Reading Material for

CSST

Punjab Medical Faculty

Specialized Healthcare & Medical Education Department

Government of the Punjab

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Book-2

PREFACE

After introduction of the new service structure for AHPs in 2012 the qualification requirement for entry in service has been changed to a diploma of two years' duration. This decision has necessitated the development of curricula for the new scheme of studies. The evolving health needs of the community, exponential advances in medical and allied technologies and changes in health services provision, functions and structure also demand continual and responsive changes in education and training programs meant for AHPs. The revised curricula would carry out the following important functions:

- link pre-service education and training with actual task AHPCSST have to perform after being employed, especially in the public sector

The CSST Profession continues to evolve at a rapid pace, with new surgical items being introduced regularly. The processing of robotic, endoscopic, complex orthopedic, spinal and other related instruments and equipment requires special skills and knowledge of decontamination and sterilization process.

By necessity, CSST training has also changed from an on-the-job, hands-on model to a more formal course of study. This CSST manual PMF is design to provide CSST Information needed to understand the basic concept of be contamination sterilization sterility maintenance and related processes so they are batter equipped to handle the increasingly specialized requirements of medical devices reprocessing.

Best Wishes to All AHP Students.

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Dr. Amina Asif
Muhammad Hasnain

Dedication

I dedicate all the work done to the students so that they may be able to contribute for the provision of the quality health services to the ailing humanity.

The ownership of Muhammad Husnain to his students of CSST in future is really exemplary. It will be unfair if I shall miss the name of Dr. Amina Asif who has been a flag bearer for infection prevention for role projects.

I am really thankful to Dr. Balakh Sher Zaman, AP, North Surgical Ward, Mayo Hospital, Lahore who reviewed the book.

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Chapter 13
Point-of-Use Processing

Learning Objectives

As a result of successfully completing this chapter, readers will be able to:

1. Define the term Immediate Use Steam Sterilization and review the industry standards
2. Describe point-of-use processing and examine its requirements
3. Explain the basic procedures necessary to safely perform Immediate Use Steam Sterilization
4. Address point-of-use processing for heat-sensitive medical devices

INTRODUCTION

The majority of processing takes place in the Central Service (CS) department; however, there are times when processing is performed at the point of use. There are two basic types of **point-of-use processing**. The first is **Immediate Use Steam Sterilization (IUSS),** which consists of cleaning, steam sterilization and immediate delivery of heat-resistant items to the procedure room. This process is designed for instances when there is no time to send the item(s) to the CS department for processing. The second type of point-of-use processing is designed for heat-sensitive items. Regardless of the process used, the goal is to provide an item that is safe for patient use. This chapter will examine methods of point-of-use processing.

Point-of-use processing That which occurs when a medical device is processed immediately before use, and/or close to the patient care area.

Immediate Use Steam Sterilization (IUSS) Process designed for the cleaning, steam sterilization and delivery of patient care items for immediate use; formerly known as flash sterilization.

IMMEDIATE USE STEAM STERILIZATION

A Brief History

In patient care, there are always unexpected events that require quick action. Instrument demands become urgent when there is an immediate patient need and no instruments are ready for use. In previous years, "flash" sterilization was designed for use in the Operating Room (OR) for emergencies and immediate use. Flash sterilization was a process where unwrapped instruments were steam-sterilized using an abbreviated cycle (a cycle with no dry time) in order to ready the instruments for patient use.

In 2009, the name flash sterilization was replaced with a new term (and process): Immediate Use Steam Sterilization (IUSS). Items processed using IUSS are cleaned according to their manufacturers' Instructions for Use (IFU), placed in containers specifically designated for IUSS sterilization and sterilized according to manufacturer instructions. (See **Figure 13.1**)

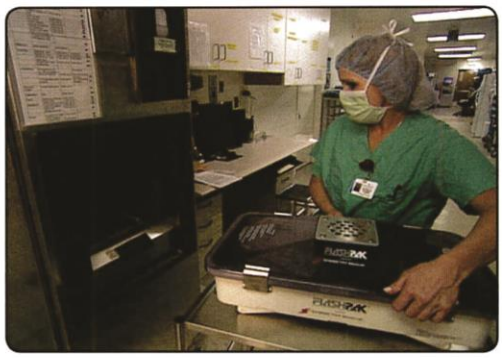

Figure 13.1

What Happened to "Flash"?

Many Central Service professionals will remember the term "flash" sterilization and may ask what happened to that term. "Flash" referred to the abbreviated steam sterilization cycle of an unwrapped device. With the move to Immediate Use Steam Sterilization (IUSS), the process shifted from an unwrapped container to a sealed containment device that provides greater protection from contamination during transport.

Processing devices for immediate use can be safe and effective, but only if all steps recommended by the device manufacturer are followed. This includes proper cleaning, decontamination, sterilization using the correct cycle and aseptic transfer to the point of use. Those performing IUSS are responsible for processing every item in a way that best ensures it is safe for reuse. Shortcuts, such as improper cleaning in the interest of saving time, can jeopardize patient safety. Following validated manufacturer's IFU and controlling process quality helps protect patients from infections and prolongs the life of instrumentation.

A multi-society IUSS Position Paper providing information about the change to IUSS was developed in 2011 by the Association for the Advancement of Medical Instrumentation

(AAMI), the Association of periOperative Registered Nurses (AORN), the International Association of Healthcare Central Service Materiel Management (IAHCSMM), the Accreditation Association for Ambulatory Health Care, ASC Quality Initiative and the Association of Surgical Technologists (AST). The paper provided support for the change to IUSS and offered additional information about the process.

Standards and Recommended Practices

Several associations have developed standards to help ensure IUSS procedures are performed properly.

Association for the Advancement of Medical Instrumentation

AAMI standards are not law; however, they are the recognized industry standards for sterilization and may be relevant in any legal proceeding. AAMI standards represent a national consensus and many have been approved by the American National Standards Institute (ANSI).

ANSI/AAMI ST79, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities,* is a broad document covering recommended practices for steam sterilization. The document states that IUSS can be performed when deemed appropriate, and when all of the following conditions are met:

- Items are needed for immediate use.
- Items are dissembled and thoroughly cleaned according to the manufacturer's IFU, with approved detergents and water to remove soil, blood, body fats and other substances.
- Lumens are brushed and flushed under the water with appropriate cleaning solutions, and items are thoroughly rinsed.
- The device manufacturer's written instructions on sterilization cycle and exposure times, temperature settings and dry times are followed.
- Processed items are transported in a manner to prevent contamination.

The Association of peri-Operative Registered Nurses

AORN publishes its Guidelines for Perioperative Practices, formally titled Perioperative Standards and Recommended Practices. Surveying agencies refer to the AORN guidelines, as well as the AAMI standards. AORN guidelines state that:

- IUSS should be kept to a minimum and should only be used in selected clinical situations and in a controlled manner.
- IUSS should only be used when there is no time to process the items using the preferred (wrapped) method.
- Devices undergoing IUSS should be subjected to the same decontamination processes as in AORN's *Change to: Guidelines for PeriOperative Practice: Sterilization and Disinfection.* Guidelines for PeriOperative Practice. 2015.
- The items must have manufacturer's instructions for IUSS.
- Manufacturer's recommendations for cleaning, exposure times, temperatures and drying times are followed.
- Processed items are transferred to point of use aseptically.
- Staff is educated on the IUSS process.
- Recordkeeping allows for the tracking of the device after use.

Surveying Agencies

IUSS is designed for urgent situations when there is not sufficient time to send an item through the normal **terminal sterilization** process. Surveying agencies are closely monitoring IUSS to ensure everything is being done by the healthcare facility to decrease this practice and ensure that where and

when IUSS is practiced, the processes are done correctly.

Terminal sterilization The process by which surgical instruments and medical devices are sterilized in their final containers, allowing them to be stored until needed.

The Joint Commission

In 2009, The Joint Commission (TJC) revised its position statement on IUSS and emphasized that three critical steps of processing must be followed to ensure sterility. TJC requires that complete documentation must be available for each IUSS cycle, so the device is traceable to the patient if a problem should arise. In the recent past, TJC focused on how many IUSS cycles were run and how to reduce the amount of IUSS sterilization in any facility. Now, in addition to focusing on IUSS reduction, TJC surveyors are focusing on the IUSS process to ensure all processes are completed properly. They expect the same safeguards and quality controls to be in place, regardless of who operates a sterilizer or where the sterilizer is located. The following are the four key areas TJC surveyors will focus their attention:

- Cleaning and decontamination. Before an item can be sterilized, it must be properly cleaned and decontaminated according to the manufacturer's recommendations.
- Sterilization. The manufacturer's instructions must specify the type of cycle (e.g., gravity displacement and dynamic air removal) and length of time needed for sterilization. Some instruments may require an extended cycle or a specified dry time; some instruments cannot undergo IUSS at all. The manufacturer's IFU must specify that the item can undergo IUSS cycles.
- Transfer to the sterile field. Aseptic transfer from the sterilizer to the sterile field is required to prevent recontamination of the sterilized item.
- Frequency of IUSS use. Lack of instrumentation is not an excuse for IUSS. A plan should be in place to reduce IUSS cycles.

Examples of TJC findings could include failure to adequately clean the instruments before IUSS, inappropriate use of chemical indicators and unsafe transporting of instruments back to the procedure room after they have been sterilized.

Centers for Medicare and Medicaid Services

The Social Security Act mandated the establishment of minimum health and safety standards that must be met by providers and suppliers participating in Medicare and Medicaid programs. These standards are found in the 42 Code of Federal Regulations. The Secretary of the Department of Health and Human Services has designated the Centers for Medicare and Medicaid Services (CMS) to administer the standards compliance aspects of these programs.

Like TJC, CMS has established requirements regarding the use of IUSS:

- The same multi-step process used to prepare instruments for terminal sterilization must be completed for IUSS.
- Parameters for all phases of the sterilization cycle must be determined by consulting the IFU for the instrument(s), sterilizer and containment device.
- Each IUSS cycle must use physical monitors and chemical indicators. At least weekly, the sterilizer must be tested with a biological test for each IUSS cycle.
- If IUSS must be used for an implant, a tracking system should be in place to trace the IUSS load to the patient.
- Medical instruments and devices processed using IUSS must be contained in a packaging system labeled for the IUSS cycle(s) used.

- Items sterilized by IUSS must be used immediately.

CMS also indicates that IUSS is not acceptable in the following circumstances:

- When sterilizing implants, except in documented emergency situations.
- For post-procedure decontamination of instruments used on patients with possible Creutzfeldt-Jakob Disease (CJD) or other prion diseases.
- When devices or loads have not been validated for the specific cycle used.
- On single-use devices.

PROCEDURES FOR IMMEDIATE USE STEAM STERILIZATION

Safe and effective IUSS requires that all steps in the process be done properly each and every time to achieve sterilization and maintain sterility of instruments and instrument sets all the way to the point of use. Improperly sterilized or contaminated instruments used in a surgical procedure can result in serious concerns, from surgical site infections to increased costs and legal liability.

Precleaning

Precleaning of instrumentation is a necessary step to help promote effective, thorough decontamination and sterilization. AORN guidelines state that items should be kept free of gross soil during surgery. These standards are critical factors when items are to be prepared for IUSS. Soil is easier to remove when items are properly pre-treated in the OR.

Point-of-Use Decontamination

Thorough decontamination of medical devices is required for IUSS to be safe and effective. Manufacturers of sterilizers and medical devices assume that the level of contamination has been adequately reduced on the surfaces of instruments before they are placed in the sterilizer. **If items are not properly cleaned, they cannot be sterilized.**

Standard precautions require that staff handling contaminated devices wear the appropriate personal protective equipment (PPE).This includes gloves, hair covering, eye protection, masks, fluid-impervious gown or jumpsuit, and shoe covers. PPE should be removed and discarded, and not worn outside of the cleaning/decontamination area.

Manufacturer instructions for instrument processing should be available and consulted to ensure proper cleaning and decontamination before IUSS. These may contain special cleaning instructions, such as the disassembly process and the recommended use of cleaning solutions and mechanical cleaners. Instruments must be cleaned as thoroughly at the point of use as they would in the CS decontamination area. Items must be decontaminated in an area designed to clean instruments, and never in a scrub or handwashing sink. Surveying agencies will check to ensure that the staff is trained in proper cleaning methods.

Prior to placing instruments in the sterilizer, instruments must be carefully inspected to ensure they are clean and functional. Instruments must be placed in the sterilizer in a manner that facilitates full steam contact.

Immediate Use Steam Sterilization Cycles

Steam sterilizers used for IUSS are usually placed in close proximity to user areas. (See **Figure 13.2**) There are two types of steam cycles commonly used: gravity displacement and dynamic air removal, which includes the prevacuum and steam flush pressure pulse (SFPP) cycles. The type of cycle to be used depends on the manufacturer's IFU. **Figure 13.3** shows minimum IUSS cycles as identified by AAMI. *Note: Steam sterilization processes are discussed in detail in Chapter 14.*

Figure 13.2

Consult the manufacturer's IFU for exposure times and cycles when using containment devices or packaging systems.

Safe Transport after Immediate Use Steam Sterilization

Instruments subjected to IUSS should be transported to the point of use in a manner that reduces the potential for contamination. Failure to take appropriate measures to protect IUSS processed instruments after their removal from the sterilizer and during transport to the point of use will increase the potential for contamination and the patient's risk for acquiring a surgical site infection. *Note: Use of the single wrapped method helps protect sterile instruments; however, this method cannot be used unless the sterilizer has the "single wrapped" function built into the system.* Utilizing sealed rigid containers approved for IUSS offers the best protection for the sterile instruments. Instruments processed in these rigid containers still cannot be stored for later use, unless approved by the U.S. Food and Drug Administration (FDA); therefore, the items must be used as soon as possible after the sterilization cycle is complete.

Staff Education

Educating staff members who perform IUSS is important to decrease the possibility of errors that could occur during the process. Staff members should receive initial training and competency assessment, followed by continuing education at regular intervals to review and update their knowledge.

QUALITY CONTROL MONITORS FOR IMMEDIATE USE STEAM STERILIZATION

The efficacy of every sterilization cycle must be monitored. The quality assurance of each process includes physical, chemical and biological monitors. All of these monitors should be carefully watched and reviewed to identify potential issues.

AAMI Minimum Recommended IUSS cycles			
Type of sterilizer	**Load configuration**	**Temperature**	**Time**
Gravity displacement	Nonporous items only (e.g., routine metal instruments, no lumens)	270°F (132°C)	3 minutes
	Nonporous and porous items (e.g., rubber or plastic items, items with lumens) sterilized together	270°F (132°C)	10 minutes
Prevacuum	Nonporous items only (e.g., routine metal instruments, no lumens)	270°F (132°C)	3 minutes
	Nonporous and porous items (e.g., rubber or plastic items, items with lumens) sterilized together	270°F (132°C)	4 minutes
Steam-flush pressure-pulse	Nonporous or mixed nonporous/porous items Manufacturers' instructions	270°F (132°C)	4 minutes

Figure 13.3

Note: Sterilization monitoring processes are discussed in Chapter 17.

A dynamic air removal test, as the name implies, is only done in dynamic air removal sterilizers. This test should be run each day the sterilizer is used.

Recordkeeping

IUSS records allow for traceability of every item sterilized to the patient. It is important to keep accurate and complete records that include evidence of cycle performance, such as sterilization cycle printouts and biological and chemical indicator results. Sterilizer cycle records should include:

- Patient identification. There must be a way to identify the patient on whom the items were used in the event of a problem, such as sterilization cycle failure or the patient acquiring a healthcare-associated infection.
- The sterilizer and sterilizer cycle identification.
- The instrument(s) sterilized in the cycle.
- The cycle parameters.
- The reason the IUSS cycle was run (e.g., instrument dropped on floor).
- Operator's signature or other identification.

No national standard exists for how long sterilization records should be kept. Local statute requirements and individual facility policies should be followed.

POINT-OF-USE PROCESSING FOR HEAT-SENSITIVE DEVICES

Low-Temperature Disinfection and Sterilization Processes

Advancing sterilization technologies have changed the way procedures are performed. The medical devices used in many procedures have changed, as well. Many of the medical devices used today are heat sensitive. In other words, processing them in a heated process, such as with steam, will lead to damage. Facilities must look to low-temperature methods to safely process those heat-sensitive items.

There are several types of low-temperature options for point-of-use processing. Selection is determined by the types of items that will be processed and their compatibility with that low-temperature process.

In some cases, the decision to process heat-sensitive items at point of use is made in an effort to reduce instrument turnaround time. In others, it is made to reduce the distance that unwrapped processed items must be transported before use.

The choices for point-of-use processing for heat-sensitive medical devices include high-level disinfection (HLD) or sterilization. The level of biocidal process required is based on the intended use of the item. Options include wrapped processes (e.g., vaporized hydrogen peroxide or hydrogen peroxide gas plasma) where the device is packaged and processed through a type of chemical sterilization cycle, or an unwrapped process where the device is processed using a liquid chemical. (See **Figure 13.4**)

Note: The wrapped sterilization processes mentioned above are discussed in detail in Chapter 15.

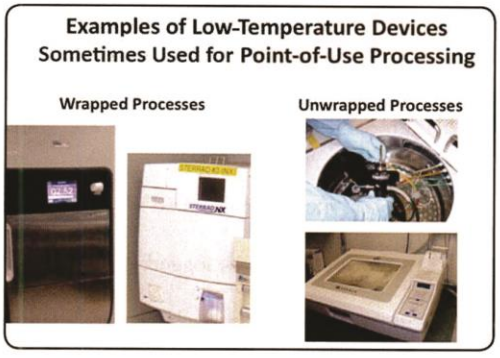

Figure 13.4

All low-temperature processes utilize a chemical process. CS technicians must understand the specific type of process used in their facility and must be educated on proper handling and

operational procedures, as well as safety protocols for the specific process.

Preparation of Devices for Low-Temperature Processes

As with IUSS processes, proper preparation is critical to the success of the low-temperature point-of-use process. Items must be cleaned thoroughly. Any soil remaining on the device will result in a failed process and will pose a danger to the patient. Items must be prepared for the low-temperature process according to the manufacturer's IFU.

If using a wrapped process, items must be wrapped using packaging that is compatible with the process to be used. Those packages must be positioned correctly within the sterilizer.

When using an unwrapped process, technicians must also be certain to position the device correctly. Any connections between the device and the processor must be appropriately connected to ensure the proper flow of liquid through the device.

As with all HLD and sterilization processes, the medical device manufacturer must have approved the device for the specific biocidal process to be performed.

Quality Control Monitors for Point-of-Use Low-Temperature Processes

Quality control monitors will vary depending on the process used; however, there are some commonalities:

- The process must be monitored
- Items processed must be logged

Monitoring will be unique to each low-temperature process. For manual HLD using a soak process, the solution must be checked for Minimum Effective Concentration (MEC).

For mechanical processes, testing should be performed according to the equipment and chemical manufacturer's IFU. That testing may include chemical, biological or diagnostic tests.

All items processed at point of use must be logged and those records, along with documentation of quality testing, should be kept on file.

CONCLUSION

Point-of-use processing meets a specific need in procedural areas. Although it is performed away from the Central Service department, the basic principles of reprocessing and the need to accurately follow the device manufacturers' instructions remain the same. When performed appropriately, point-of-use processing can provide items that are safe for patient use.

RESOURCES

Association of periOperative Registered Nurses. *Guidelines for PeriOperative Practice: Sterilization and Disinfection.* Guidelines for PeriOperative Practice. 2015.

The Joint Commission. The Joint Commission Accreditation Manual. 2013.

Centers for Disease Control and Prevention. *Guidelines for Disinfection and Sterilization in Healthcare Facilities.* 2008.

AAMI, AAHSP, AORN, APIC, ASCQC, AST, IAHCSMM. Statement on Immediate Use Steam Sterilization. 2011.

Association for the Advancement of Medical Instrumentation. ANSI/AAMI ST79: *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Healthcare Facilities.* 2013.

PeriOperative Practice: Sterilization and Disinfection. Guidelines for PeriOperative Practice. 2015

Gillespie S. Flash Sterilization: Many Users, Many Questions About This Technique. Biomedical Instrumentation & Technology. Vol. 44, No. 1. (p 62). 2010.

Nania P. Immediate Use Steam Sterilization: It's All About the Process. AORN Journal. Vol. 98, No. 1. 2013. (pp. 32-38).

Rutala W, Weber D. Guideline for Disinfection and Sterilization in Healthcare Facilities. Centers for Disease Control and Prevention. 2008.

U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services. Ref: S&C:14-44-Hospital/CAH/ASC. 2014. http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-14-44.pdf (Accessed 10-1-14).

Conner R. Sterile Processing in the Surgical Suite, 2014 FGI Guidelines Series, Update #4, September 2014.

CENTRAL SERVICE TERMS

Point-of-use processing

Immediate Use Steam Sterilization (IUSS)

Terminal sterilization

Chapter 14

High-Temperature Sterilization

Learning Objectives

As a result of successfully completing this chapter, readers will be able to:

1. Discuss factors that impact the effectiveness of sterilization
2. Discuss the advantages of steam sterilization
3. Explain the anatomy of a steam sterilizer and identify the function of each major component
4. Provide basic information about the types of steam sterilizers
5. Explain basic information about steam sterilizer cycles
6 Describe the conditions necessary for an effective steam sterilization process
7. Explain basic work practices for steam sterilization
8. Review sterilization process indicators and explain the need for quality control

INTRODUCTION

High-temperature sterilization is the process of choice in many healthcare facilities. It is achieved by subjecting items being processed to thermal energy from moist heat (steam) or dry heat. High-temperature sterilization has long been recognized as an effective way to kill microorganisms. Steam is the most frequently-used sterilant for devices not adversely affected by moisture or heat because of its successful record of safety, efficacy, reliability and low cost. In fact, other methods are only used when the object being processed cannot withstand the heat and/or moisture required for steam sterilization. By contrast, dry heat sterilization is seldom used because of the required lengthy exposure times.

As with all sterilization methods, devices to be processed must first be thoroughly cleaned, decontaminated and properly prepared. Cleaning involves the removal of all visible soil and decontamination kills most, but not all, microorganisms. Sterilization is required to kill any remaining microorganisms, including spores.

Sterilization failure could result in serious, even life-threatening, patient outcomes. A Central Service (CS) technician must understand the anatomy of a steam sterilizer to better understand how it operates, and how it impacts quality outcomes and patient safety.

FACTORS THAT IMPACT STERILIZATION

The success of every sterilization process is not guaranteed. Several factors and conditions impact the effectiveness of all sterilization methods, including those using high temperature. These factors include:

- The type of microorganisms present; some microorganisms are more resistant to the sterilization process than others.
- The design of the medical device; complex devices present a challenge to the sterilization process.
- The number of microorganisms (**bioburden**) present; when there are more microorganisms on a medical device, the sterilization process becomes more difficult.
- The amount and type of soil present; soil acts as a shield to protect microorganisms.

Note: The cleaning process is absolutely essential as a first step in processing. A device can be cleaned without sterilizing, but sterilization cannot be achieved if a device hasn't been thoroughly cleaned.

Bioburden The number of microorganisms on a contaminated object; also called "bioload" or "microbial load."

ADVANTAGES OF STEAM STERILIZATION

Steam is the sterilant of choice for several reasons:

- Low cost
- Rapid sterilization cycles
- Relatively simple technology
- Leaves no chemical residues or byproducts

Steam sterilizers date back to the early days of formalized healthcare. Prior to steam sterilization, boiling water was commonly used to kill bacteria. Scientists recognized the need to increase temperatures beyond the boiling point to kill greater numbers of heat-resistant bacteria. **Figure 14.1** is an illustration of the first pressure steam sterilizer (autoclave) that was developed in 1880 by Charles Chamberlain, a colleague of Louis Pasteur. The autoclave resembled a pressure cooker and was able to use pressurized steam to reach temperatures of 248°F (120°C) and higher. Although it looks primitive by today's standards, it was the first generation model of the steam sterilizers used today.

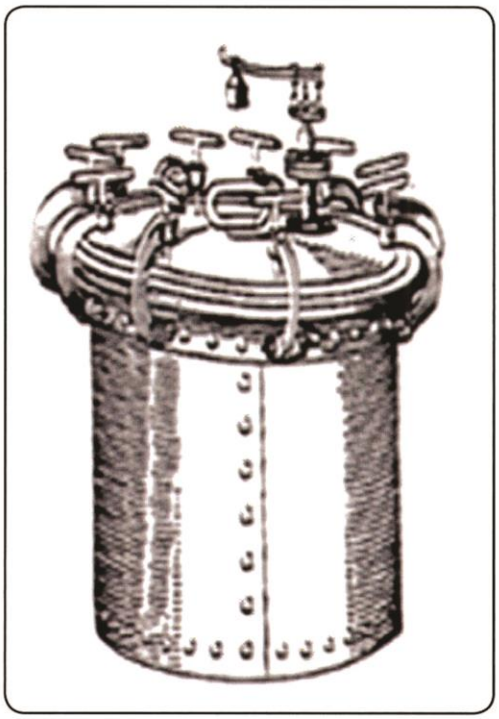

Figure 14.1

ANATOMY OF A STEAM STERILIZER

Steam sterilizers come in many sizes and cycle choices, from small tabletop sterilizers used primarily in clinic and dental settings, to mid-sized and large units designed to sterilize large quantities of items. **Figures 14.2**, **14.3** and **14.4** illustrate various sizes of steam sterilizers.

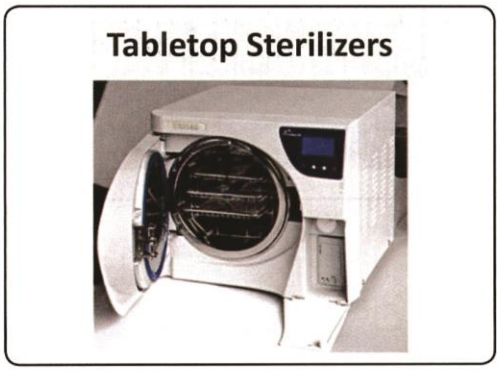

Figure 14.2

Figure 14.3

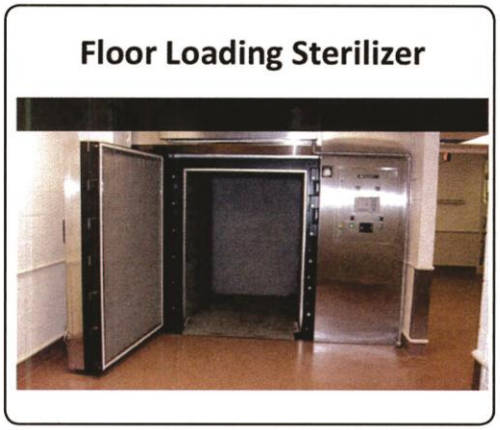

Figure 14.4

A CS technician must know the anatomy of a sterilizer to better understand how it operates.

Components of Steam Sterilizers

Jacket

CS departments typically use jacketed sterilizers. The illustration in **Figure 14.5** shows a cutaway diagram of a steam sterilizer and illustrates how steam from an external source enters the jacket. In most hospitals, steam is supplied to the sterilizers from a main steam line; these units themselves do not generate the steam. Smaller sterilizers in clinics and dental practices usually manufacture their own steam or get their steam from an independent generator. **Figure 14.6** provides an example of a steam generator.

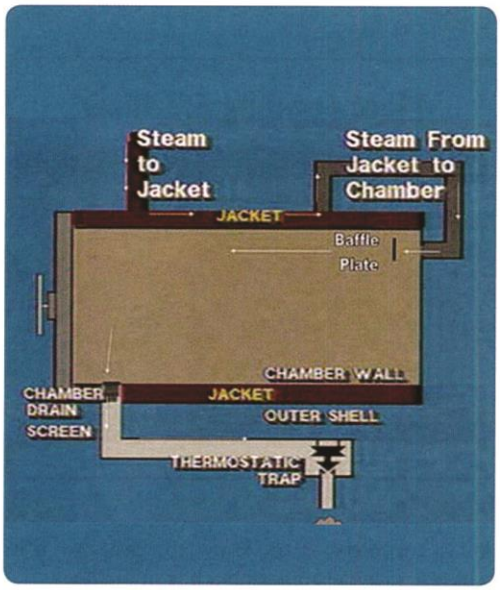

Figure 14.5

The interior chamber walls of the sterilizer are heated by steam in the metal jacket. This helps minimize the amount of condensation (moisture) that forms when hot steam contacts the chamber walls as a cycle begins. **Figure 14.7** shows the condensation that forms during the steam cycle. The jacket surrounds the sides, top and bottom of the vessel, and steam circulates in this space to pre-heat the interior chamber walls.

Figure 14.6

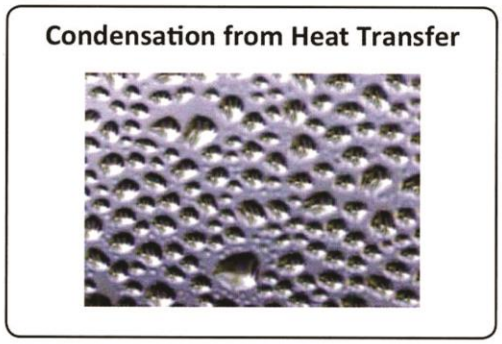

Figure 14.7

The outside of the jacket is covered with insulation to help prevent condensation from forming on the jacket's outer and inner walls. This insulation also provides a safety feature because it reduces the likelihood that personnel working behind the sterilizer will be burned. The outer shell is typically located behind a wall and is not readily visible to the sterilizer technician. **Figure 14.8** shows the insulation covering the sterilizer jacket.

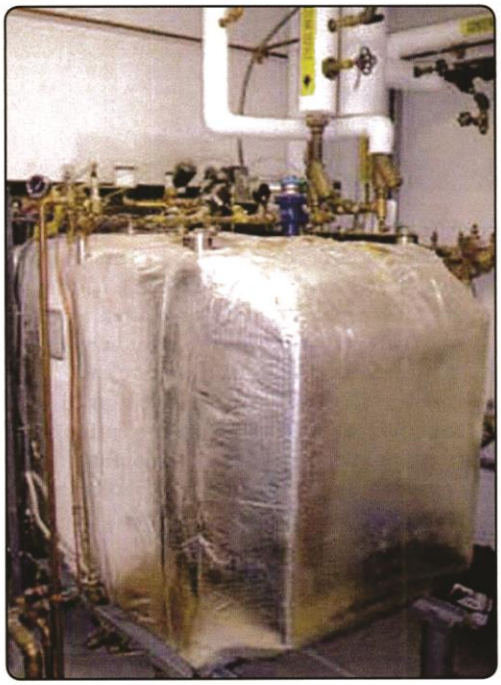

Figure 14 .8

Door, Gasket and Chamber Drain

The door is the weakest part of a steam sterilizer. It has a safety locking mechanism that automatically activates when chamber pressure is applied and it can only be unlocked when pressure is exhausted. Some model sterilizers use radial arm locking doors, which can be tightened, but not loosened, while the chamber is under pressure. Some sterilizers have active gaskets with pressure behind them to seal the chamber.

The door gasket is designed to maintain a tight seal that prevents steam from escaping from the chamber and air from entering the chamber. (See **Figure 14.9**)

Figure 14.9

On most steam sterilizers, the chamber drain is located at the front or center of the floor. The drain screen must be cleaned at least daily, and more often, as needed. Debris in the chamber drain screen can impede cycle performance. (See **Figure 14.10**)

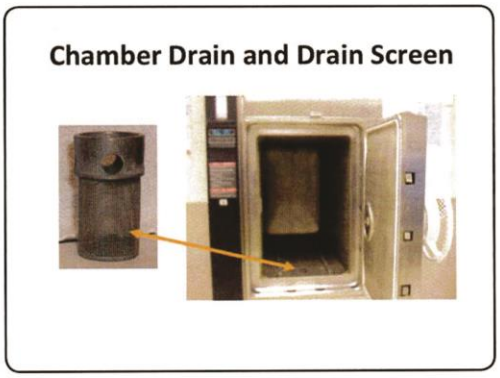

Figure 14.10

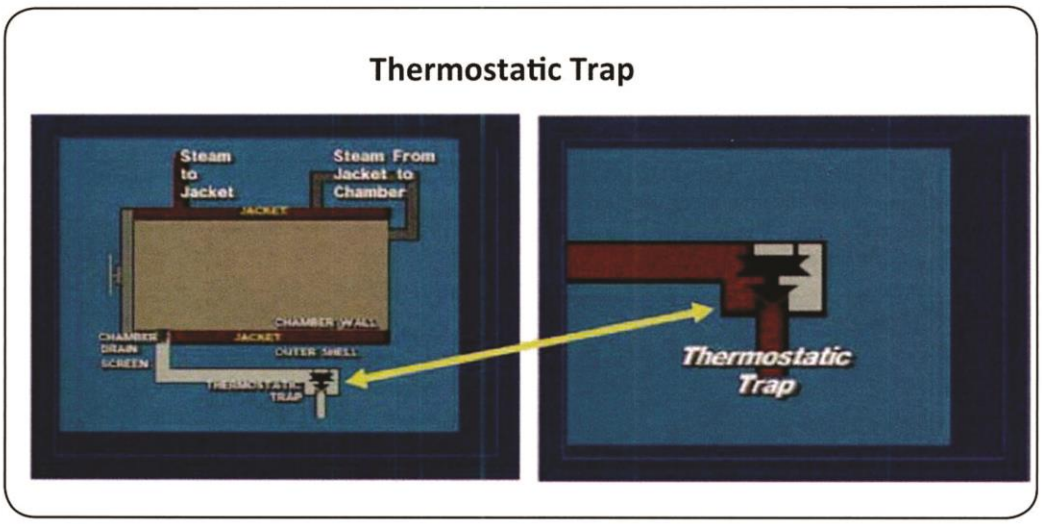

Figure 14.11

Thermostatic Trap

As seen in **Figure 14.11**, the thermostatic trap is located in the drain line. The drain and the area surrounding it are the coolest areas in the sterilizer. A sensor in the chamber drain measures steam temperature and automatically controls the flow of air and condensate from the sterilizing chamber.

Gauges and Controls (Monitors)

The sterilizer's gauges and/or controls (monitors) provide a visual and written record of sterilization conditions. CS technicians must check them throughout the sterilization cycle to ensure that necessary parameters are met. A printout from a steam sterilization cycle usually contains the following information:

- Date and time the cycle began.
- Selected cycle parameters, such as type of cycle, sterilization temperature and dry times.
- A written record of actual cycle activities (e.g., temperatures, exposure times and pressure). Some steam sterilizers can also provide the information in a digital format (see **Figure 14.12**), and some can even be integrated into an instrument tracking system. Older steam sterilizers have circular patient charts that record sterilization activities. Charts are changed daily and the time listed on the chart is aligned with the recording pen to the correct time of day. The date and sterilizer location are noted on the graph, and the pens are checked daily to ensure they are recording. Charts or printouts are signed by the sterilizer operator, indicating that parameters have been reviewed.

The CS technician is responsible for determining if all sterilization parameters were met and if the load may be released. If any steam sterilization parameter was not met, the supervisor should be notified immediately and the sterilization load should not be released.

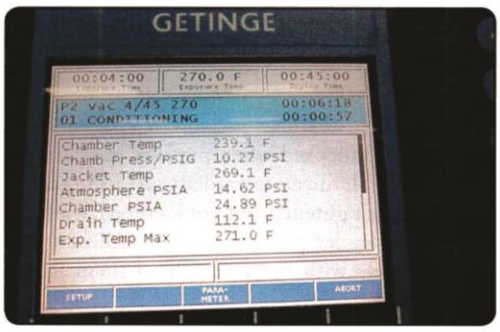

Figure 14.12

TYPES OF STEAM STERILIZERS USED IN CENTRAL SERVICE

Several types of steam sterilizers are available today. Healthcare facilities purchasing sterilizers that will meet their specific needs, including chamber size, style and available cycle options.

Tabletop Sterilizers

Tabletop sterilizers are frequently used in clinics and dental offices. These units operate by having water poured into the sterilizer, either through a port or the bottom of the chamber, and are electrically heated until the water turns to steam. Water quality is an important factor, and is specified in the sterilizer Instructions for Use (IFU). In a tabletop sterilizer cycle steam rises to the chamber's top and as more steam is produced, air is forced out through the drain near the bottom of the chamber. When steam enters the drain, a thermostatic valve closes, which causes the steam to build up pressure until the operating temperature is reached. When the proper temperature is reached, the timer is activated. At the end of the cycle, the relief valve opens to allow the steam to escape. The steam passes through the water reservoir where it condenses back to water. After the pressure has dropped to zero, the door can be opened. As with all sterilizers, CS technicians should carefully review the sterilizer manufacturer's IFU for specific operating instructions.

Gravity Air Displacement Sterilizers

Some small- to medium-sized sterilizers have gravity displacement and dynamic air removal cycles. In a gravity displacement cycles, steam enters the chamber and because air is heavier than steam, the steam forces the cooler air to the bottom of the chamber and out the drain. While their operation appears simple, many mistakes can be made, such as improper loading or unloading; therefore, a thorough knowledge of sterilization theory and practice is essential for those operating these units. Gravity air displacement sterilizers have sophisticated automatic controls, such as temperature-indicating charts and printouts for recordkeeping.

Dynamic Air Removal Sterilizers

Dynamic air removal sterilizers are similar in construction to gravity air displacement sterilizers, except there is a vacuum pump or water ejector. That removes air from the chamber more effectively during the preconditioning phase, prior to reaching the exposure temperature. Dynamic air removal sterilizers usually operate at higher temperatures [270°F to 275°F] (132°C to 135°C) than gravity sterilizers. The preconditioning phase increases the speed of operation and reduces the chance of air pockets in the chamber during the cycle. Dynamic air removal sterilizers use different types of preconditioning methods for air removal. These include variations of prevacuum air removal and above-atmospheric-pressure processes, such as the steam–flush pressure–pulse process (SFPP). The preconditioning cycle removes air from both the sterilizing chamber and the load before the chamber is pressurized with steam to the exposure temperature. Effective air removal is critical for steam penetration.

Prevacuum Steam Sterilizers

In prevacuum steam sterilizers, the dynamic air removal cycle depends on one or more pressure and vacuum sequences at the beginning of the cycle to remove air during the preconditioning phase. Typical operating temperatures are 270°F to 275°F (132°C to 135°C). To ensure air removal in these sterilizers, the integrity of the sterilizers should be checked daily by processing a Bowie Dick (or daily air removal) test. *Note: Bowie Dick air removal tests are outlined in Chapter 17.* Some sterilizers have an automatic cycle (vacuum leak test) to test the vacuum tightness of the chamber.

Steam-Flush Pressure-Pulse Sterilizers

SFPP sterilizers use a repeated sequence of a steam flush and pressure pulse to remove air from the

sterilizing chamber and processed materials. Air removal occurs above atmospheric pressure; no vacuum is required. Like a prevacuum sterilizer, this process rapidly removes air from the sterilizer's chamber and wrapped items.

Immediate Use Steam Sterilizers

Immediate use steam sterilizers are located in Operating Rooms (ORs) or surgical suite substerile rooms, Labor & Delivery units and special procedure areas that perform invasive procedures. Their intended use is for the emergency sterilization of instruments when there is not enough time for terminal sterilization. These types of sterilization processes have little to no dry time; therefore, at the end of the sterilization process, instrumentation is expected to be hot and wet. **Figure 14.13** is an example of a sterilizer approved for IUSS cycles.

STEAM STERILIZER CYCLES

Along with understanding the types of steam sterilizers used in the healthcare facility, CS technicians must also understand how these machines function. To begin, CS technicians should be familiar with two basic sterilization cycles: IUSS sterilization and terminal sterilization. Items processed using IUSS must undergo the same cleaning and preparation as items that are terminally sterilized. Time is usually shortened due to the reduced dry cycle. All items do not have IUSS instructions from the device manufacturer; consult the medical device manufacturer's IFU to determine if IUSS is possible and to learn the proper sterilization cycle. Items sterilized using IUSS should be used immediately and cannot be stored for use at a later time, unless such a process has been approved by the U.S. Food and Drug Administration (FDA).

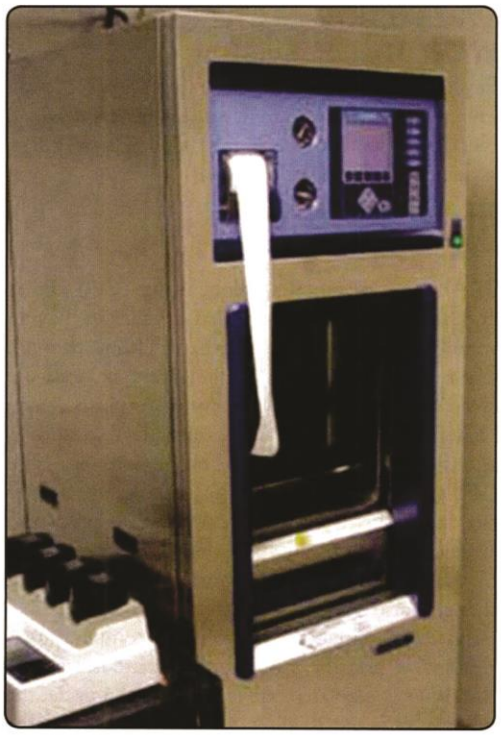

Figure 14.13

By contrast, "terminal sterilization" refers to the sterilization of an item that is expected to be dry upon completion of the sterilization process. Terminal sterilization is most often performed in the CS department, but may be performed in other departments.

A saturated steam sterilization cycle has at least three (and possibly four) phases:

- Conditioning
- Exposure
- Exhaust
- Drying (in most instances)

Conditioning

At the beginning of the sterilization cycle, steam enters at the upper back portion of the sterilizer. As steam enters, air is displaced through the drain. As steam continues to enter the sterilizer's chamber, pressure begins to rise, as does the steam temperature.

Exposure

After the desired temperature is reached, the sterilizer's control system begins timing the cycle's exposure phase. *Note: The instrument manufacturer's IFU should be consulted for the specific time and temperature for each instrument/set sterilized to ensure the cycle is appropriate.*

Exhaust

At the end of the exposure phase, the chamber's drain is opened and the steam is removed through the discharge line. This creates a void in the chamber; filtered air is gradually reintroduced into the chamber and the chamber gradually returns to room pressure.

Figures **14.14** through **14.17** provide illustrations of the conditioning, exposure and exhaust phases in the steam sterilization process.

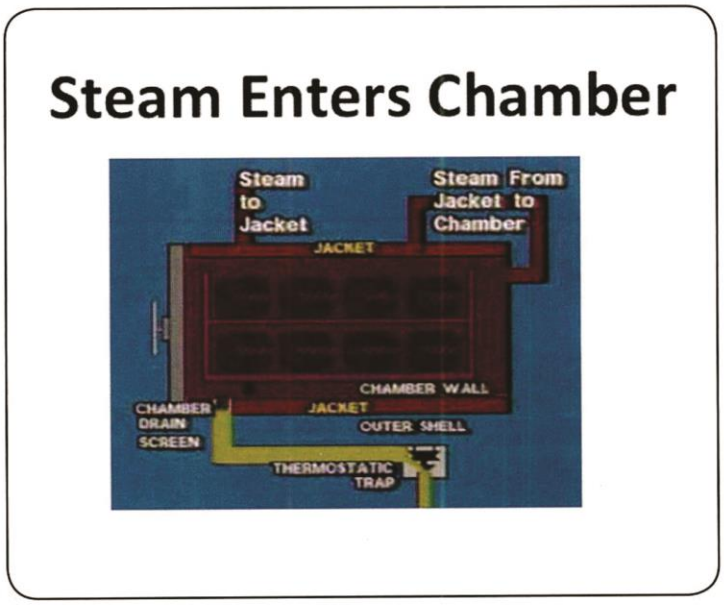

Figure 14.14 shows (in red) steam entering the chamber, and air being displaced (in green) down the chamber's drain.

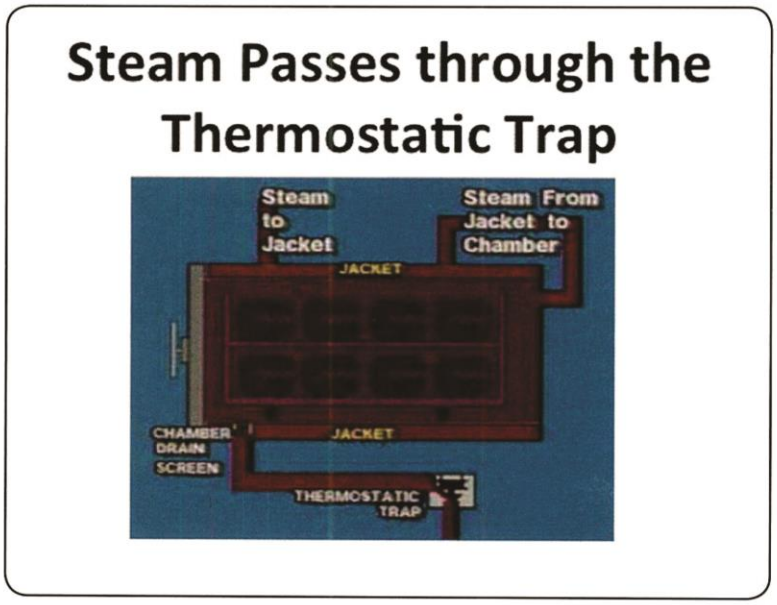

Figure 14.15 shows (in red) steam that has passed the chamber drain screen and travels past the thermostatic trap.

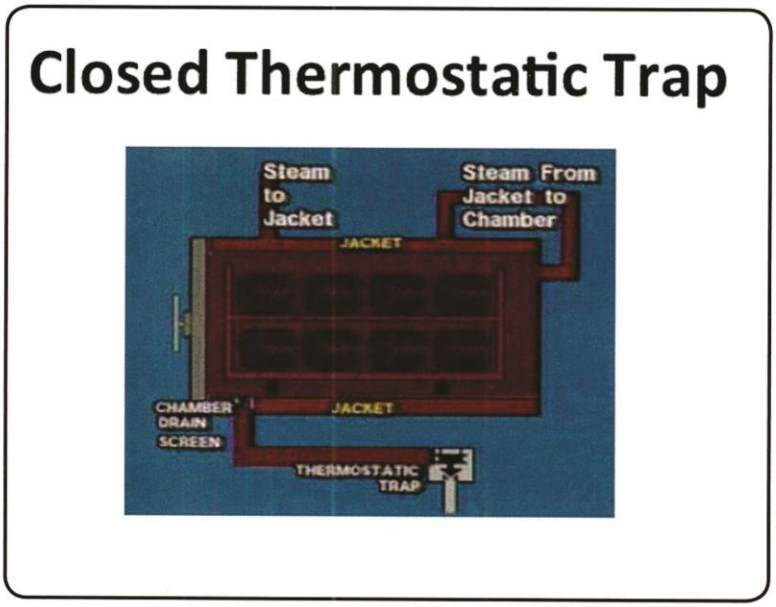

Figure 14.16 shows (in red) the thermostatic trap being closed after the desired temperature is reached.

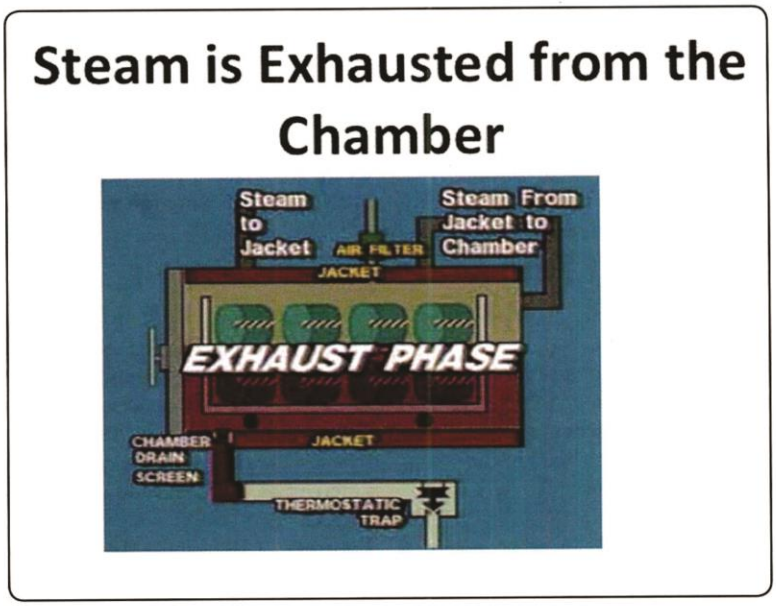

Figure 14.17 shows (in red) steam being exhausted from the sterilizer.

Drying

Drying begins at the conclusion of the exhaust phase. Dry times are based on the device, packaging and the sterilizer's IFU. At the end of this dry time, the end-of-cycle signal sounds and the door may be opened.

CONDITIONS NECESSARY FOR EFFECTIVE STEAM STERILIZATION

Regardless of the type of steam sterilization method used, the same four conditions (contact, temperature, time and moisture) must be met.

Contact

The most common reason for sterilization failure is the lack of contact between steam and the entire surface of the device being sterilized. This failure may be related to human error or mechanical malfunction. Frequent causes of steam contact failure include:

- Failure to adequately clean the object being sterilized. Any coating of soil, such as protein or oils, can protect the microorganisms from direct steam contact.
- Sets that are too dense or instruments positioned in a way that does not allow steam contact.
- Packages wrapped too tightly. If packs are wrapped too tightly, air becomes trapped and cannot escape.
- Loads that are too crowded. Packs must be arranged with adequate spacing on the cart. If they are packed too tightly, air may be entrapped and steam may not be able to penetrate into all areas.
- Containers that are positioned incorrectly. Basins and other items that can hold water must be positioned, so air can be removed and water (condensed steam) can escape. When sterilizing bottles or other airtight containers, tops must be removed.

- Clogged drain strainer. Most sterilizers have a small drain strainer at the bottom of the chamber to keep lint, tape and other small objects from entering the exhaust line.

- Mechanical malfunctions. Defective steam traps, clogged exhaust lines and similar mechanical malfunctions can occur, and cannot be repaired by a CS technician. A qualified service representative should be called to perform the necessary maintenance.

- Utility malfunctions. Boiler or steam delivery system problems can occur, and a qualified service representative is needed to make repairs, as specified in the sterilizer manufacturer's service manual.

While mechanical malfunctions can occur, many sterilization failures are caused by human error and can be prevented by good work practices.

Temperature

To be effective, steam sterilization must occur at specific temperatures. These temperatures are needed to kill heat-resistant bacteria. The two most commonly-encountered temperatures for steam sterilization are: gravity sterilization 250°F (121°C) and dynamic air removal 270°F to 275°F (132.2°C to 134°C).

Time

The steam sterilization process can only be effective if all items within the load are exposed to the elevated temperatures and steam contact (moisture) for an adequate amount of time. Inadequate sterilization exposure times can lead to failure of the sterilization process.

Figures 14.18 and **14.19** show time and temperature relationships. This data represents the minimum sterilization cycles identified by the Association for the Advancement of Medical Instrumentation (AAMI).

Gravity Air Displacement

Item	Exposure time at 250°F (121°C)	Exposure Time at 270°F (132°C)	Exposure Time at 275°F (135°C)	Drying Time
Wrapped instruments	30 minutes	15 minutes	10 minutes	15-30 minutes 30 minutes
Textile packs	30 minutes	25 minutes	10 minutes	15 minutes 30 minutes
Wrapped utensils	30 minutes	15 minutes	10 minutes	15-30 minutes 30 minutes
Unwrapped nonporous items/ instruments (IUSS Cycle)		3 minutes	3 minutes	0-1 minute
Unwrapped nonporous and porous items in a mixed load (IUSS cycle)		10 minutes	10 minutes	0-1 minute

Figure 14.18

Dynamic Air Removal

Item	Exposure Time at 270°F (132°C)	Exposure Time at 275°F (135°C)	Drying Times
Wrapped instruments	4 minutes	3 minutes	20-30 minutes 16 minutes
Textile packs	4 minutes	3 minutes	5-20 minutes 3 minutes
Wrapped utensils	4 minutes	3 minutes	20 minutes 16 minutes
Unwrapped instruments (IUSS cycle)	3 minutes	3 minutes	N/A
Unwrapped nonporous and porous items in a mixed load (IUSS cycle)	3 minutes	3 minutes	N/A

Figure 14.19

Moisture

Dry, **saturated steam** is required for effective steam sterilization. Saturated steam acts similar to fog because it holds many tiny water droplets in suspension. The moisture content of saturated steam should possess a relative humidity (r.h.) of 97% to 100%. In other words, steam ideally should consist (by weight) of two to three parts of saturated water and 97 to 98 parts of dry, saturated steam.

Saturated steam is similar to air with 100% r.h. When saturated steam cools, water condenses as a liquid. The pressure exerted by saturated steam is constant for a given temperature, and the pressure varies in direct proportion to that temperature. In other words, the higher the temperature, the higher the pressure. To increase steam temperature, pressure must be increased; to decrease the steam temperature, pressure must be decreased.

Saturated steam Steam that contains the maximum amount of water vapor.

The atmospheric room pressure at sea level is 14.7 pounds per square inch (psi) at room temperature. While the pressure gauges on sterilizers at sea level are set at zero, in reality, the pressure is 14.7 pounds psi. After the sterilizer's door is closed and the sterilization cycle begins, steam is injected into the chamber. Then, the temperature rises, as does the pressure in the compartment. **Figure 14.20** shows the temperature and pressure relationship.

One of the concerns with steam sterilization is super-heated (dry) steam. Super-heated steam reaches higher temperatures than saturated steam, and due to the lack of moisture, it is a poor sterilant. If the steam is not saturated (less than 97% to 100% r.h.), the following two problems can develop (either

Steam Table

Temperature		Absolute Pressure	Gauge Pressure (lbs/in²)	
F	C	psia	Sea Level	One Mile Altitude
212	100	14.696	0	2.7
220	104	17.186	2.5	5
225	107	18.912	4	7
230	110	20.779	6	9
235	113	22.800	8	11
240	115.5	24.968	10	13
245	118	27.312	13	15
250	121	29.825	15	18
255	125	32.532	18	20.5
260	127	35.427	21	23
265	129	38.537	24	26.5
270	132	41.856	27	30
270	135	45.426	31	33
280	138	49.200	35	37
285	140.5	53.249	39	41

Figure 14.20

or both of which will interfere with the effectiveness of sterilization):

- Items in the sterilizer will remain dry, and microorganisms cannot be killed as readily as under wet conditions.

- Items in the sterilizer will remain "cool" much longer, especially if they are wrapped. To understand this, think about baking a turkey in an oven with dry heat. It may take hours for the center of the turkey to become cooked compared to one placed in a pressure cooker with saturated steam. Saturated steam is a much better "carrier" of thermal energy than dry air.

BASIC WORK PRACTICES FOR STEAM STERILIZATION

Medical devices must be properly prepared before sterilization to ensure steam will come in contact with all surfaces. This section provides sterilization preparation guidance for processing some common medical devices.

Preparing Devices and Packs for Steam Sterilization

As noted earlier, all devices should be thoroughly cleaned before sterilization.

Effective sterilization requires that the sterilizing agent be in contact with all surfaces for the prescribed time. Air removal, steam penetration and condensate drainage are enhanced by proper positioning, and by the use of perforated or mesh-

bottomed trays or baskets. **Figure 14.21** illustrates a mesh bottom tray. Instrument sets should be prepared in trays large enough to equally distribute the mass and the configuration of instrument sets should be evaluated to help ensure they remain dry.

Note: Oils, powders, cork and wood cannot be steam-sterilized.

