achieved.

Sterilization Process Indicators

Chemical indicators are critical visual indicators that assist in distinguishing between processed and unprocessed packs. They can also verify sterilant penetration, air removal of prevacuum sterilizers and can be used to monitor and release loads for patient use.

Classes of Indicators

AAMI (ST79:2006) and ISO (EN ISO 11140-1:2005) recognize six classes of chemical indicators (CIs). Each class has different performance specifications. The use and application for indicators in Classes 1 through 5 can be found in AAMI ST79:2006. However, use recommendations for Class 6 indicators have not been incorporated into ST79. The following list details the definitions for each type of chemical indicator:

Class 1: process indicators

The first chemical indicator ever to be used was a process indicator. These simple indicators are used to identify the difference between processed and unprocessed items. Today, they come in a multitude of shapes and forms from sterilization tape to indicator strips on rigid container external data cards, or record keeping cards that are included in sterilization loads. Class 1 process indicators DO NOT relate to the delivery of sterilization parameters and they DO NOT

indicate a successful cycle or sterilization parameter.

Class 2: indicators for use in specific tests

Today, they are defined as a Class 2 indicator. This is a little misleading because a Class 2 is "An Indicator for Special Test." These are tests that are not used to verify sterility, but used to verify a specific feature or performance specification of the equipment. To date, only one indicator fits this definition, the Bowie Dick Test. The Bowie-Dick test is designed to test for air removal in vacuum-assisted steam sterilizers.

Class 3: single variable indicators

Class 3 are internal indicators that are single-parameter. They are much like the class one CI, except one is an external and the other is internal. This type of indicator would not be a typical indicator used for steam sterilization, but it is an indicator used for sterilization methods such as vaporized hydrogen peroxide.

Class 4: multi-variable indicators

Class 4 internal indicators are multi-parameter indicators, responding to two or more of the critical variables of the sterilization cycle. Class 4 indicators are NOT correlated to the BI kill. These chemical indicators do provide a high degree of sterility assurance. The class 4 CI, when used in every pack, confirms that the steam at the right temperature has penetrated the pack for a sufficient length of time.

Class 5: integrating indicators

Class 5 chemical indicators are called integrators. They respond to ALL the critical variables of the sterilizing cycle. The response is correlated to the BI kill. Class 5 integrators can be used in gravity and pre-vacuum cycles. These chemical indicators continue to monitor the sterilizing cycle after the biological spores have been killed so the class 5 integrators are more accurate at monitoring the sterilizing cycle than the BI challenge.

Class 6: emulating indicators

Emulating indicators are cycle verification indicators that are designed to react to all critical variables for specified sterilization cycles. The indicator demonstrates a passing condition only when the minimum programmed exposure has been achieved. This type of indicator or emulator measures all of the critical variables/parameters of steam sterilization and has a tighter tolerance. This means that it measures even more of the cycle than the Class 5 integrator.

This classification system of chemical indicators refers primarily to indicator strips, but it also applies to challenge packs containing chemical indicators. When used for load monitoring, the challenge packs provide an immediate confirmation of a sterile load. At minimum, a Class 5 indicator must be used in biological indicator test packs. Alternatively, a Class 6 emulating indicator may be used to release loads. Class 6 emulating indicators are currently used throughout the world. Class 6 indicator strips and challenge packs consist of thermochromic ink printed on either an indicator strip or a test sheet. Indicator strips should be included in each pack to be sterilized in the most challenging area's of each pack. Class 6 challenge packs are used to monitor and release sterilization loads consistent with country regulatory requirements.

The CS manager evaluates the items to be sterilized and determines whether a Class 4, 5 or 6 process indicator will be used inside each package. Consideration should be made to use an indicator on each tier level of a set and in areas of greatest challenge. When the package is opened, the indicator will show whether or not the sterilant penetrated the most challenging part of the pack. CS management should teach anyone who opens sterile packs in a healthcare facility how to interpret these process indicators.

Dynamic air removal sterilizer residual air testing is performed using the Class 2 process indicator each day that the sterilizer is used and before the first processed load of the day. It is important that a warm-up cycle is run before running the test cycle. Failure to do so may result in a failed Bowie-Dick test, because of noncondensable gases that may accumulate in down-time. This test evaluates the effectiveness of air removal at the beginning of the dynamic air removal cycle (typically known as the prevacuum cycle). It is not a sterility assurance test and is not performed on the gravity displacement steam sterilization cycle. The steam flush pressure pulse (SFPP) steam sterilization cycle provided on some sterilizers does not require this test. Always follow the sterilizer manufacturer's instructions regarding the need for residual air testing. CS staff must be thoroughly trained in recognizing subtle differences for determining pass or fail results.

Biological indicators are a sterilization process monitoring device used to determine whether appropriate parameters were achieved during a sterilization cycle. The test strips carry a viable population of microorganisms, usually bacterial spores known to be most resistant to a specific sterilization method. Steam, vaporized hydrogen peroxide, hydrogen peroxide gas plasma, liquid peracetic acid and ozone sterilization methods are biologically monitored using *Geobacillus stearothermophilus* spores. Ethylene oxide and dry heat sterilization is biologically monitored using *Bacillus atrophaeus* spores.

A negative biological test result only indicates that the sterilization cycle delivered the appropriate parameters for kill. It does not indicate that everything in the load is sterile. As discussed earlier, a properly functioning sterilizer is only one of the elements needed for successful sterilization.

Steam and ethylene oxide sterilization are the only two methods that have an AAMI standard that describes how to perform biological testing. The tests should be performed after a sterilizer has been installed, relocated or undergone major repairs. Routine biological monitoring is also performed at least weekly and preferably daily, for each type of steam sterilization cycle used. In addition, every steam sterilization cycle load containing implantable medical devices must be biologically monitored. Every ethylene oxide sterilization cycle is biologically monitored.

Testing these methods of sterilization requires the use of specific AAMI test packs or their commercial equivalent. CS departments who make their own test packs should ensure they are prepared properly according to AAMI guidelines. The configuration of AAMI test packs and methods have been scientifically validated for use. Process challenge devices containing biological indicators are commercially available from many manufacturers.

Periodic quality assurance biological testing should also be performed on the actual products that are being sterilized. To perform the periodic testing, biological indicators and appropriate chemical indicators are placed inside the test sets/containers. The test packs are placed in a routine sterilizer load among other sets being sterilized. At the end of the sterilizer cycle, the BI's + CI's are retrieved, handled appropriately and the results recorded.

The standards and recommended practices that CS professionals follow are presented in the AAMI documents "Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities" (ANSI/AAMI ST 79:2006) and "Ethylene Oxide Sterilization in Health Care Facilities: Safety and Effectiveness" (AAMI, 1999). The AORN Standards, Recommended Practices and

Guidelines "Sterilization in the Practice Setting" is also referenced (AORN, 2008).

Sterilization cycle information is to be kept by hand-written records if computer printouts are not available, or with a combination of both. The information should include the

- > sterilizer identification (name or number)
- > date and time a cycle is run
- > exposure time and temperature
- > name or initials of the sterilizer operator for the specific cycle
- > results of chemical indicator placed in PCD and/or biological indicator in PCD

Load Identification

Lot control numbers are used on packages that indicate the date an item was sterilized, the exact sterilizer used, the cycle number and sometimes an expiration date.

Load control cards identify everything sterilized in each sterilization load so that if a product recall is necessary CS staff can track every item.

Product Recalls

Although it is rare, there are times when CS has to initiate a recall of the products they have sterilized because of a positive biological test result (one that shows bacterial growth) from a sterilization cycle. When this occurs, all products that were processed in that particular sterilizer since the last good (no growth) biological test results are recalled.