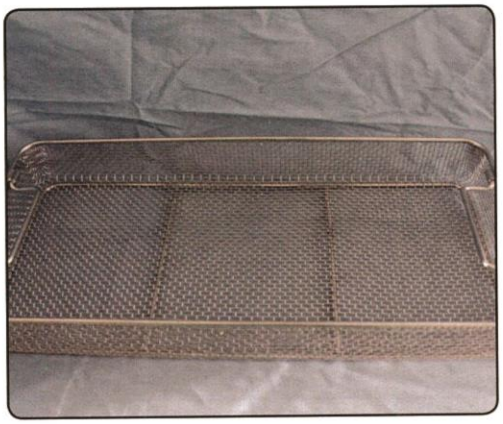

Figure 14.21

Loading a Steam Sterilizer

To ensure full steam contact and removal of air, the sterilizer must be properly loaded to allow adequate air circulation and drainage of the condensate.

Basic procedures for loading a sterilizer include:

- Allow for proper steam penetration and avoid overloading. Packages must be placed for efficient air removal, steam penetration and evacuation.
- If a shelf liner is used, it should only be made of absorbent material. (see **Figure 14.22**)

Figure 14.22

- Solid containers must be positioned so air can exit and steam can enter.
- There should be visible space between packs to allow steam circulation and drying.
- When combining loads, place hard goods on the bottom to prevent condensation from dripping onto lower packs.
- Packages must not touch chamber walls.
- Basin sets should stand on edge. They should be tilted for drainage, so if water is present, it will run out. **Figure 14.23** uses an unwrapped basin to illustrate how basins should be positioned for adequate drainage.

Figure 14.23

- Position textile packs so the layers within them are perpendicular to the shelf. **Figure 14.24** uses two unwrapped towel packs to illustrate how they should be placed on the sterilizer rack to facilitate the sterilization process.

Figure 14.24

- Stand paper/plastic peel pouches on edge using a basket or rack. Placing them plastic side down may cause moisture to remain inside, and placing them plastic side up may cause water to stand on top of the plastic. Place them so the sterilization pouches are placed paper-to-plastic for air and steam circulation.

- When possible, sterilize textiles and hard goods in separate loads. If this is not possible, textiles should be placed on top shelves, with hard goods below to avoid condensation runoff from the hard goods onto the textiles below.

- Surgical instrument trays with perforated bottoms should sit flat on the shelf to maintain even instrument distribution and to facilitate proper drainage. Standing these instrument sets on their edge permits moisture to collect at the standing edge. **Figure 14.25** uses an unwrapped, perforated instrument tray to illustrate how perforated instrument trays should be placed on the sterilizer rack.

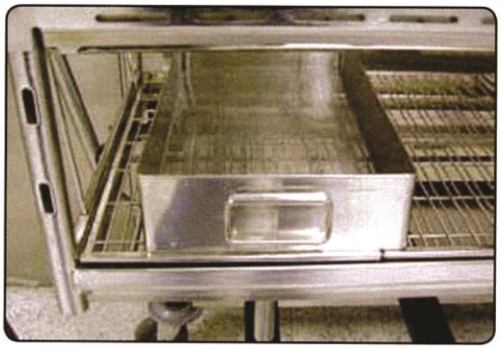

Figure 14.25

Unloading a Steam Sterilizer

When sterilization is complete, follow the sterilizer IFU for opening the door.

When the cart is removed, it should be placed in a low-traffic area where there are no air conditioning or other cold air vents in close proximity. For sterilizers without carts, items should remain in the sterilizer chamber until properly cooled.

The cooling time may be only 30 minutes for small sets or peel pouches, but can take two hours or longer for larger sets. The cooling time must account for critical factors, such as the type of sterilizer used, the design of the device and packaging being sterilized and the temperature and humidity of the room. The packages may still contain some steam vapor. If packages are touched at this point, the vapor present might carry microorganisms from one's hand through the packaging material and contaminate the item.

The load contents should be visibly free of any liquid. Water droplets on the outside of packages or on the rails of carts are signals that every item in the load should be visually inspected. *Caution: Do not touch items during visual inspection.*

Wet items should be considered contaminated, even if they have not been touched.

To unload sterile items:

- Do not unload packages before they are cool. Placing hot or warm packages on cold surfaces will cause condensation to occur beneath and/or between them. If warm packages are placed in plastic dust covers, condensate will be trapped until opened and the moisture may damage items protected by the dust cover.
- Handle the sterile packages as little as possible. Items should not be moved or touched until they have cooled to room temperature.

Controlling Wet Packs

Wet packs may occur when a steam sterilization process is used. Packages are considered wet when moisture in the form of dampness, droplets or puddles of water are found on or within a package after a completed sterilization cycle. Moisture can create a pathway for microorganisms to travel from the outside to the inside of a package. **Figure 14.26** provides an example of condensation (wetness) on the outside of a tray. **Figure 14.27** provides an example of moisture on the inside of a tray. If moisture is present on or in one pack, the problem may be isolated to that one set. To ensure the problem is isolated to only one pack, other packs in the load may be opened to check for moisture. If there are several wet packs from one load, the entire load should be considered "wet." Wet packs cannot be released and should be reported for immediate follow up.

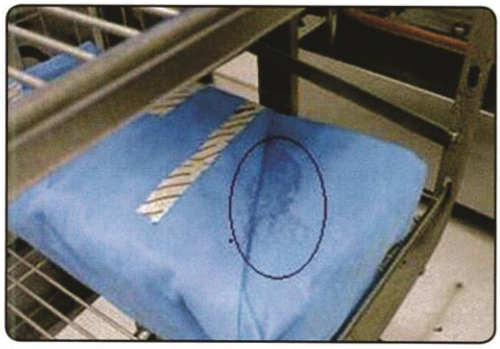

Figure 14.26

Figure 14.27

A wet pack is considered contaminated and must be completely repackaged and reprocessed. When doing so, all textiles should be relaundered and process indicators in the tray or pack must be replaced.

Wet Pack Documentation

All wet packs should be documented. Because of the complexity of the issue, finding the cause and cure of wet packs and/or wet loads can be difficult as there are many factors to take into consideration. Investigation is a multiple-step process. Documenting wet pack occurrences may identify a pattern that can pinpoint the root cause. For example, documentation may show that only the plastic instrument sets, specialty devices, packages prepared by another department or processed by a specific CS technician are involved. It may also show a pattern of steam usage within the facility or changes in steam quality during a certain time of

year. Identifying the root cause of the wet packs is crucial to preventing additional wet packs. External moisture on packs is usually noticed immediately when the packs are removed from the sterilizer. Internal wetness will not be noticed until the packs are opened for use, unless the moisture wicks through the wrap. (See **Figure 14.28**)

Causes of Wet Packs

Primary causes of wet packs arising from CS preparation techniques include:

- Packs that were improperly prepared or loaded incorrectly for sterilization. This is the most frequent cause of wet packs.
- Heavy or dense instrument sets.
- Not using absorbent material to wick moisture between heavy metal, such as basin sets.
- Textile packs wrapped too tightly.
- Improperly prepared items, such as items wrapped while moist.

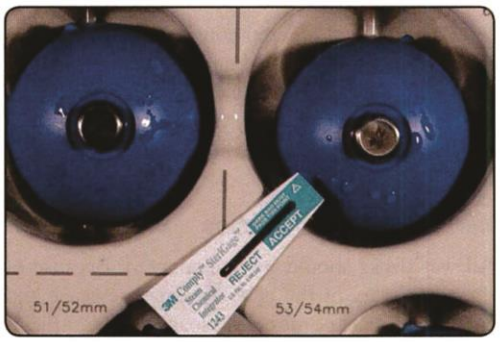

Figure 14.28

- Metal items positioned in a way that allows water to pool or trap steam. Instrument and basin sets that are too dense or overloaded.
- Linen packs wrapped too tightly, causing them to retain moisture.
- Improper placement of concave items, such as medicine cups, in a position that does not allow for drainage.
- Not using the correct filters or incorrect filter placement on a container.

Another reason for wet packs may be the sterilizer itself. Listed below are two of the most common reasons that can be identified by a CS technician:

- Gasket not completely intact.
- Clogged chamber drain strainer.

Other causes of wet packs can only be identified and resolved by a qualified sterilizer service technician. Such causes may include:

- Broken valves.
- Malfunctioning steam traps or drain check valves.
- Faulty sterilizer gauges or controllers.
- Clogged drain line.
- Faulty drain valves.

Wet packs may be caused for reasons occurring outside of CS. As previously stated, these reasons can be attributed to the boiler or stream delivery system. Although CS does not control these factors, it is important to be aware of some of factors from outside CS that can contribute to wet packs, including:

- Steam quality that does not meet the requirements of the sterilizer.
- Blocked steam lines.
- Boiler feed water that contains too many non-condensable gases, including air.
- Boiler not properly maintained.

- Malfunctioning steam traps or check valves.
- Poorly engineered steam piping.
- Increased demands for the steam supply.

Wet packs can also be caused by environmental factors, such as removing a hot load and placing it in an air conditioned area or an area with humidity exceeding 70%.

Extended Sterilization Cycles

Healthcare facilities typically use standard cycles for a majority of items processed; however, medical instrumentation manufacturers are now incorporating complex designs and materials into their devices. They may provide written processing instructions that lengthen the exposure phase of the steam sterilization cycle. This is referred to an "extended cycles."

CS technicians must obtain, review and consistently follow the manufacturer's written recommendations for all of the medical devices they process, including medical devices purchased, consigned or loaned to the facility.

Most medical devices require standard cycle times. Damage to some items can occur if items requiring standard sterilizing times are processed with other devices that require an extended cycle. For that reason, extended cycle items should not be sterilized with items that require a different cycle time. Items should never be sterilized in any cycle that deviates from the specific manufacturer's instructions.

Cleaning and Maintaining Sterilizers

The sterilizer manufacturer's written recommendations for sterilizer maintenance must always be followed. The following general cleaning and maintenance guidelines are illustrative of manufacturer's recommendations:

- Cool the chamber before performing any cleaning or maintenance procedure.
- The chamber drain strainer should be removed at least daily and cleaned thoroughly under running water using a non-abrasive brush and a mild detergent. This procedure may be needed more frequently, depending upon the types of loads processed. If debris is allowed to build up, it may be necessary to soak the strainer before cleaning. **Figure 14.29** shows an improperly-maintained strainer that is clogged and will not allow proper air removal.

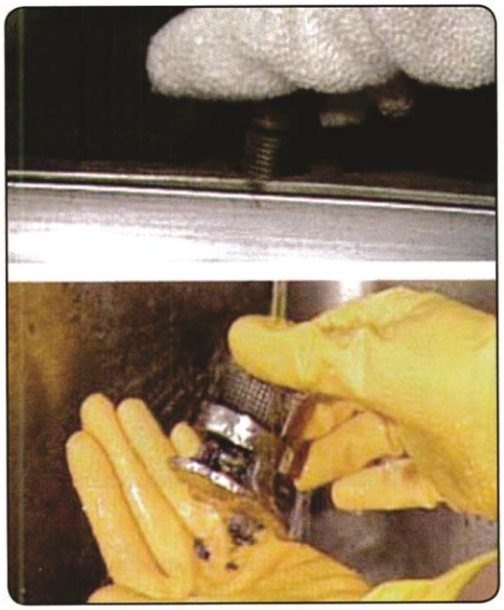

Figure 14.29

- The inside of the chamber should be cleaned according to the manufacturer's instructions. Problems with residue buildup on the chamber's interior can affect the cycle's drying ability. Residues in the chamber can leave deposits on instruments and wrappers. **Figure 14.30** illustrates residue buildup in a sterilizer chamber. Clean with nonabrasive and nonlinting products. Rinse detergent and residue from the chamber thoroughly to avoid deposits on devices during sterilization.

- The door gasket should be inspected and wiped clean daily with a clean, damp, nonlinting cloth. During inspection, look for defects or signs of wear or deterioration, especially if the unit has a vacuum cycle.

- Carriages, carts and loading baskets should be routinely cleaned with a mild solution. Follow the manufacturer's IFU for cleaning and lubrication requirements.

- Carriages, carts and loading baskets should be checked to ensure they are not damaged and can move freely in and out of the sterilizer chamber.

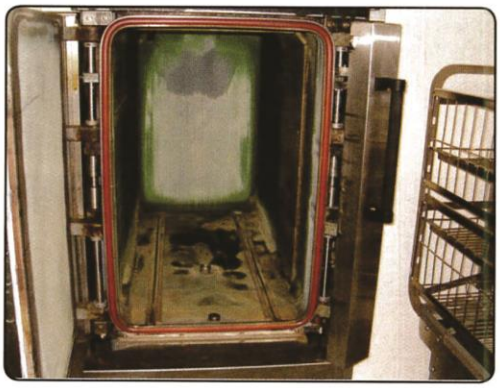

Figure 14.30

- Follow the manufacturer's instructions about the need and method for cleaning and flushing the chamber's drain. Air and steam will not pass efficiently if the drain line is blocked.

- Strong abrasives or steel wool should never be used on the sterilizer because they can scratch the surface and encourage corrosion. While sterilizer chambers are made of corrosion-resistant materials, some steam boiler water treatment chemicals can penetrate the chamber if the surface is damaged. Chambers that have not been properly maintained may require professional cleaning.

- Inspect recording devices daily, including paper charts and printer paper.

STERILIZATION QUALITY CONTROL

Sterilization quality control is an essential part of the sterilization process. Because it is difficult to prove an item's sterility without contaminating it, conditions that indicate sterilization parameters were met must be monitored. Sterilization monitoring is addressed in Chapter 17.

CONCLUSION

Central Service professionals who understand the steam sterilization process reduce the risk of sterilization failure. Knowing when there may be an issue with a steam cycle may allow the load contents to be reviewed and, if necessary, reprocessed before the items are distributed or used on a patient.

RESOURCES

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

Centers for Disease Control and Prevention. *Guideline for Disinfection and Sterilization in Healthcare Facilities.* 2008.

Huys J. *Sterilization of Medical Supplies by Steam, Volume 1, General Theory.* 2010.

CENTRAL SERVICE TERMS

Bioburden

Saturated steam

Chapter 15

Low-Temperature Sterilization

Learning Objectives

As a result of successfully completing this chapter, readers will be able to:

1. Discuss basic requirements important for low-temperature sterilization systems
2. Explain specific requirements for low-temperature sterilization methods commonly used by healthcare facilities:
   - Ethylene oxide
   - Hydrogen peroxide
   - Ozone
3. Review important parameters of the low-temperature sterilization methods

INTRODUCTION

Low-temperature sterilization has become increasingly important due to the development and growing use of delicate, heat- and moisture-sensitive medical devices and surgical instruments. Ethylene oxide (EtO), hydrogen peroxide (H_2O_2) and ozone (O_3) are the low-temperature sterilization methods commonly used in healthcare settings, and each provides terminal sterilization. Chemicals used to sterilize instruments have toxic properties, although levels of toxicity and potential for exposure vary widely, based on the sterilization method and sterilant used. As a result, Central Service (CS) technicians must be trained on how to use them safely and effectively. Each low-temperature sterilization method has advantages and limitations, and it is the responsibility of sterilization professionals to understand when and how to safely use the low-temperature sterilization methods that are available.

LOW-TEMPERATURE BASIC STERILIZATION REQUIREMENTS

Eight basic requirements are important for any type of low-temperature sterilization system:

- Efficacy (effectiveness) - Has the capability of providing the minimum-required **sterility assurance level (SAL)**.
- Safety - There should be no toxic residuals remaining on the packaging or device upon completion of the sterilization cycle.
- Exposure monitoring - Ability to monitor the sterilization process to ensure concentrations of sterilants in the work area remain within any required exposure limits.
- Sterilization performance monitoring - Must be capable of being reliably monitored using physical, chemical and biological indicators.
- Penetration - Quality assurance must be able to penetrate through packaging materials and into lumens and other hard-to-reach areas of the device.
- Material compatibility - There should be no changes in the device's functionality after sterilization.
- Adaptability - Should be compatible with or easily modified to meet existing healthcare practices.
- Approval - Must be cleared by or registered with the appropriate regulatory agencies.

To be effective in the healthcare environment, a sterilization system must satisfy all requirements; failure to meet even one requirement may pose a significant risk to patients and healthcare workers.

Efficacy

To be legally marketed in the U.S., the U.S. Food and Drug Administration (FDA) requires each sterilant and sterilization technology to be rigorously tested against a broad range of microorganisms encountered in today's healthcare environment. The low-temperature sterilization technologies discussed in this chapter use different sterilizing agents and have significantly different processing methods. When used according to the sterilizer's Instructions for Use (IFU), each sterilization method meets the required minimum SAL, as outlined by the FDA, Centers for Disease Control and Prevention (CDC) and other organizations.

Sterility assurance level (SAL) The probability of a viable microorganism being present on a product unit after sterilization.

Safety

Chemicals used as sterilants are designed to destroy a wide range of pathogens; however, the same properties that make them effective sterilants also make them harmful to humans. In particular, in sterilization methods such as EtO, significant toxic residues can build up in medical devices and packaging. To ensure a safe work environment, low-temperature sterilization systems should be

Toxicity Standards for Low-Temperature Sterilants			
Sterilant	**OSHA PEL Eight-hour TWA Limit**	**NIOSH IDLH Limit**	**Monitoring Required?**
Ethylene oxide (EtO)	1.0 ppm	800 ppm	Yes
Hydrogen peroxide (H_2O_2)	1.0 ppm	75 ppm	No
Ozone (O_3)	0.1 ppm	5 ppm	No
PEL—permissible exposure limits; ppm—parts per million; TWA—time weighted average; IDLH—immediately dangerous to life or health			

Figure15.1

used according to the manufacturers' instructions and appropriate work practices, engineering controls, personal protective equipment (PPE) and monitoring should be employed.

Exposure Monitoring

EtO has been widely used as a low-temperature sterilant since the 1950s. It has potential health risks that require monitoring, long aeration times and other precautions. While safer for healthcare workers, newer low-temperature sterilization technologies also can pose health risks. To ensure the safety of healthcare workers, the Occupational Safety and Health Administration (OSHA) has established **permissible exposure limits (PELs)** for all low-temperature sterilants. These exposure limits are expressed as an eight-hour, **time weighted average (TWA)**: the total allowable worker exposure during an eight-hour period.

Permissible exposure limits (PEL) The maximum amount or concentration of a chemical that a worker may be exposed to under OSHA regulations.

Time weighted average (TWA) The amount of a substance employees can be exposed to over an eight-hour day.

The National Institute for Occupational Safety and Health (NIOSH) also has developed standards for Immediately Dangerous to Life or Health (IDLH) concentrations for low-temperature sterilants. **Figure 15.1** lists the standards established by OSHA and the NIOSH for each sterilant.

Sterilizer Performance Monitors

Monitoring sterilizer performance is essential to ensure the successful sterilization of medical instruments and devices and to protect patients. No single monitoring method provides all the information necessary to ensure effective sterilization; therefore, recommended practices state that available information from physical, chemical and biological indictors should be used to assess the effectiveness of a process before releasing a load. It is absolutely essential that CS technicians understand how to read and interpret physical monitoring information and chemical indicator color changes and know how to handle, use and interpret the results of biological indicators.

Penetration

Many modern medical devices and instruments are significantly more complex than their counterparts of just a few years ago. Not only must the sterilant penetrate packaging material (in some cases, multiple layers), it also must reach narrow lumens. If the sterilant cannot reach the most difficult to access site where microorganisms may hide, the sterilization process will not be effective.

The properties of a chemical sterilant impact its ability to penetrate effectively. For example, EtO inactivates microbes by a process called alkylation (seeking out specific proteins in microbes with which to react). This allows EtO to penetrate packaging and materials to reach remote surfaces where microbes may be located. Hydrogen peroxide and 0_3 destroy microbes through **oxidation.** Chemicals that are gases at room temperature are more effective penetrants because they will not cause condensation on packaging. In order

to monitor the efficacy of all sterilant gases, it is important to place indicators in the most difficult to sterilize area of the load.

Oxidation The process by which several low-temperature sterilization processes, including hydrogen peroxide gas plasma, vaporized hydrogen peroxide and ozone, destroy microorganisms. Oxidation involves the act or process of oxidizing, which is the addition of oxygen to a compound with a loss of electrons.

Materials Compatibility

Medical devices and surgical instruments are composed of a variety of materials that may be affected by ingredients in sterilants; therefore, sterilizers must be tested to establish compatibility with a wide range of materials. Medical device manufacturers typically test the compatibility of their instruments with one or more of the available sterilization technologies; therefore, manufacturer recommendations should be followed to help ensure successful sterilization, instrument integrity, and prevention of damage that may increase costs and limit the availability of instruments for patient procedures.

Adaptability

The low-temperature sterilization process should be compatible with or easily integrated into existing healthcare and instrument processing practices.

Approval

The sterilization system must be cleared and registered with the appropriate regulatory agencies, with a clearly-defined intended use.

ETHYLENE OXIDE

Background

For more than 60 years, EtO gas has been an effective sterilization technology for heat- and moisture-sensitive medical devices and surgical instruments. EtO contributed to the development and increased use of delicate, sophisticated surgical instruments that would be damaged in the intense heat and high moisture required for other sterilization methods. **Figure 15.2** shows an EtO sterilizer.

Efficacy

EtO has excellent microbicidal activity. During the alkylation process, EtO destroys the cell's ability to metabolize or reproduce, which leads to the organism's death.

Penetration

EtO is a small molecule that vaporizes easily and can permeate throughout a wide range of materials, including plastics, to reach recessed areas. It has a high vapor pressure and a low boiling point of 51.3°F (10.7°C). As a result, it is easily maintained in the gas phase.

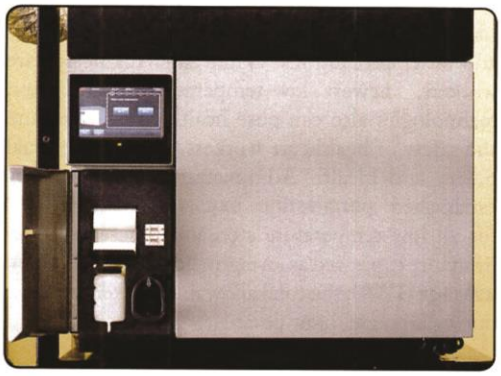

Figure 15.2

Sterilization Cycle and Process Parameters

In healthcare EtO systems, the gas is provided in individual dose cartridges that are placed inside chambers of less than 10 cubic feet. The cartridge is punctured under vacuum. (See **Figure 15.3**) If a leak develops in an EtO system, the vacuum will pull room air into the chamber, rather than allow EtO to be released.

100% Ethylene Oxide Cartridges

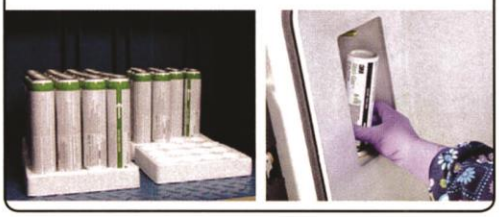

Figure 15.3

The basic EtO sterilization cycle consists of five stages: preconditioning and humidification, gas introduction, exposure, evacuation and air washes. The cycle takes approximately 2 ½ hours, excluding **aeration** time. Upon completion of the sterilization cycle, the items must go through an aeration process to remove all **residual EtO** before the sterilizer chamber can be unlocked and the items removed.

Aeration A process in which sterilized packages are subjected to moving air to facilitate removal of toxic residuals after exposure to a sterilizing agent, such as EtO.

Residual EtO Amount of EtO that remains inside materials after they are sterilized.

Operators should demonstrate competency in all parameters of EtO sterilization, as well as possess a comprehensive knowledge of the system. (See **Figure 15.4)**

Safety

EtO is a toxic gas classified by OSHA as a carcinogen and reproductive hazard. To protect CS technicians, EtO sterilizers should be located in a well ventilated area, with a room air exchange rate of at least 10 changes per hour. The sterilizers are usually installed in negative-pressure rooms with contained ventilation systems venting to the outside. (See **Figure 15.5**) Ventilation systems, exhaust lines and floor drains should be periodically checked by qualified personnel to ensure they are working properly.

Today's EtO sterilizers are designed for safety and have many engineering safeguards to prevent personnel from coming in contact with EtO (vapor or liquid). In addition, environmental engineering controls protect CS technicians.

Example of an Ethylene Oxide Negative Pressure Room

Figure 15.5

To minimize the safety risks associated with the use of EtO, employees should be instructed about:

- Hazards of EtO.
- Sterilizer manufacturer and EtO supplier IFU.

EtO Sterilization Process Parameters	
Gas concentration	450 to 1,200 mg/l
Temperature	98°F to 145°F (37°C to 63°C)
Relative humidity	40% to 80% (critical to the penetration of bacterial cells and successful sterilization)
Exposure time	1 to 6 hours
Aeration time	8 to 12 hours at 122°F to 140°F (50°C to 140°C)

Figure15.4

- Processing procedures.
- Storage and handling of EtO gas cartridges.
- Procedures to reduce employee exposure.
- Use of PPE.
- Principles of EtO monitoring and interpretation of results.
- Handling canceled cycles.
- Applicable OSHA standards.
- **Safety data sheets (SDS).**
- EtO emergency plans.

Safety data sheet (SDS) A written statement providing detailed information about a chemical or toxic substance, including potential hazards and appropriate handling methods. An SDS is provided by the product manufacturer to the product buyer, and it must be posted and/or made available in a place that is easily accessible to those who will use the product.

Exposure Monitoring

Personal monitoring normally involves the use of devices affixed directly to the employee's clothing in the breathing zone (within one foot of the person's nose) to test airborne EtO concentrations. (See **Figure 15.6**) One limitation of personal monitoring devices is that sampling results are not available until after the actual sampling period has ended. OSHA requires that facilities using EtO sterilization have a system/procedure to immediately alert affected employees in case of an emergency, such as a leak, spill or equipment failure.

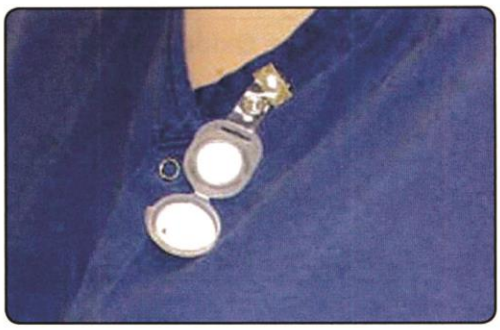

Figure 15.6

Area monitoring is used to measure EtO working area in which EtO sterilizers are used, and the monitoring may identify potential problems. (See **Figure 15.7**) These monitors can potentially detect emergencies and sound an alarm when leaks or spills are detected. Leak detection tests also should be performed.

For specific monitoring requirements refer to federal, state and local regulations.

Example of an Area Monitoring System

Figure 15.7

Materials Compatibility

EtO has excellent compatibility with nearly all of the materials used in the construction of both single-use and reusable medical devices; however, as with all sterilization methods, it is imperative that CS technicians follow specific device manufacturer recommendations for the appropriate sterilization process for each specific item.

EtO should not be used to sterilize:

- Liquids. EtO will combine with liquids and may produce harmful chemical byproducts.
- Devices with energy sources. Energy sources could create a spark in the sterilization chamber during the sterilization cycle.
- Leather items. Chemicals used in the tanning process will combine with EtO to form chlorohydrin, which can cause negative health effects.

Packaging

Packaging of instruments should be performed according to standards for packaging products for sterilization. Appropriate packaging materials must be selected based on recommendations of the sterilizer manufacturer. EtO sterilization is compatible with a variety of packaging materials, including paper/plastic or Tyvek peel pouches, approved fabric wrappers, medical crepe paper, polypropylene and most container systems. *Note: Aluminum foil, cellophane, nylon films, polyester, PVC (plastic) films and styrofoam should not be used.*

Loading and Unloading Ethylene Oxide Sterilizers

EtO sterilizers must be properly loaded for effective sterilization. Overloading impedes proper air removal, load humidification, sterilant penetration and aeration. Items should be arranged to avoid contact with chamber walls. Pouches should be placed on edge in wire baskets. Stacking one package on another should be avoided.

Aeration

Because EtO can be absorbed by many materials, aeration is required to remove EtO residual gases before instruments and packaging can be safely handled by healthcare workers, or used for patient procedures.

When the exposure cycle ends, one or more vacuum pulses remove EtO from the chamber. The aeration phase then takes place as warm air circulates through the chamber to remove residuals from instruments. Minimum general recommendations for aeration are eight hours at 140°F (60°C), and 12 hours at 122°F (50°C). The rate of aeration is dependent upon many factors, including the nature of the materials used to construct the device; therefore, the manufacturer of the medical device must provide recommendations for appropriate aeration times and temperatures.

Sterilizer Performance Monitors

An EtO sterilizer should be monitored with physical, chemical and biological indicators. While none of these provide conclusive evidence of device sterility by themselves, they provide a high degree of sterility assurance when used in combination.

- Physical monitors. Include operating pressure gauges, temperature control/measurement devices, timing recorders and humidity sensors. Charts, tapes and graphs detailing the measurements made by physical monitors must be carefully examined before instruments are removed from the sterilizer.
- Chemical monitoring. External chemical indicators (CIs) should be used on the outside of every instrument package to demonstrate that each pack has been processed. Internal CIs should be used inside every package to measure whether the sterilant has penetrated the packaging.
- Biological monitoring. Biological indicators (BIs) are the most accepted means for providing quality assurance for EtO sterilization. (See **Figure 15.8**) The microorganism of choice for EtO is the *Bacillus atrophaeus* spore. Biological monitoring is required for each cycle run in an EtO sterilizer. Follow sterilizer manufacturer's IFU for proper BI placement.

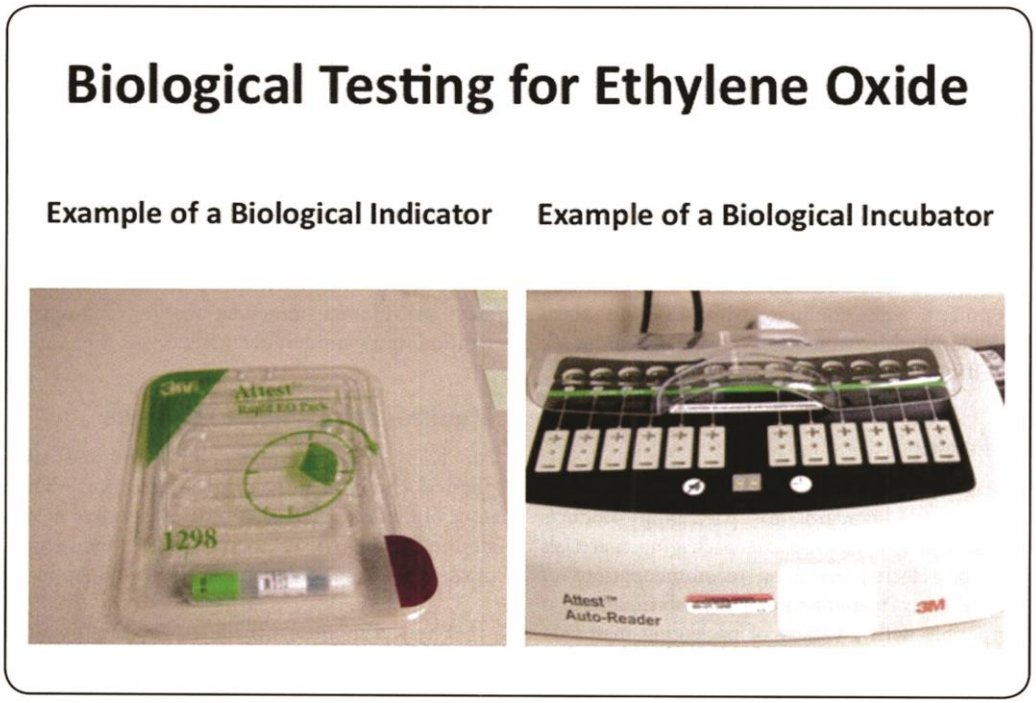

Figure 15.8

HYDROGEN PEROXIDE SYSTEMS

Several types of low-temperature systems use hydrogen peroxide as the sterilant. While the systems operate similarly, there are some key differences in the types of systems.

Hydrogen Peroxide Gas Plasma

Background

The more recent low-temperature sterilization technologies cleared by the FDA are considered oxidative processes. This includes hydrogen peroxide gas plasma. This method is popular due to its safety, relative to EtO, and its rapid cycle times that allow faster turnaround of medical devices. The process uses low-temperature hydrogen peroxide gas plasma for rapid inactivation of microorganisms. The byproducts of the cycle, (water vapor and oxygen) are nontoxic, eliminating the need for a lengthy aeration phase.

Hydrogen peroxide is a highly effective sterilant that sterilizes by oxidation of key cellular components.

Plasma is a state of matter distinguishable from a solid, liquid or gas. Gas plasmas are highly ionized gases.

Efficacy

Hydrogen peroxide gas plasma using a hydrogen peroxide solution ranging from 59% to 95% for the sterilization cycle is proven effective at killing microorganisms. Laboratory tests have demonstrated that the systems destroy a broad spectrum of microorganisms, including Gram negative and Gram positive vegetative bacteria, mycobacteria, yeasts, fungi, lipophilic viruses and hydrophilic viruses, and highly resistant aerobic and anaerobic bacterial spores.

Penetration

Hydrogen peroxide gas plasma sterilizers use deep vacuums, multiple pulse additions of the sterilant, and increased concentrations. These systems can sterilize a wide range of instruments, including some single-channel flexible endoscopes, cameras, rigid endoscopes, light cords, batteries and power drills.

Guidelines have been developed for lumen diameter and length to ensure adequate penetration and efficacy for various cycle parameters. Newer generations of hydrogen peroxide gas plasma sterilizers utilize a higher concentration of hydrogen peroxide (up to 95%) to shorten exposure time and lessen lumen restrictions. There are still some restrictions involving the size, length and number of lumens, and on the type of material and number of instruments per cycle. As always, users should closely follow the instrument and sterilizer manufacturers' instructions and recommendations.

Types of Hydrogen Peroxide Gas Plasma Systems

There are several types of hydrogen peroxide gas plasma sterilizers available, ranging from compact systems with 28- to 38-minute processing times to large-capacity systems with 75-minute cycle times. Different models have different cycle times, load capacities and capabilities for processing instruments. (See **Figure 15.9**)

Figure 15.9

Sterilization Cycle and Process Parameters

The phases of hydrogen peroxide gas plasma include:

- Vacuum. The load is heated while the vacuum system removes any remaining water as it evaporates. Air is removed from the chamber and packages until the pressure is reduced to below atmospheric pressure.
- Injection. Once the correct pressure has been reached, a premeasured amount of concentrated hydrogen peroxide is pumped from a cassette into the vaporizer bowl and then vaporized into the chamber.
- Diffusion. The diffusion stage drives hydrogen peroxide vapor into the small crevices and lumens of devices. The chamber returns to atmospheric pressure to accomplish this.
- Plasma. A vacuum decreases the pressure, and radio frequency (RF) energy is radiated within the chamber from an electrode screen. The RF energy ionizes the hydrogen peroxide, creating hydrogen peroxide gas plasma. The injection and plasma phases are repeated a second time.
- Vent. At the end of the second plasma sequence, the RF is turned off. Air is then vented into the chamber through bacterial high-efficiency particulate air (HEPA) filters, returning it to atmospheric pressure. The process byproducts are only water vapor and oxygen. Aeration is not required, and instruments can be used immediately following the 24- to 75-minute sterilization cycle.

Operators should demonstrate competency in all parameters of hydrogen peroxide gas plasma sterilization. (See **Figure 15.10**)

Hydrogen Peroxide Gas Plasma Sterilization Process Parameters	
Time	24 to 75 minutes, depending on the model
Cycle temperature	Less than 131°F (55°C)
Hydrogen peroxide concentration	59% to 95%, depending on the model
Vacuum level	Automatically controlled
Plasma	Automatically controlled

Figure 15.10

Safety

Concentrated hydrogen peroxide liquid can irritate skin and, like other oxidants, is damaging to eyes if direct contact occurs. In the vapor phase, concentrated hydrogen peroxide is irritating to the eyes, nose, throat and lungs; however, a number of safeguards built into hydrogen peroxide sterilizers are designed to minimize the likelihood of personnel contacting hydrogen peroxide in either the liquid or vapor phase.

The hydrogen peroxide is packaged in sealed cassettes (See **Figure 15.11**) containing chemical leak indicators on each side of the package. These change from yellow or white to red when exposed to liquid or vapor hydrogen peroxide. The leak indicator is visible through a clear plastic overwrap to protect personnel handling the cassette. Once the cassette has been placed in the sterilizer, it is automatically advanced by the machine, eliminating any danger of exposure to liquid hydrogen peroxide through handling of the cassette. After five sterilization cycles, the cassette is automatically ejected into a collection box for safe disposal.

Example of a Cassette for Hydrogen Peroxide Gas Plasma Sterilization

Figure 15.11

To minimize the likelihood of exposure to hydrogen peroxide when removing items from a canceled cycle, CS technicians should always wear latex, vinyl (PVC) or nitrile gloves. As with any chemical used for sterilization, healthcare workers should consult the SDS and follow all manufacturer recommendations and departmental procedures.

To minimize hydrogen peroxide risks, employees should be instructed about:

- Hazards of hydrogen peroxide.
- Storage, handling and disposal of hydrogen peroxide cassettes.
- Handling canceled cycles.
- Applicable OSHA standards.
- The use of PPE.
- Applicable SDS.
- Recommendations for routine maintenance of sterilization equipment.

Exposure Monitoring

Monitoring of the area around the system during operation should be conducted according to the manufacturer's IFU and established guidelines.

Materials Compatibility

Hydrogen peroxide gas plasma sterilization is compatible with a wide variety of materials found in medical devices and surgical instruments, including some flexible endoscopes, semi-rigid ureteroscopes, cameras, light cords, batteries, power drills, rigid scopes and more.

Many items processed in high-temperature sterilization systems, such as stainless steel instruments, are also compatible with hydrogen peroxide gas plasma; however, hydrogen peroxide gas plasma is not compatible with:

- Liquids and powders.
- Any material that absorbs liquids.
- Items that contain cellulose, such as cotton, paper or cardboard, linens, huck towels, gauze sponges or any item containing wood pulp.

Manufacturers of newer low-temperature sterilization technologies, such as hydrogen peroxide, have active device testing programs. These involve cooperative testing with device manufacturers to evaluate sterilization efficacy and materials compatibility. If hospital personnel have a question about the compatibility of a device with a specific sterilization process, the product manufacturer should be contacted.

Packaging

Packaging materials can affect the penetration of hydrogen peroxide. Packaging materials used in the sterilizers should be designed to optimize diffusion of the hydrogen peroxide and not interfere with the RF energy or absorb hydrogen peroxide. Trays and container systems from the sterilizer manufacturer and Tyvek pouches are compatible. Check with tray and sterilizer manufacturers before purchase and use of containers.

Cellulose-containing packaging materials, such as paper/plastic pouches, cellulose-based disposable wrappers and muslin wraps, should not be used with hydrogen peroxide gas plasma sterilizers because they absorb the peroxide and inhibit effective penetration.

Loading Hydrogen Peroxide Gas Plasma Sterilizers

As with other low-temperature sterilization technologies, hydrogen peroxide gas plasma sterilizers must be properly loaded for effective sterilization. If the available amount of hydrogen peroxide is reduced because it reacts or is absorbed before reaching all surfaces, a sterilization failure could occur; therefore, the chamber should not be overloaded. (See **Figure 15.12**)

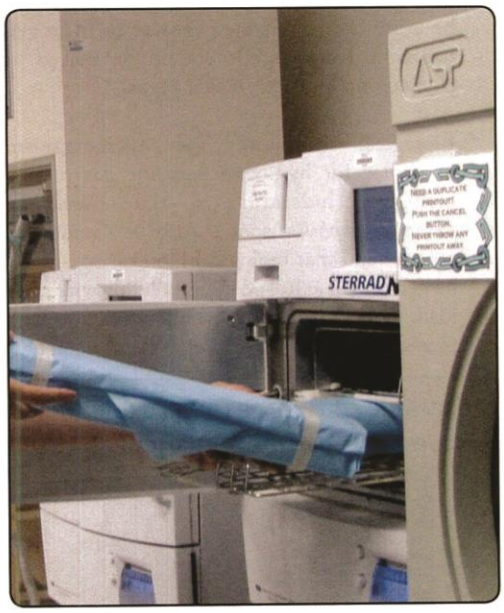

Figure 15.12

Excess moisture remaining on devices can cause the cycle to abort. Consult the manufacturer's IFU for suggested drying methods.

Sterilizer Performance Monitors

Hydrogen peroxide gas plasma sterilizers should be monitored with physical, chemical and biological indicators. Sterilizer performance monitors include:

- Physical monitors. Hydrogen peroxide gas plasma sterilizers operate on a fixed automatic cycle controlled by a microprocessor. All critical parameters are monitored during the operation of the cycle and a printed record documenting the process parameters is provided at the end of each cycle. If any process parameter does not meet established acceptable limits, the cycle will be canceled and the printed record will indicate the reason for the cancellation.

- Chemical monitoring. External CIs should be used on the outside of every instrument package to demonstrate exposure to hydrogen peroxide gas plasma. Internal CIs should also be used to demonstrate exposure to hydrogen peroxide. Internal CIs should be placed at challenging locations inside packs.

- Biological indicators. The microorganism of choice for hydrogen peroxide gas plasma biological indicators is the *Geobacillus stearothermophilus* spore. AORN Guidelines recommend that biological monitoring should be performed at least daily, preferably with each load. (See **Figure 15.13**) Follow the sterilizer manufacturer's IFU for proper BI placement.

Example of Hydrogen Peroxide Gas Plasma Biologicals and an Incubator

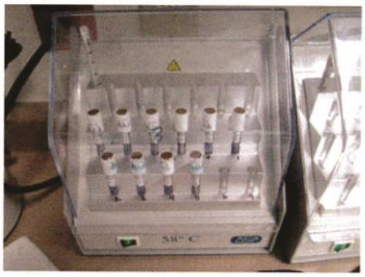

Figure 15.13

Vaporized Hydrogen Peroxide

Background

Low-temperature sterilization technology utilizing vaporized hydrogen peroxide (VHP) has been available to hospitals in the U.S. since 2007. As with hydrogen peroxide gas plasma, VHP systems utilize an oxidative process and provide a rapid cycle time that improves the throughput of medical devices and surgical instruments. (See **Figure 15.14**)

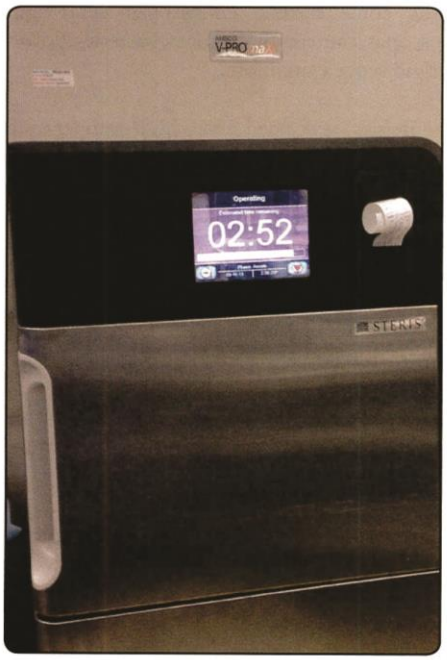

Figure 15.14

Efficacy

Vaporized hydrogen peroxide sterilization uses a 59% hydrogen peroxide solution. It has been shown to be effective against a broad spectrum of pathogens, including spores, bacteria, mycobacteria, nonenveloped viruses, enveloped viruses, cysts, fungi and protozoa.

Penetration

Vaporized hydrogen peroxide is injected four times during each sterilization cycle. Upon completion of the fourth injection hold period, the load is automatically aerated in the sterilizer. The VHP is exhausted from the chamber through a catalytic converter that converts the VHP to water and oxygen.

Types of Vaporized Hydrogen Peroxide Systems

There are two types of VHP sterilizers. One system has a single, preprogrammed, 55-minute sterilization cycle for use with both lumened and nonlumened instruments and devices. The second system offers two preprogrammed cycles: a 28-minute cycle for nonlumened instruments and a 55-minute cycle used to sterilize instruments with lumens and non stainless steel mated surfaces. Review manufacturer's guidelines for details about instrumentation that can be processed in both systems and cycle types.

Sterilization Cycle and Process Parameters

The sterilization cycle of VHP systems operates at low pressure and temperature, and is suitable for processing heat- and moisture-sensitive medical devices. The hydrogen peroxide vapor is generated by injecting aqueous hydrogen peroxide into a vaporization chamber (See **Figure 15.15**) where the solution is heated and converted to a vapor, and then introduced into the sterilizer chamber under negative pressure. The phases of VHP systems include:

- Conditioning. To remove air and excess moisture from the chamber and packaging, the chamber is evacuated and then recharged with dry, sterile air.
- Leak test. Vacuum is held to ensure a leak tight chamber.
- Sterilization. Enhances penetration by injecting hydrogen peroxide vapor into the chamber with a series of four pulses, each followed by a hold period.
- Aeration. Upon completion of the last VHP injection hold period, the load is automatically aerated in the sterilizer. The chamber VHP is exhausted through a catalytic converter that changes the VHP to water and oxygen. No special venting is required.

Vaporized Hydrogen Peroxide Sterilant

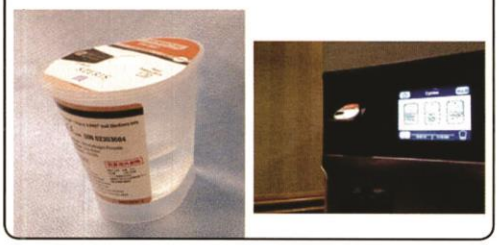

Figure 15.15

As with all methods of sterilization, operators must demonstrate competency in all parameters of VHP sterilization. (See **Figure 15.16**)

Vaporized Hydrogen Peroxide Sterilization Process Parameters	
Cycle temperature	Less than 122°F (50°C)
Hydrogen peroxide concentration	59%
Time	28 to 55 minutes
Other	Preset cycles

Figure15.16

Safety

Concentrated hydrogen peroxide is corrosive to skin, eyes, nose, throat, lungs and gastrointestinal tract. Under normal conditions of use, the VHP sterilizer operator is not exposed to the contents of the sterilant container. The sterilizer automatically dispenses and injects liquid hydrogen peroxide into the chamber. After each sterilization pulse, hydrogen peroxide vapor is removed from the chamber and converted to water and oxygen. An aeration phase facilitates the removal of hydrogen peroxide residuals from instruments and packaging. To avoid exposure to hydrogen peroxide when removing items from a canceled cycle, CS technicians should always wear latex, vinyl (PVC) or nitrile gloves.

To minimize risks, employees should be instructed about:

- Hazards of hydrogen peroxide.
- Applicable SDS.
- Handling canceled loads.
- Applicable OSHA standards.
- The use of PPE.
- Storage, handling and disposal of hydrogen peroxide cartridges.

Exposure Monitoring

No personal or area monitors are required. Testing to check for hydrogen peroxide vapors in the environment around the sterilizer has shown acceptable VHP levels during typical sterilization cycle conditions.

Materials Compatibility

Vaporized hydrogen peroxide sterilization is compatible with a wide range of medical instruments and materials, including telescopes, cameras, light cables, batteries and many lumened devices. Instrument materials compatibility evaluations have been completed to ensure that VHP sterilization systems are safe for medical instruments; however, the user must select the correct cycle for the instruments being processed. The VHP system is not intended to process liquids, linens, powders or any cellulose materials.

Packaging

Packaging materials can affect the penetrating capability of vaporized hydrogen peroxide. Packaging materials approved for use with VHP sterilization include polywrap, a nonwoven sterilization packaging made of 100% polypropylene. Tyvek also has been validated for use with VHP systems. Trays and organizers are available from the manufacturer that allow gas penetration and are compatible with the VHP process.

Loading Vaporized Hydrogen Peroxide Sterilizers

Vaporized hydrogen peroxide sterilizers must be properly loaded for effective sterilization. Items to be sterilized are placed on a rack system within the aluminum chamber. Organizers are also available that allow for positioning of instruments in the tray. To ensure successful sterilization, the chamber should not be overloaded. **Figure 15.17** shows a properly loaded sterilization chamber.

Figure 15.17

Sterilizer Performance Monitors

VHP sterilizers should be monitored with physical, CIs and BIs. As previously mentioned, none of these indicators provide conclusive evidence of device sterility by themselves; however, when used in combination, they provide a high degree of sterility assurance.

Sterilizer performance monitors include:

- Physical monitors. Vaporized hydrogen peroxide sterilizers operate on fixed automatic cycles controlled by a microprocessor and are designed and validated to independently monitor key process cycle parameters.
- Chemical indicators. CI strips for VHP sterilization change color when exposed to the VHP process. They should be used in each

pouch, pack or tray as a process indicator to show that items have completed a cycle.

- Biological indicators. BIs are used for periodic biological monitoring of the VHP process. (See **Figure 15.18**) The microorganism of choice for VHP is the *Geobacillus stearothermophilus* spore. Biological monitoring is required each day the the sterilizer is used, but recommended every cycle. Follow sterilizer manufacturer's IFU for proper BI placement.

Example of Vaporized Hydrogen Peroxide Biologicals and an Incubator

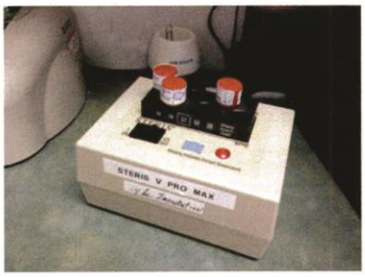

Figure 15.18

OZONE STERILIZATION

Background

O_3 is a low-temperature sterilization method that received FDA clearance in 2003. The system generates O_3 used for sterilization, eliminating the need to purchase or handle a sterilant. The system also does not require aeration and medical devices and surgical instruments can be used as soon as the 4½-hour cycle is complete. (See **Figure 15.19**)

Figure 15.19

Low-Temperature Sterilization

Efficacy

O_3 sterilizers generate sterilant using medical-grade oxygen and water. O_3 is highly effective as an oxidizing agent for low-temperature sterilization. O_3 sterilizes by oxidizing proteins and enzymes, causing the death of the organism.

Penetration

O_3 is a contact sterilant, and the process used for O_3 sterilization is similar to that used for other low-temperature sterilization methods. O_3 is highly reactive and has penetration limitations similar to hydrogen peroxide. It has some restrictions relating to the size and length of lumens, and sterilizer and device manufacturer recommendations must be consistently followed.

Sterilization Cycle and Process Parameters

The 4½-hour O_3 sterilization cycle is composed of two identical half cycles. After instruments have been loaded into the chamber, the door is closed and the cycle begins. A vacuum is drawn followed by a humidification phase. O_3 is then injected into the chamber, and the sterilization process begins. When the first half-cycle has been completed, the steps — from the vacuum to the O_3 injection phases — are repeated, followed by a final ventilation phase to remove ozone from the chamber and packaging. At the end of the sterilization cycle, the O_3 is converted to oxygen.

The O_3 sterilizer is controlled by a programmable logic controller. All critical process parameters are monitored during the cycle. At the end of each cycle step, the process parameters are printed. During the sterilization cycle, if one of the critical process parameters is not reached, the cycle will abort, and the reason for the interruption will be displayed on the screen and printout.

OSHA regulations require that operators demonstrate competency in all parameters of O_3 sterilization. (See **Figure 15.20**)

Ozone Sterilization Process Parameters	
Cycle temperature	87.4°F to 97°F (30.8 to 36°C)
Ozone concentration	59%
Relative humidity	85% to 100%
Time	4 hours, 30 minutes

Figure 15.20

Safety

O_3 reacts strongly with other molecules, and high levels of O_3 are toxic to living systems. At low levels, it is a respiratory irritant. OSHA, FDA and NIOSH regulate O_3 as a toxic gas. O_3 is a bluish gas with a very pungent characteristic odor. The odor threshold for humans is from 0.003 to 0.01 ppm. It is possible to detect O_3 at a concentration lower than the exposure limit for an eight-hour period, which is 0.1 ppm, as established by OSHA.

The O_3 sterilizer design limits the risk of exposure of hospital personnel. All O_3 produced passes through a catalyst that converts it back to oxygen before being exhausted into the room. Since the O_3 gas is created in an enclosed O_3 generator within the unit, there is no handling of the sterilant. The O_3 sterilizer possesses built-in safety features that protect the user from exposure to high O_3 concentrations.

To minimize O_3 risks, employees should be instructed about:

- Hazards of O_3.
- Handling canceled loads.
- Applicable SDS.
- Applicable OSHA standards.

Exposure Monitoring

No personal or area monitors are required, although O_3 sterilization requires a well ventilated room with 10 air exchanges per hour.

Materials Compatibility

O_3 sterilization is compatible with most reusable medical devices currently sterilized by EtO, other oxidative methods, peracetic acid or steam. O_3 sterilization is compatible with many heat-sensitive surgical and diagnostic instruments, including those containing polymers. The process is not recommended for sterilizing sealed ampules, liquids, natural rubber, latex and fabrics. O_3 sterilization of implants has not been validated. Medical devices should always be processed by following the device manufacturer's recommendations and instructions provided by the manufacturer of the sterilization system.

Packaging

The manufacturer of the O_3 sterilizer recom-mends specific wraps, peel pouches and rigid (anodized aluminum) containers for packaging of items to be processed. Other forms of packaging should be verified as acceptable before use.

Packaging made of woven fabric or metal foils are inappropriate for use with the O_3 process, as well as packaging that creates a solid barrier, such as hermetically-sealed (airtight) packs or any other packaging not specifically recommended by the manufacturer.

Loading Ozone Sterilizers

As with all low-temperature sterilization methods, O_3 sterilizers must be properly loaded for effective sterilization. Also, if the available amount of O_3 is reduced because it reacts or is absorbed before reaching all surfaces at remote load locations, a sterilization failure could occur; therefore, the chamber should not be overloaded.

Sterilizer Performance Monitors

Physical, chemical and biological indicators are needed to assess the effectiveness of the O_3 sterilization process:

- Physical monitors. All critical process parameters are monitored during the cycle. At the end of each cycle step, the process parameters are printed. At the end of the cycle, the screen will indicate "cycle completed," and a printout will be produced. During the sterilization cycle, if one of the critical process parameters is not reached, the cycle will abort and the reason of the interruption will be displayed on the screen and printout.
- Chemical indicators. CIs should be placed outside and inside every pack to identify packages that have gone through the process from those that have not, and to demonstrate that the sterilant has penetrated the packaging.
- Biological indicators. A process challenge device has been developed for routine process monitoring of O_3 sterilization. The BI for O_3 sterilization contains *Geobacillus stearothermophilus* spores. Biological monitoring is required each day the sterilizer is used, but recommended every cycle. Follow the sterilizer manufacturer's IFU for proper BI placement.

REVIEW OF LOW-TEMPERATURE STERILIZATION PROCESSES

Figure 15.21 compares the four low-temperature processes discussed in this chapter.

Advantages and Disadvantages of Low-Temperature Sterilization Technologies

Sterilization Method	Advantages	Limitations
100% Ethylene Oxide (EtO)	• Penetrates medical packaging, many plastics and device lumens • Compatible with most medical materials • Simple to operate and monitor • Single-dose cartridge and negative-pressure chamber minimizes the potential for gas leak and EtO exposure	• EtO is toxic, flammable, a carcinogen and mutagen • Requires lengthy aeration time to remove EtO residue (eight to 12 hours) • Requires personal and area monitoring • EtO emission regulated by states • EtO cartridges should be stored in flammable liquid storage cabinet
Hydrogen Peroxide (H_2O_2) Gas Plasma	• Safe for the environment • Leaves negligible toxic residuals—no aeration required • Compatible with most medical devices • Fast cycle time of 24 to 75 minutes (varies with model type) • Used for heat- and moisture-sensitive items • Sterilant contained in a multi-use cassette to prevent user contact with hydrogen peroxide • Simple to operate and monitor • Easy installation (requires only an electrical outlet)	• Hydrogen peroxide may be toxic at levels greater than 1 ppm TWA • Avoid prolonged inhalation and contact with skin and eyes • Gloves should be worn when removing items from a canceled load • Cellulose (paper), linens, liquids and powders cannot be processed

Figure 15.21

Sterilization Method	Advantages	Limitations
Vaporized Hydrogen Peroxide	• Safe for the environment • Leaves negligible toxic residuals—no aeration required • Compatible with most medical devices • Used for heat- and moisture-sensitive items • Fast cycle time of 28 to 55 minutes (varies with model type) • Sterilant contained in a multi-use cartridge to prevent user contact with hydrogen peroxide • Simple to operate and monitor • Easy installation (requires only an electrical outlet)	• Hydrogen peroxide may be harmful at levels greater than 1 ppm TWA • Avoid prolonged inhalation and contact with skin and eyes • Gloves should be worn when removing items from a canceled load • Cellulose (paper), linens, liquids and powders cannot be processed
Ozone (O_3)	• Safe for the environment • Compatible with most medical devices • Used for heat- and moisture-sensitive items • Leaves negligible toxic residuals • No sterilants to handle	• Respiratory irritant at low levels • Require a well-ventilated room with 10 air exchanges per hour • Long cycle time (4 hours, 30 minutes) • Natural rubber, latex, textile fabrics, copper, brass, bronze, zinc and nickel cannot be processed

Figure 15.21

CONCLUSION

Today's instrumentation is far more sophisticated and complex than devices of the past, and many of their materials cannot withstand the high-temperatures or moisture required for steam sterilization.