AAMI has outlined a protocol to follow that is included in the steam and ethylene oxide standards mentioned earlier. It is recommended that CS departments have a recall procedure that

- > is written
- > outlines the circumstances for a recall
- > designates persons responsible for initiating the recall
- > designates who is responsible for reporting execution of the recall

A recall order should be written for each event that

- > identifies sterilizer and lot number and identifies the items to be retrieved
- > lists the departments where they can be found
- > requires recording the kinds and quantities of items recalled and the results
- > specifies action to be taken by the receiver of this recall order

A recall report should be written that

- > identifies the circumstances that prompted the recall
- > specifies corrective action to prevent recurrence
- > states the results of the recall and the items retrieved
- > indicates how the recalled items were handled once retrieved

This same recall protocol can be used for items recalled by various medical product and device manufacturers.

Sterility Maintenance

Sterility maintenance must be placed high on the list of things to do properly for infection prevention. After investing the effort and time to produce sterile products for patient care, we must be careful not to contaminate them before use. If safely handled and stored, a package can remain sterile for an indefinite period of time.

Expiration Dating

For at least the last 20 years, many hospitals have been using a statement such as “Contents are sterile unless the package is opened or damaged,” indicating conditional expiration rather than a specific date. If a sterilized package contains something that has a definite degradation date, that date becomes the expiration date.

Shelf Life

The shelf life of a sterilized item is event-related. Its sterile integrity depends on

- > the quality and bacterial barrier properties of the packaging method and material
- > its storage conditions – open or closed carts, shelves or cupboards, in restricted or non-restricted areas and
- > how it is handled and transported

CS departments protect sterile items by following protocol.

Cooling Sterilized Items

Once a sterilization or aeration cycle has completed, the items are not touched until they are thoroughly cooled. Cooling can take

30 minutes up to two hours depending on the items. Heavy metal orthopedic instrument sets usually take the longest amount of time to cool. The items must cool on the sterilizer cart in a low traffic area, away from air conditioning vents, to prevent condensation that can result in a wet pack.

If wrapped or paper/plastic pouched items are warm or hot they must not be touched because moisture and bacteria from hands and other surfaces can be wicked into the package. Never place warm or hot wrapped packages and rigid sterilization container systems on cold solid surfaces because condensation can occur on and within the packs, making them unsafe to use.

Handling Sterilized Items

CS personnel handle clean and sterile packages with clean and dry hands. They visually inspect every cool (to touch) sterile item as it is removed from the sterilizer cart to be certain the wrapper is dry and

intact. Do not squeeze or compress a wrapped package so as not to force particulate into it via the “bellows effect.” Packages are held away from the body and are never placed under the armpit (axilla), or stacked between it and the hand, or between the hand and the chin against the abdomen. These are only a few of the ways in which CS staff and other healthcare workers can improperly handle a package.

Ideally, a sterilized package should be handled only four times:

1. As it is being removed from the sterilizer cart to storage
2. From storage to transport to the user area
3. From the transport box/cart to storage in the user area
4. When it is removed from the user storage to be opened

CS departments often prevent unnecessary handling by limiting the inventory kept in storage and by clearly identifying items without touching the package.

Sterility Maintenance Covers

CS staff may apply a sterility maintenance cover (dust cover) to infrequently used items to maintain sterility. However, the cover should be placed only after the item is thoroughly cooled. Covers are also placed on wrapped products that may face environmental challenges in storage, transport, or handling. Carefully apply this dust cover as soon as a sterilized package is cool and then securely seal it. Some will wear disposable exam gloves when doing this to avoid direct contact with the item, although it is not a requirement.

Sterile Storage and Stock Rotation

Sterile storage in the CS department is usually in a clean low-traffic area with limited access. Open wire shelves, open solid shelves and closed cabinets can be used.

Closed storage is preferred for items stored in user departments. CS management should assess all storage areas in the user department to ensure they are appropriate. Storage should not be in rooms with open windows, on window sills, on the floor, or under sinks where plumbing leaks can occur. The bottom shelf of a storage cart should be solid or covered and be at least 8-10 inches above the floor, 18 inches below the ceiling or sprinkler system and two inches from outside walls for proper air circulation.