When procedures are carefully followed, these methods are safe for patients, medical devices and Central Service technicians.

RESOURCES

Center for Devices and Radiological Health, U.S. Food and Drug Administration. *Updated 510(k) Sterility Review Guidance K90-1; Guidance for Industry and FDA.* 2011.

Rutala W, Weber D. *Guideline for Disinfection and Steril-ization in Healthcare Facilities.* 2008.

OSHA Fact Sheet: Ethylene Oxide. 2002.

Occupational Safety and Health Administration. *Chemical Sampling Information: Ozone.* 2007.

Centers for Disease Control and Prevention. *Documentation for Immediately Dangerous to Life or Health Concentrations (IDLH): NIOSH Chemical Listing and Documentation of Revised IDLH Values.* 1994.

Occupational Safety and Health Administration. *Understanding OSHA's Exposure Monitoring Requirements.* 2007.

Occupational Safety and Health Administration. *Guideline for Hydrogen Peroxide.*

Chaunet M, Dufresne S, Robitaille S. The Sterilization Technology for the 21st Century. TSO3. 2007.

Carter P, Wright M. *The lowdown on low-temperature steril-ization for packaged devices.* Healthcare Purchasing News. July 2008.

Reichert M, Schultz J. *Is new ozone sterilizer right for your OR?* OR Manager. 2003.

Centers for Disease Control and Prevention. *Guideline for Disinfection and Sterilization in Healthcare Facilities.* 2008.

Scheider MS. *New Technologies for Disinfection and Sterilization. Principles, Practices, Challenges, and New Research.* Association for Professionals in Infection Control and Epidemiology. 2003.

Conway RA, et al. *Environmental Fate and Effects of Ethylene Oxide.* Environmental Science & Technology. 1983.

Kobayashi H, Yoshida R. *Hydrogen Peroxide Varour in the Proximity of Hydrogen Peroxide Sterilisers.* Japanese Journal of Environmental Infection, Vol. 26, No. 4. 2011.

Kobayashi H, Yoshida R. *Hydrogen Peroxide Vapourised from Surface of Fiberscope after Low-Temperature Hydrogen Peroxide Sterilisation.* The Japanese Journal of Medical Instrumentation, Vol. 83, No. 3. 2012.

Robinson NA, Eveland RW. *Using HPG sterilization for heat-sensitive devices.* Healthcare Purchasing News. STERIS Self-Study Series. January 2015.

Association of periOperative Registered Nurses. *AORN Guidelines, Sterilization Monitoring.* 2015.

CENTRAL SERVICE TERMS

Sterility assurance level (SAL)

Permissible exposure level (PEL)

Time weighted average (TWA)

Oxidation

Aeration

Residual EtO

Safety data sheet (SDS)

Chapter 16

Sterile Storage and Transport

Learning Objectives

As a result of successfully completing this chapter, readers will be able to:

1. Review basic sterile storage considerations
2. Describe basic types of sterile storage shelving
3. Identify procedures for moving sterile items into storage
4. Explain the concept of event-related sterility
5. Discuss basic storage guidelines
6. Discuss other sterile storage and transport concerns:
   - Basic procedures for cleaning sterile storage areas
   - Sterile storage personnel
   - Transporting sterile items
   - Transportation guidelines

INTRODUCTION

A great deal of work goes into ensuring items are sterile and ready for patient use. Once items are sterile, they can easily become contaminated. Extreme caution must be exercised to keep each sterile item safe until it is used. While **barrier packaging** protects sterile items from contamination, it is not an impenetrable barrier. Sterile packages must be protected from events that can cause them to become unsterile. This is accomplished by keeping the items in a safe environment and consistently practicing good handling protocols whenever handling a sterile package. This chapter will examine strategies to help keep items sterile until use.

Barrier packaging Packaging that prevents ingress of microorganisms and allows aseptic presentation of the product at the point of use.

STERILE STORAGE CONSIDERATIONS

After sterilization, or after purchased sterile items are received from an outside vendor, the items are stored until needed. The activities of personnel in the storage area and the environment itself impact the maintenance of item sterility.

Just like at home, if items are not properly protected, or something unexpected happens, stored items may become unusable. If there is a flood in the kitchen, for example food items like flour or sugar in their original packaging could be ruined by the water. If there is a flood in sterile storage, some or all of the packaged items may be ruined. Healthcare sterile storage areas need to be well-planned and constantly maintained to keep items sterile until use.

The sterile storage process actually starts as soon as the sterilizer door is opened at the end of a cycle, or when purchased sterile supplies are received into the facility. (See **Figure 16.1**)

Protecting sterile items from contamination begins with considering the environment where the items will be stored. Providing the proper environment is critical to maintaining sterility. The following are all considerations that must be addressed when determining an appropriate sterile storage area.

Location

The sterile storage area should be located next to or near the sterilization cooling area. This area should ideally be an enclosed room easily accessible from the sterilization, **break out** and case cart staging areas, while being out of the facility's main traffic areas. The storage location should be removed from general traffic flow patterns to minimize airborne contaminants and keep items away from untrained personnel. (See **Figure 16.2**)

Break out The process of removing commercially-sterilized items from their outer shipper containers in an area adjacent to the storage area to prevent contamination that is present on the containers from being introduced into the storage area.

Figure 16.1

Figure 16.2

This area should be designed and designated for storage of sterile items only. Non-sterile items should not be stored in this area as they could contaminate sterile packaging. While it may be impossible to create a separate sterile storage area, every effort should be made to place items in an area that meets criteria for sterility maintenance. It must be noted that sterile items may be stored in other areas of the healthcare facility, such as nursing units, etc.

Space

When designing or selecting an area for sterile storage, it is important to be sure there is adequate space for storage and cart movement.

Sterile Storage and Transport

When considering floor space needed for proper storage the following must be considered:

- Type and number of instrument trays to be stored. A rigid container usually requires more space than a wrapped tray; however, containers may be stacked on top of each other, while wrapped trays cannot be stacked.
- Adequate space for smaller items and peel packages to allow for appropriate storage techniques.
- Adequate space to store purchased presterilized items, such as surgery procedure packs, gowns and sterile supplies for distribution.
- Adequate room between aisles to allow for cart movement up and down the aisles and to allow for enough space for easy access to all shelves.
- The room set up should allow for thorough cleaning.
- Room for future growth.

Figure 16.3

Storage Conditions

Sterile storage areas should have no exposed water, sewer or air conditioning lines that could leak and contaminate the items. Work surfaces should be made of easy-to-clean smooth and durable material. There should be no exposed light fixtures, pipes or ducts that can collect and shed dust. The area should be physically separated from other areas of the department. If this is not possible, extra care is required, so air and traffic always flows from sterile to clean to dirty. No pass-through traffic should be permitted.

Air supply to the storage areas should be as clean and dust free as possible, and this usually requires filtration. Because this area will store sterile items, air pressure should be positive in relation to surrounding areas so air flows out of the area when a door is opened, reducing the chance of airborne contamination. The room should also have at least four complete air exchanges per hour.

Temperature in the sterile storage area may be as high as 75°F (24°C), with less than 70% relative humidity. Very dry air can affect seals and cause plastic materials to become brittle. Excessive humidity can cause tapes and labels to lose their adhesion, loosen seals or affect package content identification. Moisture can also condense on the packaging material and seep or "wick" through it while carrying microorganisms to compromise pack sterility leading to wet packs. Moisture also provides an excellent opportunity for fungal growth through the packages. It is important to keep packs at least two inches away from exterior walls, windows and window seals where condensation can form on interior surfaces of exterior walls. Temperature and humidity levels should be checked and recorded at least daily. (See **Figure 16.4**)

This area should have proper lighting so package labels can be easily read. The recommended lighting for this area is 200 to 500 **lux**. There should be no dark corners or blind spots, which could lead to improper product identification and misplaced or forgotten inventory. Adequate lighting is also critical for personnel safety.

Temperature, Humidity and Air Pressure should be monitored in the sterile storage area.

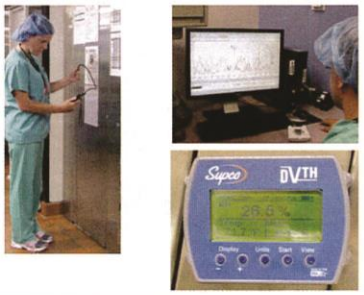

Figure 16.4

Lux A unit of illumination equal to one lumen per square meter.

A hand wash sink or hand sanitizer dispensers should be located in this area. If installing a sink, do not place the sink too close to the shelving units, as water splash could contaminate the sterile packaging.

Storage Shelving

Many companies manufacture shelving that is appropriate for storing sterile supplies. Some facilities have custom-made shelving units to properly fit their allotted space. Regardless of the shelving type, there are several things to consider when choosing or replacing shelving. (See **Figure 16.5**)

- Storage shelving should be designed to protect the sterile product.
- Shelving should be sized to properly fit the stored items without product overhang. Trays that do not properly fit on the shelf pose a safety hazard to all who work in the area. Trays that overhang shelving may also become contaminated by people walking by and brushing against them.
- Shelving must be designed to easily hold the total weight of the trays to be stored.

Figure 16.5

- Shelving should also be ergonomically friendly for the Central Service (CS) technician.
- Shelving should allow for easy access to the stored product.
- Shelving must be easily cleaned. Metal or plastic shelving is recommended for this reason. Porous materials, such as wood, should not be used as it cannot be properly cleaned and can harbor microorganisms.

Closed Shelving

Closed shelving is the most preferred type of shelving because it protects the sterile packaging from dust, traffic air flow, as well as other environmental and physical challenges within the storage area. (See **Figure 16.6)** Shelves are usually constructed as solid units, allowing for secure storage and easy cleaning. Closed shelving is expensive, so many facilities do not use this system (or it is used only for the most delicate and expensive items.)

Doors should be kept closed at all times, unless items are being accessed. When opening the doors, they should be opened slowly to avoid causing swift air currents that could potentially contaminate the sterile product.

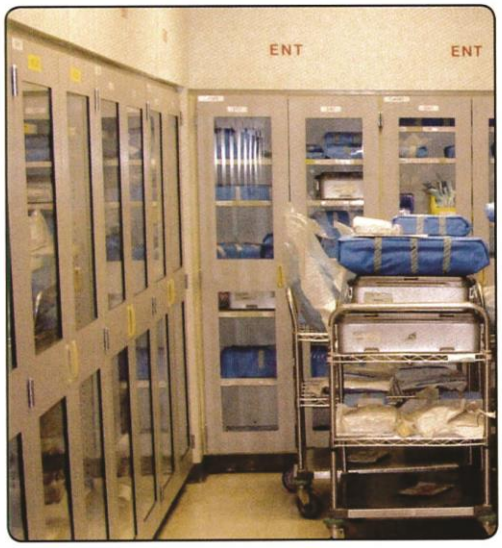

Figure 16.6

Semi-Closed Shelving

Semi-closed shelving is shelving that has at least three solid sides (top and two sides) and forms a closed unit when the shelves are moved together; these units are usually on tracks or have independent wheels. (See **Figure 16.7**) This type of shelving is also expensive; however it is very versatile, user friendly and offers good protection for shelved items. Shelves may be solid or open

wire. The bottom shelf must be solid to protect the stored item from contamination. The units should be pushed to the closed position when not accessing sterile product.

Figure 16.7

Open Shelving

In open shelf storage systems, items are placed on shelves that are not enclosed. Shelves usually have open racks to prevent dust accumulation; however, the bottom shelf must be solid to protect the stored items from contamination. Open shelving is convenient and less expensive than closed shelving; however, packages are more vulnerable to physical hazards (usually accidental) and environmental challenges from cleaning solutions and microorganisms.

Figure 16.8

Regardless of the system in use, there are a few standards that must be followed.

- The bottom shelf of each unit must be between eight and 10 inches from the floor. This protects stored items from contamination due to floor cleaning agents and dust.
- The bottom shelf must be solid to protect items from environmental cleaning. If the shelf itself is not solid, commercially-purchased shelf liners may be purchased to line the bottom shelf. (See **Figure 16.8**)
- Although not required, having solid top shelves will help protect sterile items from dust.
- All shelves must be cleaned regularly. Cleaning is discussed later in this chapter.

RECEIPT OF STERILE ITEMS INTO STORAGE

As previously stated, the sterile storage process starts when the sterilizer door is opened after a cycle or upon receipt of purchased presterilized items.

In-House Sterilized Items

Once items are removed from the sterilizer they should be moved to a designated cooling area. (See **Figure 16.9**) This area should be close to the sterilizers because moving the warm cart causes air currents to flow over the warm items. Since the room air is cooler than the sterilized items, this movement can cause condensation making the items unsterile. Air currents can also help microbes penetrate the warm packaging material, again contaminating the sterilized packages.

Figure 16.9

Packages should not be touched until they reach ambient (room) temperature. Touching warm packages can cause the packages to become contaminated from microbes on the skin transferring through the warm packaging material.

A temperature meter, such as an infrared meter, is designed to determine the temperature of a package without touching the package. (See **Figure 16.10**)

Once items are properly cooled they may be placed on the storage shelf. Carefully check each item prior to placing it on the shelf. Ensure the indicator tape, peel package seal or container locks are intact. Visible chemical indicators (CIs) should show appropriate color change. There should be no holes or tearing of the package material.

Lift (do not drag) wrapped trays; dragging will cause holes or tears in the packaging material. Wrapped trays should not be stacked on top of each other as stacking causes the lower trays to compress. (See **Figures 16.11** and **16.12**) When the upper trays are removed, air will be pulled into the lower packages, causing contamination. Stacking wrapped trays may also cause holes in the wrapper of the lower trays.

Rigid container systems may be stacked; however, do not stack them too high, as the weight may damage the gaskets of the lower trays. Trays may also be damaged from the weight. Stacking trays too high can also be a safety hazard. Consult the container manufacturer for specific instructions.

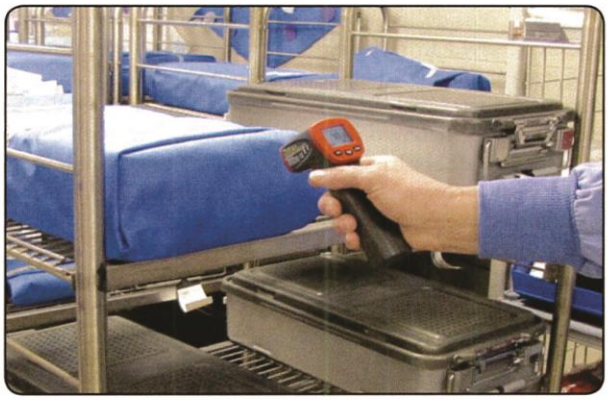

Figure 16.10

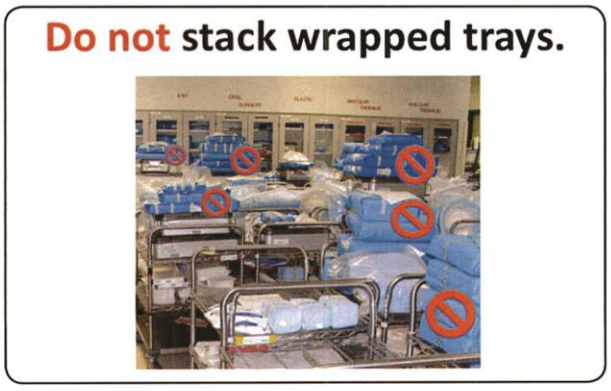

Figure 16.11

Figure 16.12

Purchased Presterilized Items

Sterile storage areas are also used to store presterilized products from outside vendors. These products are typically received in shipping containers made of corrugated cardboard, although other forms of shipping containers exist. These outer shipping containers should be removed in a controlled break out area as the outside box has been exposed to environmental challenges, including weather, insects, fungus and other microorganisms. (See **Figure 16.13**) Sterile items should not be removed from their outside box on the receiving dock, unless there is an area protected from the outside environment that has been designed for this purpose.

Received items should be delivered to an area close to the sterile storage area where the items can be removed from the outside box. Sterile items should be placed inside a clean enclosed transport cart, tote bin, or container so the items can be delivered to the sterile storage area. Outside shipping cartons should never be allowed in the sterile storage area as they are a major source of contamination. Transfer bins and carts must be cleaned on a regular basis to help keep the sterility of the items intact. Cardboard boxes should be removed from this area as quickly as possible to decrease the chance for cross contamination from the cardboard to the sterile items.

Figure 16.13

Items should be handled gently during transfer from the box to the transport cart/container. Place items loosely, do not pack items tightly, as it may compromise the items sterility.

Transport items directly to the sterile storage area. Never leave sterile items unattended where others may have access to the items. Curious staff or visitors may handle items and unintentionally damage the packaging causing the items to become unsterile.

Carefully place items on the shelves. (See **Figure 16.14**) Do not pack items tightly, as it will compromise the package sterility and may damage items inside the package. Always follow proper stock rotation procedures.

Figure 16.14

EVENT-RELATED STERILITY

Shelf life is related to events that may compromise the pack sterility. Event-related sterility is the concept that sterile products remain sterile until an event occurs to make them unsterile. The following list describes events that may render a package unsterile. This list is not inclusive, as there are many events that can compromise sterility.

Product Life

Some products and packaging material will degrade over time. Using these items once they have expired is unsafe. As items begin to degrade an event has occurred that can affect the items sterility.

Type of Packaging Material Utilized

Many packaging materials have a defined useful life. CS technicians must be sure to follow the manufacturer's recommendations for shelf life before and after sterilization as the products ability to perform appropriately is diminished after the stated expiration date. One of the events that could occur after the expiration date is loss of microbial barrier protection of the packaging. When this happens, items will not remain sterile.

Condition of Package

Package integrity is very important. Rough handling, poor storage practices, moisture, dust and poor transportation procedures are some of the events that can occur to damage a package. Once a package is damaged, the items inside must be considered unsterile. (See **Figure 16.15**)

Package Condition Can Compromise Sterility

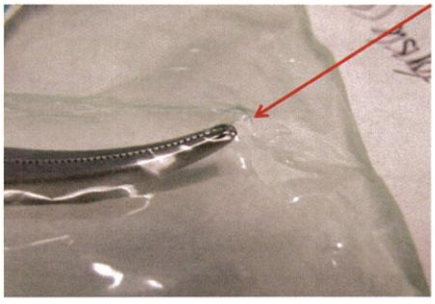

Figure 16.15

Storage/Transportation Conditions

Clean, dry shelving in the storage area or in the transportation carts is required to keep items sterile. Whether the shelving or carts are opened or closed can affect item sterility. Open shelving allows for greater chance of contamination from the environment or personnel working in the area. Temperature and humidity must be monitored, and ensuring the absence of dust and insects helps maintain package integrity.

Handling

Lack of proper handling can cause items to become unsterile. Handling items while they are still warm, over handling items and the hygiene of the personnel handling the items are all considered events.

All sterile items should be monitored for events that may render them unsterile. If any event occurs to jeopardize an item, the item in question must be removed and processed or disposed of according to the facility's policy. Whenever there is doubt regarding the sterility of a package, the item should be considered unsterile.

BASIC STORAGE GUIDELINES

Once items are delivered to the sterile storage area they need to be carefully placed in their designated storage space. It doesn't matter if the items are processed in house or purchased outside the facility the guidelines for storage of sterile items are the same.

The primary conditions that can adversely affect the ability of a sterile package to maintain its sterility until it is opened by the user at the point of use include:

- Moisture and liquid/fluid contamination.
- Dirt and dust.
- Physical damage to the package, including abrasions, cuts, tears, punctures, broken seals and the breakdown of packaging material (e.g., some plastics become brittle).

Storage environments should be clean, dry and easily accessible by authorized personnel.

Stored items should be arranged so that packages are not crushed, bent or compressed. If the air inside a package is forced out, it can potentially rupture closures and seams. Additionally, by forcing the air out of the pack, a void is created. When the source of compression is released, (i.e., the weight on its top is removed) a slight suction can be created by the void. This can potentially establish conditions for the packs to "suck in" contaminated air.

Per fire codes, stored items should be placed at least 18 inches below sprinkler heads to allow for proper air circulation and allow for water to flow unimpeded during a smoke or fire situation. Spacing must also be planned and maintained to prevent packages from being touched, bumped or leaned upon when the room is cleaned or when personnel are storing or retrieving packs.

Sterile packages should not be stored near or under sinks, exposed water pipes, sewage lines or air conditioning drains.

Always place sterile items on clean surfaces. Do not trust the package barrier to protect contents from soil.

When placing items on shelves or when removing them from the shelf, always check package integrity, including the filter area of rigid containers and ensure all external CIs have turned to the proper color. If sterilized in-house be sure the load (lot) control label is still intact and all seals are securely in place. (See **Figure 16.16**) If the item has an expiration date, ensure the item has not expired. Do not place anything on the shelf until the items have been checked and verified to be intact.

Figure 16.16

Sterile items should fit on the shelf; they should never overhang the edge of the shelf. The shelf edge may cause damage to the item and the overhang can create a safety hazard.

Place heavy items on middle shelves to allow for safe lifting. Light packages should be placed on the higher shelves.

Always lift items, do not drag them across the shelf, as that will damage the packaging and may damage the shelf.

Handle all items gently. Rough handling of sterile packages can cause damage to the packaging, causing the items to become unsterile.

Never place unsterile items on the shelves with sterile items. Unsterile items may contaminate the sterile product. (See **Figure 16.17**)

Figure 16.17

Arrangement of Instruments and Supplies

Storage areas for instruments and supplies must be carefully planned. The goal is to help ensure that items are easy to locate and are protected from events that may cause them to become unsterile. Proper use of stock rotation principles is also important to ensure that older items are used first and that supplies with time-sensitive expiration dates are used before they must be discarded.

The logical arrangement of stock improves efficiency, decreases staff injuries and facilitates appropriate stock rotation.

CS professionals should review the manufacturer's IFU to determine if there are any special storage requirements.

Sterile items should be arranged so they are easy to locate. This may best be accomplished by organizing them alphabetically by name, functionality or specialty (related items shelved together) or numerically, based on stock codes. Shelves should be clearly labeled, designating where items should be stored including pertinent ordering information. (See **Figure 16.18**)

Figure 16.18

Stock Rotation

Sterile packages should be arranged and maintained to allow stock rotation on a **first in, first out (FIFO)** system. This ensures that the oldest items are used first. The longer a sterilized item remains in storage, the greater chance the item can become contaminated, due to handling and environmental issues, such as dust. Even if the item does not become contaminated it may not be able to be opened aseptically. Practicing a FIFO inventory control system prevents a "neglected packs syndrome" where hard-to-reach packs remain in storage much longer than others, and are more likely to be damaged or contaminated. *Note: Items with expiration dates should be used in the order of their expiration dates, with the items that will expire first being used first.*

First in, first out (FIFO) A stock rotation system in which the oldest product (that which has been in storage the longest) is used first.

The goal of a stock arrangement system is to provide minimal pack handling, while allowing FIFO rotation. Many facilities use a left-to-right system: the newest item is placed on the left and the older items move to the right. The pack on the far right is the first to be picked up for use. Other facilities place the new packs in from the back of the shelf, and pick up the oldest from the front of the shelf.

Satellite Sterile Storage

Many facilities store sterile items in user departments. Storage areas for sterile supplies located outside of the CS department, such as in the Operating Room (OR), must follow the same guidelines as stated above and be included in quality assurance and infection prevention audits conducted for the sterile storage area in the department. Regardless of where a sterile item is stored, it must be protected from events that can render it unsterile. If satellite storage sites are used, personnel responsible for the areas should be trained about requirements for sterility maintenance.

CLEANING

To maintain product sterility, it is important to keep the sterile storage area clean and dust and debris free. Standards for environmental cleaning should be the same as those for an OR or Labor & Delivery suite.

The floors should be damp mopped and trash should be emptied at least daily. Walls and vents should also be on a routine schedule for cleaning.

Shelving, racks and other storage devices should also be routinely cleaned. The actual frequency depends on several factors. Closed shelving usually does not need to be cleaned as frequently as opened shelving. The air filtration system in the storage area is also a factor in determining cleaning schedules. The better the filtration system functions, the less frequently the area must be cleaned.

When cleaning the shelves all items should be carefully removed from the shelf. Using a facility-approved solution, wipe the entire shelf, including the sides and top. Alcohol may be used as a drying agent, if approved by the facility's protocols. After the shelves, base and shelf bottom have been cleaned, the wheels should also be cleaned. Be sure the shelves are completely dry before placing items back on the shelf. Also, clean and completely dry all storage bins before placing them back on the clean shelf. Carefully check each item for package integrity and ensure seals are intact. Look for proper external indicator color change and check expiration dates. Ensure the load control number is still on the in-house processed items. As with most processes, sterile storage cleaning should be documented and the documentation maintained for use in the department's quality assurance program. The process for sterile storage shelf cleaning is outlined in **Figure 16.19**.

Shelf Cleaning

1. Remove all items from the shelves and storage bins.
2. Wipe entire shelf, including sides and top, using a facility-approved solution.
3. Clean all bins and shelf organizers using a facility-approved solution.
4. After cleaning surfaces touched by sterile packages, clean the shelf base, under the bottom shelf, and wheels.
5. Allow to dry thoroughly. *Note: Alcohol may be used as a drying agent, if approved by facility protocols.*
6. Wait until shelves, bins and organizers are completely dry.
7. Place items back in their assigned location. Check items for package integrity, external indicator change, expiration dates and lot control numbers for in-house sterilized items.
8. Document cleaning per the facility's quality assurance requirements.

Figure 16.19

STERILE STORAGE PROFESSIONALS

All CS professionals should maintain a high level of personal hygiene, including clean hair, body, nails (no artificial nails) and clothing at all times. CS technicians should frequently wash their hands or use waterless hand sanitizers according to departmental policy.

Fingernails should be short to reduce the microbial load under the nails, and to minimize the potential for rupturing packages and pouches.

Jewelry is discouraged because it can tear holes in packaging and may harbor microorganisms. Rings, neck and wrist jewelry may become caught in the package, causing damage to the sterilized item and the wearer. If badge lanyards are worn, they should be placed in a pocket or contained in some manner to avoid catching them in the shelving or a package. Lanyards should also be cleaned on a routine basis, so they do not contaminate the sterile items.

Personnel working in the sterile storage area must be properly trained in all aspects of the storage process.

Authorized individuals entering a storage area must follow hand hygiene policies, wear proper attire, be in good health and maintain good personal hygiene.

TRANSPORTING STERILE ITEMS

Transportation of sterile packages should be done in a manner that protects the sterility of the items. It is important to follow the department's established procedures to ensure the items are delivered intact and ready to use. There are several ways to transport sterile items. Regardless of the method used, it is important to protect the items from crushing, bending, falling or other damage. (See **Figure 16.20**)

Hand Carry

It is often faster and easier to hand carry small, lightweight items to the point of use area. Items being delivered should be protected from the environment and air currents from hallway traffic. Carefully place the items to be delivered in a protective cover, such as a dust cover or a clean closed bin. Keep items away from the body to avoid contaminating them. The sterile items should be held with both hands, keeping the items flat so instruments and products do not shift and become damaged.

Cart Transport

Transporting items by cart is easier and safer than hand carrying items. As with shelving, transport carts can be opened or closed. The bottom shelf should be solid to protect the items from dirt and dust contamination. When transporting with open carts, including wheeled tables, items should be covered and protected against the hallway traffic. Items should be placed on the cart flat to protect contents. Trays and packs should not overhang the edges of the cart.

Closed carts are the transportation method of choice, as they provide the best protection for sterile items. (See **Figure 16.21**) Carefully place items inside the cart. Do not overcrowd the cart. The cart doors should close and latch without touching the sterile item.

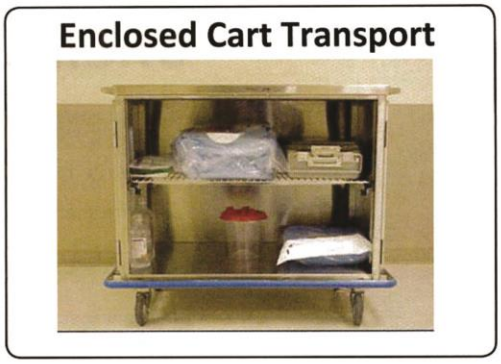

Figure 16.21

All carts should be kept in good repair, and cart doors should be properly attached and dent free. Wheels should be properly maintained so the cart will move easily and quietly.

Elevator/Lifts

Many facilities have dedicated clean elevators for sterile product transportation. These elevators should be used for clean and sterile transportation only. Soiled items should be returned using an elevator designated for soiled items. When using a dedicated lift, items must still be contained because air currents from outside the lift can contaminate the sterile items.

Figure 16.20

Vehicle

Healthcare facilities today may transport sterile items between sister facilities and to offsite clinics and physician offices. Items should not be transported in the trunk of a car because temperature and humidity levels cannot be properly controlled. There must be clear separation of clean and soiled items within the transport vehicle. The vehicle must be completely enclosed and in good repair, with no holes in the walls that will allow outside contaminates to enter. Sterile items should be placed inside clean, protective bins or carts. Protect the items from movement within the

enclosed device, as packaging and instruments can be damaged from movement during transport. The cart or bin must be properly secured inside the vehicle to keep it from moving. Temperature and humidity levels should be monitored. When the vehicle is not running, items should not be left inside the vehicle for extended periods of time, as condensation may form inside the sterile packages, making them unsterile. The transport vehicle should be cleaned on a regular basis.

TRANSPORTATION GUIDELINES

Keeping items sterile during transportation is the number one priority. Below are a few basic guidelines to follow when transporting sterile items.

The importance of avoiding contact with sterile packages cannot be overemphasized. This includes bumping into, leaning on, backing into, touching when counting and excessively handling the the packages. When a package is moved or handled, it should not be "cradled." Any sterile items that are dropped to the floor should be considered contaminated and removed, even if no damage is apparent. Jarring and compression upon landing can force dust and airborne microorganisms into the package. The floor could be wet, sharp edges of trays could puncture through the wrap, and dirt could be carried onto the storage shelf to contaminate the next pack placed in that location.

CS technicians and end users must be trained to recognize any signs of sterility compromise. A log of sterile pack contamination events should be maintained and analyzed to implement preventive actions.

When removing the package from the shelf, its front should be lifted from underneath with one hand. The other hand should be placed midway under the package, and the unit should then be lifted off the shelf. Packages should not be dragged or pushed against any surface because this causes friction or abrasion, which can potentially cause a pressure cut or snag and compromise sterility. Shelf liners help create a cushion between the hard surface of the shelf and bottom of the packages. These are recommended if the facility is experiencing tearing on pack bottoms. This is usually a greater concern with heavy packs, procedure sets and, especially, instrument trays. The edges of the metal trays and weight of the instruments increase the adverse impact of the friction. Burrs or sharp edges on the shelves themselves may also contribute to sterile pack damage.

When packs are removed from storage, they must be carefully inspected for expiration date, tears, abrasion, tracks, worn areas, punctures, compromised seals, dirt and evidence of moisture. The external CI must be checked to ensure that the package was subjected to the sterilization process. If any adverse conditions are noted, the pack should be considered contaminated. The majority of holes in wrap come from mishandling. If the pack contents are reusable, they should be removed from the package for processing. If the contents are disposable, they should be discarded. Single-use wrap should not be reused after it has been sterilized.

All items should be protected from damage, moisture, humidity and dust during transport.

Transport carts and bins should be cleaned before use. Carts and bins should be completely dried before items are placed on or in them.

Carts should be kept in good repair; both for package integrity and staff safety. Doors should be dent free and able to close securely. Wheels must move smoothly and quietly.

Sterile items transported offsite to another facility must be transported in a vehicle specifically designed for sterile transport. The vehicle should have temperature and humidity control, and enough space to completely separate clean from dirty items.

Sterile items should never be left unattended in an unsecured area. Individuals unfamiliar with sterile product handling may inadvertently contaminate them.

Policies and procedures for sterile item transport should always be followed.

CONCLUSION

Maintaining product sterility during storage and transport is one of the most important Central Service job tasks. If unsterile instruments or supplies are used, patients could acquire an infection. Carefully following written storage and transport procedures, and keeping the area clean and maintained will help keep patients safe.

RESOURCES

Association for the Advancement of Medical Instrumentation. *ANSI/AAMI ST79, Comprehensive guide to steam sterilization and sterility assurance in healthcare facilities.* Sections 3.3, 8.9.2-8.11.5. 2013.

Guidelines for PeriOperative Practice: Packaging Systems. Guidelines for PeriOperative Practice. 2015

International Association of Central Service Material Management. *Central Service Leadership Manual*, Chapter 23. 2011.

CENTRAL SERVICE TERMS

Barrier packaging

Break out

Lux

First in, first out (FIFO)

Chapter 17

Monitoring and Recordkeeping for Central Service

Learning Objectives

As a result of successfully completing this chapter, readers will be able to:

1. Discuss the importance of monitoring work areas and processes within the Central Service department
2. Discuss the importance of recordkeeping
3. Explain the types of monitoring needed in each area of the Central Service department
4. Explain the need for monitoring and review of the sterilization process indicators that help assure quality control:
   - Need for monitoring
   - Chemical indicators
   - Sterilization load control information
   - Physical and mechanical monitors
   - Biological indicators
   - Bowie-Dick tests
5. Discuss the importance of employee training and continuing education records

INTRODUCTION

A great deal of planning and effort goes into every aspect of the Central Service (CS) department. From the decontamination area to the storage area, rigid requirements must be met to help ensure the safety of patients and healthcare workers.

Documentation is required to provide a record that those requirements were met; and if requirements were not adequately met, documentation provides a record to assist with performance improvement.

CS technicians are involved in the recordkeeping process across many different functions of their jobs. Records provide evidence that processes were routinely checked, and the information collected provides a quality framework that will be examined by surveying agencies, such as The Joint Commission (TJC), the Centers for Medicare and Medicaid Services (CMS) and state agencies. If the healthcare facility is involved in a legal claim regarding any products that were dispensed from (or processed through) CS, records can help demonstrate that a specific standard of practice was followed.

This chapter provides information about recordkeeping requirements for CS and addresses methods used to **monitor** and document conditions and processes to meet established requirements. Special emphasis will be placed on the methods used to monitor sterilization processes and the recordkeeping required for those processes.

THE IMPORTANCE OF ACCURATE RECORDS

Records are kept to document many processes and conditions in the CS department, including sterilization cycles, preventative maintenance and routine equipment testing and cleaning. It is important to note, however, that records are only as good as the information they contain. Having incomplete records is essentially the same as having no records at all. The following are some facts about CS department records:

- Recordkeeping is mandatory. CS department recordkeeping is not optional. It is as much a part of the job as assembling instruments or operating sterilizers.

- Records must be accurate. Information must be documented as it is, even if the information indicates a process has failed to meet the expected standard.

- Records must be legible and understandable. Handwritten records should be legible to anyone who needs to review them. Slang, unapproved abbreviations and nicknames should not be used, as that terminology may confuse the reader.

- Records must be complete. All information should be documented according to the department's specific requirements.

- Records should be audited routinely. Routine audits ensure that documents contain all necessary information.

Accurate and complete records provide documentation that the CS department is following standards, regulations and its own procedures to help ensure continual adherence to best practices.

Monitor To watch, observe, listen to or check (something) for a special purpose over a period of time.

GENERAL MONITORING

CS technicians should continually monitor their environment to help ensure that the integrity of each work area and the processes performed in those areas are maintained. Some monitoring is informal, such as watching to ensure that everyone who enters the area is dressed appropriately, practices good hand hygiene and follows established traffic control guidelines. This type of informal monitoring is not recorded, but each employee is expected to identify and correct breaches in established protocols. Visual monitoring is especially important when monitoring dress codes in the decontamination area. Visitors, such as loaner instrument vendor personnel or facility employees from other

departments (e.g., Maintenance, Biomedical Engineering, Environmental Services, etc.), may not be familiar with or understand the importance of personal protective equipment (PPE) and may endanger themselves if they enter the area without proper attire.

Formal monitoring of the physical environment is also required. For example, room temperature and humidity must be monitored at least daily to ensure they meet the established standard. That data must be recorded. Some departments use electronic devices to collect the data and transfer it to an electronic record, while others collect the data manually. In either case, CS technicians must have that data recorded and accessible. **Figures 17.1** and **17.2** illustrate examples of manual and computerized data collection methods used to monitor temperature and humidity.

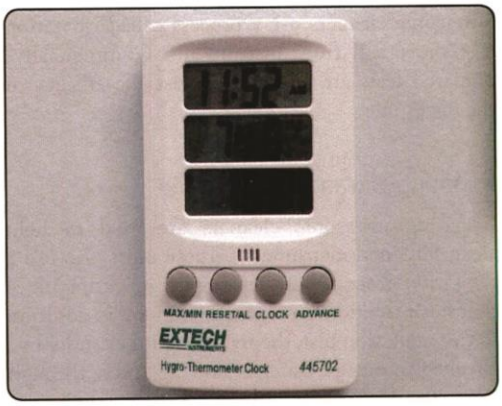

Figure 17.1

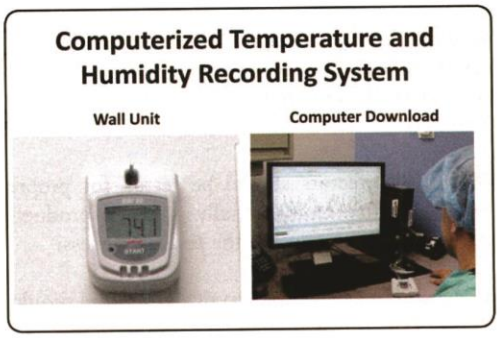

Figure 17.2

CS technicians also monitor their work areas for safety hazards. They learn to keep a watchful eye for unsafe conditions, broken or unsafe equipment, and other issues that may put themselves and others at risk. Once identified, they remedy the situation, if possible (e.g., wiping up a spill) or report it to the appropriate person to initiate a repair or replacement process.

Departmental cleanliness is also monitored by CS technicians. While routine cleaning is performed by the Environmental Services department, there are areas in the CS department that staff are required to maintain (i.e., CS technicians are responsible for keeping their work area clean). This not only means cleaning their work areas at designated times (i.e., at the end of their shift), but also means cleaning the area whenever it becomes contaminated or soiled.

CS technicians are often assigned specific cleaning duties within the CS department. For example, they often are responsible for cleaning cabinets, racks and carts in the sterile storage area. CS staff are assigned to clean those areas because of their understanding of sterile package handling and their ability to handle sterile items, clean storage shelves and return those items to their proper location without compromising the integrity of the sterile packs. The cleaning process in this very important area must be documented to provide a record of routine cleaning.

CS technicians are also responsible for cleaning the transport equipment in their area. Every effort must be made to limit the presence of dust, lint and microbial contamination in the work area. Microbial contamination must be kept to a minimum in all work areas. Excess dust in the work area can easily be transported to items being prepared for sterilization, or onto sterile packages. In either case, that dust may then become airborne and be introduced into an open wound during a procedure.

Figure 17.3 provides an example of a sterilizer loading cart that has not been recently cleaned. The dust and lint pose a significant threat to patient safety.

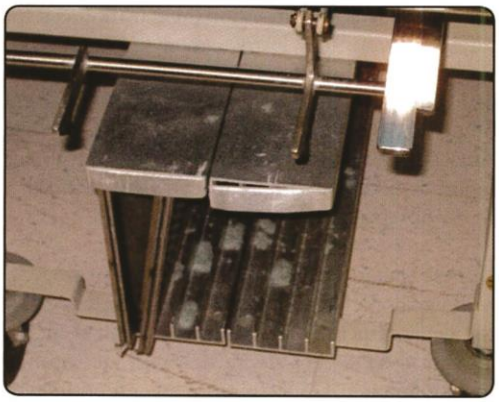

Figure 17.3

CS staff also monitor equipment within their work areas. Some of that monitoring is informal, such as checking the temperature of a heat sealer. Other monitoring is formal. All small electrical equipment has a current preventive maintenance (PM) sticker. Items falling outside of their PM date should be rechecked according to facility policy.

In addition to general guidelines for all work areas, there are unique requirements for each specific work area. The following sections review those requirements.

DECONTAMINATION AREA MONITORING

Monitoring of the decontamination area is important to ensure all cleaning equipment is working properly. If the equipment is not working properly, instruments will not be clean and safe to handle.

Water Quality

Poor water quality will impact every process in the decontamination area. Cleaning chemicals must be used with the recommended water pH and will not function as designed if the water's pH is incompatible with the chemical. Hard water will cause scale to form on equipment, reducing the equipment's cleaning effectiveness. Water quality should be monitored to ensure that the appropriate dilution of the chemicals utilized is correct.

Commercially-prepared water testing products may be purchased to test water on a weekly or daily basis.

Mechanical Cleaning Equipment

Specific tests are available for each type of equipment. CS technicians must follow the equipment manufacturer's Instructions for Use (IFU) for inspection and testing. If the machine does not meet the inspection requirements outlined by the manufacturer, or if the test fails, the CS manager should be notified immediately. All test results should be documented.

Ultrasonic Cleaners

Ultrasonic cleaners use a process called cavitation to remove soil from instruments. Commercially-prepared tests are available to test the efficacy of the ultrasonic.

Irrigating Ultrasonic Cleaners

Irrigating ultrasonic cleaners are used to help clean lumened instruments. These units also use a cavitation process, but they employ irrigating tubes that flush solution through each lumen. In addition to the cavitation test, the irrigating tubes should be checked to ensure water is flowing freely through the tubes. Test results should be documented.

Washer disinfectors

Washer disinfectors should be visually checked at least daily to ensure screens are clean and that rotating arms are properly attached, rotating and unclogged.

Washer disinfectors should be tested for proper cleaning ability. Commercially-prepared products are available to assist with the testing process.

At the end of each cycle, physical monitors should be checked. On a washer, the physical monitor

is the cycle printout or data log. The printout should be verified by the operator to ensure that the thermal disinfection temperature set by the manufacturer was attained and all other cycle parameters were met.

Cart Washers

Cart washers must be monitored to ensure they are working properly. Floor screens should be checked at least daily to ensure they are free of debris. Check rotating arms or cables to make certain they are operating as intended by the manufacturer.

Cart washers must also be tested to ensure they are cleaning effectively. This can be done using a commercially-prepared test.

HIGH-LEVEL DISINFECTION MONITORING

Many items processed today, such as flexible endoscopes, some respiratory therapy equipment, and other heat-sensitive, Class II semi-critical items, are high-level disinfected. The disinfection process contains many variables that can render it ineffective; therefore, it is important to carefully monitor the process. Surveying agencies review disinfection records as carefully as they review sterilization records.

Chemical Disinfection Monitoring

Test strips are used to ensure the minimum effective concentration (MEC) of the disinfectant solution. (See **Figure 17.4**) When a new bottle of test strips is opened:

- Test the efficacy of the strips, according to the the manufacturer's IFU.
- Document the date the test strips are opened and the final date the strips may be used, per the manufacturer's IFU.
- Document the test results, per facility policy.

Example of Disinfectant Test Strips

Figure 17.4

Manual Disinfection

Documentation of the manual disinfection process should include the following:

- Date.
- Test strip results (MEC).
- Expiration date of test strips and disinfecting solution.
- Items disinfected.

Note: Some products also require that solution temperature be recorded.

If the disinfected item is a flexible or rigid endoscope, the following must also be documented:

- Name of the technician who cleaned the scope.
- Name of the patient on whom the scope was used (patient ID information, if available).

Automated Endoscope Reprocessor Monitoring

As the name implies an Automated Endoscope Reprocessor (AER) is used to disinfect endoscopes using an automated process. While this process is less labor intensive than the manual method, monitoring is still just as important.

As with manual disinfection, the disinfecting solution in the AER must be tested for each cycle. The test strips and testing procedure remain the same as with the manual system. The AER

manufacturer's IFU must be followed to ensure proper testing of the disinfecting solution.

Most types of AERs have a physical printout of the cycle available after the cycle is complete. This printout should be reviewed to ensure all set parameters were properly met. Technicians should then sign the printout to show the cycle has been reviewed.

Some AERs have a computerized control panel that allows the input of items sterilized in each cycle. If this feature is not available then the items must be manually documented. With the exception of the printout, documentation for AER disinfection is the same as with the manual system.

STERILIZATION AREA

The sterilization process requires a monitoring system to help ensure that sterilization parameters are being met. Because it is difficult to prove an item's sterility without contaminating it through handling, conditions that can indicate that the parameters for sterilization have been met must be monitored.

These sterilization monitoring protocols are an important part of the CS department's monitoring and quality assurance systems. Several control measures must be used to ensure the conditions within the sterilizers are adequate to achieve sterilization.

Process Indicators

Sterilization process indicators help to confirm that packages have been properly exposed to the sterilization process.

ANSI/AAMI ST79:2013, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities* states, "Chemical indicators are designed to respond with a chemical or physical change to one or more of the physical conditions within the sterilizing chamber."

There are two basic types of process indicators: internal chemical indicators (CIs) that are placed inside a package to be sterilized, and external CIs that are placed on the outside of packages.

CIs provide a visual indication to help identify possible sterilization failures. They can detect problems with incorrect packaging, loading or other procedures and can also detect certain equipment malfunctions, such as air leaks, wet steam and inadequate temperature. CIs are an integral part of the sterilization monitoring program and are used in conjunction with physical monitors and biological indicators to demonstrate the efficacy of the sterilization process.

After sterilization, process indicators are examined by the CS technician to ensure complete exposure. If processes such as packaging and loading have been done correctly, the CI will have changed color. By contrast, an incomplete color change may provide the first sign that part or all of a load has not been properly sterilized. While chemical indicators do not verify sterility, they are an important part of the larger sterilization monitoring system.

External Chemical Indicators

External CIs are often the first performance test the user sees upon removing a package from the sterilizer. They provide instant results and visual evidence that the package was exposed to a sterilant. *Note: External CIs do not indicate that the item is sterile.*

External process indicators, including tape, load cards or labels on the outside of the packages, are also examined before the items are dispensed and opened to ensure that proper processing has occurred. (See **Figure 17.5**)

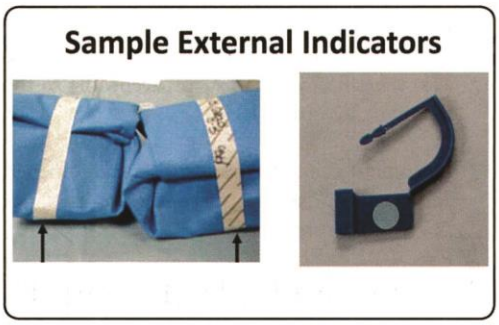

Figure 17.5

Internal Chemical Indicators

Internal CIs are placed inside a package and provide evidence that the sterilant penetrated the package. *Note: Internal CIs do not prove sterility.* **Figure 17.6** provides examples of some CIs.

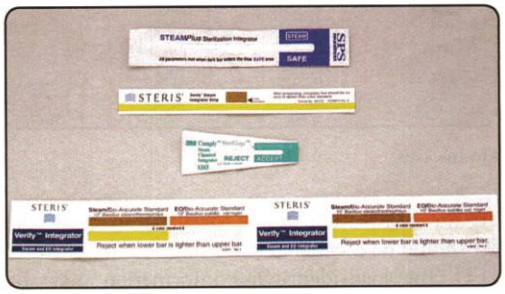

Figure 17.6

CIs should be placed in the area of the package, tray or container considered to be least accessible to sterilant penetration. *Note: This location is not necessarily at the center of the package, tray or container.*

If the interpretation of the CI in a package, tray or container suggests inadequate sterilant penetration, the contents cannot be used and should be returned to the CS department for investigation. *Note: It is possible to have one or more unacceptable indicators in a load because of improper packaging or loading, with the remainder of the load acceptable.*

CIs showing a "fail" result require further investigation to determine the cause. The following could cause a CI test failure:

- Utility or sterilizer malfunction.
- Inappropriate sterilizer loading techniques.
- Not using the correct CI monitor.
- Wrong cycle selected.
- Poor storage of the CI indicator.
- Improper packaging techniques.
- Not following the container IFU.
- Not following the medical device manufacturer's IFU.

Some facilities use CIs that consist of heat-sensitive dye applied to a cardboard strip or a dye that moves along a window. When exposed to a sterilant, these devices gradually change color, thereby integrating a time component to the measurement.

Physical Monitoring

Physical monitors include time, temperature and pressure recorders, displays, digital printouts and gauges. (See **Figure 17.7**) During and at the end of the cycle, and before items are removed from the sterilizer, the operator should review the monitor to ensure all cycle parameters were met.

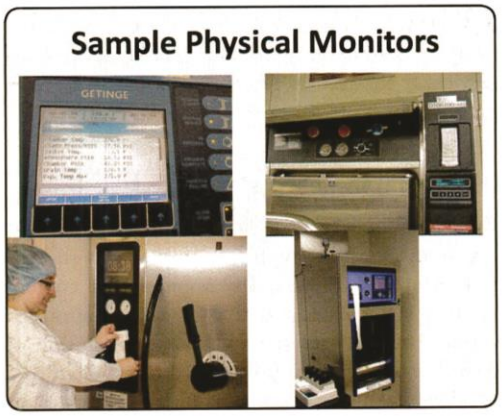

Figure 17.7

Upon completion of the cycle, the operator must sign the chart as proof that it was monitored and that all sterilization parameters were met. Physical monitors are needed to detect equipment malfunctions as soon as possible, so appropriate corrective actions can be taken. (See **Figure 17.8**)

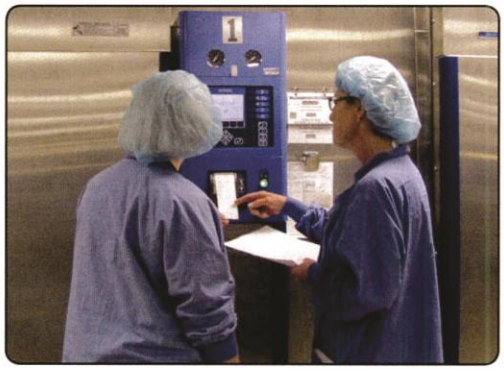

Figure 17.8

If there is any indication of malfunction, the department manager or designee must be notified immediately. The load should be considered unsterile and the sterilizer should be removed from service. It should not be reused until the problem is corrected.

Biological Indicators

Biological indicators (BIs) are one of the most important sterilizer monitors available to the CS technician. BIs are usually ampules that contain a paper strip impregnated with a predetermined amount of live bacterial spores and a solution of growth media. (See **Figure 17.9**) The growth media provides a source for any remaining live bacteria to feed on after sterilization, thus allowing bacteria to grow and be detected. The type of bacteria varies with the method of sterilization, as the spore-producing bacteria most resistant to that sterilization method is used in the test. This test directly determines whether the conditions have been met to kill these resistant organisms. If the most resistant organisms are killed, then less resistant organisms should also be killed. If the proper conditions are not met to kill the spores, then the test organism will grow when incubated after the sterilization cycle.

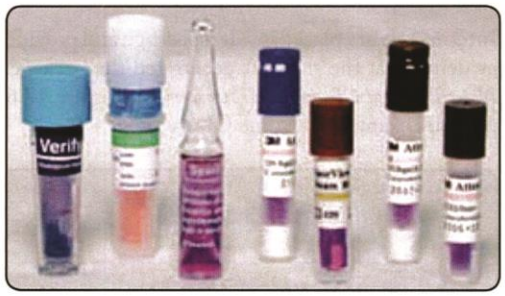

Figure 17.9

At the completion of the sterilization cycle, the BI should be incubated according to manufacturer IFU. The load-identifying information must be identified on the BI, in a manner consistent with the IFU. If the bacteria have been killed, there will be no color change or indication of life during incubation. This is known as a negative test result (no growth). If there is a color change in the ampule or there is indication of life through the incubator reading, it is known as a positive test (live bacteria), and items within the load should be recalled and reprocessed.

A test ampule, called a control, should be run at least daily, when a BI is run, and each time a new lot is opened. A control test is the same as the BI, except it has not been put through a sterilization cycle; therefore, the impregnated bacteria will grow when incubated (positive test results). This demonstrates that the ampules in that specific lot are still viable (alive). If the control ampule does not show bacterial growth when incubated (negative test), that means the impregnated bacteria were likely dead before sterilization; therefore, the BI test run with the items being sterilized is inaccurate and will give a false negative reading.

When running a BI and control test, the results CS technicians will look for are a positive reading for the control (growth) and a negative reading for the BI (no growth). All test results and lot numbers must be carefully documented.

A negative BI result does not prove that all items in the load are sterile, or that were all exposed to adequate sterilization conditions. Instead, it

shows that all conditions required for sterilization were met. CS technicians must follow proper preparation, packaging and and loading procedures to help ensure proper sterilization parameters will be attained.

BI process challenge devices (PCDs) – addressed further in the next section of this chapter — should be used for routine sterilizer efficacy monitoring (at least weekly, but preferably every day the sterilizer is used). BI PCDs must be used with every implant and they are also required in each load sterilized with ethylene oxide (EtO).

Reasons for Positive Biological Monitors

Positive BI results can be due to an operator error or a sterilizer or utility malfunction. Whenever a positive BI result occurs, its must be investigated to determine its cause.

An operator error can be caused by:

- Using the wrong BI or PCD. Using a BI validated for another mode of sterilization.
- Incorrect placement of the BI in the sterilizer load. BIs placed in the wrong section of the sterilizer, under trays or on their sides may give inaccurate results.
- Not following the BI manufacturer's IFU.
- Incorrect storage of the BI. BIs stored in temperatures that are too cold or too warm can be damaged and lead to incorrect results. Storing BIs where there is inadequate humidity can also impact results.
- Incorrect cycle selection.
- Not loading the sterilizer cart to allow for air removal and sterilant penetration around and through the load. Placing items too closely together (overloading) or placing items on top of the BI can cause an inaccurate test result.

If the cause of the positive BI is not determined, the facility department or outside agency responsible for sterilizer maintenance should be contacted to conduct further investigation. The sterilizer should not be used until the issue is corrected.

Process Challenge Devices

A PCD is designed to challenge a sterilization cycle. These packs may be commercially-prepared or made at the healthcare facility. PCD packs may contain only a CI, but more frequently, they contain a BI and a CI/integrator. For those cycles where a PCD has been developed, the PCD should be used to challenge the sterilization cycle. (See **Figure 17.10**)

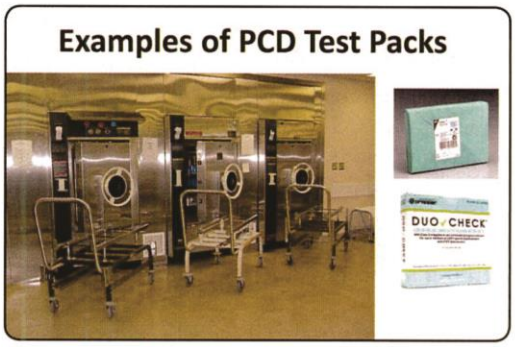

Figure 17.10

Protocols for using PCDs include:

- The PCD should be labeled with sterilizer load information before being placed into the sterilizer.
- The PCD should be positioned in the chamber according to the sterilizer manufacturer's written recommendations.
- The sterilization cycle should be run. Check the sterilizer and PCD's IFU for specific instructions.

Implants

ANSI/AAMI ST79:2013 recommends that every load containing implantable devices should be monitored with a PCD that contains a BI and a Class 5 integrating CI. An implantable device should not be released before the BI results are

known. As with all cycles, the sterilizer operator should review the sterilizer printout and the results of other indicators used to monitor the sterilization process.

Implants should be quarantined until the results of the BI testing are available. In the case of a documented emergency, an implant may be released from the results of the Class 5 CI and physical monitors; however, the BI must continue to be processed to obtain and document a final result. If, due to an emergency, the implantable items must be released before the BI has been read, the release and reason for the release must be documented.

Sterilizer Printouts

Sterilizer printouts should be reviewed and signed by the CS technician responsible for cycle monitoring and if all sterilization parameters were met, the load may be released. It is important for the CS technician to know and understand the parameters that must be met by each type of sterilizer in order to properly monitor the cycles.

Sterilization Load Control Numbers

All items to be sterilized should be labeled with a **load control (lot) number** that identifies:

- Sterilizer identification number.
- Sterilization cycle number.
- Date sterilized – Example: 12-18-2015.
- Some facilities use a **Julian date** on their packages. The Julian date is the number of days that have elapsed since January 1. For example, January 1 is day #001 and December 31 is day #365.

Load control information is usually applied to each package with a labeling applicator gun to place an identification sticker containing the load information. (See **Figure 17.11**)

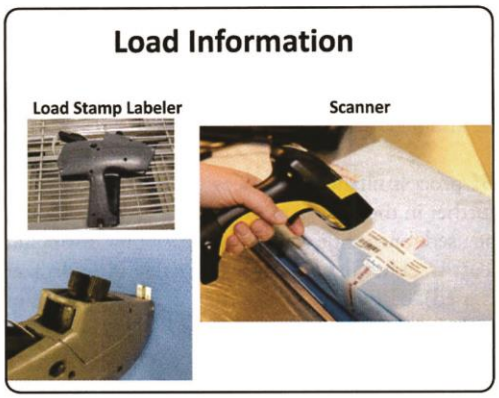

Figure 17.11

Load control (lot) number Label information on sterilization packages, trays or containers that identifies the sterilizer, cycle run and date of sterilization.

Julian date The Julian day or Julian day number (JDN) is the number of days that have elapsed since January 1.

All packages sterilized by the CS department should contain load control (lot) information. Load information helps to retrieve items during recalls and trace problems, such as a positive CI test result.

The following information should be recorded on a load log sheet and maintained for each sterilization cycle:

- Load control number date and time (cycle number) of the sterilizer load.
- Specific items sterilized, including quantity, department and item description (e.g., minor pan 1 OR, towel pack 10 CS, or sternal saw 1 CVOR).
- Exposure time and temperature.
- Sterilizer operator identification.
- Results of biological testing (if applicable).

- Response of the CI placed in the BI test pack, if applicable.
- Results of Bowie-Dick testing, if performed.

This documentation ensures that cycle parameters were monitored and met, and helps personnel determine whether a recall is necessary. *Note: A recall is initiated for a positive BI or nonresponsive CI, wet packs, or other sterility problems. Knowing the contents of the load enables personnel to know where to go to reclaim the packages. This documentation can be compiled manually in a sterilization log book, or there are computer software programs available to compile and maintain these records.*

Validation and Verification

No discussion of sterilization monitoring can be complete without mention of **validation** and **verification** processes. There is a significant difference between "validation" and "verification." Validation is done by the device manufacturer using a documented procedure to obtain, record and interpret the testing results required to determine a process consistently produces a sterile product. Validation requires extensive laboratory testing and retesting of the processes that will be recommended. and the results must be appropriate and reproducible. Testing must also show that the validated sterilization process will not jeopardize the integrity of the product. To validate the sterilization cycle, microbiological challenges are placed in the most difficult to sterilize locations of the device. If it is not possible to reach these areas of the device with a BI, then the device may be inoculated with the specified microbiological challenge via liquid suspension. The medical device is then subjected to three sterilization cycles at one-half the exposure time. In all sterilization qualification runs, the device is packaged (if applicable) in a manner defined by the device manufacturer. The packaging should be appropriate for the device and available to healthcare personnel. The test results must show total microbial kill in the half cycles. Due to the complex requirements, validation cannot be performed in CS.

By contrast, "verification" is performed by the healthcare facility to confirm that the validation undertaken by the manufacturer is applicable to the specific equipment and settings in their facility.

CS technicians perform verification by documenting the procedures to obtain, record and interpret the healthcare facility's test results. The validation provided by the medical device manufacturer provides the framework for these studies.

For information on product verification refer to ANSI/AAMI ST79:2013, Section 10.9.

Validation Procedures used by equipment manufacturers to obtain, record and interpret test results required to establish that a process consistently produces a sterile product.

Verification Procedures used by healthcare facilities to confirm that the validation undertaken by the equipment manufacturer is applicable to the specific setting.

Important Note

While product verification can be accomplished in a healthcare facility, the parameters validated by the manufacturer cannot be changed and properly verified. For example, if a manufacturer has validated a device to be steam-sterilized in a 10-minute 270°F cycle, a facility cannot test this item in a five-minute 270°F cycle.

Healthcare facilities do not have the proper products or equipment to properly test and ensure the item is sterile in the shorter cycle. Also, the FDA has approved the manufacturer's cycle, not the healthcare facility's cycle.

Sterilizer Qualification (Verification) Testing

Qualification testing is performed to verify that the sterilizer is in good working condition in the location in which it is being used. This testing also ensures that the sterilizer performs to manufacturer's specifications.

Qualification testing is performed after sterilizer installation, relocation, malfunctions, major repairs, or any time there is a significant change to the utilities connected to the sterilizer. A major repair is considered outside the scope of normal repairs. The replacement of a door gasket is considered a normal repair; however, weld repairs, chamber door replacement, vacuum pump repairs, major piping assembly repairs or rebuilds or control upgrades are considered major repairs.

For more information on sterilizer qualification testing, refer to the sterilizer operation manual and ANSI/AAMI ST79:2013, Section 10.9

STERILIZER-SPECIFIC MONITORING

In addition to the previously discussed monitoring parameters, each sterilization method may have specific parameters that must be monitored to help ensure that it is performing correctly.

Dynamic Air Removal Sterilizers

Dynamic Air Removal Test

This test is also known as a Bowie-Dick test. It is a Class II CI, also known as a specialty indicator. Class II indicators are designed for specific procedures, such as monitoring the effectiveness of the steam sterilizer to remove air from the chamber. (See **Figure 17.12**)

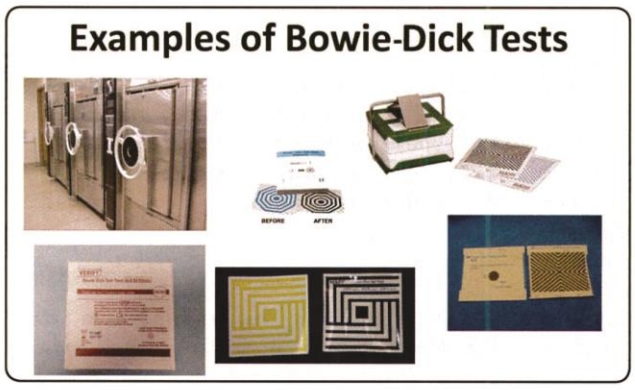

Figure 17.12

This test should be performed each day the sterilizer is used, at the same time of day and after major repairs. The only items that should be in the chamber during this test are the sterilizer loading carriage (to hold the test), and the test itself. The dynamic air removal test should be placed over the chamber drain and run per the manufacturer's IFU, usually with a reduced sterilization time.

Some sterilizers have a designated air removal test cycle; check to ensure this cycle matches the air removal test manufacturer's instructions. When the cycle is complete, remove the test pack. If the chemically-impregnated sheet has a complete uniform color change, the test is considered negative and the sterilizer is ready to use. If the color change is not uniform and there are blotchy areas of unchanged color, the test is considered positive, and the sterilizer should be taken out of service until the issue can be found and corrected.

Note: Dynamic air removal tests are not run in gravity displacement sterilizers. This is because the air is removed from the chamber using gravity, not a dynamic method.

Leak Testing

Leak testing of dynamic air removal sterilizers is performed to ensure there are no air leaks within the chamber. This test checks the sterilizer's ability to hold a vacuum by testing all the sealed areas and piping to ensure air is not allowed into the chamber during a cycle's vacuum phase. Leak tests should be performed at least weekly in an empty sterilizer chamber. Leak testing is more sensitive than a dynamic air removal test, so it will detect problems before the air removal test might detect the leak. *Note: Refer to the manufacturer's operating manual to determine the acceptable leak test for the sterilizers at the facility.*

Biological Indicators/Process Challenge Devices

The spore-producing microorganism used in steam sterilizer testing is *Geobacillus stearothermophilus*. This bacterium is used because it

is a heat-loving bacteria and is, therefore, resistant to the temperatures used for steam sterilization.

It is recommended that commercially-prepared PCDs be used; the materials utilized in the packages remain consistent because they are manufactured for single use, so there is no wear or erosion of the product. If commercially-prepared packs cannot be used, refer to ANSI/AAMI ST79: 2012, Section 10.7.2.1.

Gravity Sterilizers

Biological Indicators/Process Challenge Devices

The spore-producing microorganism used in gravity steam sterilizer testing is *Geobacillus stearothermophilus*.

It is recommended that commercially-prepared PCDs be used; the materials utilized in the packages remain consistent bacause they are manufactured for single use, so there is no wear or erosion of the product. If commercially-prepared packs cannot be used, refer to ANSI/AAMI ST79: 2013, Section10.7.2.1.

Ensure the PCD to be used is designed for gravity sterilizers.

Immediate Use Steam Sterilizers

Biological Indicators/Process Challenge Devices

The spore-producing microorganism used in steam sterilizer testing is *Geobacillus stearothermophilus*.

BIs are processed in Immediate Use Steam Sterilizers (IUSS) without a PCD. This is because items are processed unwrapped or in special containers designed for IUSS. BI ampules should be run in IUSS, according to the manufacturer's IFU. BIs should be run at least weekly, preferably each day the sterilizer is used, and with every load containing an implantable item.

Monitoring and Recordkeeping for Central Service

IUSS monitoring includes detailed recordkeeping, so patients can be monitored, if necessary. When an IUSS cycle is run, the following information should be documented.

- Date and time of the sterilization cycle.
- Sterilizer identification (ID).
- Cycle temperature and sterilization time (e.g., 270° F at 10 minutes).
- Item(s) being sterilized.
- Patient identification.
- Reason for sterilizing the item using IUSS.
- CI results.
- BI results, if appropriate.

Multiple Cycle Testing

Some dynamic air removal and immediate use steam sterilizers have the ability to operate in either a dynamic air removal mode or a gravity mode. If a sterilizer is used in both sterilization methods, then BI/PCD testing must be done at least weekly, preferably daily, in both modes. Refer to ANSI/AAMI ST79 and to the sterilizer manufacturer's IFU for specific details.

Tabletop Steam Sterilizers

Biological Indicators/Process Challenge Devices

The spore-producing microorganism used in tabletop steam sterilizer testing is *Geobacillus stearothermophilus*.

Commercially-prepared PCDs are currently not available for tabletop sterilizers. Types of items sterilized varies greatly from facility to facility, so creating a standard PCD would be extremely difficult. To create a PCD for the tabletop sterilizer:

- Select a tray of instruments or package that

represents the most difficult item routinely sterilized in the tabletop sterilizer.

- Once the tray or pack has been identified it should be used for each test performed.
- Place at least one BI and at least one CI in the most challenging area of the tray or pack to sterilize.

After a major repair to a tabletop steam sterilizer, three consecutive test cycles with a PCD should be run and the results should be read before the sterilizer is put back into use.

Ethylene Oxide Sterilizers

Biological Indicators/Process Challenge Devices

BIs are the most acceptable means for providing quality assurance monitoring for EtO sterilization. Like BIs used in steam sterilization, an EtO BI has a carrier that has been inoculated with a known population of a microorganism that is highly-resistant to the sterilant. The microorganism of choice for EtO is the *Bacillus atrophaeus* spore. It is assumed that killing all spores on a standardized BI indicates a successful sterilization cycle; this is because the BI's population and resistance exceeds that of the bioburden on items being sterilized. *Note: This assumption only applies to properly cleaned, prepared, packaged, and loaded supplies. It is recommended that a PCD be run in every EtO load.*

Remember the "4R's"

Process monitoring consists of the "4 R's": Run, Read, Record and Retain. No single monitoring product provides all information necessary to ensure effective sterilization; therefore, recommended practices state that available information from physical, chemical and biological indictors should be used to assess the process before releasing a load.

Note: It is essential that CS technicians are able to read and interpret physical monitoring information and chemical indicator color changes, and know how to handle, use and interpret the results of biological indicators.

Hydrogen Peroxide Sterilizers

There are several different types of hydrogen peroxide (H_2O_2) sterilizers available in today's healthcare market; however, the basic monitoring requirements remain the same for all types of H_2O_2 sterilizers.

Biological Indicators/Process Challenge Devices

BIs are most accepted means for providing quality assurance for hydrogen peroxide (H_2O_2) sterilizers. The microorganism of choice for H_2O_2 is the *Geobacillus stearothermophilus* spore because this bacteria is the most difficult to kill using H_2O_2 methods. As noted earlier, the killing of all the spores on a standardized BI indicates a successful sterilization cycle (assuming supplies have been properly cleaned, prepared, packaged and loaded). A BI PCD should be run at least each day the sterilizer is used, but preferably in every load.

Commercially-prepared PCDs are available; however they are sold to monitor specific sterilizer models. Ensure the correct PCD is being used for the sterilizer.

Ozone Sterilizer

Biological Indicators/Process Challenge Devices

BIs are the most accepted means for providing quality assurance for ozone (O_3) sterilizers. The microorganism of choice for O_3 is the *Geobacillus stearothermophilus* spore because this bacteria is the most difficult to kill using O_3 sterilization. A BI PCD should be run at least daily, each day the sterilizer is used, but, preferably in each load.

PERSONNEL MONITORING

Personnel monitoring can involve several different types of devices. One type of monitoring system uses a badge-type monitor that affixes directly to the employee's clothing in the breathing zone (within one foot of the person's nose). Area monitors are also commonly used. These measure the quality of air in a specific area and alarm if air quality levels are breached.

STAFF EDUCATION

Tasks performed by CS technicians require specific knowledge and skills. The safety of both staff and patients depends on proper execution of specific skills. New instruments, equipment, standards and regulations make ongoing education necessary for even the most experienced CS technicians.

CS departments must provide evidence of the training and education provided for staff. That evidence is usually contained in training documents, competencies and continuing education records.

Training Documents

When a new employee enters the CS department or when an existing employee moves to a new position within the department, the formal process of orienting and training the staff member to their new responsibilities begins. That process should follow a carefully designed training plan that will prepare the employee to correctly perform the required duties. Training and/or orientation documents must be kept on file for each employee as evidence that formal training occurred.

Competencies

Employee competency records are an important monitoring tool for the CS department. Competencies provide evidence that the employee understands specific tasks and is qualified to perform them. Competency records are important for the growth of the department and serve as a basis for a quality improvement (QI) program.

Detailed, step-by-step lists should be developed and utilized for each task performed within the CS department. Competencies should be done during initial orientation, whenever a new device is received, and on a routine basis for daily CS tasks. Some competencies will need to be done annually (i.e., tasks pertaining to sterilizer operation and documentation), while other job duties, such as wrapping techniques, may only need to be done when issues arise or on a rotating basis.

Competency records can be reviewed to determine areas where each employee excels or where more training is needed. They can also be used to show process improvement.

Continuing Education Records

The CS discipline is constantly changing and CS technicians must change with it. Continuing education provides a means of staying abreast of changes in regulations, standards, technology, scientific knowledge and equipment. Continuing education records provide evidence that the employee has kept current and is aware of new best practices. **Figure 17.13** provides an example of an employee inservice, a common method used to help educate CS staff.

Figure 17.13

Education records should be kept on file for all CS employees and should be monitored to help ensure they are current.

CONCLUSION

Properly and consistently monitoring the Central Service department and processing equipment helps ensure patient and staff safety. It also helps ensure the consistent production of high-quality products.

Every member of the CS department must monitor the environment, work practices, mechanical processes, and training and education to ensure that standards, regulations and best practices are properly and consistently followed.

RESOURCES

Occupational Safety and Health Administration. OSHA Standard 29 CFR 1910.151(c).

Centers for Disease Control and Prevention. *Guideline for Disinfection and Sterilization in Healthcare Facilities*. 2008.

Association for the Advancement of Medical Instrumentation. ANSI/AAMI ST58, *Chemical sterilization and high-level disinfection in health care facilities,* Section 9.4.4.3.

Association for the Advancement of Medical Instrumentation. ANSI/AAMI ST79:2010 & A1: 2010 & A2: 2011 & A3:2012, Section 10.

CENTRAL SERVICE TERMS

Monitor

Load control number

Julian date

Validation

Verification

Chapter 18
Quality Assurance

Learning Objectives

As a result of successfully completing this chapter, readers will be able to:

1. Define quality in the context of Central Service operations
2. Describe the components of a Central Service quality program
3. Explain the basics of failure mode and effects analysis and root cause analysis
4. Discuss common quality programs:
   - Total quality improvement
   - Continuous quality improvement
   - Total quality management
   - Six Sigma and Lean
   - Other quality programs and standards
5. Review common quality procedures in the Central Service department

INTRODUCTION

Healthcare consumers demand quality in the products and services they receive. They expect nothing less than the best for themselves and their loved ones while using inpatient and outpatient healthcare services. Central Service (CS) professionals must establish appropriate quality levels for the products and services they produce, and ensure that these levels are consistently maintained.

CS technicians directly serve **internal customers** (physicians, nurses and other professionals working in the facility). The success of CS depends upon satisfying the needs of these internal customers, so they can best serve the patients. Quality (or lack of quality) can have dramatic consequences on the health and safety of both patients and facility personnel. Providing quality products and services directly impacts patient outcomes and significantly impacts the department's (and the healthcare facility's) success.

CS technicians are an integral part of quality service throughout the healthcare facility. CS technicians are now processing medical devices for surgery centers, physician's offices, off-site clinics, nursing rehabilitation facilities, dental offices and third-party reprocessors. With emerging antibiotic-resistant bacteria and the ever-increasing complexity of surgical instrumentation, it has never been more challenging or rewarding for CS personnel to consistently provide quality products and services.

This chapter will discuss several established quality indicators to assist in monitoring quality within CS departments. The ultimate goal is high quality patient care. This can best be achieved through comprehensive training programs and ongoing quality monitoring.

Customer (internal) The physicians, nurses and other professional personnel served by Central Service personnel.

Quality The consistent delivery of products and services according to established standards. Quality "integrates" the concerns for the customers (including patients and user department personnel) with those of the department and facility.

QUALITY IN CENTRAL SERVICE OPERATIONS

Quality requires CS technicians to look at what they do from their customers' perspectives. In many respects, CS production is only as good as the last device processed or the most recent service provided. One hundred error-free items can be processed, but one imperfect tray or service will be noticed and considered as the department's quality outputs are evaluated. While this may seem unreasonable, it is important to understand that just one error can cause significant harm to patients and employees.

What is Quality?

The concept of **quality** relates to the degree or grade of excellence of a product or service. For example: Emergency Department personnel may believe that an emergency code cart was delivered efficiently (on a timely basis), but the cart might not provide a needed item that was requested on the pick list (supply listing). This indicates poor service quality. By contrast, when a surgical instrument set is needed quickly and the CS department delivers it promptly with all necessary components, poor service quality can still result if the surgical staff was not informed of the set delivery. In short, quality is measured through the eyes of the customers and their concerns relate to both products and service.

The patient must be at the center of every quality concern. CS professionals must provide properly processed products when they are needed. Just being "good" is not good enough. A surgical tray delivered to the Operating Room (OR) on time, but with incomplete or incorrect instruments does not represent quality service and can cause the

patient to have a less than desirable outcome due to instrumentation problems. CS technicians accept this responsibility and the challenge to consistently meet requirements.

Looking at functions from customers' perspectives allows the CS team to critically review its processes to determine where improvements can be made. Remember that:

- Increased education should help staff provide a higher quality of service.
- Quality takes time, effort and participation from everyone in the healthcare facility.
- When measuring quality, best practices provide a good starting point.
- CS staff can use their knowledge to increase efficiencies.

How Is Quality Identified?

Products and services might be considered "excellent" if they meet one's needs (they do what they are supposed to do). If a new washer disinfector is properly used, but instruments are still dirty after a complete cycle, the equipment will be judged inferior; however, if the equipment meets expectations (it produces clean decontaminated instruments), it is easier to assume that, "This is a great manufacturer, and I would purchase from this company again."

This feeling provides a subjective view of quality that provides no basis for measurement. What's more, it does not consider the customers' service levels.

Branding is another subjective form of quality identification. If one has a great experience with specific equipment, a future purchase from that manufacturer is more likely than if negative experiences occur.

Products processed by CS professionals should always be complete and properly assembled with no errors. An internal department system should be implemented to identify inferior products before they leave the area. External department information can be obtained from customers by using the count sheets for trays, pick tickets for case carts and requested items, and/or by formal surveys designed to learn about quality dimensions from customers' perspective. (See **Figure 18.1**) Statistics from both internal and external sources should be analyzed, errors should be studied and corrective actions should be implemented to best ensure quality improvement.

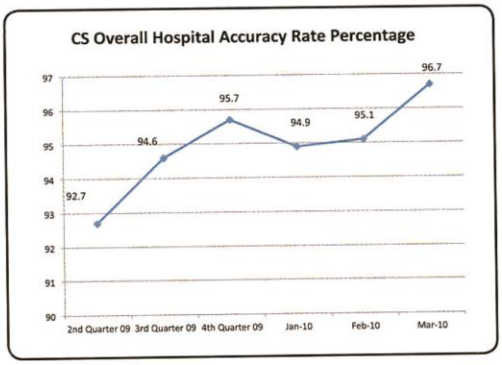

Figure 18.1

COMPONENTS OF QUALITY

Quality is not a quick fix for healthcare facilities. Achieving world class (best in the industry) quality requires a multi-year plan to move a facility from its current quality level to the ideal (highest achievable) quality. For example, the Ritz-Carlton hotel chain, the only U.S. lodging organization to win the prestigious Malcolm Baldrige award for quality, began its quality journey with a benchmark of 60,000 defects per million transactions. It planned a six-year process to move to 0.60 (less than one) defect per million transactions. The Ritz-Carlton's definition of world-class quality also required a 50% reduction in cycle time (the time that passes between an order being placed and being completed). This planned approach to move toward an ideal quality goal is just as relevant to healthcare as it is to hospitality.

Top-level administrators must emphasize quality because their support is critical for success. Most problems affecting the employees' ability to accomplish work are caused by systems and procedures that have, in some way, been required or implemented by top-level leaders.

Figure 18.2

Departmental quality should be multidisciplinary, as well as intradepartmental. A true quality program utilizes all CS professionals and a cross-section of its customers. (See **Figure 18.2**)

Empowerment

Empowerment is the action of driving the process of decision-making and implementation down the facility's chain of command. In other words, some decisions that have traditionally been made by managers or higher level departmental staff or administrators are now made by supervisors or front line staff members. Empowerment is typically limited to well defined areas, such as **process improvement** changes within the employee's defined areas of responsibility.

Employees assigned to specific work areas must know how to properly perform all work tasks before they can be empowered. Managers must provide training about the concept of empowerment and they must encourage the sharing of ideas and suggestions that can lead to improvements.

Leadership

Quality requires committed leaders to help manage the data, plan opportunities, establish priorities and empower people to implement process improvements.

Effective leaders define standards to be attained in quality products/services. Those standards will drive the development of strategies that address customer satisfaction and the attainment of the facility's goals.

Departmental leaders, including shift supervisors and lead technicians, should be the first-line "guardians" of the quality program to ensure that all department personnel consistently adhere to the standards and priorities set by senior managers. Employees should help their teammates follow established guidelines. This can be accomplished by interacting with new or less qualified staff members, assisting in ongoing training and participating in daily quality control checks.

Empowerment The act of granting authority (power) to employees so they may make decisions within their areas of responsibility.

Process improvement Activity to identify and resolve task-related problems that yield poor quality; the strategy of finding solutions to eliminate the root causes of process performance problems.

Standard Data

Each department must select the data that will be used to monitor its quality processes. **Figure 18.3** provides an example of data that has been collected and compiled for analysis.

Measurement	Goal	Actual	Color
Avg. Trays Backlogged 7am	< 15	42	
Avg. Trays Backlogged 11pm	< 25	76	
# Errors Reported	< 3	2	
% Case Carts Complete Supplies	99%	97%	
% Case Carts Complete Instruments	95%	91%	
% Complete Instrument Trays	98%	94%	
Total Hours per Tray Processed	1.80	2.03	
Staff Productivity	90%	92%	

Figure 18.3

Planning Tools and Procedures

Quality planning can reduce existing problems and prevent potential problems. It involves:

- Studying other facilities. How do other facilities deliver each product and service that their patients/customers want?
- Remembering that the process (not people) is the cause of most problems.
- Thinking about how to improve.

Steps of quality planning include the following:

- Step One: Identify the needs and requests of the department's customers.
- Step Two: Identify an ideal process to consistently address each need/request.
- Step Three: Compare actual steps and outcomes of each process to the ideal outcome (e.g., 100% error-free trays).
- Step Four: Plan process control activities to improve the system.
- Step Five: Measure the errors.

With a good quality system in place, the number of errors should decrease.

Principles of Quality Management

Several principles of quality management form the foundation of a quality process:

- Patient focus – Assuring that patients' needs are the driving force in decision making, problem solving and other activities.
- Process management – Placing the emphasis on managing the process, rather than upon managing the employees.
- Continuous quality improvement – Believing that things can always be done better and then undertaking improvement efforts.
- Fact-based decisions – Basing decisions on facts, rather than assumptions.

Staff Members

To have a successful quality program, all departmental staff members must be fully engaged with the program. While management may set the standards and goals, technicians, for the most part, carry out the processes to achieve success. Providing all staff members with a solid education foundation will help ensure they use critical thinking skills on the job.

Employees must be empowered to address solutions to immediate problems within their realm of expertise. For example, they should be allowed to stop what they are doing to help another employee. They should be able to enlist the assistance of other workers in problem-solving tasks, when necessary. Also, employees who desire additional responsibilities should be allowed to work on longer-term problem-solving projects. This may be done with the use of **cross-functional teams** that select a process problem, analyze it, develop alternatives, offer solutions and make implementation suggestions. It is important for senior leaders to recognize superior staff members and teams.

Cross-functional team Group of employees from different departments within the healthcare facility that works together to resolve operating problems.

Process Management

Studying processes is critical because process problems cause errors. If errors are identified and resolved, patients and customers will experience fewer problems. (See **Figures 18.4** and **18.5**) Also, employees will have greater success in consistently delivering products and services that meet quality standards. Some processes commonly studied for improvement are:

- Instrument set turnaround times.
- Instrument set accuracy.
- Surgical case cart accuracy.
- Inventory fill rates.

The highest levels of quality are difficult to attain and maintain. When quality is not emphasized, inconsistent products, service delays, negative patient outcomes and employee conflicts can arise. These problems contribute to higher costs for the facility and the patient, and lower revenues for the healthcare facility.

Skills Flexibility Matrix Standard

Ratings: 1 = Oriented Only, 2 = Needs

# of Skills	Average Skill Rating	J. Abraham	J. Doe	J. Smith
35	2.6	2.3	2.4	2.5

#	Activity	Skill Trainer	Rating	Rating	Rating	Rating
1	Station Set-Up, Use & Clean Up	JK	3.1	4	4	3
2	Wrapped In-House Items	CN, JK	2.1	1	2	3
3	Container In-House Items	CN, MG	2.9	3	3	3
4	Clean From Hospital Items	JK	2.4	2	3	2
5	Peel Packages	JK	2.2	3	1	1
6	Identification & Use of Indicators	JK	2.4	2	4	3
7	Proper Operation	JK	2.2	1	2	1
8	Troubleshooting	CN, DJ	2.3	1	2	1

Figure 18.4

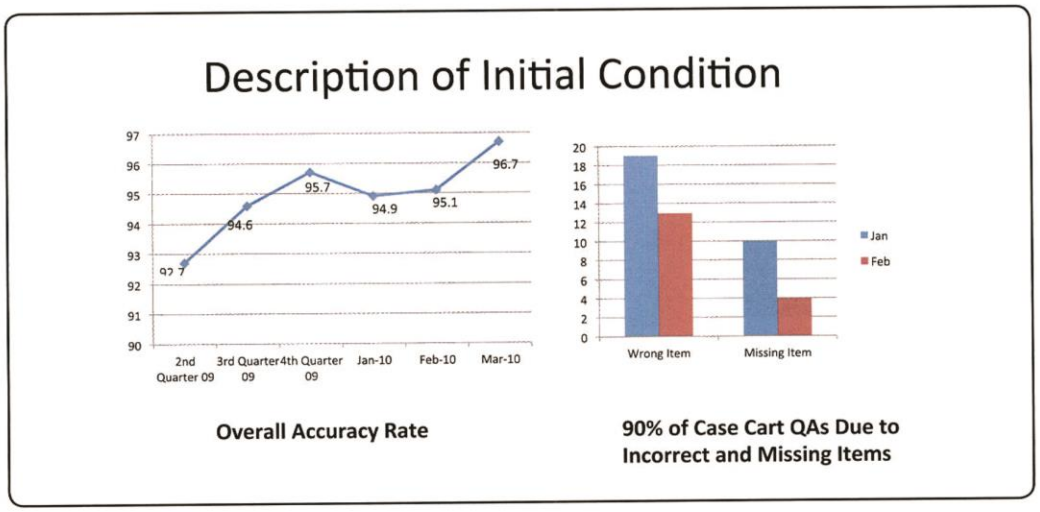

Figure 18.5

QUALITY CONTROL INDICATORS

Purpose of Quality Control Indicators

CS quality control indicators are often used to determine how well the department is meeting its objectives. Several quality indicators should be monitored periodically. (See **Figure 18.6**) Some examples of CS quality indicators are:

- Customer departments receive STAT (urgent) medical supplies within five minutes of request.
- Only sterile supplies with current dates are available on unit supply carts.
- Sterilization processes are acceptable, based upon results of physical, chemical and biological indicators.
- Instrument sets contain clean, functional and correct contents.
- Patient care equipment and supplies are available and in proper working condition.
- Instruments are available for scheduled procedures to avoid the use of Immediate Use Steam Sterilization (IUSS).
- Biological indicators accompany every load requiring biological monitoring.
- Case carts contain correct contents.

ANALYSIS OF QUALITY CONCERNS

Failure mode and effects analysis (FMEA) and root cause analysis (RCA) are two widely used methods to analyze issues discovered within quality systems. Although these methods are not always recognized or practiced in their original form, their popularity has continued to grow. Both concepts are important tools that can be used in a quality program.

Failure Mode and Effects Analysis

FMEA has its origins in the military and industrial fields, and is a method of identifying and preventing problems with products and processes before they occur. The FMEA process seeks to accomplish several things. First, it aims to define the topic that must be addressed (e.g., replacing a hospital boiler), then assemble a group of multidisciplinary staff to identify possible hazards and causes (e.g., poor steam quality, pipe ruptures and service disruption). Finally, the team identifies actions and outcomes for each potential problem. For example, before replacing the boiler, it may be important to rent a temporary steam generator to use if problems arise,

Figure 18.6

so the food service department, OR and CS may remain functional if any of the identified problems occur.

Failure mode and effect analysis (FMEA) A process designed to predict the adverse outcomes of various human and machine failures to prevent future adverse outcomes.

Root cause analysis (RCA) A process that "looks backward" at an event to help prevent its future occurrence.

Root Cause Analysis

Root cause analysis (RCA) is a reactive process that uses historical analysis of an adverse outcome to help prevent its recurrence. Assume a washer disinfector pump malfunctioned and caused instruments to be improperly cleaned. Each event after the pump failure would be examined to determine what could have occurred and what can be done to prevent this issue in the future. Another example is the tip of a carbide insert on a needle holder breaking during surgery. All members involved with the set will meet to determine what happened and how to prevent this from happening again. Members of this meeting should be:

- The surgeon (How was the instrument used?).
- The scrub technician and circulating nurse (What happened? Was the instrument checked before giving it to the surgeon?).
- The CS manager and the technician who assembled the tray (What are the set policies and procedures for instrument assembly/testing? Was the instrument properly checked?).
- Risk manager (usually serves as meeting facilitator).

- Any other interested parties (instrument repair technician, Infection Prevention personnel).

This group will determine what went wrong at each step of the process and determine how to prevent the problem from happening again.

RCA is widely utilized in the medical field to examine contributing factors to adverse events. Note: *The Joint Commission (TJC) standard LD 5.2 requires facilities to conduct root cause analysis on any* **sentinel event** *that is recurring.*

Sentinal event An unexpected occurrence involving death, serious physical or psychological injury, or the risk thereof.

QUALITY PROGRAM ALTERNATIVES

Many CS departments utilize a quality assurance program because it is comprehensive and requires the gathering of data to ensure that a quality product is regularly produced. The number of items not meeting quality requirements is compared to the total number of items produced. There are many **quality assurance** programs utilized within the healthcare industry. Some of the most popular are:

- **Total quality improvement (TQI)** involves measuring the current output of a process or procedure, and then modifying it to increase the output, increase efficiency, and/or increase effectiveness. TQI recognizes that improvement can occur with an individual, a team, an organizational unit, such as the CS department, or the organization itself.

- **Continuous quality improvement (CQI)** is a statistical method to improve **work processes**. Planning and implementing a CQI program for instrument processing involves the receipt and use of input from decontamination staff, processing employees, clinicians and physician personnel and all others involved in equipment use. This team can assist in identifying where more training is needed (multiple users), where process changes are needed (multiple departments) and what the expected quality outcomes should be.

- **Total quality management (TQM)** is an organization-wide quality approach based on participation of all members. The aim is long-term success through customer satisfaction and benefit to all members of the organization and society. TQM requires that the facility maintain its quality standards in all aspects of its business. It also ensures work tasks are performed correctly the first time, and that operational defects and waste are eliminated.

The above are just a few of the formal quality programs used in healthcare. Many facilities develop their own quality program utilizing a combination of several of the above programs. As long as the program works for the facility and emphasizes the main focus of quality patient care, it doesn't matter which program or combinations of programs are used.

Figure 18.7 provides an example of a quality report that identifies the types of instrument errors. **Figure 18.8** provides an example of a report indicating progress in efforts to reduce IUSS.

Quality assurance A comprehensive and measured effort to provide total quality. Also, a technical, statistical sampling method that measures production quality.

Total quality improvement (TQI) The concept of measuring the current output of a process or procedure and then modifying it to increase the output, increase efficiency, and/or increase effectiveness.

Continuous quality improvement (CQI) A scientific approach that applies statistical methods to improve work processes.

Processes (work) A series of work activities which produce a product or service.

Total quality management (TQM) A quality management approach based on participation of all members aimed at long-term success through customer satisfaction and benefits to all members of the organization and society.

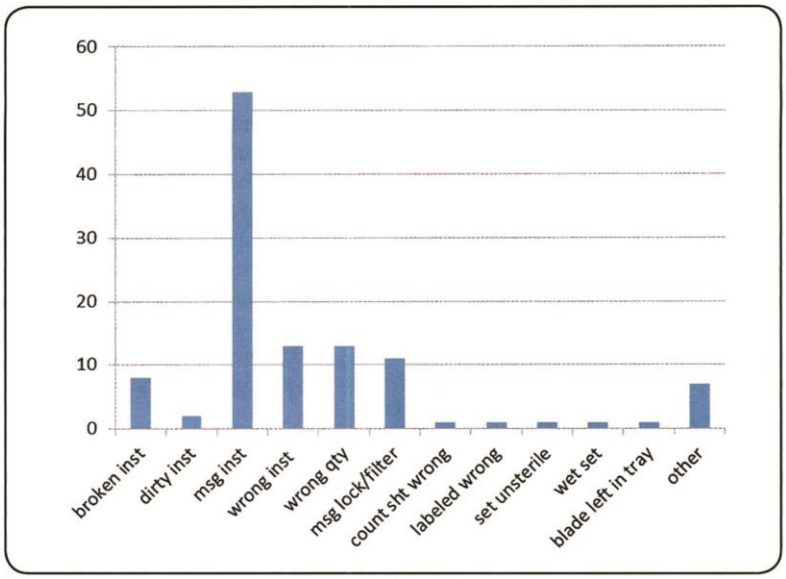

Figure 18.7

CSF - QUALITY
IMMEDIATE USE STEAM STERILIZATION (IUSS)

TOTAL ITEMS

	FY2010	FY 2011	FY 2012	FY 2013	FY 2014
OCTOBER	105	251	27	26	6
NOVEMBER	124	65	42	14	
DECEMBER	134	181	30	14	
JANUARY	80	37	20	4	
FEBRUARY	110	57	31	2	
MARCH	132	203	20	3	
APRIL	140	209	16	4	
MAY	130	90	23	7	
JUNE	195	45	21	3	
JULY	146	33	17	1	
AUGUST	149	69	31	7	
SEPTEMBER	326	79	32	7	
TOTAL	1771	1319	310	92	

This year, our goal for Immediate Use Steam Sterilization (IUSS) is to send **7** or less items out of CSP, unsterile, per month.

We had another great month in reducing immediate sterilization!

This is a great way to increase QUALITY PATIENT CARE!!

Thank you so much!!

Figure 18.8

Six Sigma and Lean Six Sigma

In recent years, healthcare facilities have begun adding **Six Sigma** and Lean Six Sigma programs to their existing quality programs.

Six Sigma

The objective of Six Sigma is to deliver high performance, reliability and value to the end customer. It is a highly disciplined and complex process that focuses on developing and delivering near-perfect products and services in an ongoing quality effort. This process strives to eliminate variations in a product (a tray will look the same each and every time it is assembled, and will look like the same product produced before it), eliminating variations to prevent defects. It focuses on process improvement and variation reduction by use of Six Sigma improvement projects. Two of the processes most used in six sigma are:

- DMADV (define, measure, analyze, design and verify) process is used to develop new processes.
- DMAIC (define, measure, analyze, improve and control) procedures monitor and improve existing processes.

Lean

Lean is a production practice with the key tenet of preserving value with less work (eliminating waste). Eliminating wasteful processes reduces production time and costs.

Lean's strength is its fast implementation. Immediate benefits relate to productivity, error reduction, and customer lead times. Long-term benefits include improvements to financial performance, customer satisfaction and staff morale.

Both Six Sigma and Lean focus on refining the process while reducing defects to an extremely low rate (less than three to four errors per 1,000,000 products produced).

Figure 18.9 provides a comparison of Lean and Six Sigma processes.

Six Sigma A quality process that focuses on developing and delivering near-perfect products and services.

Lean A quality process that focuses on eliminating waste in the production of products.

Lean	Six Sigma
Map out the process. In the case of instrument assembly, each step the instruments take from use to reuse is documented.	Map out the process. In the case of instrument assembly, each step the instruments take from use to reuse is documented.
Refine the process. Identify what steps in the mapped process are not necessary.	Identify the defects; where are the mistakes happening?
Developing the new process, based on the information identified during the refining process.	What is causing these mistakes? Correct the actions that are causing the mistakes.
Try the new process.	Try the new process.
Gather, analyze and document data.	Gather, analyze and document data.
Adjust and refine the process, as necessary.	Adjust and refine the process, as necessary.
Monitor and report data.	Monitor and report data.

Figure 18.9

Quality at Work

Being an active participant in any quality process helps ensure the solutions generated are workable for everyone involved. Whether the activity involves the CS workgroup or a broader, cross-functional team, taking the time to examine processes and identify opportunities for improvement is worthwhile.

The following figures provide examples of some common methods to identify issues and improve quality. **Figure 18.10** illustrates a simple process where representatives from two workgroups, the OR and CS, identified issues with trays sent to CS and the OR. Using a simple problem analysis chart fostered better communication, captured issues and gave the group information to make changes to improve their processes.

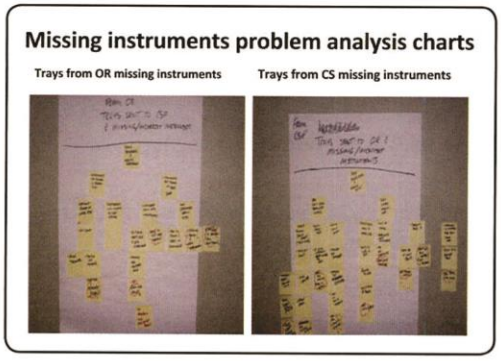

Figure 18.10

Figure 18.11 shows the result of a workgroup's efforts to identify waste in their processes. This information was then used to simplify processes, reduce waste and educate staff.

Figure 18.11

		SPD Labor Hour Needs				Cycle Starts	
		Decontam	Assembly	Sterilize	Total	Washer Loads	Sterilizer Loads
1st Shift	7:00	0.3	0.8	0.1	1.2	0.4	0.2
	8:00	0.2	1.0	0.0	1.2	0.3	0.1
	9:00	0.2	0.7	0.0	0.9	0.3	0.2
	10:00	1.8	0.7	0.0	2.5	3.0	0.1
	11:00	3.0	7.4	0.0	10.4	4.9	0.1
	12:00	4.4	12.0	0.3	16.8	7.3	1.2
	13:00	4.2	17.8	0.5	22.4	6.9	2.0
	14:00	4.1	16.7	0.7	21.5	6.7	2.9

Figure 18.12

CENTRAL STERILE PROCESSING

DATE	FY2010 SETS STERILIZED	FY2010 EQUIPMENT	DATE	FY2011 SETS STERILIZED	FY2011 EQUIPMENT	DATE	FY2012 SETS STERILIZED	FY2012 EQUIPMENT	DATE	FY2013 SETS STERILIZED	FY2013 EQUIPMENT	DATE	FY2014 SETS STERILIZED	FY2014 EQUIPMENT
OCT. 2009	9608	3533	OCT. 2010	9930	4170	OCT. 2011	11883	3873	OCT. 2012	11,775	5,404	OCT. 2013	11,643	6,774
NOV. 2009	8531	3078	NOV. 2010	8941	4003	NOV. 2011	10525	3430	NOV. 2012	10,098	4,813	NOV. 2013		
DEC. 2009	8653	2907	DEC. 2010	8920	4083	DEC. 2011	10947	3388	DEC. 2012	10,242	5,965	DEC. 2013		
JAN. 2010	8480	3374	JAN. 2011	8417	3490	JAN. 2012	10667	2850	JAN. 2013	10,094	6,919	JAN. 2014		
FEB. 2010	8428	2880	FEB. 2011	7820	3255	FEB. 2012	10336	3148	FEB. 2013	9,689	6,157	FEB. 2014		
MAR. 2010	9447	2573	MAR. 2011	9696	3793	MAR. 2012	10999	2813	MAR. 2013	11,066	5,969	MAR. 2014		
APR. 2010	9095	2958	APR. 2011	9712	3297	APR. 2012	9937	2591	APR. 2013	10,517	6,256	APR. 2014		
MAY. 2010	8859	3706	MAY. 2011	9827	2962	MAY. 2012	11153	3163	MAY. 2013	10,088	5,874	MAY. 2014		
JUN. 2010	8890	3609	JUN. 2011	10186	3259	JUN. 2012	10546	4000	JUN. 2013	10,336	6,098	JUN. 2014		
JUL. 2010	8816	3848	JUL. 2011	9991	3674	JUL. 2012	10539	5129	JUL. 2013	9,635	6,635	JUL. 2014		
AUG. 2010	9320	4389	AUG. 2011	11788	3593	AUG. 2012	11783	5287	AUG. 2013	10,339	7,343	AUG. 2014		
SEP. 2010	8869	3960	SEP. 2011	11630	3244	SEP. 2012	10143	4562	SEP. 2013	10,250	7,401	SEP. 2014		
TOTAL	106996	40815		116858	42823		129458	44234		124,129	74,844			

Figure 18.13

Figures 18.12 and **18.13** address labor trends and processing volumes for the CS department. Each provides a tool to address quality issues.

Other Quality Programs and Standards

Quality efforts of healthcare facilities are also impacted by external agencies whose requirements must be addressed. CS technicians should be familiar with the following:

The Joint Commission

TJC is an accreditation organization that ensures quality standards are set, monitored and maintained by member healthcare facilities. It has established many health and safety program requirements for patients and staff using recommended practices and guidelines from agencies and associations, including the Occupational Safety and Health Administration (OSHA) and the Association for the Advancement of Medical Instrumentation (AAMI). Routine and unannounced inspections are used to monitor standards, and each member facility is graded on its performance. TJC requires that any sentinel event be reported and thoroughly investigated to correct the causes.

The Centers for Medicare & Medicaid Services

The Centers for Medicare & Medicaid Services (CMS) is a government agency that focuses on quality in healthcare, as well as patient safety and security. Like TJC, CMS performs announced and unannounced surveys of healthcare facilities to ensure industry standards and regulations are being followed and maintained, and that high quality patient care is the outcome.

National Committee for Quality Assurance

NCQA is a nonprofit organization dedicated to improving healthcare quality. The organization is known for assisting healthcare facilities in identifying how to prioritize quality goals and measure them and promote ongoing improvement.

The Hospital Consumer Assessment of Healthcare Providers and Systems Survey and Value-Based Initiatives

The Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) (pronounced "H-caps") is a standardized survey tool. Hospitals utilize survey results to measure the patient's perception of their experience during their hospital stay. Three broad goals shape HCAHPS:

1. The standardized survey allows meaningful comparisons of hospitals from the patient's perspective.
2. Public reporting of HCAHPS results creates new incentives for hospitals to improve their quality of care
3. Public reporting serves to enhance accountability in healthcare.

The Value-Based Purchasing (VBP) initiatives compare a hospital's HCAHPS scores in a baseline period to those in a later performance period. Healthcare facilities that do not reach HCAHPS goals are penalized through reduced government reimbursement.

Magnet Status

Magnet status is an award given by the American Nurses Credentialing Center to hospitals for quality patient care, nursing excellence and innovations in professional nursing practice.

International Standards Organization

ISO 9000 is an international standard that companies use to ensure their quality system is effective. This process is believed to guarantee that a company consistently delivers quality services and products. While many healthcare organizations have subscribed to ISO standards, few CS departments have applied or qualified for ISO status.

Magnet status An award given by the American Nurses Credentialing Center to hospitals that satisfy factors that measure the strength and quality of nursing care.

ISO 9000 An international standard used by participating organizations to help ensure that quality services and products are consistently delivered.

QUALITY CENTRAL SERVICE PROCEDURES

Attaining and maintaining high quality CS standards is everyone's responsibility. Every technician should play an active role in the department's quality program. It is also each technician's responsibility to help or report others who are struggling with a process. Keeping the patient as the focus means helping ensure everyone is properly trained and performing at optimum levels while working in the department. Allowing a known defective product out of the department is inexcusable and can be very dangerous for patients. There are several tools that can be used by technicians to help ensure quality is always addressed:

- Performing departmental audits of each area of the department on a regular basis helps to keep the department and its functions at optimal levels. Audits can be performed by outside departments, such as Safety or Infection Prevention and Control, or they can be done by the CS staff, or a combination of the above. Technicians are a valuable asset to these audits because they know the environment and processes better than anyone else.
- Following the departmental policies, procedures and processing protocols. These documents were developed to help ensure the safety of all CS department members and ensure that all products produced are of the highest quality. Not following policies, procedures and protocols will result in a

lower-quality product (i.e., missing, incorrect or soiled instruments) which may harm a patient.

- Keeping current with new technology and appropriately sharing what has been learned with co-workers and supervisors. As technology advances, the ability to check work becomes more effective. New products are always being developed to help check for residual blood and protein.Better products are on the market to check for lumen cleanliness, as well as products that help ensure our processing equipment is working properly. As instrumentation becomes more complex, it becomes more important to utilize technology to help ensure quality products are being delivered.

- Taking an active role in quality improvement processes. CS technicians should take an active role in all process improvement projects. Technicians are very familiar with all department activities and can be a vital asset in helping determine problems and how best to resolve them.

- Assuming responsibility for survey readiness. As part of the CS team, each person is responsible for keeping the department ready for TJC and CMS surveys. Cleanliness, following set practices and knowing the required information on safety, disaster and department processes is a year-round practice.

- Adopting a team mentality. Help co-workers and accept help from them. No one is an expert at all processes within the department. Seek help where skills are not as strong and help those who need assistance.

- Attaining CS certification. Certified technicians know why they perform procedures a specific way. This knowledge of the science behind the practices helps ensure practices will be followed correctly, thus helping ensure a quality product.

Quality Assurance

CS professionals are expected to consistently attain desired quality standards as they undertake their normal responsibilities. While this is a difficult goal to attain, it is a necessary one. CS technicians have a significant role to play in implementing quality within their facilities. They can, for example, consistently follow all of the instrument procedures discussed throughout this manual. They do not, however, work by themselves. They are an integral part of the entire healthcare team. To ensure the highest quality of patient care, all staff members must work together. The sum of all contributions by all personnel in all departments represents the facility's accomplishments.

QUALITY IN CENTRAL SERVICE PROCESSING AREAS

There are many quality processes that all CS technicians must consistently practice in their daily routine. This section reviews some of these processes on an area-by-area basis within the department.

Decontamination Area

- Always wear personal protective equipment (PPE) when working in this area to protect oneself, other staff, and patients when leaving the area.

- Disassemble all items, where applicable, to ensure all instrument parts are accessible for cleaning.

- Measure chemicals properly. Improperly measured chemicals are not effective cleaners or disinfectants.

- Load and operate equipment properly. Improperly loaded or operated equipment cannot effectively clean instruments.

- Follow all written procedures for cleaning and disinfection. Ensure that items are cleaned and disinfected according to the manufacturer's Instructions for Use (IFU).

- Check processing equipment before use to ensure that it is in proper working order. Improperly working equipment can harm staff and patients.

Preparation and Packing Areas

- Check for holes in all wrappers and disposable filters to ensure that they are intact before sterilization. Even normal handling can sometimes cause a small percentage of wrappers and filters to become damaged prior to use.
- Never use a wrapper, filter or instrument that has fallen on the floor. If this occurs, instruments should be recleaned, and wrappers and filters should be discarded.
- Use only U.S. Food and Drug Administration-approved wrappers and containers approved for the specific method of sterilization utilized.
- Always follow count sheets. Even if one has extensive experience performing the assigned task, changes may have occurred to a case cart or instrument count sheet. Remember that patient care personnel require the correct supplies when they are needed.
- Check instruments for functionality, cleanliness, alignment, proper assembly and sharpness. Failure to do so could result in patient harm.

Sterilization Area

- Always load sterilizer carts as trained. Improperly loaded carts can result in wet or nonsterile loads.
- Ensure the sterilizer parameters are set properly for the load contents. This should include proper temperature, exposure and dry time.
- Always verify physical and chemical indicators after a sterilization cycle to ensure that the process was properly completed.
- Do not touch sterilized items until cool.
- Properly complete all documentation including load, biological and implant logs.

Storage and Distribution Areas

- Always follow established pick sheets to ensure that all items are picked and delivered.
- Ensure transport and case carts are clean and dry before placing items on or inside them.
- Check product packaging for compromised integrity, expiration dating and appropriate color changes of all indicators.

All Central Service/Distribution Areas

- Pay attention to the job at hand: Excessive visiting or other distractions, like a loud radio, can lead to errors.
- CS professionals should not do anything they have not been trained to do. They must always inform someone when they are asked to perform a process/function in which they lack training.
- If a CS professional is unsure about a completed project, they should ask someone to check their work. This is much better than to have an incomplete or wrong item leave the department.
- If distracted, check the entire project to ensure that it is done correctly.
- If a CS professional can't perform to a 100% level, they should not do the project. Also, they should not start a project if they know someone else will need to finish it.
- Recheck all work. The short time required to do so can eliminate an incident in a patient care area.
- Remember that neatness counts.
- Always help other staff members.

- If something appears wrong, speak up.
- Report inoperative or damaged equipment.
- Attend as many educational inservices, seminars, infection prevention, service technician and vendor-sponsored programs as possible. The more education a CS technician can attain, the better they will become on the job.
- Always follow the established departmental policies, procedures and protocols. They are in place for a reason. which usually is to protect staff and the patients.
- Remember that quality is the responsibility of every employee, and every employee must be involved, motivated and knowledgeable if the CS department is to consistently produce and deliver quality products and services. (See **Figure 18.14**)

CONCLUSION

Quality is everyone's responsibility in the healthcare environment and must remain at the core of Central Service operations. Paying careful attention to all policies, procedures and protocols, actively participating in all quality projects, and helping co-workers are all cornerstones to CS quality.

A team-based approach to quality can provide measurable results that improve patient care and on-the-job satisfaction.

Quality Improvement Results

Measure	Before	After	% Improvement	Lean Tools
Daily capacity and demand	378 trays per day	437 trays per day	14% increase	Visual management layout
Rewashes	96 rewashes per day	34 rewashes per day	64% reduction	Standardized work, visual management
Reduction in walking	30 secs per tray	15 secs per tray	100% reduction	Layout
Receiving errors	14 trays per day	9 trays per day	35% reduction	Standardized work, visual management

Figure 18.14

RESOURCES

Key Elements of Quality: Customer, Process and Employee www.ge.com/sixsigma.

Making Customers Feel Six Sigma Quality. www.ge.com/sixsigma.

Six Sigma: What is Six Sigma? http://isixsigma.com.

CENTRAL SERVICE TERMS

Customer (internal)

Quality

Empowerment

Process improvement

Cross-functional teams

Failure mode and effects analysis (FMEA)

Root cause analysis (RCA)

Sentinel event

Quality assurance

Total quality improvement (TQI)

Continuous quality improvement (CQI)

Processes (work)

Total quality management (TQM)

Six Sigma

Lean

Magnet status

ISO 9000

Chapter 19

Managing Inventory within the Central Service Department

Learning Objectives

As a result of successfully completing this chapter, readers will be able to:

1. Explain the importance of inventory management in the healthcare facility
2. Define the role of Central Service technicians as it relates to inventory management
3. Explain basic inventory terms used in healthcare facilities
4. Explain the cycle of consumable items
5. Discuss the partnership between Central Service and Materiels Management
6. Describe guidelines for handling commercially sterilized packages
7. Describe common inventory replenishment systems:
   - Periodic automatic replenishment-level systems
   - Automated supply replenishment systems
   - Exchange cart systems
   - Requisition systems
   - Case cart systems
   - STAT orders
8. Discuss the role of healthcare facilities in sustainability efforts and the reduction of waste

INTRODUCTION

A patient enters the hospital for a surgical procedure. Throughout the admission process, the patient wonders, "Will the procedure go as planned? Will there be much postoperative pain? How long until I can return home? How long before I able to go back to my normal activities?" The patient does not wonder if the healthcare facility has all the supplies needed for the surgery and postoperative care. The patient trusts that these supplies will be available, and trusts in those supplies availability with his/her life.

Providing procedural support requires a vast amount of instrumentation, supplies and equipment. Every surgery requires both reusable items, such as surgical instruments, as well as disposable (consumable) items, such as suture, bandages, syringes, needles, etc. Failure to provide items needed for patient care and treatment directly impacts patient safety; therefore, inventory management in the healthcare facility is critically important.