The American Institute of Architects describes optimal environmental conditions in the document “Guidelines for Design and Construction of Hospital and Health Care Facilities” (AIA, 2001). It recommends that the storage area should be under positive air pressure so that air from less clean areas cannot flow into it. There should be at least four air exchanges per hour (CS usually has 10). AAMI recommends a maximum temperature of 75° F (24° C), with a relative humidity of 30-70%. (ANSI/AAMI:ST 79:2006)

Stock rotation is extremely important. Central Service personnel rotate stock in a regular pattern on open or closed shelves. They may move older stock to the right and place new stock on the left, or move old stock to the top of a stack placing new on the bottom. Older stock in drawers or bins is often moved forward and new stock is placed behind. The lot control numbers discussed earlier play an important role in stock rotation by identifying when items were sterilized.

Distributing Clean and Sterile Items

This is a critical link in the CS department’s chain of infection prevention. It is extremely important that methods of transport and distribution absolutely protect the clean and sterile items for the user

departments, their customers and most of all the facility's patients.

Items may be protected in clean plastic or paper bags, or in reusable boxes with lids that can be cleaned. Open transport carts should be clean and covered with disposable or reusable covers, or closed carts should be used. Carts, boxes with lids and reusable cart covers all need to be decontaminated and dried after each use.

When offsite transportation is used, the carts containing sterile products must be closed and secured in a clean truck. The trucks should be environmentally controlled, following guidelines similar to that of the CS department. Persons transporting clean and sterile items need to properly protect them from contamination.

Continuous Quality Process Improvement

The continuous quality improvement program (CQI) is implemented throughout healthcare facilities and is recognized as an essential and effective means of measuring and improving the performance of all departments. The CS department focuses its entire process on decontamination, preparation and packaging, sterilization, quality control, sterility maintenance and product distribution in order to provide a quality product in the quest for best possible practice. The CS Department plays a critical, yet indirect, role in preventing infection and providing quality patient care.

Policies and procedures are written and followed. Problem analysis should be performed any time there is an issue relating to CS processes that could pose a risk for its employees and patients.

CQI should be a planned, systematic and ongoing process that verifies that the department is functioning well and according to standards. Auditing all aspects is essential and should be performed on a regular basis, so that everyone is reminded that their work is serious business and relates directly to patient care and infection prevention.

There are resources available on the subject of CQI. Your healthcare facility probably has a plan or scheme to follow. AAMI standards and technical information documents can also provide insight.

Summary

Central Service plays a monumental role in infection prevention! Armed with this information, every CS manager should perform an audit on their department processes to be certain all areas are being properly addressed. Infection prevention professionals should also become better acquainted with this department so they can significantly support and justify any necessary improvements and defend the CS department whenever appropriate. Everyone should respect and appreciate that Central Service responsibilities are neither simple nor insignificant. Healthcare facilities could not operate safely for one day without them.

In the end, it's all about the patients and we are all patients sooner or later. We must do our best and work together to optimize infection prevention and assure the best outcomes for every patient.

References/Suggested Readings

AAMI (2006) "Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities." ST79

AAMI (2007). "Processing of Reusable Surgical Textiles for Use in Health Care Facilities-ST65." Arlington, VA: AAMI.

AIA (2001). American Institute of Architects Academy of Architecture for Health, "Guidelines for Design and Construction of Hospital and Health Care Facilities-2001." Washington, DC: American Institute of Architects Press.

AORN (2008). Association of periOperative Registered Nurses (AORN), "Recommended Practices for Cleaning and Care of Surgical Instruments and Powered Equipment" Denver, CO: AORN.

AORN (2008). "Recommended Practices for Selection and Use of Packaging Systems for Sterilization" Denver, CO: AORN.

AORN (2008). "Recommended Practices for High Level Disinfection." Denver, CO: AORN.

AORN (2008). "Recommended Practices for Sterilization in the Perioperative Setting." Denver, CO: AORN.

Reichert, M., Young, J., Sterilization Technology for the Healthcare Facility, 2nd Edition, 1997, Frederick, MD: Aspen Publishers.