It takes a tremendous amount of communication, coordination and planning to ensure that every patient has every item needed for every procedure. In most facilities, purchasing, receiving and distribution of supplies is the responsibility of the Materiels Management department. To ensure that needs are met at all times, the overall inventory management and distribution process requires input from users and from dispensing areas like Central Service (CS). CS technicians play an important role in inventory management due to the large number of inventory items that pass through the CS department.

Inventory items that arrive in the CS department can be classified under two basic categories: **operational supplies** and **patient care supplies**. Operational supplies are defined as items needed for the CS department to operate effectively. Examples include detergents, sterilization wrap and sterilization testing products. Patient care supplies are defined as supplies that will be dispensed for patient treatment and care. Examples include: catheters, implants and bandages. **Figure 19.1** provides examples of products in basic CS inventory categories.

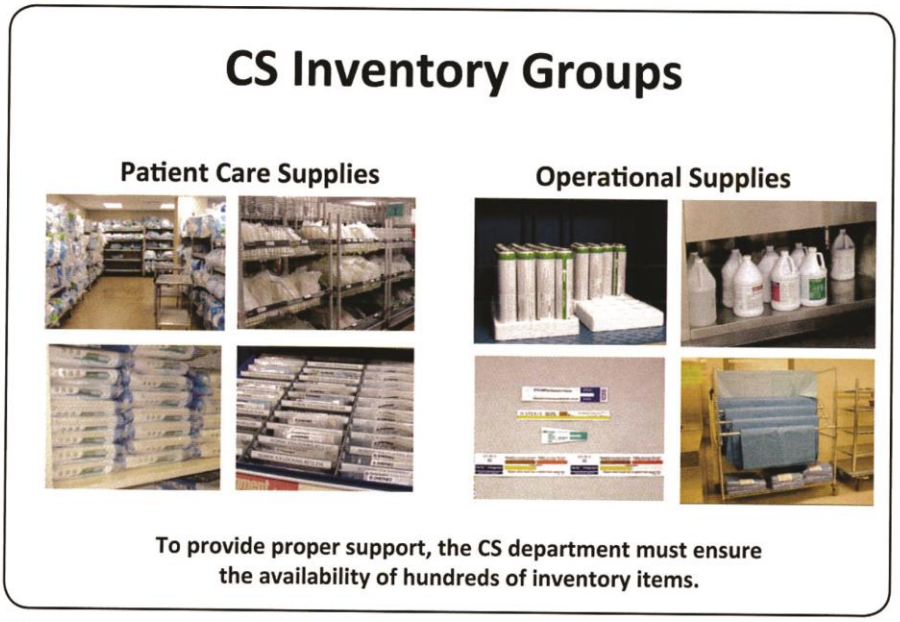

Figure 19.1

Both supply categories are very important to patient care. It is easy to see how a shortage of patient care supplies would impact patient care; however, it is also important to realize that a shortage of operational supplies would also impact patient care. Imagine trying to provide clean and sterile instruments without detergents or sterilization wrap.

Operational supplies Supplies needed for the operation of the CS department. Examples include detergents, sterilization wrap, sterilization testing products, etc.

Patient care supplies Supplies dispensed for patient treatment and care. Examples include catheters, implants, bandages, etc.

As discussed in Chapter 1, the scope of service (responsibilities) of CS departments varies. Some departments provide supplies for the entire facility. Other CS departments may only provide supplies for surgery. Regardless of the department's scope of service, all CS technicians are involved in the inventory management process in some way.

Case cart technicians work with consumable inventory supplies dispensed for each procedure. Decontamination technicians must ensure they have an adequate stock of personal protective equipment and an adequate supply of detergents, disinfectants, brushes and other decontamination supplies. Instrument assembly technicians must ensure that they have an adequate supply of packaging materials, chemical indicators, package closure supplies and other assembly supplies. In some cases, they may need to ensure they have replacement components, such as screws, plates, and pins for implant trays. Sterilizer operators must make certain they have sterility assurance tests, such as biological indicators and Bowie-Dick tests. For some types of sterilizers, they must maintain an adequate supply of the sterilant.

Managing Inventory within the Central Service Department

WHAT IS INVENTORY?

The term **inventory** has a broad meaning in healthcare facilities. It refers to both **reusable** and **consumable** items. Before beginning a discussion about inventory, it is important to become familiar with some key terms and concepts.

There are three specific types of inventory in the CS department:

- Consumable inventory items include supplies, such as detergents, disposable wraps and sterility assurance products.
- Reusable inventory items (with a lower cost) include items, such as transport carts, rigid sterilization containers, and many instruments.
- Reusable inventory items (with a higher cost) include items such as mechanical washers and sterilizers. In the healthcare facility, high cost, reusable inventory items are called **capital equipment**.

Consumable items and both higher- and lower-cost reusable items are considered **assets**. They represent a significant financial investment by the healthcare facility and must be managed in a way that enables the facility to get the most benefit from them at the lowest cost possible.

Consumable inventory has a specific life cycle. It is purchased, stored until use, used and replaced. (See **Figure 19.2**)

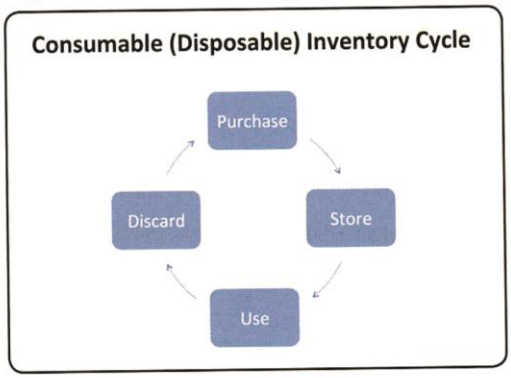

Figure 19.2

This chapter will focus on the management of consumable assets as they relate to the CS department.

Inventory Reusable equipment and consumable items used to provide healthcare services for patients.

Reusable (inventory) Relatively inexpensive assets, such as medical devices and sterilization containers, that can be reused as healthcare services are provided to patients.

Consumable (inventory) Assets, such as wrapping supplies, processing chemicals, and other items that are consumed (used up) as healthcare services are provided to patients.

Capital equipment Relatively expensive assets, such as sterilizers or washers, that require significant advance planning for their purchase.

Assets Something of value that is owned by an organization or person.

WHERE DOES INVENTORY COME FROM?

Every healthcare facility has hundreds and oftentimes thousands of items in its inventory. Each item serves a specific purpose. Some inventory items are used regularly, such as detergents for the decontamination area. Others, like certain specialty catheters, are used less often, but must always be available when needed. Unavailability of certain items may compromise patient safety by delaying treatment or care. All of these items represent a financial investment and must be managed properly to keep costs down. Managing inventory is one of the primary responsibilities of the Materiels Management department.

Material or Materiel?

The words "Material" and "Materiel" are often interchanged; however, they do have different meanings.

"Material," when used as a noun, refers to the elements, substances or parts that comprise something. (e.g., building materials, such a bricks, lumber and nails.

"Materiel," when used as a noun, refers to supplies or equipment that an organization uses in any operation of business.

The Materiels Management department is responsible for the purchase, receipt and delivery of items to user departments. It oversees the flow of supplies and equipment coming into the healthcare facility. Buyers in the Materiels Management department search for and procure (purchase) items using a variety of tools and strategies to ensure they are able to meet the facility's needs at the lowest possible cost.

Most health systems belong to purchasing groups that enable them to purchase items at pre-negotiated discount pricing. These group purchasing organizations (GPOs) represent many healthcare facilities. GPOs are able to negotiate contracts for products and services that enable facilities (members of the GPO) to receive special, reduced pricing.

Materiels Management plays an important role in the supply chain by helping ensure that everything necessary to support patient care is available when needed.

Once items are received at the healthcare facility, they are checked in to verify that what was ordered was received. From there, items are placed into storage. In most facilities, a large portion of inventory items are stored in the Materiels department. Then, items are delivered to various areas, as needed. **Figure 19.3** reviews the four steps in the flow of materiels through the healthcare facility.

HANDLING COMMERCIALLY-STERILIZED ITEMS

When commercially-sterilized items are brought into a healthcare facility, care must be taken to ensure that those items are not compromised during storage, handling and distribution. That means that those items must be stored in a manner that will protect each package from events that may render it unsterile.

Chapter 16 identified requirements for sterile storage. It is important to note that those same requirements apply to all sterile packages. Although the types of packaging may differ in appearance

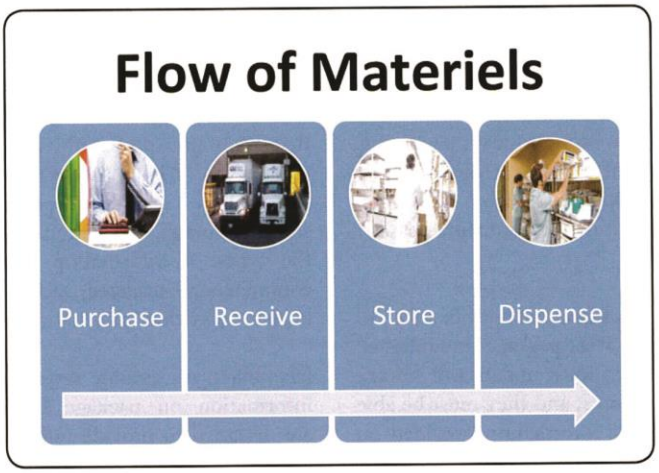

Figure 19.3

Important Information Provided on Package Labels

Category	Type of information	Why it is important
Manufacturer information	1. Manufacturer's name 2. Product name and specifics (size, etc.) 3. Product reference number 4. Date of manufacture 5. Batch (or lot) number 6. Product serial number 7. Expiration information	**#1-#3** Important for: • Reordering purposes • Verifying that the correct product is being dispensed **#4-7** Important for: • Tracking product to patient • Product recalls • Stock rotation
Sterility information	1. Sterility statement 2. Expiration date	**#1** Important for: • Determining if a product was supplied sterile **#2** Important for: • Determining the shelf life of the product
Storage information	1. Storage temperature limits 2. Moisture or humidity limits 3. Fragility	**#1-#3** Important for: • Ensuring that items are stored as required by the manufacturer
Safe use instructions	1. Identification of single-use items 2. Notification of latex contents 3. References to product instructions for use	**#1** Important for: • Ensuring single-use items are not processed **#2-#3** Important for: • Providing patient safety information

Figure 19.4

and feel, commercially-sterilized packages are vulnerable to the same potential contaminants as in-house sterilized items. Items should be stored in a clean area — away from moisture, dust and other contaminants that can compromise packaging. Dust on the outside of a package can be easily transferred into the Operating Room (OR) and introduced into that clean environment, possibly contaminating it.

As with every sterile package, care must be taken to ensure that the integrity of the package is maintained until use. CS technicians must understand storage and handling requirements, and they must be able to understand the basic information provided on each commercially-sterilized package.

Commercially-Sterilized Package Information

Unlike in-house sterilized items, commercially-sterilized packages come with printed instructions that contain pertinent information for CS technicians. Most product packaging contains information regarding product manufacturer, sterility, storage, and safe use. **Figure 19.4** reviews the types of information commonly found on commercially-sterilized packages and labels, and explains why that information is important to CS.

Manufacturers employ several symbols to convey information on package labels. Those symbols are designed to provide information that is easily understandable in the usually small space of a product label. **Figure 19.5** provides a review of common commercially-sterilized symbols and their meanings.

Symbol	Meaning	Symbol	Meaning
REF	Reference number (catalog number)	LOT	Lot number (batch code)
SN	Product serial number	2005-01	Date of manufacture
2009-01	Use by date	CE	The CE mark is an identification mark that indicates that a product has complied with the health and safety requirements, as published by European directives.
	Do not reuse		Attention; see instructions

Figure 19.5

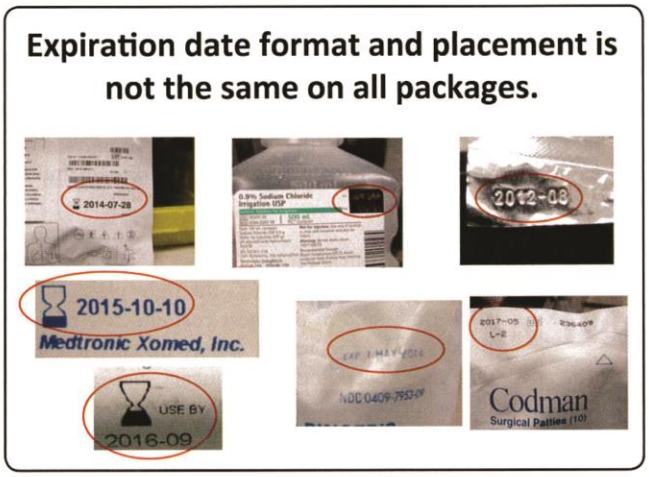

Figure 19.6

Figure 19.7

Expiration Dates

Many medical products on the market today have expiration dates and these are very important for CS technicians. It is important to note that even if a healthcare facility uses an event-related shelf life policy, expiration dates on medical products must be checked and items that have reached the end of their stated shelf life must not be used.

Identifying expiration dates can be difficult because there is no standard requirement for where they are placed on a package. For that reason, CS technicians must be diligent when checking packages for expiration dates. When new products that have expiration dates are received, all staff handling the packages should be educated on the existence and location of the expiration information. **Figure 19.6** provides examples of locations of expiration date information on commercially-sterilized packages.

Not all packages have an expiration date. Some products use an event-related shelf life system. Those packages will have a statement indicating that the package is sterile, unless opened or damaged. In a storage area filled with commercially-sterilized items, there will most likely be a combination of items with expiration dates and items with event-related sterility statements. It is important to know which items have expiration dates, and to check those dates each time a package is dispensed.

Inspection

Regardless of whether an item uses event-related or date-related shelf life, it must be inspected before being dispensed. That inspection is part of a multi-check safeguard. While it is true that the package will be inspected at the point of use, CS can reduce delays by identifying package integrity issues before they reach the point of use.

Inspections should include a visual check to ensure that the packaging has no holes, tears, signs of moisture or other visible damage. Packages that show excessive handling (wear) should also be identified. Expiration dates (if present) should be checked. **Figure 19.7** shows a CS technician checking a package before dispensing it.

ITEM LOCATOR SYSTEMS

Every healthcare facility has hundreds and, perhaps, thousands of medical supplies. Each one can impact patient safety if it cannot be located when needed. Poorly-organized storage can also lead to loss or damage, which can impact a facility's budget.

Every medical supply storage system must have a system in place that enables all employees who handle supplies to locate a specific product quickly. Systems usually use an alpha, numeric or alpha/numeric system to enable employees to easily locate supplies.

LOSS OF STERILE ITEMS

Ideally, disposable items are purchased, used and replaced; however, there are times when a disposable item may fall out of that sequence. When that happens, the item is lost, which may delay patient care and treatment and cost the facility money for replacement. **Figure 19.8** lists some common causes for the loss of sterile items.

Common Causes of Waste (Loss)

Expiration	The item was not used before the end of its designated shelf life.
Contamination	The item suffered an event that rendered it unusable.
Obsolescence	The item was replaced by a newer, different item.
Loss	The item was lost and cannot be located.
Theft	The item was taken by an unauthorized individual.

Figure 19.8

Each of the above examples represents a financial loss to the healthcare facility.

TRANSPORT OF COMMERCIALLY-STERILIZED PACKAGES

Equipment, such as carts and totes used to transport devices/supplies, must be frequently cleaned. Items that are to be transported outside the facility must be contained in appropriate containment devices, as they are transported. These transport devices must be cleaned routinely to ensure that bioburden is removed.

Care should be taken to protect packages from contamination during transport. Items should not be exposed to conditions that may compromise the sterility of the package, such as excessive temperatures, humidity or moisture.

DISTRIBUTION OF SUPPLIES

Distribution involves moving supplies throughout the facility, generally from their storage location to the point of use. In most facilities, this activity includes distributing consumable supplies from the storeroom or CS to clinical units, including the OR.

The goal of distribution is to move the correct items in appropriate quantities to the right places at the right times and in the most cost effective manner possible. The method of supply distribution used will vary depending on frequency and/or volume of use, peak activity times, the amount of storage space available in the areas to which the supplies are distributed, and other factors. For that reason, it is important to note that no single distribution method is the best choice for all facilities. Each healthcare facility will need to assess its particular needs and develop a system that will best suit those needs. In most cases, many different methods of distribution will be used to meet the needs of different departments.

Distribution The movement of supplies (primarily consumable supplies from the storeroom to clinical units, and processed supplies from Central Service to the Operating Room) throughout the facility.

Carts and Totes used to Transport Sterile Items Must be Kept Clean.

Figure 19.9

Inventory Replenishment and Distribution Systems

The method(s) used to replenish needed consumable supplies throughout the healthcare facility must be carefully considered and planned to best manage

costs, to have items available when needed and to minimize the supply efforts of responsible staff members. Effective systems are, to the extent possible, automatic (little or no intervention by the user or user department is necessary to reorder).

The following are examples of inventory replenishment and distribution systems commonly used in healthcare facilities:

Periodic Automated Replenishment Level Systems

Periodic automated replenishment (PAR) systems establish a standard level (PAR) for each supply item stored in a specific department. This level is usually jointly determined by the user department and Materiel Management staff. After these levels are set, there is typically no need for items to be ordered by clinicians. Instead, CS/Materiel Management (CS/MM) personnel inventory (count) each area that houses inventory. They check the current on-hand supply and note the quantity of each item still available. The amount needed to bring the quantity of supplies to the agreed-upon standard (PAR level) is determined and automatically transmitted to the Materiel Management department (or vendor) who will send the required supplies. **Figure 19.10** shows checking and restocking PAR levels on a shelf.

Periodic automatic replenishment (often called PAR level or PAR system) An inventory replenishment system in which the desired amount of products that should be on hand is established, and inventory replenishment returns the quantity of products to this level.

Figure 19.10

Managing Inventory within the Central Service Department

Automated Supply Replenishment Systems

Automated supply replenishment systems use a computerized system to gather and track the issuing of patient items. PAR and reorder levels for each item are established. Clinical staff scan or push a button to account for each item removed from the inventory location. An order is generated at a scheduled time for all items that are at or below their reorder point, and the order for the entire location is then placed. The supply pick list is printed and is used to gather replacement products to refill the unit.

Automated systems are generally **interfaced** with the healthcare facility's Materiels Management system for managing inventory. The use of these interfaces reduces the amount of staff required to perform these functions.

Automated supply replenishment system Replenishment system in which items removed from inventory are automatically identified and tracked. When a reorder point is reached, item information is generated on a supply pick list in the central storeroom, or with a contracted vendor. Items are then issued and transferred to the appropriate user area.

Interfaced An area or system through which one machine is connected to another machine in order to share information. For example, two computers may be interfaced, or a computer and a sterilizer may be interfaced.

Benefits of automated systems relate to the facility's size and the number of items being monitored. These systems are expensive and may not be cost justified for all or some of the remote storage locations. **Figure 19.11** provides examples of equipment used in an automated system.

Examples of Automated Replenishment Systems

Figure 19.11

Exchange Cart Systems

An **exchange cart system** is an inventory replenishment method that involves the exchange of a freshly-filled supply cart on a user unit. Supply items and quantities on the exchange cart, as well as its location, are determined by user unit staff and CS/MM personnel. At a pre-determined time, a full cart is brought to the unit. The partially-depleted cart is returned to the replenishment area, and remaining items are inventoried to determine the supplies and quantities that were used. The cart is then replenished with the supplies needed to return the cart back to full inventory. As supplies are removed from inventory and added to the cart, they are charged to the budget of the unit that "owns" the cart. At the scheduled time, this full cart is delivered to the unit, the depleted cart is retrieved for restocking, and the cycle repeats. **Figure 19.12** provides an example of exchange carts that are designed to stock anesthesia supplies.

Figure 19.12

An advantage of an exchange cart system is that it is "automatic" unless there is a need to change the cart's items or quantities. Clinical staff do not need to order these items, and Materiel Management staff does not have to determine which supplies are needed.

Disadvantages associated with exchange carts include the need for duplicate inventory and carts. The system is labor-intensive and requires adequate space to stage the carts. In addition, unless the system is well-managed, numerous unused supplies will be transported back and forth each cycle. This system does work well for emergency medical supply carts (code carts), which are exchanged for a newly-restocked cart each time they are used. (See **Figure 19.13**)

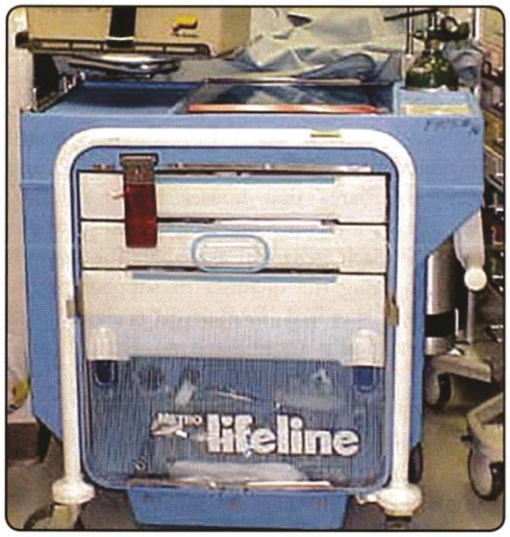

Figure 19.13

Exchange cart system An inventory system where desired inventory items are placed on a cart assigned a specific location and quantity. A second duplicate cart is maintained in another location and exchanged on a scheduled basis to ensure that sufficient supplies are available at all times.

Requisition Systems

Even when PAR level or exchange cart systems exist, it will still be necessary to order additional supplies. That usually happens because of insufficient quantities on hand or because a

specific item is not included among those routinely provided. **Requisition systems** exist in every facility.

Requisition systems require users to request (order) needed supplies by completing a requisition. Requisitions may be manual (paper based) or computer generated. Manual systems do not offer the productivity advantages of computerized systems. Requisition systems that electronically requisition supplies typically eliminate the need for Materiels Management personnel to re-enter ordering information from a paper order form. The accuracy and productivity improvements associated with automated data entry are lost when manual requisition systems are used. **Figure 19.14** provides an example of a technician completing a requisition for special order catheters.

Figure 19.14

Requisition system A method of inventory distribution where items needed are requested (requisitioned) by user department personnel and removed from a central storage location for transport to the user department.

Specialty Items

Every facility has a need for patient-specific and infrequently ordered specialty items that are not maintained in the routine replenishment system. CS technicians must understand the requisition, ordering, tracking and replenishment processes used by their facility for these items. If a patient is scheduled for surgery and a specialty item is needed, it may need to be ordered several days before surgery to ensure that it is available. If an item is not available when needed, patient safety may be compromised.

Managing Inventory within the Central Service Department

Case Cart System

Perhaps the most common form of inventory management and distribution in the CS department is the case cart system. In a case cart system, items needed for each specific procedure are assembled in individual carts by CS staff and delivered to the department where the procedure will be performed. There are several benefits to case cart systems, including:

- Reducing the amount of space needed for supply storage in the user department.
- Promoting more standardized infection prevention practices.
- Reducing operational costs associated with supply and instrument management.
- Allowing more efficient equipment and supply tracking.

Case cart systems range from those providing disposable supplies or instruments for each procedure to comprehensive systems, which provide each case's instrument, supply, equipment, and implant needs. While they are most commonly used for the OR, case cart systems can be used anywhere that procedures requiring supplies and instruments are performed, including Cardiac Catheterization labs and Labor & Delivery (L&D) units. When implemented correctly, these systems help to meet the needs of each physician and still maintain an orderly system for tracking and handling supplies, instruments and equipment.

In a case cart system, specific needs for each procedure are identified by users. These needs are compiled on a requisition form called a preference card (or pick list). The preference card usually contains two components: the first is a list of instruments, supplies and implants needed for the specific procedure; the second component contains notes that are helpful to the procedure room staff.

When a procedure is scheduled, a copy of the list of needed items is sent to CS, and the case cart is assembled. (**See Figure 19.15**) That case cart

is delivered to the OR (or other user unit) before the procedure. Additional unanticipated needs are communicated to CS, as necessary, and CS responds to those additional requests.

Figure 19.15

Following the procedure unused, unopened (clean and sterile) items are returned to storage; waste is separated, bagged and removed; reusable linens (if used) are bagged; and all opened and soiled instruments are sent to the decontamination area for processing. This process is repeated multiple times throughout the day as additional procedures are performed. (See **Figure 19.16**)

Case cart systems can also provide effective control of supplies and instruments. Because a separate case cart is assembled for each individual procedure, it is easier to track what is actually used, and identify supplies and instruments that are often requested, but seldom used. Quantities of supplies can then be reduced, which can reduce the amount of inventory that must be on hand. Close monitoring of instrument usage allows the facility to shift instruments not being used to other areas where they are needed. Monitoring can also identify instrument shortages, which may be addressed with scheduling changes and/or the purchase of additional instrumentation.

Case cart systems enhance infection prevention practices. Because all instruments are returned to the decontamination area immediately after use, decontamination and sterilization processes can begin immediately. CS technicians assigned to processing in a case cart system devote most of their time and efforts to preparing items for reuse. That is their primary job function, so they become specialists in cleaning, inspecting, assembling and sterilizing complex instruments. This expertise yields better infection prevention practices.

Case cart systems rely on user input to be effective. Physicians and other healthcare personnel utilizing

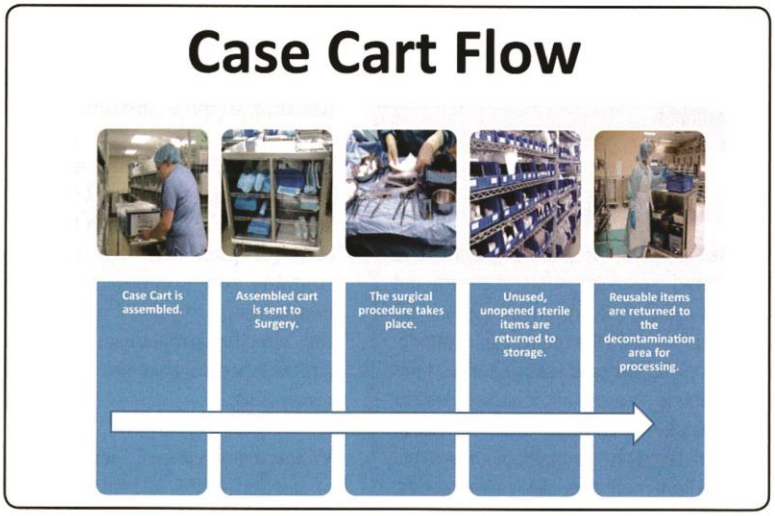

Figure 19.16

the case cart must identify their specific needs in advance. These needs are then transferred to pick lists that CS staff use to assemble each cart. Care should be taken when developing requisitions to ensure that products are standardized, whenever possible. Routine follow up is needed to adjust requisition quantities to actual usage. Properly stocked case carts should be delivered to the user unit. Personnel assigned to the case cart area must maintain direct contact with unit staff, so additional items can be supplied as needed. After the procedure is completed, used and reprocessable items must be returned to the decontamination area. CS technicians should return uncompromised items to stock and then proceed with inventory replenishment and charging activities.

While case cart systems typically use carts assembled as needed for specific procedures, most systems also utilize some form of preassembled carts that remain assembled and "on standby" for emergency situations. These carts are used for STAT situations (for example, emergency cesarean sections) when there is no time for cart assembly.

An effective case cart system requires good communication between OR and CS personnel. As cases are performed, CS and OR staff must be in constant communication to ensure that items are correct and arrive on time. Personnel in each department must be familiar with one another's routine duties and workflow patterns. Frustration can be eliminated if, for example, OR personnel understand the steps involved in processing instruments for another case. Instead of questioning instrument turnaround times, they will understand that this time is required for safe, effective cleaning, inspection, assembly and sterilization.

CS technicians working with case cart systems should have good medical terminology skills and a thorough understanding of surgical instruments, so they can easily communicate with their OR counterparts. They must also remain up to date about new products because they serve as the link between the inventory system and the user department. Along with effective oral communication skills, case cart systems rely heavily on written procedures and communications. Personnel from all user departments must establish procedures for product handling, outage notification and scheduling. Even the best-planned case cart system will be substandard without good communication.

Case cart systems also require upkeep. As instruments and supplies are added to or removed from the system, physician's preference cards must be updated to reflect changes in the system. (See **Figure 19.17**) Failure to update preference cards to reflect current needs can result in unavailability of supplies and instruments, which can then lead to compromised patient safety and user frustration.

Case cart systems require significant input from CS professionals, and to be efficient, they require a full array of processing skills and inventory management methods.

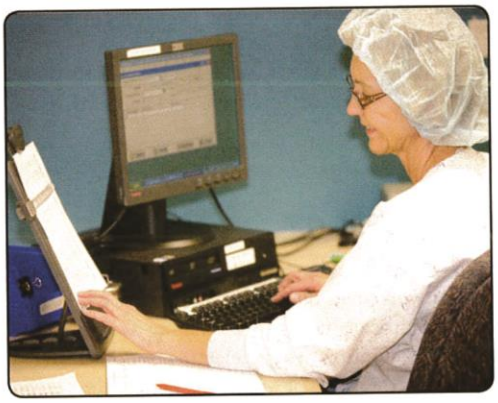

Figure 19.17

STAT Orders

Emergency supply orders requiring immediate action (STAT orders) are a fact of life in every facility. STAT orders can also occur for a procedure scheduled for the next day, if the item is not available. These orders are time consuming and costly to fill, and they usually disrupt routine inventory management activities. Consider, for example, times when additional external resources, such as overnight air shipments or borrowing from

another facility may be required. All reasonable efforts to minimize the need for STAT requests should be made; these include reviewing why they occur, and how they can be prevented.

Many STAT requests result from deficiencies in a poorly-managed daily supply and distribution system. STAT requests can become a patient safety issue if the root cause is not addressed, and routine reviews may determine if PAR level adjustments will help ensure appropriate inventory levels. When STAT requests result from improper planning by clinical staff, Materiel Management and CS managers should assist in the planning and education efforts to resolve the issue. While OR staff cannot predict that an emergency patient will require a specific **non-stock item**, they may be able to plan for such a need and ensure that the item is available.

Non-stock items Items that are not carried in the central storeroom or in Central Service storage area but are purchased from an outside vendor, as needed, and then delivered to the requesting department.

SUSTAINABILITY

The Materiels Management department is also often involved in **sustainability** efforts. More and more healthcare facilities are taking sustainability into consideration when selecting supplies. Items that can be recycled or otherwise help reduce waste can benefit patients, healthcare facilities and the environment.

Many facilities are moving toward systems that allow them to reduce the amount of waste being generated. CS departments may be involved in those efforts. (See **Figure 19.18**)

Sustainability Processes designed to reduce harm to the environment or deplete natural resources, thereby supporting long-term ecological balance.

Figure 19.18

THE ROLE OF CENTRAL SERVICE IN INVENTORY MANAGEMENT

Although the primary responsibilities of procurement, receiving, storage and distribution may be performed outside the CS department, CS technicians still play an important role in the healthcare facility's inventory management system. CS technicians are responsible for several key duties, including:

- Learning processes at their specific healthcare facility, such as:
  - › How orders are placed.
  - › How to identify items.
  - › How to locate items.
  - › How to properly dispense items.
- Knowing how to stay informed of new products as they enter the system.

- Understanding and following information contained on commercially-sterilized packages.
- Handling sterile products with care.
- Reporting concerns, such as:
  - › Excessive, unexpected demand on specific products.
  - › Low quantities.
  - › Frequent outages.
  - › Storage issues.

Each step in the life cycle of a sterile medical supply is an important one. Through keen observation and best work practices, CS technicians can protect the integrity of products until they reach their point of use.

CONCLUSION

Inventory management is an important part of every healthcare facility. Managing inventory effectively and efficiently assists caregivers in providing quality care at lower costs. More importantly, it helps ensure that the items needed to provide patient care and treatment are available when needed.

When Central Service and Materiel Management staff work together to manage and control inventory, they help create a safe environment for the patient, while increasing provider and patient satisfaction.

Managing Inventory within the Central Service Department

RESOURCE

International Central Service Materiel Management. *Central Service Leadership Manual*, Chapters 9, 23, 24. 2010.

CENTRAL SERVICE TERMS

Operational supplies

Patient care supplies

Inventory

Reusable inventory

Consumable inventory

Capital equipment

Assets

Distribution

Periodic automatic replenishment (PAR)

Automated supply replenishment system

Interfaced

Exchange cart system

Requisition system

Non-stock items

Sustainability

Chapter 20

The Role of Central Service in Ancillary Department Support

Learning Objectives

As a result of successfully completing this chapter, readers will be able to:

1. Discuss the role of the Central Service department in supporting ancillary departments
2. Discuss strategies for managing patient care equipment
3. Explain the importance of communication and coordination as it relates to ancillary support

INTRODUCTION

While the Operating Room (OR) is the Central Service (CS) department's largest customer, it is by no means its only customer. CS departments provide support for other areas of the healthcare facility by providing instruments, disposable supplies and equipment. Providing service to diverse departments and ensuring they have all the proper items when needed can be challenging. This chapter will focus on common support services provided by CS departments.

IDENTIFYING THE CENTRAL SERVICE DEPARTMENT'S SCOPE OF SERVICE

The level of service provided by the CS department varies by healthcare facility. In some facilities, the services provided by CS are limited to servicing the needs of the OR, and providing reprocessing and sterilization services for instruments used in other departments. In other facilities, the CS department may be responsible for providing sterile instruments, equipment and supplies to healthcare units throughout the facility. CS departments that provide services to areas outside of the OR must ensure that they develop a system that meets the needs of all patients and providers in the safest, most timely and cost-effective manner possible.

PATIENT CARE EQUIPMENT

Along with instruments and supplies, CS departments manage a large portion of the healthcare facility's patient care equipment. Tasks include assembly, delivery, tracking, retrieval, decontamination and storage. Effective handling of this equipment is an important part of the CS department's job. Managing it properly can have a significant impact on patient safety.

Patient care equipment must be readily available when needed. This requires that it be safe, functional, ready to use and free from soil and contaminants. CS technicians are responsible for ensuring that these requirements are met. They must also manage equipment in a manner that minimizes costs to the healthcare facility. An effective patient care equipment management program is essential for managing these costs.

Specific guidelines should be developed for the cleaning, preparation and tracking of patient care equipment. Failure to properly manage equipment can have a dramatic impact on patient and employee safety. Equipment that has not been properly cleaned poses an infection threat to patients and healthcare workers. That threat is magnified because the equipment may be handled by several workers during the course of preparation, storage and distribution. If it is not properly assembled and ready for use, there may be a delay in treatment if staff must obtain necessary components, such as tubing, collection devices and pads. Equipment that is not accurately tracked can be "lost" within the system. This inavailability may cause treatment delay or add unnecessary expense if it becomes necessary to rent additional equipment to replace the missing equipment.

Patient care equipment Portable (mobile) equipment used to assist in the care and treatment of patients. Examples include: suction units, temperature management units, infusion therapy devices, etc.

There are numerous types of patient care equipment in healthcare today. Some general device categories include infusion therapy, temperature management, wound care and suction. Examples of specialized categories include equipment used for maternal and infant care, bariatric care, patient monitoring, specialty surfaces and beds. Many devices are cleaned, tracked and dispensed through CS. Specific types, models and brands will vary from facility to facility.

Basic Types of Patient Care Equipment

Understanding the purpose of basic types of patient care equipment can improve customer service. **Figure 20.1** identifies and defines some of this equipment that is typically handled by CS professionals. CS technicians must also understand requirements for cleaning, inspecting, preparing, storing, dispensing and tracking patient care equipment. Each step in the patient care equipment process is an important component of a comprehensive patient care equipment program.

Equipment	Purpose
Breast pump	Mechanical device that extracts and collects milk from the breast.
Continuous passive motion (CPM) device	Device that treats synovial joints (hip, knee, ankle, shoulder, elbow, wrist) following surgery or trauma. The device moves the affected joint regularly, without patient assistance.
Defibrillator	A device that applies a brief electroshock to restore the rhythm of the heart.
Enteral nutrition (infusion) pump (also called a feeding pump)	A device that provides nutrition to patients who cannot ingest food because of recent surgery, or because digestive organs do not function properly.
Foot pump	A device that artificially stimulates the venous plantar plexus (the large vein located in the foot). It increases blood circulation in bed-ridden patients by simulating the motion produced during walking.
Gastric suction unit	A device that aspirates (withdraws) gastric and intestinal contents.
Hot and cold therapy devices	A device used to reduce swelling, pain and muscle cramps. Also used to treat arthritis, pyrogenic infection and gastrointestinal cramps. Depending on the required therapy, water is cooled or heated and then runs through a disposable pad, which is wrapped around the area being treated. Smaller (heat-only) devices similar to electric heating pads are used on sore muscles.
Hyper/Hypothermia unit	A device that pumps heated or cooled water through a coiled pad to therapeutically raise or lower body temperature. *Note: These pads are much larger than hot or cold therapy device pads.*
Infant incubator	A device that creates and controls the environment (temperature and humidity) of newborns.
IV infusion pump	A device that mechanically controls the administration of intravenous (IV) therapy fluids.
Intermittent suction device	A device that starts and stops suctioning at periodic intervals.
Microdrip pump	Intravenous infusion pump with a drop control that emits a drop that is smaller than a normal drop.
Oral suction device	A device that suctions mucous from oral and nasal cavities.
Patient-controlled analgesia (PCA) pump	A device designed to provide automatic (self) administration of pain medication.
Sequential compression device (SCD)	A device designed to limit the development of deep vein thrombosis (DVT) and peripheral edema in immobile patients.
Suction pump	A device that provides suction by altering the expansion and contraction of air within a cylinder at regular intervals. Also known as aspirators, they use a continuous or intermittent pump and a collection container to aspirate (withdraw fluids or air from a cavity) in patients with lung or throat problems. They can also be used to provide wound drainage, usually from the chest or abdominal areas.
Portable suction unit	A mechanical suction device powered by battery or electrical current, used in various facility locations.
Wall suction unit	A mechanical suction device that must be attached to a wall suction (outlet) for power.
Wound VAC therapy	A device that provides negative pressure wound therapy by using controlled suction to close large wounds and promote faster healing.

Figure 20.1 Patient care equipment

A Close Look at Responsibilities

CS departments maintain the flow of the patient equipment system. They also partner with the **Biomedical/Clinical Engineering department** (Biomed). Technicians in the Biomedical/Clinical Engineering department perform safety inspections and function tests on medical equipment. They are specially trained to inspect, test and repair patient care equipment. CS technicians should not attempt to perform equipment testing and maintenance functions, unless they have received specific training and approval to do so. Biomedical technicians must also not clean used equipment, unless they have been properly trained.

When equipment enters a healthcare facility, it must be safety checked and tested by a Biomedical technician before being cleared for patient use. These items must also receive periodic follow-up inspections, scheduled according to the equipment manufacturer's Instructions for Use (IFU) and the healthcare facility's policies. Biomedical professionals maintain complete records about routine checks, repairs and other important information for all patient care equipment in the facility.

Biomedical/Clinical Engineering department The hospital department responsible for performing safety inspections and function tests on medical equipment. It is frequently abbreviated to "Biomed department" and is also known as the Healthcare Technology Management department.

The Joint Commission (TJC) requires that **preventive maintenance** (PM) standards be established for healthcare equipment. The following information should be recorded and maintained for each piece of patient care equipment:

- Assigned equipment location.
- Ownership status (rented, leased, owned, borrowed).
- Schedule for PM.
- PM history.
- Hospital-defined PM standards.
- Repair history.

Preventive maintenance (PM) Service provided to equipment to maintain its proper operating condition by providing planned inspection, and by detecting and correcting failures before they occur.

CS and the Biomedical department partner in several ways. Each time patient care equipment is returned to the CS for cleaning, its preventive maintenance sticker should be checked. Items due for a preventive maintenance inspection should be routed to the Biomedical department, rather than be returned to service. (**Figure 20.2** is an example of a PM sticker.) As part of their routine inspection process, CS technicians should also check for damaged (cracked, torn or frayed) electrical cords, cracked equipment casings, loose knobs and switches, and other signs of damage that should be corrected before the item is reused. All equipment that appears to need repair should also be routed to Biomedical personnel for inspection. Equipment-related issues can be minimized when all staff remain alert to obvious signs of the need for equipment inspection and/or repair. This, in turn, increases the level of patient and employee safety.

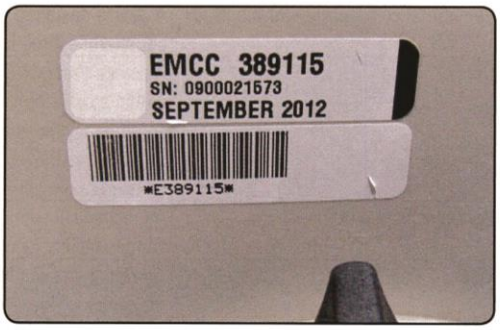

Figure 20.2

Handling Used (Soiled) Patient Care Equipment

All patient care equipment used must be considered contaminated and handled as such, regardless of its appearance. *Note: Patient care equipment may not be visibly soiled and may appear clean; however, it is likely to harbor microorganisms that may pose a threat to patients and staff.* CS technicians make routinely-scheduled rounds to pick up soiled equipment from user units (See **Figure 20.3**) and transport it to the decontamination area for cleaning. In some cases, they may also make special trips to user departments to retrieve specific equipment. In either case, the equipment should be considered contaminated and transported according to soiled item transport guidelines. Disposable components, such as pads, tubing and suction canisters, should be removed from each piece of equipment and discarded at the point of use. Only those items that will be cleaned and reused should be transported to the decontamination area.

Figure 20.3

Cleaning Patient Care Equipment

Patient care equipment should be cleaned per equipment manufacturer instructions and the healthcare facility's infection prevention protocols. The manufacturer's cleaning instructions are typically found in the operator's manual that accompanies the equipment when it is purchased. Alternatively, the manufacturer can be directly contacted and, in many instances, instructions are available on the manufacturer's website. Whenever a new item of patient care equipment is brought into the facility, CS professionals should receive written instructions about procedures for cleaning and handling. All surfaces, including cords, switches and crevices, must be thoroughly cleaned. **Figure 20.4** illustrates an area that may be missed without using the IFU.

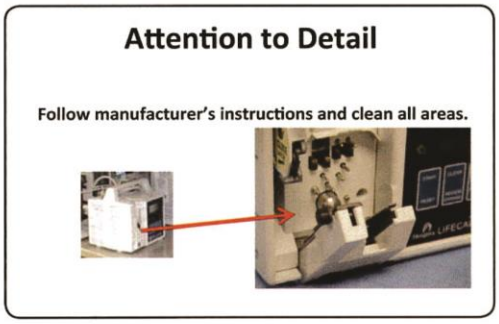

Figure 20.4

Managing Inoperative Equipment

Equipment that is nonfunctioning should be identified and tagged by the user. (See **Figure 20.5**) CS technicians must ensure that equipment tagged for repair is routed to the Biomedical department after cleaning. If an equipment malfunction causes harm to a patient, it should not be disassembled or have its settings adjusted. It should be removed from service and returned immediately to the Biomedical department for inspection and follow up. Since it will not have been disassembled or adjusted, Biomedical technicians can better establish how the equipment was assembled or used, and they can recognize clues about the cause of the malfunction, such as incorrect assembly or operator error.

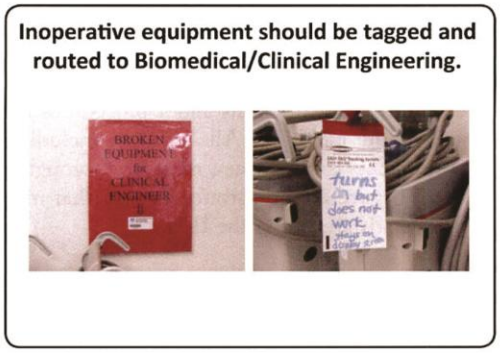

Figure 20.5

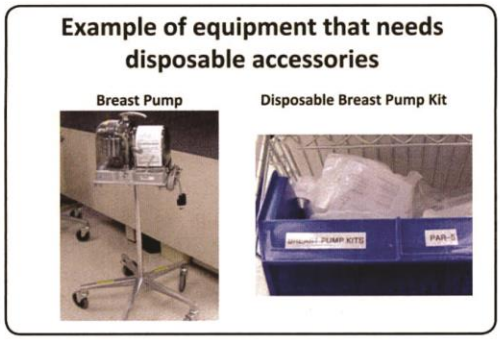

Figure 20.6

Legislation and Patient Safety

The Federal Safe Medical Devices Act of 1990 requires that the healthcare facility report malfunctions of medical devices that have contributed to patient injury, illness and/or death to the manufacturer and the U.S. Food and Drug Administration (FDA). Although the Act broadly defines a "device," mobile patient care equipment is included within the legislation. A proactive equipment management system should accurately record the specific data, including the equipment model, serial number and other information pertinent to the incident, to comply with this legislation.

Preparing Equipment for Use

Patient care equipment should be prepared for use and stored in a "ready to dispense" state. Preparation for use may include assembly, the addition of new disposable components, such as tubing and pads and a check and/or replacement of batteries per the equipment manufacturer's assembly instructions. (See **Figure 20.6**)

Some patient care equipment requires water for operation. CS technicians should become familiar with the equipment manufacturer's recommendations for the care of water reservoirs and how to fill them properly. CS technicians should also be aware of any testing that they need to perform prior to dispensing for use.

Storage of Patient Care Equipment

After patient care equipment has been cleaned, inspected and assembled, it should be placed in storage until needed. In most cases, storage is confined to the CS department (See **Figure 20.7**) or a secure location nearby. Sometimes, however, it may be stored in user units. This makes it more accessible for nursing and other patient care staff and reduces waiting time when the equipment is needed immediately.

All equipment should be stored in a clean, secure location, away from high traffic areas, such as visitor hallways.

Figure 20.7

Some types of patient care equipment have battery back-up systems that must be recharged. An adequate number of electrical outlets is needed in all applicable storage areas to enable these items to be plugged in at all times for battery recharge. (See **Figure 20.8**). While this equipment is designed

to run using electricity, there may be times when patients are moved while still connected to equipment, and during power disruptions, when the equipment must rely on pre-charged batteries to function.

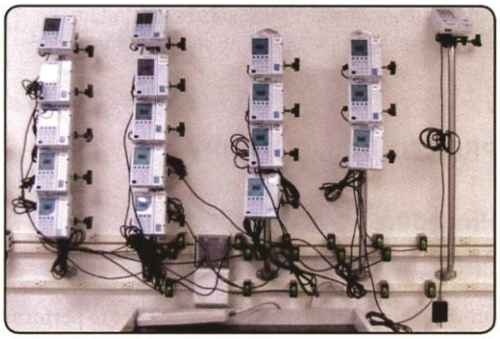

Figure 20.8

Tracking Patient Care Equipment

Tracking patient care equipment is a challenge for any CS department. The equipment is mobile and in many cases, small, and it can easily be placed in an incorrect location, set aside on a user unit or otherwise misplaced. Equipment that is difficult to locate can cause equipment shortages, which may delay treatment, necessitate short-term rental of replacement equipment, and increase the healthcare facility's operating costs.

There are several ways to track patient care equipment. It can be done manually, using a paper system that tracks each equipment item's specific identifying number. Alternatively, it can be done using computerized programs that automate the tracking process by using barcodes that are applied to the device. (See **Figure 20.9**) In some hospitals, equipment is tracked with radio frequency computer chips applied to each device that send signals to a locator system. Regardless of the type of tracking system used, the main goal is to provide information:

- About the current location of the equipment.
- To charge patients for use of the equipment, if applicable.
- On equipment usage and trends.

Tracking patient care equipment allows CS professionals to monitor locations and helps ensure that equipment is available when needed. That information can also be used to justify additional equipment.

Equipment Tracking Using Barcodes

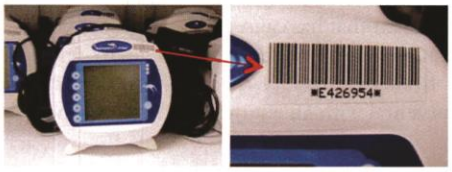

Figure 20.9

PROCURING NEW AND ADDITIONAL EQUIPMENT

New technologies and increased need (patient volume) often require healthcare facilities to procure additional patient care equipment. New equipment may be purchased, leased or rented, or it can even be loaned to the healthcare facility by a manufacturer. There are advantages and disadvantages to each approach, and the facility should make decisions based upon its specific needs.

Equipment Purchase

This method of equipment acquisition has been used by healthcare facilities for decades. Facility personnel identify the need for specific equipment, determine the type (model, style or brand) that is required, budget for its purchase and incorporate it into the system. The equipment is then owned by the healthcare facility.

Equipment Lease

As with purchasing, healthcare facility personnel must determine equipment needs. From there, they contract with a manufacturer or leasing company to lease (use) the equipment for a specific time period. At the end of the contract, the healthcare facility

can usually return the equipment (and acquire a newer technology) or purchase it.

Equipment Rental

Equipment rental differs from leasing because it is usually done on a short-term basis. For example, leasing contracts may be for months or years, but rental contracts may be as short as a single day. When renting, the healthcare facility identifies an immediate need, usually because high patient volume has created a demand for existing equipment that has caused a shortage, or because of the unique needs of a specific patient. In either case, the healthcare facility then contracts for a short-term rental with an equipment rental company.

Manufacturer's Loan

Manufacturers occasionally provide equipment to healthcare facilities as part of an agreement in which the facility will use the manufacturer's disposable products, such as pads, tubing and sleeves.

Decisions about the type of equipment acquisition process that will be most beneficial to the healthcare facility should be made by facility administrators.

Whichever method is used to acquire equipment, the CS technician's responsibilities remain the same: to provide clean, safe and complete equipment and to maintain the availability of that equipment by coordinating workflow.

OTHER PATIENT CARE EQUIPMENT CONCERNS

Equipment Maintenance and Repair

All mechanical equipment must be properly maintained and will sometimes require **repair**. Preventive maintenance will help identify potential problems before they occur. PM is conducted on a routine, scheduled basis, and is designed to ensure that equipment is in proper operating condition. Equipment repair is performed as needed when equipment fails to function properly, and when it appears to be damaged.

Both preventive maintenance and equipment repair should only be performed by trained biomedical equipment technicians or the equipment manufacturer.

Repair (equipment) Procedures used to return equipment to proper operating condition after it has become inoperative.

PROCEDURAL SUPPORT

Procedure Trays and Kits

Many procedures are performed within the healthcare facility and CS departments often provide the sterile instruments necessary to perform those procedures. Procedures that are done outside of the OR can be divided into two categories: those performed in a designated **procedure area**, and those performed at the patient's bedside. In either case, safe and accurate instruments and supplies are critical to patient safety.

Procedure area An area within the healthcare facility that conducts invasive and minimally-invasive procedures requiring instruments, supplies and equipment.

The CS department is the provider of sterile instrumentation and often provides trays and kits for procedure areas located outside the OR. Common procedure areas include:

- Cardiac catheterization lab.
- Emergency department.
- Labor and Delivery.
- Minor procedure rooms.
- Radiology.
- Endoscopy.

Just as each procedure area provides a very different type of treatment, each area will also have different types of trays, instruments and supplies.

Disposable or Reusable?

When a facility determines whether to use disposable or reusable trays and kits, several factors are taken into account, such as physician preference, logistics, storage and replenishment cost.

When reusable trays and kits are used, a process must be adopted to help ensure that instruments are returned to CS for reprocessing. When disposable instruments are used, CS staff must identify and remove disposable instruments that are inadvertently returned to CS, so they are not reprocessed.

Regardless of the type of tray used (disposable or reusable), the user department must identify the tray's contents.

Managing Reusable Instruments

In addition to reprocessing instruments for ancillary departments, many CS departments also perform the function for off-site entities, such as affiliated clinics. (See **Figure 20.10**) Care must be taken to help ensure that the process for transporting soiled instruments meets biohazard transport and infection prevention guidelines, and that the return of clean instruments follows specific protocols for sterile item transport.

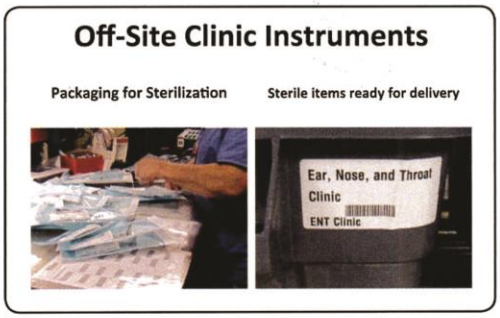

Figure 20.10

If instruments are purchased and brought into the ancillary department through a channel other than CS, the user units must also provide written manufacturer IFU to the CS department.

The Role of Central Service in Ancillary Department Support

As with the instruments used in the OR, the CS department should develop tray listings and written reprocessing protocols for all items processed for ancillary departments.

UTENSILS AND OTHER MEDICAL EQUIPMENT

CS departments may also be involved in handling utensils, such as wash basins and equipment, as well as transport devices and specialty beds. In many cases, the CS department is the only space in the facility that has the proper equipment and facilities to clean these devices. As with all items reprocessed through CS, manufacturer's reprocessing instructions should be obtained, made readily available to staff, and followed.

COMMUNICATION AND COORDINATION IS KEY

Any discussion of service to ancillary departments must address communication and coordination. Meeting the needs of many departments with various specialties can be challenging. Careful planning and good communication are critical.

Basic questions must be addressed for each item and CS technicians must be aware of the procedures for each unit. Important information includes:

- What is needed? (Which items will be available for the specific unit?)
- When will items be needed? (As requested, on standby in the user unit?)
- How will communication take place? (Phone? Computer-generated message?)
- Where will the items be stored?
- How will the items be delivered? (Stocked on the unit? Delivered upon request? Delivered on courier rounds?)
- How will items be returned? (Picked up by CS? Delivered to CS by the user unit? Delivered by courier?)

For the system to run smoothly, everyone must understand and follow the appropriate process. Inavailability of instruments or equipment could jeopardize patient safety.

CONCLUSION

Modern healthcare relies on equipment, instruments and supplies to provide patient care. Each healthcare department fills a specific need and requires specific items to fulfill its mission. The Central Service department provides the support to enable ancillary departments to provide quality patient care.

RESOURCE

U.S. Food and Drug Administration. *Medical Device Reporting 21 CFR 803.* 2014.

CENTRAL SERVICE TERMS

Patient care equipment

Biomedical/Clinical Engineering department

Preventive maintenance

Repair

Procedure area

Chapter 21

The Role of Information Technology in Central Service

Learning Objectives

As a result of successfully completing this chapter, readers will be able to:

1. Provide an overview of the use of information management systems in Central Service departments
2. Discuss the use of computers and information systems to support activities within the healthcare facility and Central Service department
3. Recognize that tracking systems enhance Central Service operations
4. Explain why tracking systems must address the specific needs of the healthcare facility and Central Service department
5. Review some features of available instrument and equipment tracking systems

INTRODUCTION

Central Service (CS) professionals must responsibly manage the equipment, instruments and supplies in their facility and entrusted to them. These items are in constant movement between departments as they are dispensed, used and replaced or processed. To maintain order and ensure the availability of items for patient care, CS staff must track each item to:

- Ensure that it can be quickly located.
- Determine when consumable supplies should be replaced.
- Monitor item usage.
- Maintain accurate records of processes, such as sterilization and distribution.
- Assist with quality assurance processes and regulatory compliance.
- Capture information for financial analysis.

Historically, all recordkeeping (documentation) performed in the CS department was done manually. Now most departments use some form of automated information management system to track products and document processes. Some departments use a combination of manual and computerized tracking, while others employ a fully integrated information management model throughout the entire facility.

Some common types of computer-based information systems used in the CS department include those for instrument tracking, sterilization logging information, case cart pick lists, patient care equipment tracking, inventory management, staffing analysis and individual productivity data. (See **Figure 21.1**)

ROLE OF COMPUTER-BASED INFORMATION SYSTEMS

CS professionals must maintain and manage a significant amount of data as supplies, instruments and equipment are stocked and issued to the Operating Room (OR) and various other users. Computers can promote basic and numerous advanced capabilities to support operational activities for healthcare Materiel Supply Chain Management and CS processing. CS technicians require a solid understanding of how computers are currently used to serve the department's core mission and functions.

Computers and information systems continue to evolve rapidly. When CS personnel are involved in evaluating and/or selecting a new computer-based application or system, they must be aware of the latest trends and technological advancements that are relevant to their role in the healthcare setting.

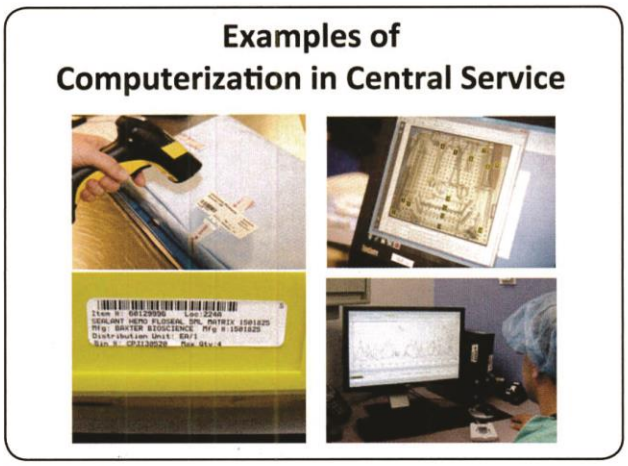

Figure 21.1

Overview of Information Technology in the Healthcare Setting

The modern healthcare environment uses information technology to provide accurate and efficient management of a very complex set of business processes. Ideally, information technology and systems are used to ensure patient safety, demonstrate quality of care, and provide efficient operational and financial management for the healthcare organization.

There are few, if any, aspects of healthcare where information technology or systems are not employed. While an organization may be currently using a mixture of computerized and/or manual processes, it is reasonable to assume that any of the manual processes in use are being routinely evaluated for conversion as resources and budgets allow.

To support the needs of the global patient population today, and in the future, the healthcare industry is intensely focused on continual improvements to the environment of care and our ability to adopt and utilize all of the tools at our disposal to provide high quality healthcare at an optimal cost.

Increasingly, emphasis is on point-of-care and point-of-use computing with mobile solutions suitable for the bedside and use in CS work areas. (See **Figure 21.2**) This has become possible with the development of electronic recordkeeping systems and wireless network capabilities that provide real-time data communication. These systems can be supported with the use of laptop computer-on-wheels (COW) solutions, tablet-based computing, and even smart phones. Computer technology will continue to advance in this manner for the foreseeable future.

Information technology is often the cornerstone of initiatives to transform healthcare. One key reason is that it can be used to clearly demonstrate accountability through the volume of data captured.

The Role of Information Technology in Central Service

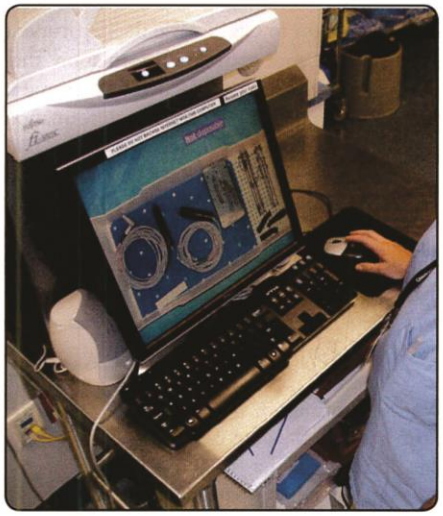

Figure 21.2

A clear understanding of the systems that can be utilized by CS management and staff is important for two critical reasons:

- The core mission is to support patient safety and quality patient care. Information systems can be used to ensure these objectives are accomplished.
- Using available systems appropriately will enhance the ability to provide efficient and cost-effective patient care.

It is also important to understand that many of the systems used in healthcare are integrated (interfaced), meaning they communicate with each other electronically. Integration is essential for eliminating redundant data entry, promoting efficiency and reducing the risk for inaccurate or conflicting data from being entered into the system. While we might receive information needed to perform certain tasks from a particular system, some of the information being used is actually coming from another system. For example, when pick lists are generated for building surgical case carts, they might be printed from the OR scheduling system; however, it is likely that certain information on the pick list, such as the product catalog number and bin locations, is created and managed in the materiels management information system (MMIS).

This is also important to CS because the department sometimes creates and manages information that feeds other systems. For example, if the department uses an electronic sterile processing information system, when inventory information is updated, that may be communicated to the OR scheduling system for use on physician preference cards.

The healthcare facility's information management system utilizes many components to meet a wide variety of needs. **Figure 21.3** provides an example of common components that comprise that system.

- Clinical information systems are at the heart of the core mission of a healthcare provider. They capture data related to direct patient care.
- Admissions and registration, also known as admissions, discharge and transfer (ADT) systems, are used to manage inpatient and outpatient registration. This is important to CS because patient census information is received from the ADT system.
- Electronic medical record or electronic health record (EMR/EHR) is the library of data related to the care provided to a patient by the organization. Healthcare providers must comply with "meaningful use" requirements. This ensures the certified EHR technology is being used to improve quality, safety, efficiency and care coordination, and maintain privacy of patient health information. *Note: The other clinical information systems will transmit relevant information to the EMR/EHR.*

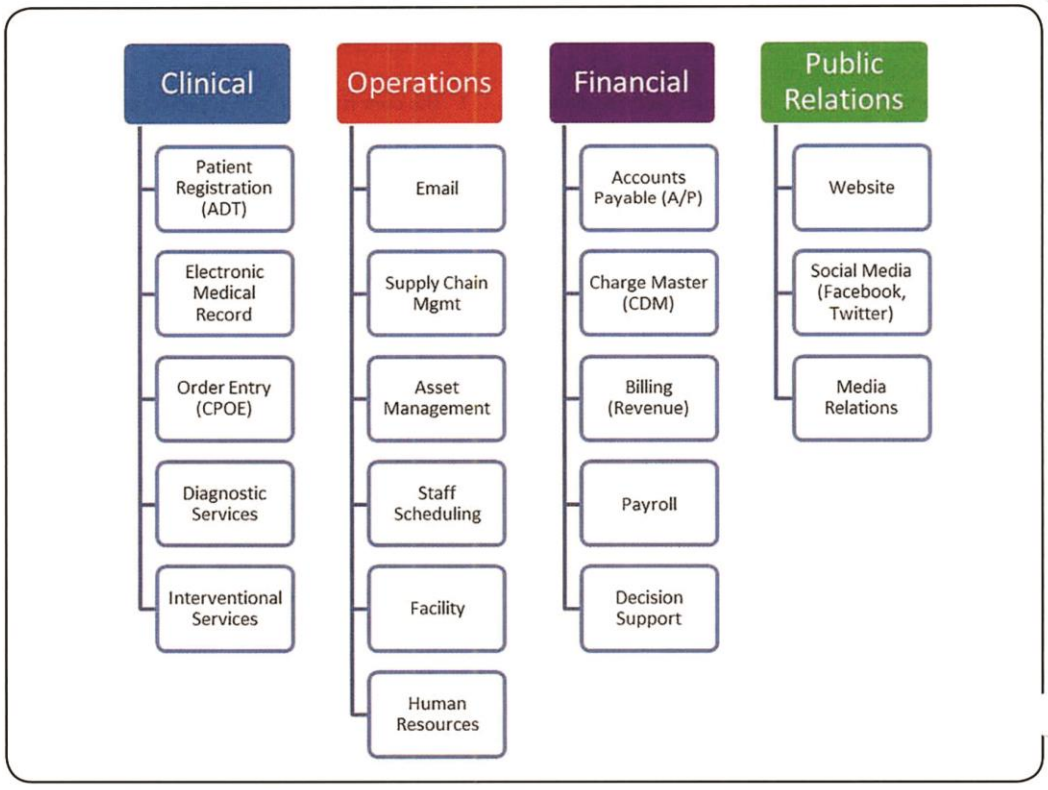

Figure 21.3 Example of Healthcare Information Technology Infrastructure (diagram)

- Centralized patient order entry (CPOE) systems are data portals used by physicians and other authorized caregivers to order tests, medications, supplies and equipment for patient use. The CPOE system also provide alerts when there are potentially conflicting orders created for a patient, such as allergies or medication incompatibility. This is important to CS because automated requests for patient care items are generated by a CPOE system.

- Diagnostic and therapeutic services systems are used to manage the scheduling, procedures performed, and results reported for their respective departments, such as radiology, ultrasound, vascular lab, ekg, respiratory and pulmonary functions lab, physical and occupational therapy, etc.

- Interventional services systems are used to manage scheduling, procedures performed and results reported for their respective departments, such as the OR, Labor & Delivery and cardiac catheterization lab. These systems are important to CS because information is received (schedules, pick lists, etc.) about the daily needs of CS's critical customers.

Operational systems are essential in managing the various functions within the organization that are not directly related to patient care.

- Email systems are a crucial platform for managing communication within any organization. Email has reduced the need for voice mail and pagers.

- Supply chain management or materiels management information systems (MMIS) are used for managing the purchasing, receipt and inventory control functions within an organization. The supply chain system is essential to CS for many reasons, including inventory control, and ordering instruments and/or supplies.

- Asset management (tracking) systems are used to manage the use, processing and location of medical equipment (See **Figure 21.4**) and/or surgical instrumentation throughout an organization. These systems serve as tools for efficiently monitoring and controlling the utilization of surgical instruments and/or patient care equipment.

Figure 21.4 Barcode scanning systems are an example of computerized methods used to track assets, such as equipment.

- Staff scheduling systems can be used to monitor compliance with the organization's time clock policies, provide a mechanism to create work schedules and analyze workforce needs and trends.

- Facility systems are used to manage the physical environment of the organization. Examples of commonly-found facility systems are heating ventilation and air conditioning (HVAC) for monitoring and managing temperature and humidity; fire control for managing fire alarms, sprinklers and magnetically-controlled doors; public address for audible announcements; and access control for managing identification badge access to secure areas within the facility. These are important to CS for managing the safety and quality of areas where items are processed and stored.

- Human resources systems are used not only for the process of recruiting and retaining staff, but also to manage employee benefits and monitor compliance with regulatory requirements for staff competency.

Financial systems are essential in managing the financial activities of the organization. These include the following:

- Accounts payable (AP) systems — Used to manage payment to vendors providing products or services to the organization.
- Charge description master (CDM) systems — Used to manage a listing of services and items that are chargeable to patients. The CDM system is designed to communicate (interface) with other software systems to support government-mandated standard billing requirements.
- Billing or patient accounting (revenue) systems — Used to manage the issuing of bills to patients/insurance payors, and assist with collections of amounts due.
- Payroll systems — Used to track hours, calculate wages, taxes and deductions, and print and deliver checks.
- Decision support systems — Used to analyze operational and financial performance, and provide key metrics to senior leadership. Decision support includes information related to the volume of procedures and services provided, as well as the operational costs and revenue received. This is an essential tool used by leadership to evaluate the financial impact of services and programs offered by the organization.

Public relations systems are essential in managing the public perception of the organization.

- The hospital's website is a significant portal for patients, employees and physicians to obtain information about the services and programs offered: employment or volunteer opportunities; the facility's core mission and values; and other details, such as phone directories, maps and directions.
- Social media portals, such as Facebook and Twitter, are becoming increasingly important to hospitals as they are frequently used by patients to express their opinion about their experience with an organization (or learn about the opinions and viewpoints shared by others).
- Media relations resources include information that resides on other websites not directly controlled by the organization, such as news articles on services provided.

Selection of Department Systems

Many factors must be considered when selecting an information system to support activities used by a specific department or facility. Key issues and requirements must first be evaluated and defined. Before selecting a system, the following questions should be asked and answered:

- Why is the system needed?
- What does the system need to do?
- Is the system capable of doing what is needed?
- Is the system compatible with existing systems?

Issues related to the appropriate range of budget costs and the projected volume of transactions that the system will process are also important. Other concerns may include the types of hardware and operating systems available, and the functional needs of the department (including the number of users). Also, if financial or patient-related information is involved, the system must be able to access the data, in compliance with industry standards and regulatory requirements.

After a system is selected, hardware and software must be installed. Vendor application software can be purchased outright or acquired through a software-based software-as-a-service (SaaS) model. Application software installation typically requires initial implementation support costs and payment of annual maintenance fees if purchased outright. If software and implementation costs are bundled, their costs may be prorated over time

through monthly, quarterly or annual payment schedules. Significant costs are generally involved, and this purchase is typically treated as a capital expenditure, even when a subscription-based solution is chosen.

TRACKING SYSTEMS FOR CENTRAL SERVICE

The processes and needs of the CS department have changed over the years. Advances in sterilization and instrument technologies, and durable medical equipment and supply inventory are ongoing, and costs for instrumentation purchase, repair and replacement have led to a greater need for improved asset tracking and management.

Overview

Tracking systems available for use in CS can forecast needs and identify processing costs for trays and single instruments. These tracking systems can also help maximize equipment and inventory utilization to provide pertinent information as future budgets are developed.

Many healthcare environments still use procedures that, while popular for many years, should now be re-evaluated. CS personnel must also move out of their comfort zones as they improve processes to maintain patient care equipment for nursing units, and track supplies, instrument sets and trays used throughout the facility.

Manual methods using handwritten tags, log-books, wall-mounted bulletin boards, etc., to track equipment are now being replaced with computerized alternatives. Many facilities acquire a **turnkey system** with limited features or support that generate less-than-ideal information. A better strategy involves using a reputable product that provides updates to ensure that the facility receives necessary support and upgrades.

Turnkey system A computer system supplied to a customer in such a complete form that it can be put to immediate use.

Tracking Methods

There are several types of tracking systems and methods available. Examples include use of bar-codes to scan an item's last known location, and radio frequency identification (RFID) tags used for real-time tracking of patient care equipment.

System ease of use cost and compatibility with other software systems in use are among the factors affecting purchasing decisions. Additionally, to ensure reliability, the tracking method must be compatible with the processing practices and technologies used by the facility. For example, RFID tags that can be sterilized reliably are a relatively new advancement and can be costly. Barcode based tracking is generally used for tracking sterile surgical trays and instruments, while RFID-based tracking, on the other hand, is generally reserved for tracking patient care equipment, as the devices are not subjected to a sterilization process, and a cost-efficient, reliable tag can be used.

A tracking system may typically be either a traditional installed software application with a database managed by facility information technology (IT) personnel or a web-based application with a database managed (hosted) by the software vendor and accessed through the internet. The latter, commonly referred to as **cloud computing**, may offer several advantages, including cost benefits and ease of installation.

Cloud computing The practice of storing regularly-used data on multiple servers that can be accessed through the Internet.

Integration (interfacing) capabilities are of importance when communicating critical information to and from the tracking system. OR scheduling system interfaces are typically desirable to both CS and the OR because they facilitate information about instruments, supplies and equipment needs, based on the surgery schedule in real-time or near real-time forecasting).

Tracking Systems Meet Specific Needs

A tracking system must meet the specific needs of the facility that uses it. For example, in a multi-hospital health network, there may be certain modules or special features in the system utilized by personnel at one site, but are not implemented or used at other sites. This is generally due to differences in the complexity of processing or logistics between sites or departments. For example, a processing area supporting a small ambulatory surgery department may not have a need for the tracking features that a CS department supporting a large inpatient OR would find beneficial. Conversely, the ambulatory surgery area might have a need for features related to flexible endoscope processing, which may not be as meaningful to a large CS department.

In short, a well-developed tracking system has built-in flexibility and scalability that can allow CS departments to tailor the configuration to meet specific needs and also allow for logical reconfiguration, or changes, as needed.

Computerized Systems in Use

Computerized methods facilitate more effective data tracking for rapid report generating, and are much more comprehensive in scope and efficiency than manual systems. Data integrity is consistently more reliable than with a manual system. Computerized standards are accepted by the **Healthcare Information Management Systems Society (HIMSS)** and are used by applicable facility departments to securely store backup data.

Healthcare Information Management Systems Society (HIMSS) A global, cause-based, nonprofit organization focused on better health through information technology.

More about Tracking Systems

The continual need to update information is critical for the success of any tracking system, regardless of whether its primary use is for instrument processing, case cart pick lists, preference cards, inventory control or other purposes. (See **Figure 21.5**)

Figure 21.5 A CS technician updates information on preference cards.

Surgical instrument sets or single peel-packed items can be tracked (located) at the packaged and sterilized product level using one dimensional (1D) barcode labels. Small RFID tags, which can be used reliably within the sterilization process, can provide real-time location data when they are affixed to instruments or trays. It is likely that RFID technology will coexist with barcodes because use of a barcode promotes line-of-sight inspection by the user when scanning an item. This is an essential step in ensuring the sterile integrity of packaged products.

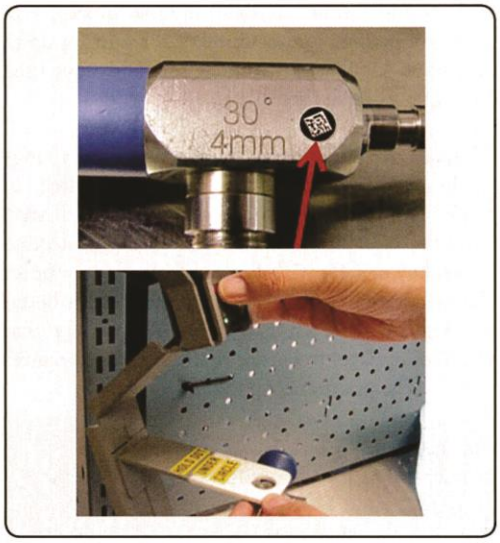

Figure 21.6 Dot matrix barcodes allow individual instrument scanning and tracking.

Individual instruments can be tracked (located) within a set/tray using two-dimensional (2D) data-matrix barcodes. These are marked directly on the instrument using a laser etching/engraving process or through the placement of a dot-type label. (See **Figure 21.6**) Individual instrument tracking ensures specific instruments are kept with a specific set. It can also locate specific high-cost, complex devices, such as powered, endoscopic or robotic instruments for required preventative maintenance inspection. In facilities where the risk of exposure to emerging pathogens, such as Creuztfeldt-Jakob Disease (CJD), is high, individual instrument tracking is crucial for demonstrating the processing or dispensing actions taken in the investigation of a suspected or confirmed exposure.

System documentation and scanning can be done with many different types of devices. These include wireless mobile handheld devices, (See **Figure 21.7**) wired directly to the computer terminal, fixed radio receivers that read RFID transponder signals throughout the facility, and manual entry of information into the computer.

Figure 21.7 – A handheld scanner is used to capture instrument information before an item is sterilized.

Decisions about system utilization should consider the specific environment to which the item(s) will be exposed. For example, the cleaning and sterilization processes for instruments and sets must be evaluated in detail during any implementation planning process to minimize the risk of any adverse impacts on the tracking system. For example, chemical agents designed to be compatible for use with instruments (based on the materials used in their manufacture) may negatively impact laser etchings, fade barcode labels, and make them unreadable to the scanner after repeated use. Heat generated during steam sterilization may damage RFID tags and may impair their functionality. Water, chemicals and drying temperatures used to clean case carts and other equipment may cause the adhesives used to affix the RFID tags to dissolve. When this occurs, they can fall off or become damaged from water leakage. As these risks are recognized, manufacturers generally respond by making improvements to components or processes to ensure reliability.

FEATURES OF INSTRUMENT AND EQUIPMENT TRACKING SYSTEMS

Instrument and equipment tracking systems can provide many different features to assist CS professionals in the facility's OR, finance, nursing and administrative departments. All tracking systems include some basic operating features; however, more advanced systems include additional features to enhance their usefulness.

Basic Systems

Basic instrument and equipment tracking systems typically can track (account for):

- Complete instrument sets and trays.
- Specific equipment items.
- Last known location of a specific instrument set, tray or equipment.
- Cost and value of specific equipment and instruments, and the total cost of an instrument set/tray.
- Number of complete processing and use cycles through which instruments and instrument sets have moved.

- Usage of specific equipment.
- Preventive maintenance schedules and repairs made to specific equipment and instrument sets/trays.

Basic instrument and equipment tracking systems also provide other information, including:

- Complete tray lists for accurate tray assembly (See **Figure 21.8**) and equipment set up, such as:
  - › Name of CS technician who assembled and inspected the set or equipment.

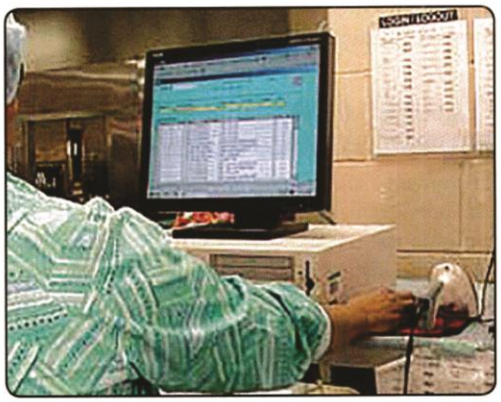

Figure 21.8

  - › Date set or equipment was processed.
  - › Sterilization and cleaning modality (process).
  - › Catalog number and manufacturer name to identify instruments and associated equipment/supplies.
  - › Quantity (individual and total) of instruments included within the set or tray.
  - › Identification of instruments missing from set. *Note: These can be identified on the list and can then be affixed to the outside of the set for identification and tracking.*
- Productivity reporting information:
  - › Sets and instruments processed and completed during a specific work shift.
  - › Sets and instruments completed by specific employees. *Note: This information is helpful for educational and training purposes.*
  - › Equipment processed and distributed.

Quality assurance data for specific facility-based information, such as:

- Sterilization load quarantines or recalls.
- Biological monitoring standards and regulations.
- Educational and inservice documentation.

Financial data for documenting/managing:

- Instrument replacement and repair.
- Equipment replacement and repair.
- Preventive maintenance notification.
- Preventive maintenance records.
- Utilization of instrument sets, trays and equipment.
- Productivity data and staffing requirements for peak operational workflow.

Integrating/interfacing with clinical systems allows facilities to associate (link) instrument trays, sets and equipment to each patient's medical record. Today's tracking systems can also interface with sterilization and washer/decontamination equipment.

Advanced Systems

Instrument and equipment tracking systems may also include some advanced features that are beneficial in certain healthcare facility applications:

- RFID enables real-time location of an instrument or equipment item as it moves through the facility and the processing cycle. The real-time location of a complete instrument set or tray can also be assessed.
- Set-level tracking features to allow staff members to know the last scanned location of an instrument set/tray.
- Individual instrument level tracking features to allow staff to track a single instrument within a set or tray, and identify the set into which a specific instrument was placed.

Note: This information represents a generalized list of features that software developers typically provide in their instrument and equipment tracking systems. A complete review of a facility's specific needs is required to select the most appropriate tracking system.

CONCLUSION

Central Service professionals must responsibly manage the equipment, instruments and supplies entrusted to them by their healthcare facility. An instrument and equipment tracking system facilitates this goal by capturing pertinent data, logging and documenting processes, practices and CS-related functions, and more.

As computer technology and information systems continue to evolve, additional capabilities will become available to help facilities better address operational activities and facilitate high-quality patient care. Even so, computers are only one part of a total information system. While computers and tracking systems provide numerous benefits, CS professionals are the key to providing efficient and effective services to help their department support the facility's core mission, which is providing safe, high-quality patient care and customer service.

RESOURCE

Glandon GH, Slovensky DJ, Smaltz GL. *Austin & Boxerman's Information Systems for Healthcare Management, 7th Ed.* 2008.

CENTRAL SERVICE TERMS

Turnkey system

Cloud computing

Healthcare Information Management Systems Society (HIMSS)

Chapter 22

Safety and Risk Management for Central Service

Learning Objectives

As a result of successfully completing this chapter, readers will be able to:

1. Explain the importance of safety and risk management in the Central Service department
2. Review three common workplace hazards: Fire, hazardous substances and bloodborne pathogens
3. Explain the importance of ergonomics and health awareness for Central Service technicians
4. Discuss common safety hazards applicable to Central Service functions and work areas, and explain how employee injuries can be prevented
5. Describe special safety precautions for handling ethylene oxide
6. Discuss the basics of internal and external disaster plans for a healthcare facility
7. Review procedures to report employee accidents and injuries
8. Explain the importance of education and reporting in a Central Source safety and risk management system

INTRODUCTION

It has been said that "safety is no accident," and that statement couldn't be more true, especially for healthcare professionals who are responsible for keeping patients, employees and visitors free from injury.

Figure 22.1

Safety requires ongoing education, safeguards, proper planning and the combined implementation of safety systems to reduce risks, prevent injury and save lives. The Central Service (CS) decontamination area is a perfect example of how safety systems and due diligence is essential for ensuring safety. This area operates in the presence of pathogenic microorganisms and presents a real risk to those who enter. Engineering controls, such as managed air pressure, physical separation from clean areas, and personal protective equipment (PPE) are provided to minimize risk. Employees are educated in biohazard safety and must follow specific regulations, such as those established by the Occupational Safety and Health Administration (OSHA), to reduce the risk of injury. (See **Figure 22.1**) This chapter will identify common risks found in the CS work areas and discuss ways to minimize the risk of injury.

RISK MANAGEMENT

Risk management is a method used to assess the risks of a specific activity and develop programs to reduce that risk. It also involves injury prevention and claims management (the settlement, defense and prevention of lawsuits).

Risk management originated in the insurance industry as the result of the increased number of medical malpractice lawsuits. These lawsuits cost healthcare facilities billions of dollars over the past several years. Healthcare facilities must effectively manage injury prevention for patients and employees as part of a risk management program. Various authorities, including The Joint Commission (TJC), require that healthcare facilities develop and implement procedures to ensure that they meet minimum safety standards.

Risk management programs are designed to prevent accidents and/or injuries, and ensure accurate reporting and follow up to help prevent similar incidents. After a situation is examined and hazards or unsafe practices have been discovered, risk management personnel ensure that corrective actions are taken to improve systems, behaviors and/or physical conditions to help prevent employee and patient accidents and injuries.

By following the protocols outlined in this textbook, as well as the manufacturer's Instructions for Use (IFU), standards and regulations, and CS technicians support patient safety.

Risk management The methods used to assess the risks of a specific activity and develop a program to reduce losses from exposure to those risks.

COMMON WORKPLACE SAFETY HAZARDS

All jobs involve some risks. The key to working safely in any work environment is to understand those risks and take appropriate steps to minimize them. CS technicians must understand potential hazards and pay close attention in work areas within and sometimes outside of their department. The belief that "an accident or injury will never happen to me" creates a false sense of security that results in many injuries each year. Following safety protocols and incorporating them into all work practices is necessary for preventing injuries and accidents.

Central Service Occupational Hazards

In CS, there are three different types of occupational hazards: physical, biological and chemical hazards. (See **Figure 22.2**) Some of those occupational hazards can be present in all areas of the department. For example, physical hazards, such as heavy or awkward lifting, can occur in any work area. Other hazards may be confined to a specific work area. For example, biohazard contamination will most likely occur in the decontamination area.

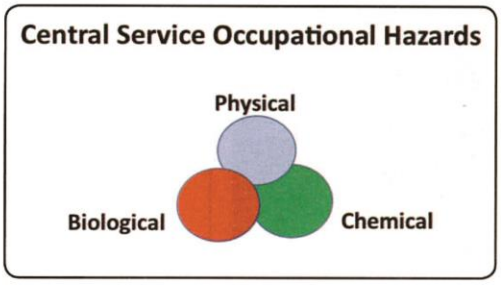

Figure 22.2

Physical safety hazards may be caused by the environment and the tasks performed within that environment. Due to the nature of the tasks performed, there are many potential physical hazards in the CS department. Physical hazards may include: wet floors, cluttered walkways, heavy carts and sharp instruments. Fire is also a physical safety concern.

Biological safety hazards (infectious waste and bloodborne pathogens) can potentially be found in any area of the department. Obviously, the decontamination area is the main area of concern for biological hazards.

Chemical safety hazards may be found throughout the work area. For example, solutions used in the decontamination area, sterilants used in the sterilization area and some patient care products may pose chemical hazards within the department.

The following sections examine general safety hazards and then outline specific safety hazards by work area. The risk of injury from all of these hazards can be minimized by following safety protocols.

GENERAL PHYSICAL HAZARDS

Ergonomic Concerns

General physical hazards include those related to **ergonomics**, slips, falls, electrical, safety and sharps. Ergonomics is the process of changing work or working conditions to reduce physical stress. CS technicians are exposed to many ergonomic stress factors, such as repetitive motion, lifting and pushing.

Ergonomic stressors that employees may encounter include:

- Force - Heavy lifting or manipulating equipment or instrument sets.
- Repetition – Using the same motion, or series of motions, continually or frequently.
- Awkward positions – Assuming positions that place stress on the body, such as reaching or twisting while lifting.
- Vibration – Rapid oscillation of the body or a body part.
- Contact stress – Continuous pressure between the body and a sharp edge.

Exposure to these stressors can cause numerous problems, including ligament sprains, joint and tendon inflammation, pinched nerves, herniated spinal discs and other injuries.

Problems, such as carpal tunnel syndrome from typing at a computer station, may develop gradually, over time, or from a single event, such as from improperly lifting a heavy object. In either case, the injuries may cause pain, loss of work and disability.

The number and severity of ergonomic injuries can be reduced if the work environment and work practices are effectively adjusted. To be effective, management commitment and employee participation are required. This forms the foundation for ergonomic improvements because a sustained effort, allocation of resources, and frequent follow up is needed. Staff member buy in of equipment and work procedure changes is of special importance.

Training can help employees to:

- Recognize the signs and symptoms of injuries, so they can respond to them.
- Report potential problems.
- Recognize jobs/tasks that have ergonomic stressors.

Ergonomics Process of changing work or working conditions to reduce employee stress.

Conducting a work site analysis can help identify conditions and aspects of work activities that increase injury risks to employees. It will also help ensure that corrective actions taken will address the problems creating the hazard. *Note:* ***Figures 22.3*** *and* ***22.4*** *show overhead lift systems, transport carts and adjustable height work tables that can be used to reduce the risk of back injuries.*

Figure 22.3

Figure 22.4

Simple changes, such as stretching before work, shifting position, learning and practicing good body mechanics and breaking up repetitive activities can help employees reduce the risks of ergonomic injuries. **Figure 22.5** shows a technician practicing good body mechanics while lifting a tray.

Figure 22.5

Proper lifting and pushing movements can also prevent injuries. When loading and unloading carts from dumbwaiters or elevators, or receiving a cart into the department, it is essential to check the weight on the cart before attempting to move it. **Figure 22.6** provides an example of a heavy cart that must be handled carefully. Ensuring that the wheels are straight, and that they will roll over door spaces or uneven edges is also important, as is unloading some items to lighten the cart if it is too heavy to move easily.

Example of a Heavy Loaner Instrument Cart

Figure 22.6

Safety and Risk Management for Central Service

Slip and Fall Concerns

Slips and falls are always a concern in the CS department. Mobile equipment and ever-present wet floors increase fall risks. To reduce these risks, mobile equipment should be parked away from common traffic areas. Areas that often have wet floors, such as in the decontamination area, around the cart wash exits, and washer unload areas, must be kept as dry as possible, and spills should be wiped immediately. Non-slip footwear should be worn and attention should be given to slippery floors. Signage, such as the wet floor sign pictured in **Figure 22.7**, alerts people to the potential hazard.

Figure 22.7

Electrical Safety Concerns

Burns and shocks from electric equipment can result if safe handling precautions are not observed.

Carefully check all electrical cords to ensure they are intact, with no breaks in the insulation. Electrical cords on mobile equipment run a greater risk of being kinked or run over by rolling carts,

which can make the equipment unsafe. All plugs on electrical equipment must be three-pronged and grounded, and all electrical outlets must accommodate these plugs. Inspecting electrical cords for breaks and plugs for bent prongs is a responsibility of CS technicians. (See **Figure 22.8**) Identifying and reporting a potential hazard during cleaning or delivery can prevent injuries to patients and staff.

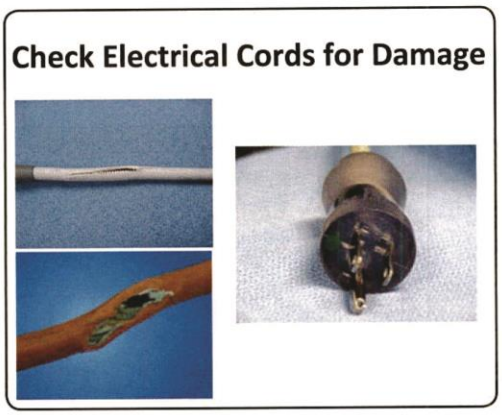

Figure 22.8

Use Caution with Electrical Equipment

All electrical equipment can pose a hazard if it is used in an unsafe manner. For example, radios placed near water sources, such as sinks and ultrasonic cleaners, can lead to staff injury in that work area. Keep the work area safe from electrical hazards.

Sharps Concerns

Cuts and puncture injuries from sharps can happen in any area of the CS department. Sharp instruments can break the skin's surface and produce puncture wounds, lacerations and abrasions. If the injury occurs in the decontamination area, these injuries can result in exposure to disease.

Some general precautions to prevent sharps injuries include:

- Handling all sharps with care.
- Not grasping several objects at the same time.
- Ensuring that sharp ends point away from any part of one's body during transport.
- Placing all disposable sharps, such as needles and blades, in the appropriate sharps container. (See **Figure 22.9**)

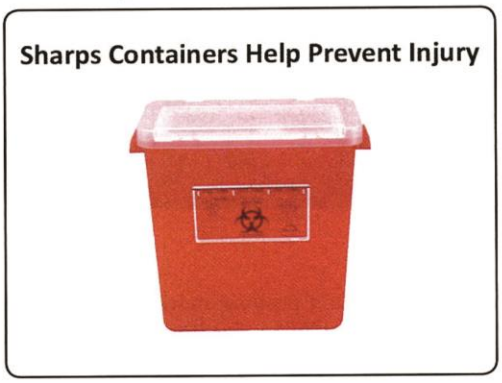

Figure 22.9

General Chemical Hazards

Although most chemicals used in CS are found in the decontamination area, chemical hazards may be found in other areas of the department, as well.

Splashing chemicals is a common cause of eye injuries, so the use of eye protection is required. Eye wash stations are also required in areas where chemical injuries are a concern. (See **Figure 22.10**)

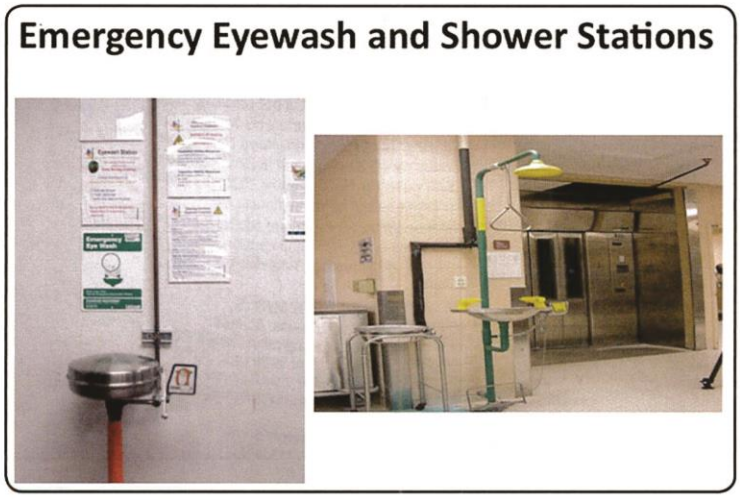

Figure 22.10

Hazardous Substance Concerns

Each state categorizes certain chemicals and substances as hazardous. Each CS department should have an easily accessible, understandable, and current list of all hazardous substances with which employees could come in contact. Most facilities today have a comprehensive computerized hazardous chemical list.

If employees are required to perform known hazardous tasks, it is important that they understand the safety procedures developed for that task. Prior to performing such tasks, employees must be given information about the hazards to which they may be exposed. This information should include identification of specific hazards, use of PPE, recommended safety measures and emergency response procedures. Employers should take measures to minimize hazards to employees. These could include increased area ventilation, respirators, presence of other employees to assist, and the rehearsal of emergency procedures.

CS managers must develop a hazardous materials management program to best ensure the health and safety of employees, as required by state and federal regulations and TJC. Information about hazardous chemicals and substances must be available to all employees.

OSHA's "Employee Right to Know" regulations mandate that a comprehensive hazard communication program be in place to help ensure that employees know about hazards around them. Components of an effective departmental hazardous substance management program include container labeling requirements; use of safety data sheets (SDS); employee information and training, procedures to manage and handle hazardous substances; employee monitoring; and **hazardous waste** management.

Hazardous waste Substances that cannot be disposed of in the facility's normal trash system.

Container Labeling

All containers that contain hazardous substances must be clearly labeled to specify contents and appropriate hazard warnings, and must indicate the name and address of the manufacturer. All **secondary containers** must be labeled with an extra

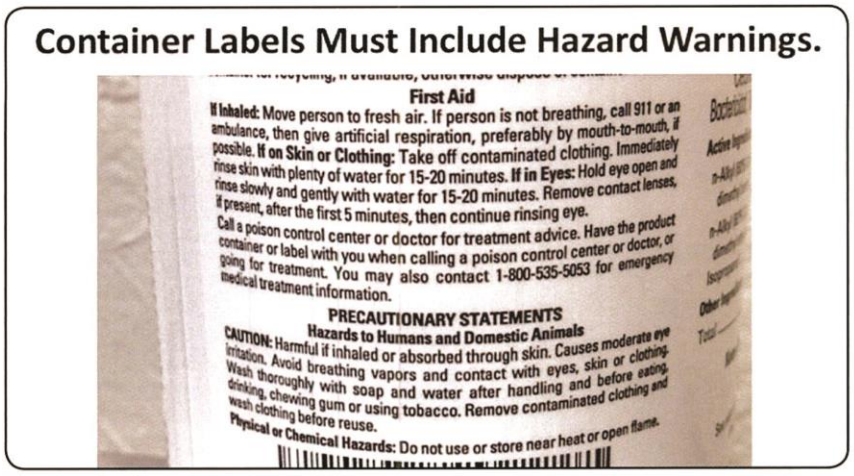

Figure 22.11

copy of the original manufacturer's label, or with a generic label that identifies hazard warnings and directions.

Secondary container A generic container that is filled from a primary container or filled with a diluted solution. Secondary containers must be clearly labeled with content.

Safety Data Sheets

An SDS (formerly called material safety data sheet - MSDS) contains important information about product materials and properties that employees must know to work safely with any given product. SDS are developed and provided by the manufacturer of the product, and they are specific for each product. SDS contain at least the following information:

- Product identification – Product name, manufacturer's name, address and telephone number, product item number (manufacturer's identification) and synonym names.
- List of hazardous ingredients.
- Physical data – Vapor pressure, evaporation rate, solubility in water, freezing and boiling points, specific gravity, acidity (pH), vapor density, appearance and odor.
- Fire and explosion information – Flash point, flammable units, extinguishing media, special firefighting procedures; and unusual fire and explosion hazards.
- Reactivity data – Stability, incompatibility, hazardous decomposition products and conditions contributing to hazardous **polymerization**.
- Health hazard data – Effects of overexposure.
- Storage recommendations – Incompatible materials and storage temperatures.
- Emergency and first-aid procedures. (See **Figure 22.11**)
- Spill or leak procedures, spill management and waste disposal methods.
- Protection information and control measures.
- Special precautions.

Polymerization A molecular reaction that creates an uncontrolled release of energy.

The employer is responsible to ensure that SDS are readily available to employees who may work with,

or be in the vicinity of, hazardous materials. (See **Figure 22.12**) In turn, employees are responsible for becoming familiar with the SDS information and consistently following the instructions given for the products they handle and use.

Figure 22.12

Employee Monitoring

To prevent potential health hazards to workers, OSHA has established permissible exposure limits (PELs) for many chemicals used in sterilant and disinfectant formulations. These include ethylene oxide (EtO), hydrogen peroxide (H_2O_2), ozone (O_3) and others.

Glutaraldehyde is a chemical commonly used in CS as a high-level disinfectant. The National Institute for Occupational Safety and Health (NIOSH) recommends that exposure to glutaraldehyde be under 0.2 parts per million (ppm) time weighted average over an eight-hour work shift. The American Conference of Governmental Industrial Hygienists (ACGIH) recommends a ceiling value of 0.05 ppm, which should not be exceeded at any time.

Healthcare facilities are required by OSHA to:

- Provide adequate ventilation systems.
- Establish safe work operating procedures.
- Provide PPE.
- Implement other methods to ensure that occupational exposure limits are not exceeded in the workplace.

Mechanical monitoring systems can aid in the detection of chemicals present in the work area. These systems can detect the presence of chemicals at levels far below the level an employee would be able to detect by smell. (See **Figure 22.13**)

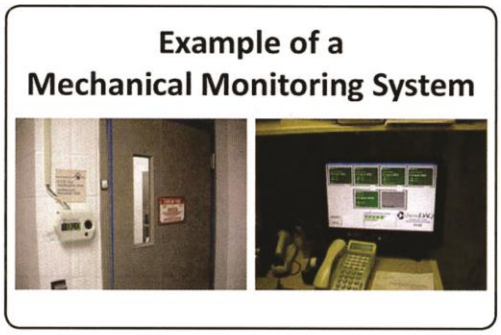

Figure 22.13

Personal monitors that measure individual exposure to chemical vapors by measuring the presence of specific chemicals in the employee's breathing zone are also available. (See **Figure 22.14**)

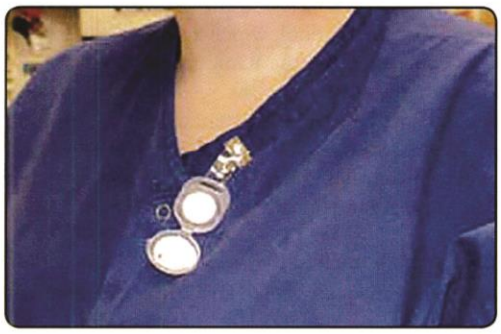

Figure 22.14

Fire Hazards

Fire requires three elements to be present at the same time; these elements make up the "Fire Triangle."

- A **combustible** or flammable substance.
- A source of oxygen.
- A source of ignition.

To prevent fires, at least one of the elements in the triangle must be eliminated. (See **Figure 22.15**)

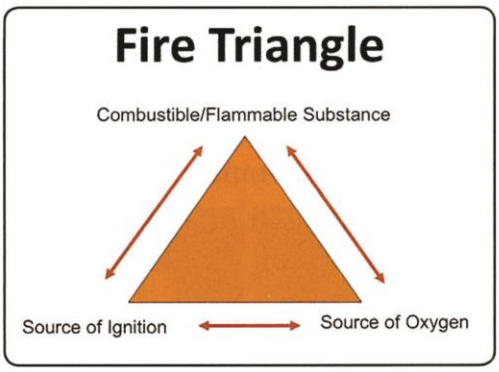

Figure 22.15

Fire and Explosions

A fire occurs when the temperature of a flammable or combustible substance is raised high enough for the individual carbon and hydrogen atoms to combine with oxygen, and the resulting energy is released. If the material is a solid, it will burn only at its surface. In contrast, if the material is a volatile liquid, such as alcohol, which readily vaporizes, or a gas, such as EtO, the flame front passes quickly through the substance. The result is an explosion accompanied by the instantaneous generation of large quantities of heated gases. Their rapid expansion creates a very loud pressure wave that can cause great damage.

Combustible loading is the weight of combustible materials per square foot of area where the materials are located.

Combustible A substance that, if ignited, will react with oxygen and burn.

Combustible loading The weight of combustible materials per square foot of area in which those materials are located.

Disposable materials, including gowns, caps, masks, shoe covers, tubing, syringes, and their packaging, contribute to heavy combustible loads in hospitals. This problem occurs principally in central storage areas such as CS, Operating Room (OR), delivery suites, nursing units and trash handling facilities.

The presence of large volumes of combustible materials and flammable substances poses unique risks. The large combustible loading created by single-use items and their wrappings in storage and as trash is especially dangerous. When these materials burn, large quantities of highly toxic smoke are produced. Even with hospital compartmentalization features that limit the spread of smoke and fire, a high-risk situation occurs; therefore, healthcare fire safety programs must include:

- Minimization of the combustible load.
- Fire response plans.
- Early detection.
- Containment of the fire and combustible products.
- Extinguishment.
- Evacuation plans.

Minimize Combustible Loads

It is important to minimize the volume of combustible substances because a prime rule of fire protection is: "Don't give fire a place to start."

Strategies to minimize combustible loads include:

- Ensure that single-use items are safely stored by keeping them in areas with the proper temperature and humidity.
- Minimize the volume of combustible substances, even when adequate storage facilities are available. Consider purchase systems in which the supplier retains possession of, but not the title to, items until actually needed.
- Minimize trash build up. Each facility must have an adequate trash handling program that includes covered trash containers of noncombustible construction and adequate volume at each site of trash generation.

Fire Response Plan

Every healthcare facility requires a comprehensive fire response plan and each staff member in every department must know his/her specific role in these plans. The fire safety emphasis should begin at the time of new employee orientation and should continue with ongoing training.

Every healthcare facility is required to have and maintain sprinkler systems, smoke detectors, fire extinguishers and audible alarms to warn and protect staff and patients. (See **Figure 22.16**)

Figure 22.16

Each CS technician must participate in their facility's fire training and become aware of the fire safety items within their work area. Carefully following the facility's fire plan is important for both staff and patient safety. When a fire emergency occurs, everyone must understand their role and act quickly.

Workplace Violence

According to OSHA, approximately two million people are the victims of **workplace violence** each year. All employees should pay attention to possible warning signs, and they should:

- Immediately report any direct threats of violence or retaliation to management.
- Note behavior, statements or attitudes that are unusual, threatening or disconcerting.

Employees should be aware of their facility's specific policies on workplace violence and attend education programs designed to provide information on prevention and response.

Workplace violence Any act or threat of physical violence, harassment, intimidation or other threatening disruptive behavior that occurs at the work site.

AREA-SPECIFIC SAFETY CONCERNS

There are safety concerns that are common in specific work areas within the CS department. **Figure 22.17** shows a sign notifying personnel about the need for PPE in the decontamination area.

Figure 22.17

Soiled Receiving and Decontamination Areas

Safety tips when working in soiled receiving and decontamination areas include:

- Never reach into a basin or container holding contaminated objects, unless the objects in the basin are clearly visible. Use a sponge forceps to grasp the object or pour out any solution that prohibits visual examination, and then remove objects from basins or containers one at a time. Never use foaming detergents when

handling contaminated instruments in the decontamination sink, as the foam can prevent visualization of sharp objects. (See **Figure 22.18**)

Foaming detergents can conceal sharp objects and increase the risk of injury.

Figure 22.18

- Never reach into trash containers or sharps containers.
- Use extreme caution when disarming scalpel blades. Do not attempt to do so without training. Never disarm by hand. Always use a needle holder or tool specifically designed to remove blades. (See **Figure 22.19**)

Figure 22.19

- When processing reusable sharps, separate them from other instruments and position them in a manner that protects anyone who may handle them.
- Follow the manufacturer's recommendations for safe use of chemicals. Always wear recommended PPE to protect all skin surfaces and mucous membranes from chemical burns.
- Follow the manufacturer's recommendations for safe operation of cleaning and testing equipment.
- Use caution when walking, and inspect the floor for slippery surfaces. Utilize mats and non-skid footwear. (See **Figure 22.20**)

Figure 22.20

- When cleaning instruments in a sink, always scrub below the surface of the water to avoid the formation of **aerosols.** (See **Figure 22.21**)

Aerosol A suspension of ultramicroscopic solid or liquid particles in air or gas; a spray.

- Sinks and other working surfaces should be at levels to afford easy access, and to reduce back and arm strain.

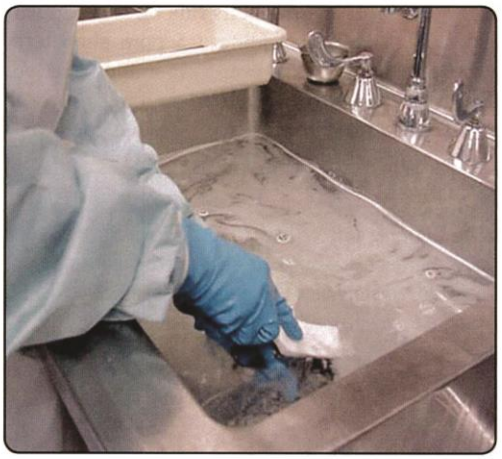

Figure 22.21

Figure 22.22

Preparation and Sterilization Areas

Safety tips when working in preparation and sterilization areas include:

- Move sterilizer carts to low/no traffic or other designated areas, so co-workers will be less likely to come in contact with hot carts. (See **Figure 22.22**)
- Use thermal insulated gloves when handling steam sterilizer carts, washer baskets and other objects subjected to high temperatures. (See **Figure 22.23**)

Figure 22.23

- Keep sterilizer doors closed when not loading or unloading the chamber to protect co-workers from coming in contact with the hot inner door. (See **Figure 22.24**)
- Use caution when using heat sealers. Keep away from heated components. Be sure to follow the manufacturer's instructions.
- Be cautious when using a cutting edge to prepare paper/plastic packs.
- Be cautious when testing instruments for sharpness.
- When lifting instrument sets, use the larger muscles in legs and arms. Hold the item as close to the body as possible without actually touching the body.
- Follow procedures for using and disposing of biological indicators.
- Ensure that proper signs and labels are posted to warn of hot surfaces or other hazards.

Figure 22.24

Sterilizer Safety

Steam sterilizers

- Use caution to avoid burns when working with steam sterilizers.

Hydrogen Peroxide Sterilizer Safety

- Use caution when handling H_2O_2 containers; damaged containers may release sterilant into the work area.

Ethylene Oxide Sterilizer Safety

EtO has been strongly regulated by the federal government for many years. In 1984, OSHA established a 1 ppm (in air) PEL, and a 0.5 ppm **action level** (AL) for EtO. *Note: AL is the concentration level of airborne EtO in or at breathing level.* The PEL and AL limits are expressed as an eight-hour time weighted average (TWA). They represent the total allowable worker exposure during an eight-hour period and express it as an average exposure during the period.

Action level (AL) Level of exposure to a harmful substance or other hazard at which an employer must take required precautions to protect the workers. It is normally one-half the permissible exposure limit (PEL).

In 1988, OSHA amended its rule on occupational exposure to EtO by adding a 5 ppm **short-term excursion limit (STEL)** over a 15-minute period. The STEL is typically related to tasks, such as transferring or handling of non-aerated goods and performing sterilizer maintenance.

Short-term excursion limit (STEL) The maximum concentration of a chemical to which workers may be exposed continuously for up to 15 minutes without danger to health or work efficiency and safety.

Common Terms:

OSHA – EtO – PEL – TWA – AL – STEL

The Occupational Safety and Health Administration (OSHA) has established several limits on occupational exposure to ethylene oxide (EtO). A permissible exposure limit (PEL) is the average concentration of a chemical in the air to which a worker can be legally exposed over a particular period of time (usually eight hours). The PEL for EtO is 1 part per million (ppm) as an eight-hour time weighted average (TWA). An action level (AL) is the concentration level of airborne EtO in or at breathing level. A short-term excursion limit (STEL) is the maximum concentration of an airborne chemical to which a worker may be exposed over a 15-minute period. OSHA has adopted a STEL of 5 ppm for EtO.

Sterilizer manufacturers now include many safety features on EtO sterilizers. These include negative-pressure air flow to help prevent any exposures if the unit malfunctions during the cycle, and automatic mechanisms keep the sterilizer locked down until the aeration cycle is completed.

Safety precautions when working with EtO equipment include:

- EtO sterilization should be performed in a separate area from other department work areas.

- Healthcare facilities using EtO must have an operational, dedicated ventilation system to remove fumes exhausted during the cycle. This exhaust system should be checked regularly to ensure that any fumes in the employees' breathing zone are captured. It is also necessary to have an audible and visual alarm that will sound in case of any malfunction.

- EtO canisters should be stored in an approved containment locker. Check local regulations for the maximum amount of canisters allowed in the area. (See **Figure 22.25**)

Figure 22.25

- Compliance with all federal, state and local air quality and worker safety regulations relating to employee safety, discharge, air monitoring and recordkeeping.

- The exposure of any person to EtO must be reported immediately to the CS manager, employee health nurse, Emergency Department or employee health service.

Safety and Risk Management for Central Service

Supply Receiving, Breakout and Storage Areas

To ensure a safe and efficient supply receiving area, adequate storage space and traffic access must be available. Supply storage and shelving units must be secure and steady. Shelves should be arranged to facilitate maximum space efficiency and allow employees easy access to supplies. Heavy materials and items used most frequently should be placed on middle shelves to enable them to be easily and safely accessed by employees. Lighter, infrequently-used items should be placed on higher shelves.

Employees should use appropriate equipment (e.g., steps, stands and ladders) to safely reach upper shelves. Climbing on shelves is not acceptable. Procedures for the safe operation of dollies, hand trucks or carts to handle bulk materials must be available, and employees must be trained to consistently comply with them. (See **Figure 22.26**)

Figure 22.26

Closed trash containers should be available to properly dispose of unwanted materials. Containers for the appropriate storage of hazardous or flammable materials must be readily available to avoid exposure to hazardous substances. Employees working in this area must also follow proper procedures when disposing of and removing hazardous materials. SDS must be available for reference where these substances are used.

Safety tips for supply receiving, breakout and storage include:

- Use caution when removing items from storage units or shelves. Allow time to perform the tasks and ensure adequate space is available to maneuver the items being received.

- When using a box-cutting tool, always cut away from the body or to the side. Retract the blade into the handle, or cover the blade with a sheath when the device is not in use. Scalpels should not be used.

- Avoid twisting and jerking movements when picking up or removing objects from tight spaces.

- Inspect work areas for objects left in pathways or equipment with parts that protrude into a traffic path. Aisles and doorways must be kept clear at all times.

- Perform appropriate stretching exercises prior to work to avoid injuries to the back and other areas affected by lifting, pushing and pulling.

- Use transport carts, when possible, to minimize lifting and carrying.

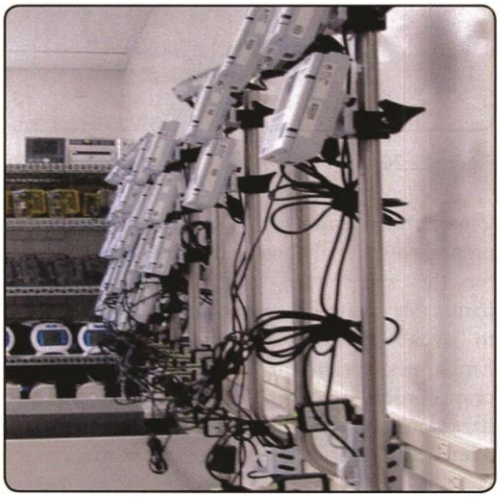

Figure 22.27

Equipment Storage Areas and Equipment Transportation

Areas where supplies and equipment are stored awaiting requests from patient care areas can also be dangerous. These areas can have substantial activity and often have limited space to move about freely. Many types of patient care equipment require electrical charging, so multiple electrical outlets must be available. (See **Figure 22.27**) All portable electrical equipment, including items used in CS and patient care areas, must comply with applicable electrical codes.

Adequate storage space should be provided, and shelving should be of adequate capacity and strength. Rugged, easily controlled carts should be provided for transferring items.

Transporting supplies and equipment through the facility can pose several safety concerns. CS technicians must be aware of their surroundings and take extra care to help ensure they keep themselves and those around them safe as they perform their duties. Food service and patient transportation devices, such as gurneys and wheelchairs, may be in use in patient care areas. There may be hallways, corners and elevators that present hazards if proper techniques are not used by employees transporting patients and other items.

Safety tips include:

- Avoid excessive speed. Be prepared to stop quickly if a person steps into the hallway from a doorway. Always yield to patients.