STERIS (2001). "Decontamination, Preparation of Instruments and Basin Sets for Sterilization, Textile Pack Preparation and Sterility Maintenance Concepts, The Steam Sterilization Process, Biological Indicators: Monitors for Sterility Assurance." Mentor, OH: STERIS Corporation Video Library.

STERIS (2003). "Preparing Instruments, Utensils, and Textiles for Sterilization & Wet Pack Problem Solving (Rev C)." Mentor, OH: STERIS Corporation.

Review Questions

1. The Association for the Advancement of Medical Instrumentation (AAMI) establishes standards and recommended practices that should be followed by Central Service because they are:
 - A. the law
 - B. the standards of practice for the U.S.
 - C. written by AORN
 - D. all of the above
2. Central Service should instruct their customer departments on how they want contaminated items to be prepared for transport and decontamination. Compliance is particularly important:
 - A. for patient safety
 - B. because it is in the AAMI standard
 - C. to protect the transporter
 - D. for worker safety
3. Wearing Personal Protective Equipment (PPE) while working in the decontamination area:
 - A. is optional
 - B. depends on the task
 - C. is not required by AAMI
 - D. is an OSHA requirement
4. Examples of safe work practices in the decontamination area include the following except:
 - A. a sensible workflow
 - B. washing items under running water
 - C. using low foaming detergents
 - D. wearing PPE when using the ultrasonic
5. Decontamination is a _____ step process.
 - A. one
 - B. two
 - C. three
 - D. four
6. Steam will sterilize all surfaces of a medical device so there is no need to open and disassemble instruments.
 - A. True
 - B. False
7. Lumens are flushed with water to prepare them for steam and ethylene oxide sterilization.
 - A. True
 - B. False
 - C. steam only
 - D. ethylene oxide only
8. Physical sterilization monitors must be checked:
 - A. before a sterilization cycle is started
 - B. during the sterilization cycle
 - C. once the sterilization cycle has finished
 - D. all of the above
9. Sterilization Process Indicators include all of the following except:
 - A. chemical indicators
 - B. charts and computer print-outs
 - C. biological indicators
 - D. dynamic air removal sterilizer residual air test
10. Product recalls are initiated because of a positive biological test result.
 - A. True
 - B. False
11. Shelf life of a sterilized package is:
 - A. biologically related
 - B. time related
 - C. event related
 - D. none of the above
12. Once a sterilization or aeration cycle has completed the items may be immediately removed from the sterilizer shelves to the department storage shelves.
 - A. True
 - B. False

- Answers to Review Questions & Section Sources:
1. B (Standards & Recommended Practices)
 2. D (Pick-up & Transport of Contaminated Items)
 3. D (Personal Protective Equipment-PPE)
 4. B (Safe Work Practices)
 5. B (Decontamination vs Cleaning)
 6. B (Preparation for Steam Sterilization)
 7. C (Preparation for Steam Sterilization & Preparation for EO Sterilization)
 8. D (Physical Monitors)
 9. B (Sterile Process Indicators)
 10. A (Product Recalls)
 11. C (Shelf Life)
 12. B (Cooling Sterilized Items)

Evaluation Form

Study Guide 12: The Role of Central Service in Infection Prevention

Last Name

First Name/M.I.

RN/LPN/LVN License Number (Circle one: RN - LPN - LVN)

Non-RN: License or Social Security Number

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Health Care Facility Street Address City State ZIP Code

Current Home Street Address City State ZIP Code

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Rate on a scale of: 1=low 5=high

To what extent did the study guide meet the 2 stated objectives below?

1. Review important work principles related to decontamination.

1 2 3 4 5

2. Describe the elements of physical, chemical and biological monitoring of sterilization cycles.

1 2 3 4 5

3. To what extent is this learning method easy-to-use?

1 2 3 4 5

4. How much time was required to read the content, take the test, compare your answers and complete the evaluation form?

_____ hours _____ minutes

5. Has the provider disclosed the conflict of interest or lack thereof declared by the planners and content specialist?

Yes _____ No _____ (Review inside cover page)

6. Was the content presented without bias of any commercial product or drug?

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I have completed all the requirements for this entire activity (please sign and date).

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