- Use caution when approaching doorways, hallways, elevators and high-traffic areas.

- Do not use a transport vehicle to push or prop open automatic doors.

- Carts and mobile equipment should not be parked in hallways where it may block traffic or door access. Always keep hallways clear for the free flow of traffic. (See **Figure 22.28**)

- When transporting carts or equipment, make certain that the path in front and on each side of the transport equipment is visible.

- Inspect floors for uneven surfaces or defective tiles or edges to ensure that equipment being transported will not be thrown off balance.

- Use caution when approaching corners or intersections of hallways; use safety mirrors whenever available.

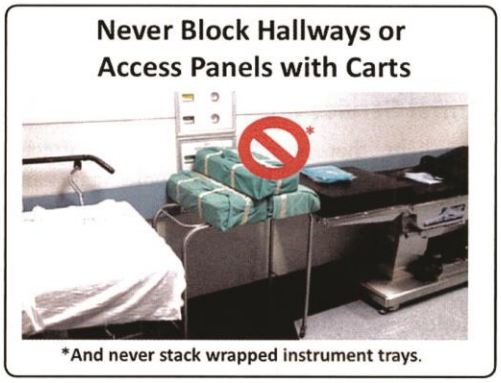

Figure 22.28

- Use caution when pushing objects up or down hallway inclines. Push from behind when going up an incline (object goes first) and pull from in front of an object being transported down an incline (person goes first).

- Do not ride or step on wheeled supply carts or other vehicles.

- Consider using powered carts for moving heavy or awkward loads, if available. (See **Figure 22.29**)

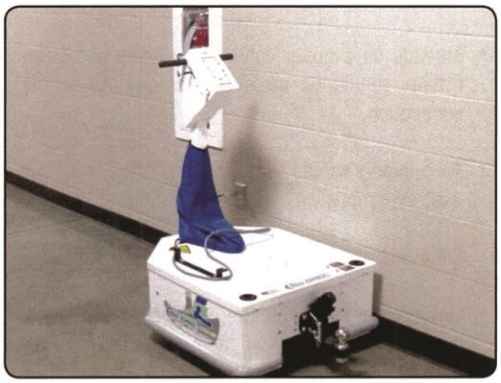

Figure 22.29

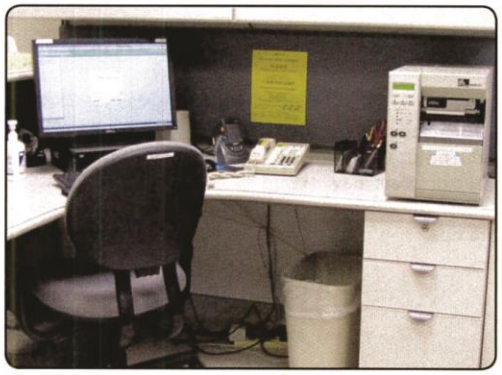

Figure 22.30

Clerical and Other Workstations

Poor workstation design can create issues for CS personnel. Repetitive activities, such as bending over sinks, sitting at a computer desk and standing while assembling instrument sets, should be evaluated in efforts to reduce unnecessary stress and strain. **Figure 22.30** shows a CS clerical workstation.

Safety tips in clerical or other workstations include:

- Assembly work should be performed at levels that will least fatigue and strain employees.

- Floors in work areas where employees must stand should have fatigue mats to relieve leg strain.

- Appropriate chairs should be used at computer, clerical and instrument workstations to properly support employees' backs.

- Items used frequently to perform routine tasks should be stored within easy reach to avoid strain to the upper body from repetitive movements to retrieve these items.

- Caution should be exercised when using filing cabinets. When multiple drawers are open at the same time, the cabinet can tip over. Also, avoid leaving bottom drawers open when not in use because people can trip or fall if they open into a walkway. (See **Figure 22.31**)

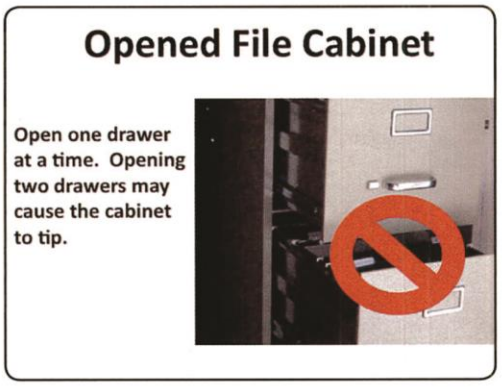

Figure 22.31

Surgical Service Areas

CS technicians may have responsibilities that include services in surgery or other areas where procedures are performed. They should become familiar with possible hazards in all areas they visit, and observe applicable safety policies and signage. These spaces have many of the same hazards found in CS areas. Additionally, they may have hazards applicable to the use of lasers, X-ray equipment, and chemicals utilized during surgical procedures. Caution is required when entering areas when this equipment is in use. Specific safety precautions provided by the manufacturers should be reviewed and followed by employees.

OTHER AREAS OF CONCERN

Central Service Equipment

Equipment that is not functioning correctly may cause injury. TJC and some state and local regulatory agencies require a preventive maintenance (PM) program to ensure optimal operation and function of equipment used for sterile processing activities. This equipment includes sterilizers, washer-disinfectors, heat sealers, and other processing equipment that should be routinely inspected and serviced by certified, experienced service personnel. Inspection records should be maintained with copies available in the CS department. These records should be verified

Handling Compressed Gas Cylinders

Central Service technicians are often involved in the handling, transport and storage of medical gas cylinders dispensed for direct patient care and treatment or for use as equipment components. These cylinders may contain oxygen, nitrous oxide, helium, nitrogen or other gasses. Specific safety protocols should be used for each specific gas, and should be in compliance with the product's handling instructions in the applicable SDS. Medical gas cylinder safety precautions include:

- No gas cylinder should be dispensed for use without a label.
- Gas cylinders should be secured at all times to prevent tipping. Place them in a secured holder for this purpose, or securely strap or chain them in an upright position.
- Cylinders should be handled carefully during transport. They should never be rolled, dragged or dropped.
- A cover cap should be used to protect the cylinder's valve during transport.
- Cylinder regulators are gas-specific and not necessarily interchangeable, so an appropriate regulator for the cylinder's contents is required.
- Threads on cylinder valves, regulators and other fittings should be inspected for damage before connection.
- All cylinders should be clearly labeled as "full," "in use" or "empty."
- Empty cylinders should not be stored with full ones.
- Gas cylinder regulators are equipped with either a hand wheel or stem valve. Stem valves require a key that should remain with the regulator at all times.

by the department manager to ensure that the equipment used by CS employees is safe for use.

CS personnel should report equipment in need of PM or repair.

CS technicians should also be familiar with any emergency procedures that may be needed when using equipment. For example, CS technicians should be familiar with emergency shut-off procedures for any equipment in their work area. (See **Figure 22.32**)

Know the Location of Emergency Shut-offs

Figure 22.32

DISASTER PREPAREDNESS

Disaster preparedness is an important component of the CS safety system. Each facility has developed a comprehensive response plan for internal and external disasters. An **internal disaster** is any situation with the potential to cause harm or injury to the healthcare facility employees or where the loss of utilities may drastically impact departmental operations. Examples of internal disasters include a hazardous chemical spill or leak, loss of power or failure of a utility, such as water, electricity or steam.

An **external disaster** is a situation in which activities outside the facility impact departmental or facility operations. Examples that may necessitate activation of the external disaster plan include earthquakes, floods, hurricanes or other events that result in large numbers of seriously injured patients being sent to the facility. When an external disaster occurs, the entire facility is placed on alert and personnel from each department are expected to perform tasks, based on the situations present.

Disaster (internal) Situation with the potential to cause harm or injury to Central Service or other employees, patients/visitors, or where the loss of utilities may drastically impact departmental operations.

Disaster (external) A situation in which activities external to the facility affects departmental or facility operations.

Disaster Plans

CS department disaster plans, like those of other departments, should be consistent with and support, the facility's plans. Most hospitals use an Incident Command System (ICS), a standardized approach to the command, control and coordination of emergency response. CS managers must ensure the CS disaster response activities and expectations are included in the overall ICS plan.

Elements of a CS disaster plan typically include:

- An emergency call list outlining the lines of authority, and the key individuals to be notified in specific types of disasters. *Note: These may differ for each type of disaster.*
- Protocols for inventory replenishment and delivery of emergency supplies. Usually, supply distribution department personnel are responsible for the maintenance of supplies and, in times of disaster, will deliver to an area for emergency patient care.
- Posted evacuation plans and practice drills for employees to ensure that they know alternative ways to leave the department if their safety is at risk.

CS technicians should actively participate in all disaster training and drills. It is important to know responsibilities during a disaster situation and be prepared to perform the assigned duties.

Biological Disasters

Many healthcare facilities have added biological incidents to their disaster plans. As with other types of disasters, CS technicians should know their role. Close communication with the Infection Prevention department is critical in this type of disaster.

CS departments should utilize appropriate resources, such as the Centers for Disease Control and Prevention (CDC; www.cdc.gov) for up-to-date information regarding emerging biological threats. Other resources, such as the World Health Organization (WHO; www.who.org) can also provide guidance. In all instances, coordination between Infection Prevention and all areas impacted by the disaster is very important.

EMPLOYEE ACCIDENTS AND INJURIES

Even significant efforts to emphasize safety and accident prevention cannot eliminate all employee accidents, and CS technicians can still be injured on the job. If an injury occurs, it must be documented and reported to the appropriate administrative personnel, in compliance with OSHA regulations for healthcare facilities. An investigation is needed to provide information about the cause, the situation, and/or the behaviors that were involved to identify contributing factors, hazards or unsafe practices. Then, corrective actions must be implemented to revise the systems or physical conditions, and/or to address the behavior which caused the injury in an effort to prevent future injuries or accidents.

Regardless of how insignificant an injury may seem, the appropriate manager should be informed immediately. Details regarding time, place, tasks performed and a description of exactly what happened must be recorded on the appropriate form. It should then be submitted to the facility's safety officer, personnel department, employee health, or other entity, according to the facility's protocol.

A process should also be in place for CS technicians to report unsafe situations before an accident or injury happens. If an unsafe situation is identified, it should be reported immediately, so the risk of injury can be minimized.

PATIENT ACCIDENTS AND INJURIES

CS professionals have responsibilities to help prevent patient injuries, accidents and infections. They do so as they perform the important tasks of decontaminating, inspecting, testing, assembling, packaging, sterilizing, aseptic handling of sterile items, and delivering items according to established procedures. When their job is done correctly, risk to the patient is greatly reduced.

When a patient incident occurs, it must be promptly investigated and documented. Any practices or physical conditions within the facility that can cause a patient injury must also be investigated and reported. All healthcare workers must report unsafe practices or hazards promptly to minimize accidents and prevent their recurrence.

EMPLOYEE INFORMATION AND TRAINING

No safety and risk management system can be successful without employee involvement. Each employee must understand their role and responsibilities in maintaining a safe environment. This requires education for all staff at all levels of experience.

All new CS employees should attend a health and safety orientation provided by the facility to become familiar with hazards and safety practices throughout the facility. They should also attend a department-specific orientation that focuses on, at least, the following:

- An overview of the requirements contained in the hazard communication regulations, including employees' rights under the regulations.
- Notification of employees about any operations in their work area where hazardous substances are present.

- Location and availability of written hazard communication program information.
- Physical and health effects of any hazardous substances they may encounter.
- Methods and observation techniques used to determine the presence or release of hazardous substances in the work area.
- Strategies to lessen or prevent exposure to these hazardous substances through safe control and work practices, and use of PPE.
- Steps the department has taken to lessen or prevent exposure to these substances.
- Instructions on how to read labels and review SDS to obtain appropriate hazard information.
- Emergency spill procedures.
- Disaster and fire plans, and the role of the CS department in their development and implementation.

EMPLOYEE PREPAREDNESS

An important factor in safety and risk management is employee awareness and preparedness. Every employee should approach each shift and each task with two questions in mind: "What can I do to ensure my safety and the safety of those in the facility?" and "What do I need to know to respond if I am faced with an emergency?" Some strategies to help ensure emergency preparedness include:

- Be familiar with safety policies. Ask questions if specific information is not understood.
- Be familiar with the chemicals used. Know how to handle them safely and what to do in the event of an emergency.
- Know how to work safely around equipment. Understand the hazards and know where emergency shut-off buttons are located.
- Be familiar with evacuation routes, the location of fire extinguishers and fire alarm boxes.
- Leave each area safe. Wipe up spills, prevent trip hazards and do not cross contaminate.
- Maintain a safe environment at all times. Pay attention to detail. Report anything that threatens the safety and well-being of those in the facility.

The success of any safety system is dependent upon the individuals who work within that system. Creating and maintaining a culture of safety reduces the risk for everyone.

CONCLUSION

Central Service technicians play an important role in every healthcare facility's safety program. It is important to know the expectations and be able to perform efficiently and calmly during any type of situation that may arise. For the safety of patients, visitors, other employees and departmental staff, training and safety drills must be taken seriously, as should the adoption of safe work habits that help ensure preparedness for any unplanned emergency.

RESOURCES

Association for the Advancement of Medical Instrumentation. ANSI/AAMI ST79, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities.* 2013.

Occupational Safety and Health Administration *Ergonomics for the Prevention of Musculoskeletal Disorders: Guidelines for Nursing Homes.* 2003.

Occupational Safety and Health Administration *OSHA Fact Sheet Workplace Violence.* www.osha.gov/OshDoc/data_General_Facts/factsheet-workplace-violence.pdf. 2002.

Federal Register 56:64004. December 6, 1991.

Chapter 22

CENTRAL SERVICE TERMS

Risk management

Ergonomics

Hazardous waste

Secondary container

Polymerization

Combustible

Combustible loading

Workplace violence

Aerosol

Action level (AL)

Short-term excursion limit (STEL)

Disaster (internal)

Disaster (external)

Chapter 24

Personal and Professional Development for Central Service

Learning Objectives

As a result of successfully completing this chapter, readers will be able to:

1. Explain the meaning of personal development and how it can impact a career in the Central Service department
2. List possible Central Service career paths
3. Review strategies for professional goal setting
4. Discuss strategies to enhance professional skills and expertise
5. Discuss resumé development
6. Review the interview process
7. Discuss promotions

INTRODUCTION

Learning is a lifelong endeavor, and change is inevitable. Never have these statements been truer than when applied to the field of Central Service (CS). CS professionals must be prepared to encounter growth regularly, and sometimes profoundly, in their positions. Whether CS professionals wish to stay in their department or seek advancement or promotion, **personal** and **professional development** will enable them to be proactive and more easily prepare for change. This chapter will highlight some of the resources and strategies available to help CS professionals grow and advance in their career.

PERSONAL DEVELOPMENT: WHAT IS IT AND WHY IS IT IMPORTANT?

In some ways, personal development is the first step toward professional development. Personal development may be defined as any activity that identifies and develops talent and personal potential, and improves employability and enhances quality of life. Personal development can help individuals develop personally rewarding goals.

Personal development is usually an individual endeavor – something a person does on their own time; however, more employers are recognizing the importance of investing in personal development. Employers may offer educational programs as part of employee benefit programs to help staff learn more about time management, stress management, teamwork, healthy lifestyles, competency development and career development. Ultimately, these programs are a win-win for both employees and the healthcare facility because personal development can create a workplace that is happier, healthier and more fulfilling. This environment can lead to greater productivity and quality in a department, which helps the healthcare facility meet its strategic goals.

Strategies for Personal Development

How does personal development work? There are four steps:

Step 1: Identify your goal. What do you want to achieve?

Step 2: Identify the requirements for your goal. What will you need to achieve the goal?

Step 3: Identify your strengths and areas that need improvement. What can you build on? What do you need to improve?

Step 4: Create an action plan with a time line for meeting that goal. How do you plan to move forward?

Personal development Activities that identify and develop talent and personal potential, improve your employability and enhance quality of life.

Professional development Commitment to continuous learning and improvement; taking responsibility for your own development.

Personal development should be a lifelong process, and it is more of a journey than a destination. Choose smaller goals that are attainable and build onto those successes. For example, if a long-term goal is a college degree, set the first goal as successfully completing one college class. Upon successful completion of that goal, the individual can set their next goal for the next class.

PROFESSIONAL DEVELOPMENT: WHAT IS IT AND WHY IS IT IMPORTANT?

Professional development specifically refers to the skills and knowledge attained for both personal and career advancement. It provides the information and experience needed to progress in a career, stay competitive with other job seekers and, ultimately, become more employable.

Figure 24.1

Two Types of Professional Development

Professional development can be divided into two categories:

Professional development to keep current in an existing job. Growth is inevitable in the field of CS, and some professional development is mandatory. For example, changes in procedures, policies, instrumentation, products, and sterilization technologies, as well as changes in regulations and standards, must be adapted by every employee. Job growth in an effort to stay current is required of all CS professionals.

Professional development to advance in one's career. Some CS professionals have goals to advance their careers through position advancement and promotion. They participate in activities to improve their professional competency, enhance their existing skills and develop new ones. They move out of their comfort zone to take on new responsibilities and learn new things.

The job market, technology, regulations and practices are always evolving, and an employer may not provide staff with all the skills needed to keep up or move forward in the profession. Whether a person prefers to remain in a current position or dreams of advancement, it is essential to consider the benefits of taking ownership of one's career by continually improving knowledge and skills.

Learning opportunities through conferences, continuing education, and on-the-job training help CS technicians keep up with trends and changes in the CS field. (See **Figure 24.1**) This allows technicians to anticipate change more easily, and helps them recognize professional opportunities.

If a CS technician is a leader or would like to become one, then professional development will provide the knowledge and confidence to influence and lead others by example.

Taking part in activities to improve professional competency will give CS technicians the skills they need to become more effective in their position. This will demonstrate a continuing commitment to the profession, improve employability with current and future employers, and lead to a more fulfilling and rewarding career.

A CS technician may be familiar with sterilization standards as a requirement of the job. If they are able to step out of their comfort zone and teach those standards to new employees, this will increase their understanding of the standards. Teaching an inservice or short course can sharpen your technical skills and help develop training and public speaking skills. (See **Figure 24.2**)

Figure 24.2

CENTRAL SERVICE CAREER PATHS

While most CS professionals choose to remain employed in a CS department and become experts at their assigned duties, some seek different career paths. Common career opportunities for CS professionals include lead technician positions in the CS department, CS management positions, OR core technicians, OR liaisons, CS department educator, faculty positions in local community and technical colleges, consultant, and vendor positions, such as sales representatives and on-site product/service facilitators. (See **Figure 24.3**)

Each career path has specific requirements. It is advisable to research the needed requirements, and develop personal and professional goals to move forward on a specific career path.

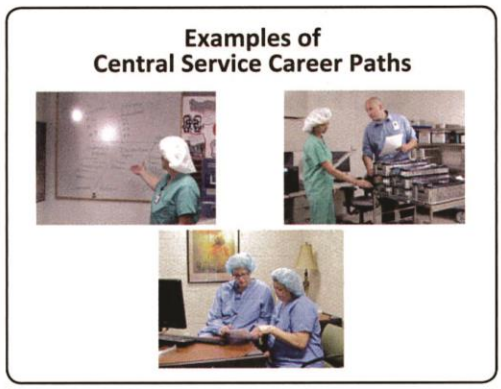

Figure 24.3

PLANNING YOUR CAREER GOALS

Those professionals looking to make their career more personally meaningful and rewarding, should establish goals and periodically review them. This will identify activities and steps that will help meet those objectives.

As with personal development, professional development requires working toward identifying areas in a present position in need of improvement, and then moving forward with set goals. In many ways, the steps to take for professional development are similar to those one would take for personal development, with a specific emphasis on developing one's position and career advancement.

Strategies for Planning Career Goals

Step 1: Determine the goal for improving professional employability or skills.

Step 2: Identify the requirements for the goal. What will be needed to achieve it?

Step 3: Identify personal strengths and areas that need improvement.

Step 4: Create an action plan with a timeline for meeting that goal.

SOME ADVICE ABOUT CAREER GOALS

Just as personal development is a lifelong process, professional development is a career-long process. Sometimes, employees get discouraged because they set lofty goals that do not materialize immediately. Most goals are achievable, but there may be many smaller goals to accomplish along the way. For example, if the goal is to be the CS department director, that requires achieving some educational goals and will most likely first require attaining some other leadership positions, such as lead technician or supervisor. When identifying what is necessary to achieve the final goal, be sure to identify individual steps that may be needed to prepare for that goal.

Those steps may include:

- Certification.
- Attending educational conferences.
- Becoming active in professional groups.
- Engage in on-the-job training in leadership, job and task-related skills.

THE IMPORTANCE OF RESOURCES

One of the most important factors in attaining goals is finding the right resources to help provide direction and support. There are many resources that can aid in professional development.

Figure 24.4

Educational resources include publications, printed resources, courses, conferences, online information and other types of information designed to enhance knowledge about a specific process or topic.

A Note about Online Resources

When using online resources, make sure the information and source is valid and current.

Developing professional resources within the field of CS can provide a network with which to share information on issues pertinent to the department. CS peers may have already faced similar situations and may be able to share insights and information.

Do not underestimate the importance of developing a network outside of one's current specialty. OR professionals, infection preventionists, safety officers and Biomedical engineers are a few of the healthcare specialists that can help CS professionals increase their knowledge about specific aspects of the field — and healthcare, in general.

There are several ways to build a network of resources. Becoming active in a local professional group is a great place to start. If there is no group in the area, contact local CS departments and explore the possibility of starting one. The first step can be as simple as gathering some interested individuals at a local business establishment.

PROFESSIONAL DEVELOPMENT ACTIVITIES

There are also ways to enhance existing skills and develop new ones to increase professional knowledge, develop professional behaviors and attain more expertise. **Figure 24.5** explores some ideas for professional development activities.

DEVELOPING A RESUMÉ

A resumé is a compilation of skills, education and accomplishments. It provides a prospective employer with information to help them determine if an employee has the necessary knowledge and skills to be successful in a specific job.

Professional Development Skills Building

Desired Skill	Skill Building Activities
Public speaking • Teaching • Presentations • Speaking in larger groups	• Start with smaller presentations, such as reports and small in-services. Work up to larger presentations for larger groups. • Join a speaking development group. • Take a public speaking class.
Technical expertise	• Pursue additional knowledge through courses, certifications, job shadowing, self study. • Participate in committees through your facility or local and national professional organization. • Take steps to keep up with changes in regulations, standards and technologies.
Writing skills	• Practice writing and ask someone to review what you have written for accuracy, clarity, grammar, spelling and punctuation. • Take a writing class.
Team building skills	• Start by examining your relationships and role with your current team. What can you improve? • Move outside your comfort zone and work with different teams for short projects. • Read articles on team building.

Figure 24.5

One concept of professional development is building a resumé through the advancement of skills. For example, if one aspires to become a CS staff educator, gaining experience presenting inservices, training new employees or developing educational tools for the department can strengthen those skills.

Sometimes, obtaining a new position, either externally or through a promotion within the current healthcare facility, can be decided by a very small margin. For example, if an individual's resumé includes past experience in staff education, that may offer an advantage in the selection process for an educator position.

Many templates exist to assist with resumé writing. Regardless of the chosen format, be certain to follow these simple rules:

- Be truthful.
- Research the duties of the job being sought and use personal experiences to help convince the employer that you are the best candidate for the job.
- Organize information in a logical fashion.
- Keep information clear and concise.
- Check for typographical errors.

UNDERSTANDING THE INTERVIEW PROCESS

CS technicians are involved in interviews as part of their initial selection process, and they participate in performance evaluations that typically include an interview-like component. While much of the interview process is controlled by the manager or another person conducting the interview, the interviewee (CS technician) can benefit from the use of basic speaking and listening techniques (as

discussed in Chapter 23) during these sessions. This is especially important because contemporary interviewing methods emphasize a participative approach in which the person conducting the interview interacts with rather than "lectures to" the interviewee.

There are two types of questions that interviewers may ask:

- Open-ended questions that permit the interviewee to respond in an unstructured manner. Examples may include:
  - "What do you think the role of a CS technician should be?"
  - "Give an example of a time when you communicated successfully with another person, even when that individual may not have agreed with your point of view."
- Closed-ended questions call for a brief response. Examples may include:
  - "Do you like your job?"
  - "Do you understand the correct way to do this task?"

Many interviews include both types of questions. One important step in preparing for any interview is to anticipate the types of questions likely to be asked, and then plan a response for them. A good response will answer the question and provide supporting details. This is an opportunity to display knowledge and an understanding for the profession, not to provide "textbook answers." Along with well-thought-out responses, an interviewee should also prepare some questions for the interviewer. This demonstrates an interest for the position and also allows the interviewee to participate in the interview process.

Steps in an Interview

There are four basic steps in any type of interview:

Step 1: It must be planned. Be sure you know the exact purpose of the interview and the "mechanics" of it (time, location and estimated duration).

Step 2: The opening conversation is helpful. Hopefully, there will be an initial discussion of mutual topics of interest to move the discussion away from ongoing work considerations to the specific topic. Professional CS technicians should have the confidence, pride, expertise and positive attitude to reduce tension and allow them to be confident during the interview.

Step 3: Questions will be asked. This is where the interviewee's anticipation of potential questions and ability to effectively speak and listen will be most useful. It is also where application of the speaking and listening tactics outlined previously will be most helpful.

Step 4: The interview discussion can be reviewed. Hopefully, the interviewer will provide a summary. The CS technician should provide reactions to this review, so both parties can agree on what was decided and which, if any, follow-up activities should be undertaken.

Interviews are important. Dress professionally, be punctual and take the interview seriously. Even if you are interviewing for a position at your current place of employment, be sure to follow general interview protocols. Doing so will demonstrate readiness for a change and added responsibilities.

Figure 24.6

PROMOTIONS

Many CS technicians who perform their jobs well have opportunities for promotion to positions with additional responsibilities and higher compensation. Those who accept these positions will likely find many differences in tasks, especially if they assume supervisory duties. Challenges arise when a staff member who has been a peer to other employees becomes their supervisor. Relationships change and they must reflect the new supervisor/**subordinate** dynamic.

Subordinate An employee who is supervised by someone in a higher organizational position.

All management positions must consider the broader needs of the department and the healthcare facility before the specific needs of individual staff members. This can be difficult when they have personal (friendship) relationships with some of those whom they supervise.

CS technicians considering promotions should also recognize that some tasks will be different. One with the knowledge and skills to perform cleaning, decontamination and related tasks may not be as comfortable performing supervisory activities, such as planning, coordinating, directing, controlling and evaluating.

Long-term planning leading to promotion decisions should be an integral part of professional development considerations of interested CS technicians.

PERSONAL AND PROFESSIONAL DEVELOPMENT TIMELINES

Some personal and professional development goals are easier to attain than others. Promotions usually don't happen overnight, but neither does preparing for them. Personal and professional development timelines should be realistic and achievable. Goals for each require planning, commitment and an understanding that things don't always go as planned. When setbacks occur, and they sometimes do, it is essential to regroup and continue moving toward established goals.

CONCLUSION

The field of Central Service is dynamic and ever-evolving, and it requires professional and dynamic individuals to help lead the way in education, systems development, and departmental management. Through personal and professional development, CS technicians can not only enhance the skills necessary to improve upon their current positions, but they can also create new opportunities for career fulfillment and growth.

RESOURCES

Safani B. *Happy about My Resume. 50 Tips for Building a Better Document and Securing a Brighter Future.* 2008.

McDaniel A. *The Young Professional's Guide to the Working World: Savvy Strategies to Get in, Get ahead, and Rise to the Top.* 2013.

International Association of Healthcare Central Service Materiel Management. *Central Service Leadership Manual.* 2010.

CENTRAL SERVICE TERMS

Personal development

Professional development

Subordinate

Glossary

A

AAMI Abbreviation for Association for the Advancement of Medical Instrumentation.

ABC analysis Inventory management strategy that indicates storeroom controls should first address the relatively few items with the greatest value (A items), and should lastly consider the many items with the lowest value (C items).

abdomen Part of the body between the chest and the pelvis.

abduction Movement away from the midline; turning outward.

abort Failed or incomplete machine cycle caused by a malfunction.

abrasive Any of a wide variety of natural or manufactured gritty substances used to grind,wear down, rub away, smooth or scour.

abscess Area of tissue breakdown; a localized space in the body containing pus and liquefied tissue.

absolute pressure (steam sterilizer) Gauge pressure (machine produced) + atmospheric pressure (14.7 pounds per square inch at sea level).

absorbent towel All-cotton towel having a plain weave with only the warp yarns tightly twisted.

acceptance sampling Inspection of a sample from a larger lot to decide whether the lot should be accepted.

ACGIH Abbreviation for American Conference of Governmental Industrial Hygienists.

acid Compound with a pH of less than 7.0 and with a sour, sharp or biting taste; a compound with a water solution that contains positive hydrogen ions (example: HCl).

acid detergent Organic, acid-based cleaning agent; best used for removing mineral deposits.

acid-fast bacteria Bacteria that do not de-colorize when acid is added to the stained smear.

acidity Measurement of the amount of acid present.

acidosis Condition that results from a decrease in the pH of body fluids.

acid scrubber Type of ethylene oxide emission control device.

acquired immune deficiency syndrome (AIDS) Viral disease that attacks the immune system.

acquired immunity Immunity acquired by a person after birth.

action level Level of exposure to a harmful substance or other hazard at which an employer must take required precautions to protect the workers. It is normally one half of the permissible exposure limit.

activated (activation) Process by which a solution is combined with an activating chemical before use. Glutaraldehydes must be activated before initial use.

acute Short in time; relatively severe in degree.

acute disease A disease or disorder that lasts a short time, comes on rapidly and is accompanied by distinct symptoms.

adhesion Holding together of two surfaces or parts; a band of connective tissue between parts that are normally separate; the molecular attraction between contacting bodies.

adipose Referring to fatty tissue.

adrenal Endocrine gland located above the kidney; suprarenal gland.

aerate To expose gas-sterilized items to warm, circulating air.

aeration A process in which sterilized packages are subjected to moving air to facilitate removal of toxic residuals after exposure to a sterilizing agent, such as ethylene oxide.

aerator (ethylene oxide) Machine designed to speed up removal of ethylene oxide residuals from sterilized items by subjecting them to warm, circulating air.

aerobe Microorganism that requires the presence of air or oxygen for growth.

aerobic (bacteria) Capable of growing in the presence of free oxygen; requiring oxygen.

Glossary

aerosol Suspension of ultramicroscopic solid or liquid particles in air or gas; a spray.

affinity Attraction.

agar Extract of red seaweed used as a solidifying agent in culture media.

AIDS Abbreviation for acquired immune deficiency syndrome; the advanced symptomatic and often fatal disease in the progression of an HIV infection.

airborne Suspended or carried in a gas or air stream.

air count Method of estimating the number of bacteria or microbes in a specific quantity of air.

albumin Protein in blood plasma and other body fluids that helps to maintain the osmotic pressure of the blood.

alimentary canal Pathway that food takes through the body's digestive system.

alkalies Chemicals that release an excess of hydroxyl ions (OH) in a solution to yield a pH of more than 7.

alkaline In solution; having a pH greater than 7.

alkalosis Condition that results from an increase in the pH of body fluids.

alkylation A chemical reaction where hydrogen is replaced with an alkyl group, this causes the cell to be unable to normally metabolize or reproduce, or both.

allergen Substance that causes hypersensitivity; substance that induces allergy.

allergic Caused by allergy.

allergy Tendency to react unfavorably to a certain substance that is normally harmless to most people; hypersensitivity.

alveolus (pl. alveoli) One of millions of tiny air sacs in the lungs through which gases are exchanged between the outside air and the blood; tooth socket.

ambient condition Environmental conditions such as pressure, temperature and humidity, which are normal for a specific location.

ameba (pl. amebas) Protozoon that moves by extruding finger-like elements (pseudopods); also spelled amoeba (pl. amoebae).

amebiasis Infection with pathogenic amebas; acute amebiasis is called amebic dysentery.

amino acid Building block of protein; organic chemical compounds containing an amino group and a carboxyl group; forms the chief structure of proteins.

amitosis Direct cell division.

amniocentesis Removal of fluid and cells from the amniotic sac for prenatal diagnostic tests.

amniotic sac Fluid-filled sac that surrounds and cushions the developing fetus.

amoeboid movement Crawling movement of cells that occurs as the cell successively becomes longer and then retracts.

anaerobe Microorganism that grows only or best in the absence of oxygen.

anaerobic (bacteria) Capable of growing in the absence of free oxygen; not requiring oxygen.

analgesic Relieving pain; a pain-relieving agent that does not cause loss of consciousness.

anaphylaxis State of hypersensitivity to a protein resulting from a previous introduction of the protein into the body; may result in death without treatment.

anastomosis Surgical or pathological formation of a passage between two normally distinct structures, such as tubular organs.

anatomy The study of the structure and relationships between body parts.

anemia Reduction in the amount of red cells or hemoglobin in the blood resulting in inadequate delivery of oxygen to the tissues.

anesthesia Loss of sensation (particularly of pain).

aneurysm Bulging sac in the wall of a vessel.

angina Severe choking pain; disease or condition producing such pain.

angina pectoris Suffocating pain in the chest usually caused by lack of oxygen supply to the heart.

angstrom A unit used to measure the length of light waves.

Glossary

animate Having life.

anion Negatively-charged particle (ion).

anionic Compounds with a negative electrical charge on the large organic portion of the molecule which are relatively hydrophobic and lipophilic; used as synthetic detergents.

anorexia Loss of appetite.

anoxia Lack of oxygen.

ANSI Abbreviation for American National Standards Institute.

antagonist Muscle with an action opposite that of a given movement; substance that opposes the action of another substance.

anterior Toward the front or belly surface; ventral.

anthrax Infectious disease of cattle and sheep caused by a spore-forming bacterium (Bacillusanthracis) which may be transmitted to man through handling of infected products.

antibacterial serum Antiserum that destroys or prevents the growth of bacteria.

antibiotic Substance produced by one microorganism that will kill or inhibit another microorganism.

antibody Protein produced in the body which reacts against a specific foreign molecule (antigen).

antigen Substance which causes the body to produce antibodies.

antiseptic Solution that inhibits the growth of bacteria; usually used topically and only on animate (living) objects.

antiserum Serum containing antibodies given to provide passive immunity.

antitoxin Immune serum that neutralizes the action of a toxin.

anus Lower opening of the alimentary canal.

anvil One of the three middle ear bones; attaches to the hammer and stirrup.

AORN Abbreviation for Association of peri-Operative Registered Nurses.

aorta Largest blood vessel in the body.

APIC Abbreviation for Association for Professionals in Infection Control and Epidemiology.

aqueous humor Watery-like fluid between the cornea and the eye lens.

aqueous solution Liquid in which a chemical substance is dissolved in water.

areriole Vessel between a small artery and a capillary.

arrhythmia Abnormal rhythm of the heartbeat.

arteries Vessels that carry blood away from the heart.

arteriosclerosis Hardening of the arteries.

arthritis Inflammation of the joints.

asepsis Absence of microorganisms that cause disease.

asepsis (medical) clean technique Procedures performed to reduce the number of microorganisms to minimize their spread.

asepsis (surgical) surgical technique Procedures to eliminate the presence of all microorganisms and/or to prevent the introduction of microorganisms to an area.

aseptic Free from pathogenic organisms; a means of preventing infection.

aseptic technique Activity or procedure that prevents infection or breaks the chain of infection.

ASHCSP Abbreviation for American Society of Healthcare Central Service Personnel.

asphyxia Condition caused by lack of oxygen in inspired air.

aspirate To draw by suction. Examples: when fluid is removed with a syringe and material is drawn into the lungs during inspiration.

assembly area A clean area of the Central Service department where inspection, assembly and packaging functions are performed. The assembly area is sometimes called the Preparation and Packaging (prep and pack) area.

asset Something of value owned by an organization or person.

asset (current) Asset that is expected to be used within one year.

Asymptomatic Shows no signs or symptoms of disease or infection.

atherosclerosis Hardening of the arteries caused by deposits of yellowish, fat-like material on blood vessel linings.

atom Fundamental unit of a chemical element.

atria The two upper chambers of the heart.

atrium One of the two upper chambers of the heart.

atrophy Wasting or decreasing in size of a part.

attenuated Weakened attitude; a person's emotions or willingness that cause him/her to react in a predetermined way to people or situations.

attitude Emotions that cause a person to react to people and/or situations in a predetermined way.

austenitic (stainless steel) This material is also known as 300 stainless steel. It is nonmagnetic, cannot be heat hardened and is more corrosion-resistant than martensitic stainless steel.

autoclave Equipment that uses steam under pressure to sterilize, usually at temperatures of 250° or 270°F (121°C or 132°C).

automated supply replenishment system Replenishment system in which items removed from inventory are automatically identified and tracked. When a reorder point is reached, item information is generated on a supply pick list in the central storeroom or at a contracted vendor. Items are then issued and transferred to the appropriate user area.

automatic endoscope reprocessor (AER) Automated equipment designed to clean, disinfect and rinse flexible endoscopes.

autonomic nervous system Part of the nervous system that controls smooth muscle, cardiac muscle and glands; motor portion of the visceral or involuntary nervous system.

autopsy Examination of the internal organs of a dead body.

axilla Hollow beneath the arm where it joins the body; armpit.

B

bacillus (pl., bacilli) Rod-shaped bacteria; a genus of the family *Bacillaceae.*

bacillus atrophaeus Resistant microorganism used to challenge ethylene oxide sterilizers.

bacillus stearothermophilus See *geobacillus stearothermophilus.*

bacillus subtilis See bacillus atrophaeus.

bacteremia Condition in which bacteria are in the bloodstream.

bacteria (sing. bacterium) Single-celled, plant-like microbes that reproduce by splitting; some cause diseases; also called "germs."

bacterial count Method of estimating the number of bacteria in a sample unit.

bactericidal Relating to the destruction of bacteria.

bactericide Substance that kills bacteria.

bacteriology Science of the study of bacteria.

bacteriophage Virus that parasitizes and multiplies exclusively in bacteria.

bacteriostasis Condition in which bacterial growth is inhibited, but the organisms are not killed.

bacteriostat Substance that inhibits the growth of bacteria.

bacteriostatic Inhibition of bacterial growth without their destruction.

balance sheet Financial summary of what a healthcare facility owns (assets), owes (liabilities) and is worth (equity) at a specific point in time. Example: the last day of every month.

bar code Numerous machine-readable rectangular bars and spaces arranged in a specific way to represent letters, numbers and other symbols.

barrier cloth Fabrics made of blends or cotton/polyester.

barrier packaging Minimum package that prevents ingress of microorganisms and allows aseptic presentation of the product at the point of use.

Glossary

barrier properties Ability of a material to resist the penetration of liquids and/or microorganisms.

basal ganglia Gray masses in the lower part of the forebrain that assist with muscle coordination.

base Compound with a pH above 7.0, a compound whose water solution yields negative hydroxyl ions (e.g., NaOH), and combines with an acid to form a salt and water; turns red litmus paper blue.

basophil Granular white blood cell that shows large, dark blue cytoplasmic granules when stained with basic stain.

BCG (Bacillus of Calmette-Guerin) Vaccine against tuberculosis made from a bovine strain of tubercle bacilli attenuated through long culturing.

benign Tumor that does not spread, is not recurrent or becoming worse; not malignant.

best practice - A method or technique that has consistently shown results superior to those achieved with other means.

bevel Angle at which the point of a needle is ground.

bile Substance produced in the liver that emulsifies fats.

binary fission Typical method of bacterial reproduction in which a cell divides into two equal parts.

bioburden The number of microorganisms on a contaminated object; also called bioload or microbial load.

biocide A substance or microorganism that kills or controls the growth of living organisms. Examples: antibiotics and disinfectants.

biodegradable Readily decomposed by bacteria or enzymatic actions.

biofilm A collection of microorganisms that attach to surfaces and each other and form a colony. The colony produces a protective gel that is very difficult to penetrate with detergents and disinfectants.

biohazard signage notices posted in easily-seen locations that alert persons in the area about the presence of harmful bacteria, viruses or other dangerous biohazardous agents or organisms.

biohazardous waste Wastes containing infectious agents that present a risk or potential risk to human health either directly through infections or indirectly through the environment.

biological Relating to biology.

biological indicator (BI) Sterilization process monitoring device consisting of a standardized, viable population of microorganisms (usually bacterial spores) known to be resistant to the mode of sterilization being monitored.

biological transfer of infection Mode of transfer of infection from host to host by an animal or insect in which the disease-causing agent goes through a development cycle.

biology Science which studies living things, both animals and plants.

Biomedical/Clinical Engineering department The hospital department responsible for performing safety inspections and function tests on medical equipment; frequently abbreviated "Biomed Department." Also known as Healthcare Technology Management department.

biopsy Removal of tissue or other material from the living body for examination, usually under the microscope.

blood Connective tissue fluid that transports many substances throughout the circulatory system.

borosilicate Alkaline-free silicate glass having at least 5% boric oxide and used especially in heat-resistant glassware; a very hard glass (Pyrex).

botulism Food poisoning caused by the toxin of an anaerobic, spore-forming bacterium, (clostridium botulinum) in contaminated canned or smoked foods.

Bowie-Dick test Test run daily to validate the vacuum function of the sterilizer. The test should be run in an empty load and at the same time each day.

box locks Point where the two jaws or blades of an instrument connect and pivot.

bradycardia Heart rate of less than 60 beats per minute.

brain Main control unit of the central nervous system.

brain stem Controls many automatic body functions such as heartbeat and breathing.

breakout The process of removing commercially-sterilized items from their outer shipper containers in an area adjacent to the storage area to prevent contamination that is present on the containers from being introduced into the storage area.

broad spectrum Term indicating that an antibiotic is effective against a large array of microorganisms.

bronchi The main passageway for air to travel from the trachea to the lungs.

bronchiole One of the small bronchial subdivisions that branch throughout the lungs.

brownian motion Dancing motion of finely divided particles in suspension.

buffer Substance that prevents sharp changes in the pH of a solution.

bursa Small, fluid-filled sac in an area subject to stress around bones and joints.

C

calibration Comparison of a measurement system or device of unknown accuracy to a national standard of known accuracy to detect, correlate, report or adjust any variation from the required performance limits of the unverified measurement system or device.

cancer Uncontrolled growth of a tumor that spreads to other tissue; a malignant neoplasm.

cannulas Surgical instruments with a hollow barrel (or lumen) through their center; often inserted for drainage.

capillaries Vessels that connect veins and arteries.

capillary action Attraction or repulsion force caused by the surface tension of liquids in hair-like tubes.

capital equipment Item of major importance; usually defined by a set dollar amount and which is depreciated over the useful life of the equipment rather than being expensed at purchase.

capital (equipment) Assets that are relatively expensive such as sterilizers or washers that require significant advance planning for their purchase.

capsule Gelatinous, colorless envelope or slime layer surrounding the cell wall of certain microorganisms; a membrane or sack containing a body part.

carbohydrate Simple sugar or compound made from simple sugars linked together.

carbon dioxide Gaseous waste product of cellular metabolism; C02.

carcinogen Cancer-causing substance.

carcinoma Malignant growth of epithelial cells; a form of cancer.

cardiopulmonary resuscitation Method to restore heartbeat and breathing by mouth-to-mouth resuscitation and closed chest cardiac massage; also called "CPR."

carditis Inflammation of the heart; myocarditis.

career ladder Plan projecting progressively more responsible professional positions that serves as a foundation for a professional development program.

caries Tooth decay.

carpals Wrist bones.

carrier A person or organism infected with an infectious disease agent, but displays no symptoms. Although unaffected by the disease themselves, carriers can transmit it to others.

cartilage Type of flexible connective tissue.

case cart A cart prepared for an individual procedure. Case carts usually contain all instruments, supplies and utensils needed for a specific procedure.

case cart pull sheet (pick list) A list of specific supplies, utensils and instruments for a specific procedure. Central Service technicians use these lists to assemble the items needed for individual procedures.

case cart system An inventory control system for products/equipment typically used in an Operating Room that involves use of an enclosed or covered cart generally prepared for one surgical case, and not used for general supply replenishment.

Glossary

CAT scan See computed tomography.

catalyst Substance that influences the speed of a chemical reaction without being consumed.

catalytic converter Type of ethylene oxide emission control device.

cataract Opacity of the eye lens or lens capsule.

catheter Slender, flexible tube of rubber, plastic or metal used for draining a body cavity or injecting fluids through a body passage.

cation Positively charged particle (ion).

cation resin tank Tank into which untreated hard water flows, and in which sodium ions are exchanged for calcium and magnesium ions to produce soft water.

cationic Compounds containing a positive electrical charge on the large organic hydrophobic molecule which exhibit germicidal properties.

causative agent (chain of infection) Microorganism that causes an infectious disease.

caustic Corrosive and burning; agent, particularly an alkali, that will destroy living tissue.

cautery Burner; a means of destroying tissue by electricity, heat or corrosive chemicals. Thermocautery consists of a red hot or white hot object, usually a wire or pointed metallic instrument, heated in a flame or with electricity.

cavitation Process used by an ultrasonic cleaner in which low-pressure bubbles in a cleaning solution burst inward to dislodge soil from instruments.

CDC Abbreviation for Centers for Disease Control and Prevention (part of the Department of Health and Human Services) whose primary function is to investigate outbreaks of and control various diseases.

cecum Small pouch at the beginning of the large intestine.

ceiling limit The maximum safe airborne concentration of a potentially toxic substance.

cell Basic unit of life; the smallest structural unit of living organisms capable of performing all basic life functions.

cell membrane Outer covering of a cell; regulates what enters and leaves the cell.

cellulitis Diffuse inflammation of connective tissues.

centigrade Thermometer temperature scale with 100° between the melting point of ice at 0° and the boiling point of water at 100°.

central nervous system (CNS) Part of the nervous system that includes the brain and spinal cord.

centrifuge Device used to spin test tubes; used in the laboratory.

cerebellum Second largest part of the brain. It controls muscle coordination, body balance and posture.

cerebrospinal fluid (CSF) Fluid that circulates in and around the brain and spinal cord.

cerebrovascular accident (CVA) Condition involving bleeding from the brain or obstruction of blood flow to brain tissue, usually resulting from hypertension or atherosclerosis; also called stroke.

cerebrum Largest part of the brain. It that controls mental activities and movement.

certification Association and industry recognition given to individuals with educational and/or work experience requirements who successfully complete an examination process that demonstrates their knowledge of subject-matter to be mastered for success in the position.

cervix Lower end (neck) of the uterus.

chlorofluorocarbon (CHC) Inert (inflammable) gas often mixed with a flammable gas to create an inflammable solution; has been used with ethylene oxide to create an inert gas.

chain of infection A way of gathering the information needed to interrupt or prevent an infection. Each of the links in the chain must be favorable to the organism for the infection to continue. Breaking any link in the chain can disrupt the infection. Which link is most effective to target will depend on the organism.

challenge test pack Used in qualification, installation and ongoing quality assurance testing of hospital sterilizers.

chamber Enclosed area that holds products to be sterilized.

chelating agents Chemicals that hold hard water minerals in solution and prevent soaps or detergents from reacting with the minerals.

chemical indicators (CIs) Devices used to monitor the presence or attainment of one or more of the parameters required for a satisfactory sterilization process.

chemical sterilization Process using a chemical agent to render a product free of viable microorganisms.

chemotherapy Treatment of disease without injury to patient with chemicals having a specific effect on microorganisms.

chickenpox Varicella; a rather mild, highly contagious virus disease characterized by fever and the appearance of vesicles.

chisels Wedge-shaped instruments used to cut or shape bone.

CHL Abbreviation for Certification in Healthcare Leadership, a certification offered by the International Association of Healthcare Central Service Materiel Management.

CHMMC Abbreviation for Certification in Healthcare Materiel Management Concepts (International Association of Healthcare Central Service Materiel Management).

chloride Compound commonly found in water created when chlorine is combined with another element or radical. Examples: salt and hydrochloric acid.

chlorophyll Molecule in plants that absorbs sunlight and converts it to energy in a process called photosynthesis.

cholesterol Organic, fat-like compound found in animal fat, bile blood, myelin, liver and other parts of the body.

chromium Blue-white metallic element found naturally only in combination and used in alloys and electroplating.

chromogenic Producing a pigment.

chromosomes Rod-shaped structures responsible for inherited characteristics passed from parent to child.

chronic Referring to a disease (illness) that is not severe, but is continuous, recurring, protracted and prolonged.

cilia (sing. cilium) Hair-like elements that spring from certain cells and, by their action, create currents in liquids; if the cells are fixed, the liquid is made to flow; if the cells are unicellular organisms suspended in the liquid, the cells move.

circumduction Circular movement at a joint.

cirrhosis Chronic disease (usually of the liver) in which active cells are replaced by inactive scar tissue.

CIS Abbreviation for Certified Instrument Specialist, a certification offered by the International Association of Healthcare Central Service Materiel Management.

CJD Abbreviation for Creutzfeld-Jakob Disease; a debilitating, fatal brain disease; see prions.

class 5 (chemical integrators) Integrating indicators designed to react to all critical parameters over a specified range of sterilization cycles.

cleaning Removal of all visible and non-visible soil, and any other foreign material from medical devices being processed.

clostridium Genus of cylindrical-shaped bacteria that are anaerobic, gram positive and spore forming.

cloud computing The practice of storing regularly used computer data on multiple servers that can be accessed through the Internet.

coaching Positive reinforcement used to encourage Central Service technicians to follow proper work behaviors, and negative reinforcement to discourage inappropriate work behaviors.

coagulase Enzyme that causes coagulation or clotting of blood serum.

coagulation Clotting (as in blood).

coccus Round-shaped (spherical) bacterium.

coccyx Tailbone.

cochlea Coiled portion of the inner ear that contains the organs of hearing.

cold boil Cavitation that is not dependent upon heat for its bubbling action.

coliform bacteria Group of intestinal microorganisms of which Escherichia coli is a member.

collagen Flexible white protein that gives strength and resilience to connective tissue, including bone and cartilage.

colon Main portion of the large intestine.

colonization Occurs when microorganisms live on or in a host organism, but do not invade tissues or cause damage.

colony Visible growth of microorganisms seen in culture medium; usually obtained from a single organism.

colony count Determination of the number of visible clumps of bacteria derived from the multiplication of specific microorganisms on or in a culture medium.

combining vowel Letter, usually an "o," that is sometimes used to ease the pronunciation of a medical word.

combustible Substance that, if ignited, will react with oxygen and burn.

combustible Loading weight of combustible materials per square foot of area in which the materials are located.

combustion Chemical process accompanied by the rapid production of heat and light.

commissioning (installation qualification) Obtaining and documenting evidence that equipment has been provided and installed in accordance with its specifications, and that it functions within predetermined limits when operated in accordance with operational instructions.

communicable Disease whose causative agent is easily transmitted from person to person by direct or indirect contact.

communication Process of transmitting information and understanding from one person to another by use of words and nonverbal expressions including body language.

complication Secondary illness imposed upon a person with a primary illness.

compound Substance composed of two or more chemical elements.

computed tomography Imaging method in which multiple x-ray views taken from different angles are analyzed by computer to show a cross section of an area; used to detect tumors and other abnormalities; abbreviated "CT" or "CAT" (computed axial tomography).

conditioning Treatment of products within the sterilization cycle but before sterilant admission to attain a predetermined temperature and relative humidity; may be carried out at atmospheric pressure or under vacuum.

conduction Heat transfer method in which heat is absorbed by an item's exterior surface and passed inward to the next layer.

conduction heating Process in which heat is transmitted in a solid substance from molecule to molecule by molecular impact or agitation.

conductivity (of water) A measurement of the ability of water to carry an electrical current.

congenital Present at birth.

conjunctiva Membrane that lines the eyelid, and covers the anterior part of the sclera.

conjunctivitis Inflammation of the conjunctiva of the eye.

consumable (inventory) Assets such as wrapping supplies, processing chemicals and other items that are consumed (used up) as healthcare services are provided to patients.

contagious Highly communicable; easily transmitted.

contaminate To render unfit for use through introduction of a substance which is harmful or injurious.

contamination State of being soiled or infected by contact with infectious organisms or other material.

continuous quality improvement (CQI) Scientific approach which applies statistical methods to improve work processes.

contraception Prevention of fertilization of an ovum or implantation of a fertilized ovum; birth control.

convalescence Period during which recovery takes place following illness.

convection Process of heat transfer by the circulation of currents from one area to another.

convection heating Transfer of heat in a fluid or gas from one place to another by the motion of the fluid or gas.

copious Present in a large amount (such as large volume of rinsing water).

cornea Clear portion of sclera that covers the front of the eye.

coronary Referring to the heart or to the arteries supplying blood to the heart.

corrosion Act of wearing away gradually by a chemical reaction.

corrosive Having the power to corrode or wear away.

cortex Outer layer of an organ, such as the brain, kidney or adrenal gland.

counterstain Second stain of a contrasting kind applied to a smear for the purpose of making the microorganisms treated with a primary stain more distinct.

CPR Abbreviation for cardiopulmonary resuscitation.

CPU Abbreviation for central processing unit.

craze Spider web cracking of plastics under chemical stress.

CRCST Abbreviation for Certified Registered Central Service Technician, a certification offered by the International Association of Healthcare Central Service Materiel Management.

crisis Change in a disease which indicates whether the result will be recovery or death.

critical devices Refers to the Spaulding medical device classification system. Instruments or objects introduced directly into the bloodstream or other normally sterile body areas.

critical parameters Parameters that are essential to the sterilization process and that require monitoring.

cross contamination Migration of contaminants from one person, object or work location to another.

cross-functional team Group of employees from different departments within the healthcare facility that work together to resolve operating problems.

cross infection Infection acquired from an animate or inanimate contaminated environment, usually accidentally.

culture Growth of microorganisms on a nutrient medium; to grow microorganisms on such medium.

culture medium Substance or preparation used for the growth and cultivation of microorganisms.

customer (internal) Physicians, nurses and other professional personnel served by Central Service personnel.

cutaneous Referring to the skin.

cyanosis Bluish color of the skin and mucous membranes resulting from insufficient oxygen in the blood.

cycle buying Purchasing method in which an order is placed at a scheduled interval.

cycle (gravitation-displacement type; steam sterilization) Sterilization cycle in which incoming steam displaces residual air through a port or drain in or near the bottom of the sterilizer chamber.

cycle (sterilization) Defined sequence of operational steps designed to achieve sterilization; carried out in a sealed chamber.

cycle time Total elapsed time of a sterilization cycle from when the sterilizer door is closed and the cycle is activated until the cycle is completed and the door is opened.

cystitis Inflammation of the urinary bladder.

cytology Study of cells.

cytoplasm Clear, jelly-like substance of a cell between the cell membrane and nucleus.

D

D-value Amount of time required to kill 90% of the microorganisms present.

debridement Surgical removal of dead or unhealthy tissue.

decontamination To make safe by removing or reducing contamination by infectious organisms or other harmful substances; the reduction of contamination to an acceptable level.

decontamination area Location within a health care facility designated for collection, retention and cleaning of soiled and/or contaminated items.

defecation Act of eliminating undigested waste from the digestive tract.

defect Variance from expected standards.

deflocculate To reduce or break up into very fine particles.

degeneration Breaking down (as from age, injury or disease).

degerm To remove bacteria and other microbes by mechanical cleaning and applying antiseptics or disinfectants.

dehydration Excessive loss of body fluid.

deionization Process by which ions with an electrical charge are removed from water.

deionize To remove ions from (as water by ion exchange); demineralize.

deionized (DI) water Water that has had all minerals removed by using an ion exchange process.

denatured alcohol Alcohol that has been rendered unfit for use as a beverage by the addition of substances which impart an unpleasant odor and taste. Examples: wood alcohol and benzene.

density Degree of compactness; closely set or thickness.

deoxyribonucleic acid (DNA) One of two nucleic acids; essential for biological inheritance.

dermatitis Inflammation of the skin.

dermis True skin; deeper part of the skin.

detergent Cleaning agent composed of a "surface wetting agent" that reduces surface tension; a "builder" which is the principle cleaning agent, and a "sequestering" or "chelating agent" to suspend the soil; detergents may also have additional additives, such as blood solvents or rust inhibitors; any chemical that causes oil or grease to dissolve in water and cleans the item on which it is used. Unlike soap, detergent does not contain fats and lye.

detergent/germicide Combination of a cleaning agent and a disinfectant.

detergent/sanitizer Combination of chemicals that possesses antibacterial and cleaning properties.

dextrose Glucose; simple sugar

diabetes mellitus Disease in which glucose is not oxidized in body tissues for energy because of insufficient insulin.

diagnosis Identification of an illness.

dialysis Method to separate molecules in solution based on differences in their rates of diffusion through a semi-permeable membrane; method for removing nitrogen waste products from the body by hemodialysis or peritoneal dialysis.

diaphragm Dome-shaped muscle under the lungs that flattens during inhalation; a separating membrane or structure.

diarrhea Loose and frequent bowel movements.

differential staining Staining techniques to distinguish between different bacteria.

diffusion Movement of molecules from a region of higher concentration to a region of lower concentration.

digestion Process of breaking down food into absorbable particles.

dilation Widening of a part (e.g., pupil of the eye, blood vessel or uterine cervix).

diphtheria Acute, infectious disease of the mucous membranes of the upper respiratory tract; characterized by patches of *pseudomembrane* and caused by *Corynebacterium diphtheriae.*

diplococci Pairs of cocci.

direct contact Spread of disease from person to person.

disaster (external) Situation in which activities external to the facility affect departmental or facility operations.

disaster (internal) Situation with the potential to cause harm or injury to Central Service or other employees, or where the loss of utilities may drastically impact departmental operations.

disease State of illness characterized by marked symptoms caused by an infectious agent producing a definite pathological pattern.

disinfectant Chemical that kills most pathogenic organisms, but not all spores.

disinfectant/detergent Chemical compound that contains both detergent and disinfectant. Usually, the action of both is compromised because of the combination.

disinfection Destruction of nearly all pathogenic microorganisms on an inanimate (non-living) surface.

disinfestation Destruction of insects, rodents or other animals that transmit infections to other animals, humans or their surroundings.

displacement Ionic change in which one element exchanges with another element by oxidation or reduction; a chemical change in which one element, molecule or radical is removed by another.

dissection The process of cutting apart or separating tissue.

dissociation Physical breaking apart of a molecule.

distal The end of an item that is farthest away from the point of origin; the end of the instrument farthest away from the operator; the distal end of the femur is closest to the knee.

distill To vaporize by heat, and condense and collect the volatilized product.

distillation Changes from liquid to vapor to liquid; a process for removing impurities from liquids.

distilled water Water that has been heated to boiling point, vaporized, cooled and condensed into liquid form. Distillation removes impurities and like gases and organic material, it also removes some bacteria.

distribution Movement of supplies (primarily consumable supplies from storeroom to clinical units and reprocessed supplies from Central Service to the Operating Room) throughout the facility.

diversity The broad range of human characteristics and dimensions that impact employees' values, opportunities and perceptions of themselves and others at work.

DNA See deoxyribonucleic acid.

doctor's (physician's) preference card Document that identifies a physician's needs (requests and preferences) for a specific medical procedure. Preference cards usually contain information regarding the instruments, equipment, supplies and utensils used by a specific physician. They may also include reminders for the staff of the physician's preferences regarding patient draping, instruments and supplies.

dominant Referring to a gene that is always expressed if present.

dorsal Toward the back; posterior.

down time rate (equipment) Number of down days/number of devices (x) 365.

droplet infection Infection transmitted by small drops (particles) of sputum or nasal discharges expelled into the air while talking, coughing or sneezing.

duct Tube or vessel.

duodenum First portion of the small intestine.

dust cover Protective plastic bag used to maintain the sterility of an item by protecting it from the environment; also known as a sterility maintenance cover.

dye Coloring material used for staining or coloring bacteria for microscopic examination.

dyspnea Difficult or labored breathing.

E

ebonize Exposure of an instrument to a chemical dip that blackens the metal.

ECG Short for electrocardiogram; a picture of the electrical activity of the heart used to determine if heart disease is present.

economic order quantity (EOQ) Specific mathematical formula used to determine the most appropriate order quantity based upon usage and other variables.

ectoplasm Outer clear zone of the cytoplasm of a one-celled organism.

edema Presence of abnormally large amounts of fluid in intercellular tissue spaces of the body.

EDI Abbreviation for electronic data interchange. Orders, invoices and other transactions are transferred electronically between the customer and the vendor to create a paperless and more efficient system.

EEG Abbreviation for electroencephalogram; a picture of the electrical activity of the brain.

effusion Escape of fluid into a space or part; the fluid itself.

ejaculation Expulsion of semen through the urethra.

ejaculatory duct Duct formed by the joining of the seminal vesicle with the vas deferens, through which semen moves during ejaculation.

electrocardiograph (ECG or EKG) Instrument to study the electric activity of the heart; record made is an electrocardiogram.

electroencephalograph (EEG) Instrument used to study electric activity of the brain; record made is an electroencephalogram.

electrolyte Compound that forms ions in solution; substance that conducts an electric current in solution.

electron Negatively-charged particle that moves around the nucleus (central core) of an atom.

electroplating To plate with an adherent continuous coating by electrodeposition.

electrostatic Pertaining to the attractions and repulsions of electrical charges.

element One substance from which all matter is made; a substance that cannot be decomposed into a simpler substance.

embolus Blood clot or other obstruction in the circulation system; the condition is an embolism.

embryo Developing offspring during the first two months of pregnancy.

emesis Vomiting.

emphysema Pulmonary disease characterized by dilation and alveoli destruction.

empowerment Granting authority (power) to employees to make decisions within their areas of responsibility.

empyema Accumulation of pus in a body cavity, especially the chest.

emulsification Dispersion of two mutually immiscible (unable to be mixed) liquids.

emulsifier Any ingredient used to bind together substances that normally do not combine, such as oil and water.

emulsify To break down large volumes of fats, oils and greases into small globules, which are held in suspension.

encephalitis Inflammation of the brain.

encephalomyelitis Inflammation of the brain and spinal cord.

endemic disease One that occurs more or less continuously throughout a community.

endocarditis Inflammation of the endocardium (lining membrane) of the heart, including heart valves.

endocardium Membrane that lines the heart chambers and covers the valves.

endocrine Gland that secretes directly into the bloodstream.

endogenous Originating within the organism.

endometrium Lining of the uterus.

endoscope An instrument used to examine the interior of a hollow organ or body cavity.

endothelium Epithelium that lines the heart, blood vessels and lymphatic vessels.

engineering controls Controls (e.g., sharps disposal containers and self-sheathing needles) that isolate or remove bloodborne pathogen hazards from the workplace.

enteric Pertaining to the intestines.

enteric bacteria Bacteria living in or isolated from the intestinal tract.

entrained Trapped in the stream. Example: water can be trapped in the stream of steam.

environment Space that surrounds or encompasses a person or object.

enzymatic solution Solution containing special enzymes that dissolves proteinaceous materials.

enzyme Substance that initiates chemical changes, such as fermentation, without participating in them; a catalyst, usually protein, produced by a living cell with a specific action and optimum activity at a definite pH value.

EPA Abbreviation for Environmental Protection Agency.

epicardium Membrane that forms the outermost layer of the heart wall and is continuous with the lining of the pericardium; visceral pericardium.

epidemic Occurrence of a disease among many people in a given region at the same time.

epidemiology Study of the occurrence and distribution of disease; usually refers to epidemics.

epidermis Outermost layer of the skin.

epididymis Tube that carries sperm cells from the testes to the vas deferens.

epiglottis Leaf-shaped cartilage that covers the larynx during swallowing

equipment (capital) Relatively expensive assets, such as sterilizers or washers, that require significant advance planning for their purchase.

equipment utilization rate Days used/Number of devices (x) 365.

ergonomics Process of changing work or working conditions to reduce employee stress.

erythema Redness of the skin.

erythrocyte Red blood cell (corpuscle).

esophagus Tube that carries food from the throat to the stomach.

estrogen Group of female sex hormones that promotes development of the uterine lining and maintains secondary sex characteristics.

ethylene oxide (EtO or EO) Chemical (gas) used in low-temperature sterilization; performs as a very effective general purpose sterilant for heat- or moisture-sensitive items.

etiology Study of the cause of a disease or the theory of its origin.

eustachian tube Tube that connects the middle ear cavity to the throat; auditory tube.

exacerbation Increase in the severity of a disease.

exchange cart system Inventory system in which desired inventory items are placed on a cart assigned a specific location. A second duplicate cart is maintained in another location and the two carts are exchanged on a scheduled to ensure that sufficient supplies are available at all times.

excretion To eliminate or give off waste products (e.g., feces, perspiration, urine).

exfoliate To come off in strips or sheets; particularly the stripping of the skin after certain exanthematous diseases.

exotoxin Soluble poisonous substance excreted by a living microorganism; can be obtained in bacteria-free filtrates without death or disintegration of the microorganism.

expiration date Date calculated by adding a specific period of time to the date of manufacture or sterilization of a medical device or component that defines its estimated useful life.

expiration statement Statement indicating that the contents of a package are sterile indefinitely, unless the integrity of the package is compromised.

exposure time Time in which the sterilizer's chamber is maintained within the specified range for temperature, sterilant concentration, pressure and humidity.

external solutions Solutions normally used for irrigating, topical application and surgical use given orally or by inhalation.

extracellular Outside the cell.

extraction Use of physical force (usually centrifugal or strike/impact) to remove excess water from a wash load prior to drying.

extraneous Outside the organism; not belonging to it.

extrinsic Coming or operating from outside.

exudate Accumulation of a fluid in a cavity or matter that penetrates through the vessel walls into adjoining tissue.

F

facultative Having the power to do something,but not ordinarily doing it; capable of adapting to different conditions. Example: a facultative anaerobe can live in the presence of oxygen, but does not ordinarily do so.

fahrenheit Thermometer scale in which the space between the freezing point and the boiling point of water is 180°; 32° is the freezing point and 212° is the boiling point. To convert from Fahrenheit to Centigrade scales: 5/9 (°F - 32) = °C.

failure mode and effect analysis (FMEA) Process to predict the adverse outcomes of various human and machine failures to prevent future adverse outcomes.

fallopian tubes Slender tubes that convey the ova (eggs) from the ovaries to the uterus.

families (chemicals) Groups of chemicals that have similar characteristics.

fascia Band or sheet of fibrous connective tissue.

FCS Abbreviation for Fellowship in Central Service, a designation offered by the International Association of Healthcare Central Service Materiel Management.

FDA Abbreviation for U.S. Food and Drug Administration.

febrile Characterized by or pertaining to fever.

feces Waste material discharged from the large intestine; excrement; stool.

feedback Step in communication that occurs when the listener asks a question, repeats information or otherwise helps the speaker know if the message has been correctly received; also defined as a method to respectfully share ideas and information on a specific issue.

femur Upper leg bone.

fenestrated Having openings.

fermentation Decomposition of complexorganic molecules under the influence offerments or enzymes; usually associated with living microorganisms.

fertilization Union of an ovum and a spermatozoon.

fetus Developing offspring from the third month of pregnancy until birth.

fever Abnormally high body temperature.

fibrin Blood protein that forms a blood clot.

fibula Smaller bone of the lower leg.

filter Device secured to a rigid sterilization container's lid and/or bottom that allows passage of air and sterilants, but provides a microbial barrier.

filter retention system Mechanism on a rigid sterilization container that secures disposable filters in place.

filtrate Liquid that has passed through a filter.

fimbriae Finger-like projections extending from the fallopian tubes that draw ova (eggs) into the fallopian tube.

first in, first out (FIFO) Stock rotation system in which the oldest product (that which has been in storage the longest) is used first.

fissure Deep groove.

flagella Long, hair-like structures extending from the cell wall of a microorganism that help an organism to move (especially in liquids).

flammable Combustible substance that ignites very easily, burns intensely or has a rapid rate of flame spread.

flash sterilization Process by which unwrapped instruments were sterilized for immediate use when an emergency situation arises; process of sterilizing an item that is not packaged. This term is no longer used in the healthcare industry (it has been replaced with the term "immediate use steam sterilization").

flash sterilizer Sterilizer that uses higher temperatures for shorter exposure times for emergency sterilization of dropped instruments.

flatus Gas in the digestive tract.

flexion Bending motion that decreases the angle between bones at a joint.

fluid invasion Damage to powered surgical instruments when water or solution enters the instrument's internal components.

focal infection Localized site of more or less chronic infection from which bacteria or their byproducts are spread to other parts of the body.

fomite Inanimate object that can transmit bacteria.

foot candle Amount of light equivalent to that produced by one standard candle at a distance of one foot.

forceps Instruments used for grasping, holding firmly or exerting traction upon objects.

forging To form by heating and hammering.

formaldehyde Class of disinfectants most often used to disinfect hemodialysis equipment; also used as a preservative and fumigant. Should be used with caution because of its potential carcinogenic effect and irritating fumes.

fractional sterilization Sterilization performed at separate intervals, usually for 15-minute periods over three to four days, so spores will develop into bacteria that can then be destroyed.

fumigation Disinfection by exposure to a lethal gas/fumigant.

fumes Emanating from a gas or vapor (such as from a disinfectant).

fungicide Substance that kills fungi.

fungus (pl. fungi) Type of plant-like microorganism; unicellular and multi-cellular vegetable organisms that feed on organic matter (e.g., molds, mushrooms and toadstools).

G

gamma globulin Protein component of blood plasma that contains antibodies.

ganglion Collection of nerve cell bodies located outside the central nervous system.

gangrene Death of tissue due to loss of blood supply; accompanied by bacterial invasion and putrefaction.

gas State of matter in which molecules are practically unrestricted by cohesive forces. A gas has neither shape or volume, nor is it liquid nor solid.

gas cylinder safety relief device Device installed in a gas cylinder or container to prevent rupture of a cylinder by overpressures resulting from certain conditions of exposure; device may be a frangible (breakable) disc, fusible plug or relief valve.

gasket Pliable strip on sterilization containers that seals the lid and the container to prevent entry of microorganisms.

gas pressure regulator Device that may be connected to the cylinder valve outlet to regulate the gas pressure delivered to a system.

gastroenteritis Inflammation of the stomach and intestines with symptoms similar to enteritis and dysentery; often caused by enteric group of bacteria (e.g., *Salmonella paratypih* and *Salmonella schottmuller*).

gastrointestinal (GI) Pertaining to the stomach and intestine or the digestive tract, as a whole.

gauge pressure (steam sterilizer) The pressure inside the sterilizer chamber above atmospheric pressure (14.7 psi at sea level).

gene Biological unit of heredity, self-reproducing and located in a definite position (locus) on a specific chromosome.

generalized infection One involving the whole body.

genetic Pertaining to genes or heredity.

genus Group of one or more related species.

geobacillus stearothermophilus Highly resistant, but relative harmless nonpathogenic microorganism used to challenge steam and dry heat sterilizers.

germ Microorganism that causes disease.

germicidal Related to destroying germs.

germicide Agent that kills germs.

glucagon A hormone that can increase the blood sugar level.

glaucoma Disorder involving increased fluid pressure within the eye.

glucose Simple sugar; main energy source for the cells; dextrose.

gonad Sex gland; ovary or testis.

gonorrhea Contagious venereal disease of the genital mucous membranes; caused by *Neisseria gonorrhoeae*.

gram Basic unit of weight in the metric system.

gram-negative Losing the purple stain or decolorized by alcohol in Gram's method of staining; a primary identification characteristic of certain microorganisms

gram-positive Retaining the purple stain or resisting decolorization by alcohol in Gram's method of staining.

gram stain Differential stain used to classify bacteria as gram positive or gram negative, depending upon whether they retain or lose the primary stain (crystal violet) when subjected to a decolorizing agent.

gravity Pull toward the center of the earth.

greenhouse gases Any of the gases that absorb solar radiation and are responsible for the greenhouse effect, including carbon dioxide, methane, ozone and fluorocarbons.

gross soil Tissue, body fat, blood and other body substances

H

HAI – See "healthcare-acquired infection."

halogen Any of the four very active non-metallic chemical elements: chlorine, iodine, bromine and fluorine.

hammer One of the three middle ear bones; attaches to the tympanic membrane.

hand bacterial count Method of estimating the number of bacteria present on one's hand.

hand hygiene Act of washing one's hands with soap and water or using an alcohol-based hand rub.

hardness Amount of dissolved minerals in water, which alters the effectiveness of many disinfectants, detergents and soaps.

hazardous waste Substances that cannot be disposed of in the facility's normal trash system.

HCFC Abbreviation for hydrochlorofluorocarbon gas; when mixed with other gases, it yields an inflammable gas.

health care products Medical devices, medicinal products (pharmaceuticals and biologics) and invitro diagnostics.

Health Insurance Portability And Accountability Act (HIPAA) The HIPAA privacy rule provides federal protections for individually identifiable health information held by covered entities and their business associates, and gives patients an array of rights with respect to that information.

healthcare-associated infection (HAI) - An infection that is not present when a patient is admitted to a hospital or healthcare facility. If the infection develops in a patient on or after day three of admission to the hospital or healthcare facility, the infection is referred to as hospital-acquired or healthcare-associated.

Healthcare Information Management Systems Society (HIMSS) Global, cause-based, not-for-profit organization focused on better health through information technology.

heart Muscular organ that pumps blood throughout the body.

heat sink Heat-absorbent material; a mass that readily absorbs heat.

heat-up time Time required for entire load to reach a pre-selected sterilizing temperature after

the chamber has reached that temperature.

hematocrit (Hct) Volume percentage of red blood cells in whole blood; packed cell volume.

hematoma Swelling filled with blood.

hematuria Blood in the urine.

hemodialysis Removal of impurities from the blood by passage through a semi-permeable membrane.

hemoglobin Iron-containing protein in red blood cells that transports oxygen; abbreviated "Hb."

Glossary

hemolysis The destruction of red blood cells, which leads to the release of hemoglobin from within the red blood cells into the blood plasma.

hemolytic Destruction of red blood cells with the liberation of hemoglobin.

hemorrhage Loss of blood.

hemostasis Stoppage of bleeding.

hemostatic forceps Surgical instrument used to control flow of blood.

heparin Substance that prevents blood clotting; anticoagulant.

hepatitis Inflammation of the liver; usually caused by the hepatitis virus.

heredity Transmission of characteristics from parent to offspring by genes.

hernia Protrusion of an organ or tissue through the wall of the cavity in which it is normally enclosed.

herpes simplex Mild, acute, eruptive, vesicular virus disease of the skin and mucous membrane.

herpes zoster Shingles; an acute virus disease characterized by a vesicular dermatitis, which follows a nerve trunk.

high efficiency particulate air filter (HEPA) Special filters with minimum efficiency of 99.97%.

high-level disinfection The destruction of all vegetative microorganisms, mycobacterium, small or non-lipid viruses, medium or lipid viruses, fungal spores and some bacterial spores.

HIPAA See Health Insurance Portability and Accountability Act

histology Study of tissues.

HIV Abbreviation for human immunodeficiency virus; an HIV infection is a chronic viral infection characterized by progressive destruction of the T-cell, which impairs the body's immune system; disease severity is relates to the degree of immune suppression.

HMO Abbreviation for health maintenance organization.

homeostasis State of balance within the body; maintenance of body conditions within set limits.

hormones Chemical messengers that travel through the blood and act on target organs.

host Animal, plant or human that supports the growth of microorganisms.

huck towel All-cotton surgical towel with a honeycomb-effect weave.

human immunodeficiency virus Virus that causes AIDS.

human relations The development and maintenance of effective interpersonal (between people) relationships that enhance teamwork.

humerus Upper arm bone.

hydration Act of combining with water.

hydrocarbon Chemically identifiable compound of carbon and hydrogen.

hydrogen ion concentration Degree of concentration of hydrogen ions in a solution used to indicate the reaction of that solution; expressed as pH (the logarithm of the reciprocal of the hydrogen ion concentration).

hydrologic cycle Continual movement of water from the atmosphere to the earth and back to the atmosphere.

hydrolysis Splitting of large molecules by the addition of water (as in digestion).

hydrophilic Refers to a substance that absorbs or adsorbs water.

hydrophobic Refers to a substance that does not absorb or adsorb water.

hyperglycemia Abnormal increase in the amount of glucose in the blood.

hypertension High blood pressure.

hypertonic Solution with a higher osmotic pressure than that of a reference solution.

hypoglycemia Abnormal decrease in the amount of glucose in the blood.

hypotension Low blood pressure.

hypothermia Abnormally low body temperature.

hypotonic Solution that is of less than isotonic concentration.

hypoxia Reduced oxygen supply to the tissues.

I

IAHCSMM Abbreviation for International Association of Healthcare Central Service Materiel Management.

icteric Yellow pigmentation of the tissues, membranes and secretions caused by the deposit of bile pigment; usually a sign of liver or gall bladder disease.

idiopathic Of unknown cause.

idiosyncrasy Individual and peculiar susceptibility or sensitivity to a drug, protein or other matter.

ileum Last portion of the small intestine.

Immediate use steam sterilization (IUSS) Process designed for the cleaning, steam sterilization and delivery of patient care items for immediate use. Previously known as flash sterilization.

immune Exempt from a given infection.

immunity Power of an individual to resist or overcome the effects of a particular disease or other harmful agent.

immunization Process of conferring immunity on an individual.

impact marker Tool which engraves with a forceful impact that indents and "breaks" the polished metal surface, leaving an inscribed marking.

impingement Spray-force action of pressurized water against instruments being processed to physically remove bioburden.

implosion Bursting inward; the opposite of an explosion; occurs when cavitation in an energized solution collapse.

inactivation To stop or destroy activity.

inanimate Not endowed with life or spirit; not alive.

incipient Just beginning.

incompatible Not capable of being mixed without undergoing destructive chemical changes or antagonism.

Incubate To maintain under optimum environmental conditions favorable for growth.

incubation period Period between when infection occurs and appearance of first symptoms.

incubator Apparatus for maintaining a constant and suitable temperature for the growth and cultivation of microorganisms.

indefinite Shelf life of hospital-sterilized items without a definite expiration date; based on premise that shelf life is event related, not time related. User must assure the integrity of the packaging is intact, clean and properly identified.

indicator (quality) Measurable variable that relates to the outcome of patient care or employee safety.

indirect contact Transfer of infection by means including inanimate objects, contaminated fingers, water and food.

infarct Area of tissue damaged from lack of blood supply caused by blockage of a vessel.

infection Invasion of body tissue by microorganisms that multiply and produce a reaction.

infection control Control of active infectious disease; requires (a) working knowledge of the usefulness and applications of physical and chemical agents that suppress or kill microorganisms and (b) familiarity with the sources of potentially dangerous microorganisms, routes by which they spread, and their portals of entry into the body.

infectious Having the ability to transmit disease.

inferior Below or lower.

infestation Lodgment, development and reproduction of arthropods on a body or clothing.

inflammation Reaction of the tissues to an injury; a protective mechanism to an irritant on tissues.

inhibition Act of checking or restraining.

inoculate To implant or introduce causative agents of disease into an animal or plant or microbes onto culture media.

inoculated carrier Carrier on which a defined number of test organisms has been deposited.

inorganic Composed of matter other than plant or animal; minerals.

installation qualification (IQ) Obtaining and documenting evidence that equipment has been provided and installed in accordance with its specifications.

instructions for use (IFU) See manufacturer's instructions for use.

instrument Utensil or implement.

instrument washer sterilizer (IWS) Combination units that wash and sterilize instruments to ensure the safety of processing personnel.

issue Act of withdrawing supplies from storage for transfer to areas for use.

insulin Hormone that reduces the level of sugar in the blood.

integrated delivery network (IDN) System of healthcare providers and organizations that provides (or arranges to provide) a coordinated range of services to a specific population.

integrating indicator Chemical indicator (CI) designed to react to all critical parameters over a specified range of sterilization cycles, and whose performance has been correlated to the performance of the relevant biological indicator (BI) under the labeled conditions of use.

intercellular Between cells.

interfaced An area or system through which one machine is connected to another machine in order to share information. Example: Two computers may be interfaced or a computer and a sterilizer may be interfaced.

Intermediate-level disinfection The destruction of viruses, mycobacteria, fungi and vegetative bacteria, but not bacterial spores.

intermittent (fractional) sterilization Destruction of microorganisms by moist heat for given periods of time on several successive days to allow spores during the rest periods to germinate into vegetative forms (which are most easily destroyed).

interstitial Between; pertaining to spaces or structures in an organ between active tissues.

intracellular Within a cell or cells.

intravenous Within or into the veins.

in-use testing Evaluation of infection control chemicals, aseptic techniques and sanitary and sterilization procedures under actual working conditions.

inventory Reusable equipment and consumable items used to provide healthcare services for patients.

inventory (consumable) Assets, such as wrapping supplies, processing chemicals and other items, that are consumed as healthcare services are provided to patients.

inventory (official) Consumable products found in Central Service and other storerooms,warehouses and satellite storage areas. Official inventory is included as an asset on a healthcare facility's balance sheet.

inventory (reusable) Relatively inexpensive assets, such as medical devices and sterilization containers, that can be reused as healthcare services are provided to patients.

inventory service level Percentage of items filled (available) when an order is placed.

inventory stock out rate Percentage of items that cannot be filled (are not available) when an order is placed.

inventory turnover rate Number of times per year (or other time period) that inventory is purchased, consumed and replaced.

inventory (unofficial) Consumable products found in user areas, such as surgical locations and labs. Unofficial inventory has usually been expensed to user units and is stored in various locations on the units.

in vitro Referring to a process or reaction carried out in a culture test tube or petri dish.

in vivo In the living body.

iodophor Disinfectant that is a combination of iodine and a solubilizing agent (or a carrier), which slowly liberates or releases free iodine when diluted with water.

ion Electronically-charged particle formed bythe loss or gain of one or more electrons.

ionize To dissociate into ions or to become electrically charged.

iris Circular colored region of the eye aroundthe pupil.

ischemia Lack of blood supply to an area.

islets Groups of cells in the pancreas that produce hormones; islets of Langerhans.

ISO 9000 International standards used by participating organizations to help ensure that quality services and products are consistently delivered.

isolate To place by itself; to separate from others.

isotonic Solution having the same osmotic pressure as that of another solution taken as a standard reference.

isotope Form of an element with the same atomic number as another, but with a different atomic weight.

IUSS – See immediate use steam sterilization.

J

jargon Specialized words or phrases often known only by individuals working in the same job or position.

jaundice Excess of bile pigments in blood, skin and mucous membranes, with a resulting yellow appearance of the individual.

jaw Two or more opposable parts that open and close for holding or crushing something between them.

jejunum Second portion of the small intestine.

JIT Abbreviation for "just in time," a method of inventory distribution where a vendor holds inventory for an organization and on a regular basis delivers items that go directly to supply carts.

job description A human resources tool that identifies the major tasks performed by individuals in specific positions.

joint Any place where two bones meet.

julian date - The Julian day or Julian day number (JDN) is the number of days that have elapsed since January 1 of a specific year.

K

kidneys Organs that remove excess water and waste substances from the blood in a process that yields urine.

killing power Ability of a chemical to kill bacteria under laboratory conditions and during in-use testing.

L

labeling Legend, work or mark attached to, included in, belonging to or accompanying any medical device.

lacrimal Referring to tears or the tear glands.

lactation Secretion of milk.

lactic acid Organic acid that accumulates in muscle cells functioning without oxygen.

laminar airflow Filtered air moving along separate parallel flow planes to surgical suites, nurseries, bacteriology work areas and pharmacies; prevents collection of bacterial contamination or hazardous chemical fumes in work areas.

large intestine (colon) Digestive organ that dehydrates digestive residues (feces).

larynx Voice box.

laser Device that produces a very intense beam of light.

latching mechanism Mechanical device that secures a rigid sterilization container's lid to the container's bottom.

latent heat Additional heat required to change the state of a substance from solid to liquid at its melting point, or from liquid to gas at its boiling point after the temperature of the substance has reached either of those points.

lateral Farther from the midline; toward the side.

latex Common form of rubber used in the manufacture of hospital and medical supplies.

latex sensitivity Sensitivity (allergic reaction)of some people to latex caused by exposure to latex that is improperly processed; symptoms range from skin rash, primarily on the hands, to an anaphylactic reaction.

leak test (endoscope) Endoscope processing procedure that ensures the device's flexible covering and internal channels are watertight.

lean A quality process that focuses on eliminating waste in the production of products.

LED Abbreviation for light emitting diode, a semiconductor diode that emits light when voltage is applied.

lens Biconvex structure of the eye that changes in thickness to accommodate near and far vision; crystalline lens.

lesion Wound or local injury; a specific change or morphological alteration by disease or injury.

lethal Pertaining to death.

leukemia Malignant blood disease characterized by abnormal development of white blood cells.

leukocyte White blood cell.

ligament Band of connective tissue that connects a bone to another bone.

lipids Group of fats or fatty substances characterized by insolubility in water.

lipid virus A virus whose core is surrounded by a coat of lipoprotein. Viruses included in this structural category are generally easily inactivated by many types of disinfectants, including low-level disinfectants.

liquid-proof Material that prevents the penetration of liquids and microorganisms.

liquid-resistant Material that inhibits the penetration of liquids.

liter Basic unit of volume in the metric system.

liver Organ that filters the blood to remove amino acids and neutralize some harmful toxins.

load configuration All attributes defining the presentation of products to sterilization process including (a) orientation of products within the primary package (b) quantity and orientation of primary packages(s) within secondary and tertiary packages (c) quantity, orientation and placement of tertiary packages on sterilizer pallets or within carriers and (d) quantity and placement of the pallets (or carriers) within the vessel or area.

load control number Label information on sterilization packages, trays or containers that identifies the sterilizer, cycle run and date of sterilization.

loaner instrumentation Instruments or sets borrowed from a vendor for emergency or scheduled surgical procedures that will be returned following use.

local exhaust hood System that captures contaminated air and conducts it into an exhaust duct; also called a venting hood.

local infection One confined to a restricted area.

logarithm Exponent indicating the power to which a fixed number (the base) must be raised to produce a given number.

lot (load) control number Numbers and/or letters by which a specific group of products can be traced to a particular manufacturing or sterilization operation.

low-level disinfection The destruction of vegetative forms of bacteria, some fungi, and lipid viruses, but not bacterial spores.

lumen Interior path through a needle, tube or surgical instrument.

lungs Main organs of the respiratory system whose function is transporting oxygen into the blood and removing carbon dioxide from the blood.

lux A unit of illumination equal to one lumen per square meter.

lymph Fluid in the lymphatic system.

lymphatic system Series of tiny vessels throughout the body that carry lymph fluid to protect the body against disease.

lymphocyte White blood cell involved in antibody production.

M

macromolecules Large molecules (proteins, carbohydrates, lipids and nucleic acids) within a microorganism.

macroscopic Visible to the naked eye.

magnet status Award given by the American Nurses Credentialing Center to hospitals that satisfy factors measuring the strength and quality of nursing care.

magnetic resonance imaging (MRI) Method for studying tissue based on nuclear movement following exposure to radio waves in a powerful magnetic field.

maintenance insurance Equipment outsourcing alternative in which a hospital retains control of its equipment, but contracts with an insurance organization to manage and insure the costs involved in maintaining it.

malaise Indisposition, discomfort or feeling of ill health.

malignant Describing a tumor that spreads or a disorder that worsens and can lead to death.

malnutrition State resulting from lack of food, lack of an essential component of the diet, or faulty use of food in the diet.

mandible Lower jaw bone.

manufacturer's instructions for use (IFU) Information developed by a device manufacturer that provides detailed instructions on how to properly use and process the device.

Mantoux test Tuberculin skin test.

manufacturer Maker or producer of items or equipment.

martensic This metal is also known as 400 series stainless steel; it is magnetic and may be heat-hardened.

materiel management department Healthcare department responsible for researching, ordering, receiving and managing inventory (consumable supplies).

mastectomy Removal of the breast; mammectomy.

mastication Act of chewing.

measles Rubeola; acute, infectious virus disease characterized by fever, catarrh, coryza, Koplik spots on buccal mucous membrane, and a papular rash.

medial Nearer the midline of the body.

mediastinum Region between the lungs and the organs and the vessels it contains.

Medicaid Federal and state assistance program paying covered medical expenses for low-income individuals. It is run by state and local governments within federal guidelines.

medical device Any instrument, apparatus, appliance, material or other article used alone or in combination, including software necessary for its proper application intended by the manufacturer; to be used for human beings for a) diagnosis, prevention, monitoring, treatment or alleviation of disease (b) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap (c) investigation, replacement or modification of the anatomy or of a physiological process, or (d) control of conception.

Medicare Federal medical insurance program that primarily serves those over 65 years of age, regardless of income, people under 65 with certain disabilities and people of all ages with end stage renal disease.

MedWatch Safety information and adverse event reporting system from the U.S. Food and Drug Administration that serves healthcare professionals and the public by reporting serious problems suspected to be associated with the drugs and medical devices they prescribe, dispense or use.

meiosis Process of cell division that halves the chromosome number in the formation of the reproductive cells.

membrane Thin sheet of tissue.

memory Inherent ability of a substance to return to its original shape and contours.

meningitis Inflammation of the meninges.

menopause Time at which menstruation ceases.

menses Monthly flow of blood from the female reproductive tract.

mesentery Membranous peritoneal ligament that attaches the small intestine to the dorsal abdominal wall.

mesophiles Bacteria that grow best at moderate temperatures: 68°F to113°F (20°C to 45°C).

metabolic rate Rate at which energy is released from nutrients in the cells.

metabolism Total chemical changes by which the nutritional and functional activities of an organism are maintained.

metacarpals Hand bones.

metallurgy Science and technology of metals.

metastasis Spread of tumor cells.

metatarsals Bones of the foot.

meter Basic unit of length in the metric system.

methicillin-resistant Staphylococcus aureus (MRSA) Staphylococcus aureus bacteria that have developed a resistance to methicillin, the drug of choice; usually occurs with patients who have had antibiotic therapy for a long time.

microaerophilic Microorganisms which require free oxygen for their growth, but in an amount less than that of the oxygen in the atmosphere.

microbes Organisms of microscopic or submicroscopic size generally, including viruses,

rickettsiae, bacteria, algae, yeasts and molds.

microbiology The study of microorganisms. The scientific study of the nature, life and action of microorganisms.

micron Unit of measurement; 1/1000 of a millimeter or 1/25,000 of an inch or one millionth of a meter. *Note: meter equals 39.37 inches.*

microorganisms Forms of life which are too small to see with the naked eye. Bacteria, viruses and fungi are types of microorganisms; also called "germs" and "microbes."

midbrain Upper portion of the brain stem.

mil Unit of length or thickness equal to .001 of an inch.

mineral Inorganic substance; diet element needed in small amounts for health.

min/max (minimum/maximum) System in which orders are placed to reach a predetermined maximum when a predetermined minimum level is reached.

minimally invasive procedure A surgical procedure done in a manner that causes little or no trauma or injury to the patient; often performed through a cannula using lasers, endoscopes or laparoscopes. Compared with other procedures, minimally invasive procedures involve less bleeding, anesthesia and pain, and minimal scarring.

minimum effective concentration (MEC) Percentage concentration of the active ingredient in a disinfectant or chemical sterilant that is the minimum concentration at which the chemical meets all label claims for activity against specific microorganisms.

mitosis Cell division that produces two daughter cells exactly like the parent cell.

mitral valve Valve between the left atrium and left ventricle of the heart; bicuspid valve.

mixed culture Growth of two or more microorganisms in the same medium.

mixed infection Simultaneous process of two or more microorganisms causing an infection.

mixture Blend of two or more substances.

mode of transmission (chain of infection) Method of transfer of an infectious agent from the reservoir to a susceptible host.

molds See fungus.

molecular attraction Adhesive forces exerted between the surface molecules of two bodies in contact.

molecule Smallest quantity of matter that can exist in a free state and retain all of its properties.

monel A trademark used for an alloy of nickel, copper, iron and manganese.

monitor To systematically check or test to control the concentration of a specific ingredient or the execution of a process; may include qualitative and/or quantitative measurements.

monitor To watch, observe, listen to or check (something) for a special purpose over a period of time.

mouth Opening through which air, food and beverages enter the body; beginning of the alimentary canal.

MRC Abbreviation for minimum recommended concentration; minimum concentration at which the manufacturer tested the product and validated its performance.

MRI See magnetic resonance imaging.

MRSA See methicillin-resistant staphyloccus aureus.

mucosa Lining membrane that produces mucus; mucous membrane.

mucous Thick, protective fluid secreted by mucous membranes and glands.

mucous membrane Mucus-secreting membrane that lines all body cavities that open externally, including mouth, nose and intestines.

multi-parameter indicator An indicator designed for two or more critical parameters that indicates exposure to a sterilization cycle at stated values of the parameters.

murmur Abnormal heart sound.

muslin Broad term describing a wide variety of plain-weave cotton or cotton/polyester fabrics with approximately 140 threads per square inch.

mutation Change or alteration in the gradual evolution of a microorganism.

mycology Study of molds, yeasts and fungi.

myocardium Middle layer of the heart wall; heart muscle.

N

nasopharynx Portion of the pharynx above the palate.

natural immunity Immunity with which a person or animal is born.

necropsy Postmortem examination or autopsy.

necrosis Death of a mass of tissue while part of the living body.

needle holders Surgical instruments to drive suture needles to close or rejoin a wound or surgical site; also known as needle drivers.

negative air pressure Situation that occurs when air flows into a room or area because the pressure in the area is less than that of surrounding areas.

neoplasm Abnormal growth of cells; tumor.

nephron Microscopic functional unit of the kidney.

nerve Nerve fibers outside the central nervous system.

neuritis Inflammation of a nerve.

neuron Nerve cell.

neutral Neither acid nor base.

neutralizer Substance added to a medium, which stops the action of a antimicrobial agent.

NFPA Abbreviation for National Fire Protection Association.

node Small mass of tissue, such as a lymph node; space between cells in the myelin sheath.

nomenclature System of names used to identify parts of a mechanism or device.

noncritical devices Refers to the Spaulding medical device classification system; devices that come in contact with intact skin.

noncritical zone Area of a gown or drape where direct contact with blood, body fluids and other potentially infectious materials is unlikely to occur.

nonionic Atoms with no electrical charges; compounds containing a non-dissociated hydrophilic group, which forms a bond with water.

nonlipid virus A virus whose nucleic acid core is not surrounded by a lipid envelope. These viruses are generally more resistant to inactivation by disinfectants.

nonpathogenic Not capable of producing disease.

nonpyrogenic Free from fever-causing substances.

nonstock items Items that are not carried in the central storeroom or in Central Service storage area; purchased from an outside vendor, as they are needed, and delivered to the requesting department.

nontoxic Not poisonous; not capable of producing injury or disease.

nonwoven Fabric made by bonding (as opposed to weaving) fibers together

normal flora Normal bacterial population of a given area.

nose Organ of smell; also filters the air we breath.

nosocomial Hospital-acquired infection (HAI); pertaining to a hospital; applied to a disease caused in the course of being treated in a hospital.

noxious Physically harmful or destructive to living beings.

nucleotide Building block of deoxyribonucleic acid (DNA) and ribonucleic acid (RNA).

nucleus Functional center of a cell that governs activity and heredity.

O

occluded Closure of an opening.

ohm Unit of measurement that expresses the amount of resistance to the flow of an electric current.

olfactory Pertaining to the sense of smell.

oncology Study of tumors.

operational supplies Supplies that are needed for the operation of the CS department. Examples: detergents, sterilization wrap, sterilization testing products, etc.

ophthalmic Pertaining to the eye.

opportunists Microbes that produce infection

only under especially favorable conditions.

optimum temperature Applied to bacterial growth, the temperature at which bacteria grow best.

order point (order quantity system) Method of reordering a predetermined quantity of products when a predetermined on-hand level is reached.

organ Part of the body containing two or more tissues that function together for a specific purpose.

organic Describing compounds containing oxygen, carbon and hydrogen; characteristic of, pertaining to or derived from living organisms.

organic material Compounds containing oxygen, carbon and hydrogen; derived from living organisms. Organic matter in the form of serum, blood, pus, or fecal or lubricant material can interfere with the antimicrobial activity of disinfectants and sterilants.

organism Living thing, plant or animal; may be unicellular or multicellular.

origin Source; beginning; end of a muscle attached to a nonmoving part.

OSHA Abbreviation for Occupational Safety and Health Administration; concerned with safe work environment and employee safety.

osmosis Net movement of solvent molecules across a selectively permeable membrane from areas of higher to lower concentrations.

osmotic pressure Tendency of a solution to draw water into it; directly related to the concentration of the solution.

ossification Process by which cartilage is replaced by bone.

osteoblast Bone-forming cell.

osteomyelitis Inflammation of bone marrow.

osteoporosis Abnormal loss of bone tissue with tendency to fracture.

osteotomes Chisel-like instruments used to cut or shave bone.

otitis media Inflammation of the middle ear.

outsourcing (equipment) Transfer of control of a hospital's equipment management system to an external entity.

ovaries Female reproductive glands.

ovulation Release of a mature ovum from a follicle in the ovary.

ovum Female sex cell.

oxidation The process by which several low-temperature sterilization processes, including hydrogen peroxide gas plasma, vaporized hydrogen peroxide and ozone, destroy microorganisms. Oxidation involves the act or process of oxidizing: addition of oxygen to a compound with a loss of electrons.

oxidative chemistries Class of compounds containing an additional atom of oxygen bound to oxygen that uses oxidation to interrupt cell function.

oxidize To change by increasing the proportion of the electronegative part or change (an element or ion) from a lower to higher positive valence.

oxidizing agent Material that removes electrons from another substance.

oxygen Gas needed to completely break down nutrients for energy within the cell.

ozone A reactive and unstable oxygen molecule.

P

packaging Application or use of appropriate closures, wrappings, cushioning, containers, and complete identification up to, but not including, the shipping container and associated packing.

pandemic Very widespread epidemic (even of worldwide extent).

papers (kraft-type) Medical grade paper packaging material used for numerous sterilization applications.

paracentesis Puncture through the wall of a cavity (usually to remove fluid or promote drainage).

parametric release Declaring product to be sterile on the basis of physical and/or chemical process data, rather than on the basis of sample testing or biological indicator results.

parasite Plant or animal that lives upon or within another living organism (host) from which it obtains nourishment and at whose expense it grows without giving anything in return.

par cart Distribution method in which a supply cart remains in a given location is inventoried and replenished on a regular basis.

parenteral Something that is put inside the body, but not by swallowing, for example, an injection given into the muscle.

parenteral solutions Solutions administered to patients intravenously.

parietal Pertaining to the wall of a space or cavity.

par level (inventory) Desired amount of inventory which should be on hand.

particle Piece of matter with observable length, width and thickness; usually measured in microns.

particulate matter General term applied to matter of miniature size with observable length, width and thickness (contrasted to nonparticulate matter without definite dimension).

parturition Childbirth; labor.

patient care equipment Portable (mobile) equipment used to assist in the care and treatment of patients. Examples: suction units and heat therapy units.

passivation Chemical process applied during instrument manufacture that provides a corrosion-resistant finish by forming a thin, transparent oxide film.

passive carrier Carrier who harbors the causative agent of a disease without having had the disease.

passive immunity Immunity produced without the body of the person or animal that becomes immune participating in its production. Example: production of immunity to diphtheria by injection of diphtheria antitoxin.

pasteurization Process of heating a fluid to a moderate temperature for a definite period of time to destroy undesirable bacteria without changing its chemical composition.

patella Kneecap.

pathogen Capable of causing disease; disease-producing microorganism

patient care equipment Portable (mobile) equipment that is used to assist in the care and treatment of patients. Examples: suction units, temperature management units, infusion therapy devices, etc.

patient care supplies Supplies that will be dispensed for patient treatment and care. Examples: catheters, implants, bandages, etc.

pathogenic Capable of producing disease.

pathology Study of disease.

pawl Pivoted tongue or sliding bolt on one part of an instrument adapted to fall into notches or interdental space on another part to permit motion in only one direction.

PEL Abbreviation for permissible exposure limit.

pelvis Basin-like structure; lower portion of the abdomen; large bone of the hip.

penicillin Antibiotic produced by the mold, *Penicillium notatum*.

penis Male organ of urination and intercourse.

peracetic acid (PA) Liquid oxidizing agent that is an effective biocide at low temperatures; used in a sterilization system that processes immersible diagnostic and surgical instruments (primarily flexible and rigid scopes); items must be used immediately after sterilization because they are wet and cannot be stored.

performance qualification (PQ) Obtaining and documenting evidence that equipment, as installed and operated in accordance with operational procedures, consistently performs according to predetermined factors and meets specifications.

perineum Pelvic floor; external region between the anus and genital organs.

periodic automatic replenishment (PAR) Also known as PAR-Level or PAR System; an inventory replenishment system in which the desired amount of products that should be on hand is established, and inventory replenishment returns the quantity of products to this level.

periosteum Membrane of connective tissue that closely invests all bones except at the articular surface.

peripheral Located away from a center or central structure.

peripheral nervous system All nerves and nerve tissue outside the central nervous system.

peristalsis Wavelike movements in the wall of an organ or duct that propel its contents forward.

peritoneum Serous membrane that lines the abdominal cavity, and forms the outer layer of abdominal organs; forms supporting ligaments for some organs.

peritonitis Inflammation of the peritoneum.

permissible exposure limit (PEL) The maximum amount or concentration of a chemical that a worker may be exposed to under OSHA regulations.

perpetual inventory system System that tracks all incoming and issued supplies to determine, on an ongoing basis, the quantity of supplies in storage.

personal development Activities that identify and develop talent and personal potential; improves employability and enhances quality of life.

personal protective equipment (PPE) A part of standard precautions for all healthcare workers that prevents skin and mucous membrane exposure when in contact with blood and body fluid of any patient. PPE includes fluid-resistant protective clothing, disposable gloves, eye protection and face masks and shoe covers.

pertussis Whooping cough.

petri dish Shallow, covered cylindrical glass or plastic dish used to culture bacteria and in which bacterial colonies may be observed without removing the cover.

pH Measure of alkalinity or acidity on a scale of 0 to14; pH of 7 is neutral (neither acid or alkaline); pH below 7 is acid; pH above 7 is alkaline.

phagocyte Cell capable of ingesting bacteria or other foreign particles.

phagotization Process by which some cells can ingest bacteria or other foreign particles.

phalanges Bones that comprise the fingers and toes.

pharynx Throat.

phenol Carbolic acid (phenyl alcohol); a colorless crystalline compound (C6H5OH) with strong disinfectant properties.

phenol coefficient Method of designating the disinfecting properties of a chemical by comparing its activity to that of phenol.

phlebitis Inflammation of a vein.

physiology The study of the functions of body parts and the body as a whole.

PI Abbreviation for performance improvement; a process to continually improve patient care that identifies performance functions and associated costs that affect patient outcomes, and the perception of patients and families about the quality and value of services provided.

pick and pack Inventory control system for forms and office supplies. Items are shipped/charged to the customer as ordered in minimal quantities, and the customer is financially responsible for the vendor's agreed-upon inventory.

pick list A list of specific instruments and supplies needed for a surgical case or a medical procedure.

placenta Structure that nourishes and maintains the developing individual during pregnancy.

plague Acute, often fatal epidemic disease caused by *Pasteurella pestis* and transmitted to man by fleas from rats and other rodents.

plasma The largest component of the blood. Plasma transports nutrients throughout the body and helps remove waste from the body.

plasmolysis Shrinkage of a cell or its contents due to withdrawal of water by osmosis.

plasmoptysis Escape of protoplasm from a cell due to rupture of the cell wall.

platelets Blood cells that function to help blood to clot.

pleura Serous membrane that lines the chest cavity and covers the lungs.

pneumonia Inflammatory consolidation or solidification of lung tissue due to presence of an exudate blotting out the air-containing spaces; see exudate.

pneumothorax Accumulation of air in the pleural space.

Point-of-use processing That which occurs when a medical device is processed immediately before use and/or close to the patient care area.

poliomyelitis Virus disease in which there is inflammation of the gray substance of the spinal cord; commonly called infantile paralysis.

pollution State of rendering unclean or impure by adding harmful substances.

pounds per square inch gauge (psig) Measure of ambient air pressure; the pressure that a gas would exert on the walls of a one cubic-foot container.

polycarbonate Type of plastic.

polyethylene Thermoplastic polymer capable of being produced in thin sheets; exhibits good moisture-vapor barrier qualities, but has a high sloughing tendency.

polymerization A molecular reaction that creates an uncontrolled release of energy

polymerize Process of joining many simple molecules into long chains of more complex molecules whose molecular weight is a multiple of the original and whose physical properties are different.

polyp Protruding growth (often grapelike) from a mucous membrane.

polypropylene Type of plastic.

polystyrene Type of plastic.

polyurethane Type of plastic.

polyvinyl chloride (PVC) Type of plastic.

porous Possessing or full of pores (minute openings).

portability Not fixed; can be transported.

portal of entry (chain of infection) Path used by an infectious agent to enter a susceptible host.

portal of exit (chain of infection) Path by which an infectious agent leaves the reservoir.

positive air pressure Situation in which air flows out of a room or area because the pressure in the area is greater than that of surrounding areas.

posterior Toward the back; dorsal.

ppm Abbreviation for parts per million.

preconditioning Treatment of product prior to the sterilization cycle in a room or chamber to attain specified limits for temperature and relative humidity; see conditioning.

preconditioning area Chamber or room in which preconditioning occurs.

prefix (word element) Word element that comes before the root word element.

preservative Substance that prevents biologic decomposition of materials when added to them.

preventive maintenance (equipment) Service provided to equipment to maintain it in proper operating condition by providing planned inspection and by detecting and correcting failures before they occur; often abbreviated "PM."

primary infection First of two or more infections.

Prion An infectious protein particle that, unlike a virus, contains no nucleic acid, does not trigger an immune response and is not destroyed by extreme heat or cold.

procedure area – An area within the healthcare facility that conducts invasive and minimally invasive procedures requiring instruments, supplies and equipment.

process challenge device (PCD) Object that simulates a predetermined set of conditions when used to test sterilizing agent(s).

process equivalency Documented evaluation that the same sterilization process can be delivered by two or more pieces of sterilization equipment.

process improvement Activity to identify and resolve work task-related problems that yield poor quality; the strategy of finding solutions to eliminate the root causes of process performance problems.

process indicators Devices used with individual units (e.g., packs or containers) to demonstrate that the unit has been exposed to the sterilization process, and to distinguish between processed and unprocessed units.

processes (work) Series of work activities which produce a product or service.

processing area Area in which decontaminated, clean instruments and other medical and surgical supplies are inspected, assembled into sets and trays and wrapped, packaged or placed into container systems for sterilization; commonly called the "preparation and packaging area" if part of Central Service, and "pack room" if textile packs are assembled there.

processing group Collection of products or product families that can be sterilized in the same ethylene oxide sterilization process. All products within the group have been determined to present an equal or lesser challenge to the sterilization process.

product adoption Process of formally including a candidate product into an existing validated sterilization process.

product family Collection of products determined to be similar or equivalent for validation purposes.

professional development Commitment to continuous learning and improvement, taking responsibility for one's own development.

progesterone Hormone produced by the corpus luteum and placenta; maintains the lining of the uterus for pregnancy.

prognosis Prediction of the probable outcome of a disease, based on the patient's condition.

prophylactic Agent used to prevent infection or disease.

prophylaxis Prevention of disease.

prostate gland Organ that produces a fluid element in semen that stimulates the movement of sperm.

prosthesis Artificial replacement of a body part such as an arm or leg.

protein Complex combinations of amino acids containing hydrogen, nitrogen, carbon, oxygen and, usually, sulfur and sometimes other elements; essential constituents of all living cells.

prothrombin Clotting factor; converted to thrombin during blood clotting.

proton Positively-charged particle in the nucleus of an atom.

protoplasm Thick, mucous-like substance that is colorless and translucent and forms the biochemical basis of life found within the cell nucleus.

protozoan One-celled animal-like microorganism of the subkingdom, protozoa.

proximal The end of an item that is closest to the point of origin; the end of the instrument closest to the operator; the proximal end of the femur is closest to the hip.

prudent Marked by wisdom or judiciousness; wise.

pseudopodia "False feet;" temporary protrusions of ectoplasm to provide locomotion.

psia Abbreviation for pounds per square inch absolute.

psychrophiles (bacteria) Cold-loving bacteria whose optimum temperature for growth is 59°F to 68°F (15°C to 20°C) or below.

pulse Wave of increased pressure in blood vessels produced by contraction of the heart.

pupil Opening in the center of the eye through which light enters.

pure culture Specific bacterial growth of only one species of microorganism.

purulent Containing pus.

pus Semifluid, creamy product of inflammation consisting of blood cells (mainly white), bacteria, dead tissue cells and serum.

pyogenic Pus producing.

pyrex Type of hard glass made from borosilicate, which is alkaline free.

pyrexia Fever.

pyrogen A substance typically produced by a bacterium that produces fever when introduced/ released into the blood .

pyrogenic Fever producing; byproducts of bacterial growth or metabolism.

Q

quadrant One part of four; to be divided into four equal parts.

qualified personnel Prepared by training and experience to perform a specified task.

quality Consistent delivery of products and services according to established standards. Quality "integrates" the concerns for the customers (including patients and user department personnel) with those of the department and facility.

quality assurance Comprehensive and measured efforts to provide total quality; a technical, statistical sampling method that measures production quality.

quality control Technical, statistical sampling method that measures production quality.

quarantine Isolation of infected people and contacts who have been exposed to communicable diseases for the time equal to the longest incubation period of the disease to which they have been exposed.

quaternary compound Group of disinfectants having derivatives of benzalkonium chloride as the active ingredient.

quiescent Not active.

R

radiation heat Transmission of heat from one object to another without heating the space in between; process of emitting radiant energy in the form of waves or particles.

radical Group of atoms that behaves as a single atom in a chemical reaction.

radio frequency identification (RFID) Term used to describe a system in which the identity (serial number) of an item is wirelessly transmitted with radio waves.

radius One of the two bones in the forearm.

random numbers (table) Compilation of numbers generated in an unpredictable, haphazardous sequence used to create a random sample.

ratchet (or rachet) Part of a surgical instrument that "locks" the handles in place.

rationale Underlying reason; basis.

recessive Gene that is not expressed if a dominant gene for the same trait is present.

rectum Last several inches of the large intestine.

red blood cells Blood cells that carry oxygen throughout the body.

reflex Involuntary response to a stimulus.

refraction Bending of light rays as they pass from one medium to another of a different density.

regulation Rules issued by administrative agencies that have the force of law.

relative humidity (RH) Amount of water vapor in the atmosphere; expressed as a percentage of the total amount of vapor the atmosphere could hold without condensation.

remission Diminution or abatement of disease symptoms.

reorder point (ROP) Inventory level available when an order is placed to replenish inventory.

repair (equipment) Procedures used to return equipment to proper operating condition after it becomes inoperative.

requisition system Method of inventory distribution in which items needed are requested (requisitioned) and removed from a central storage location for transport to the user department.

reservoir Carrier of an infectious microorganism; generally refers to a human carrier.

reservoir of agent (chain of infection) Place where an infectious agent (microorganisms) can survive.

resident bacteria Bacteria normally occurring at a given anatomical site.

residual (EtO) Amount of ethylene oxide that remains inside materials after they are sterilized.

residual property Capacity of an antiseptic or disinfectant to kill microorganisms over a long period of time after initial application.

resistance Ability of an individual to ward off infection.

resorption Loss of substance (such as bone).

respiration Exchange of oxygen and carbon dioxide between outside air and body cells.

retina Innermost layer of the eye; contains light-sensitive cells (rods and cones).

retractors Surgical instruments primarily used to move tissues and organs to keep the surgical site exposed throughout surgery.

retroperitoneal Behind the peritoneum (kidneys, pancreas and abdominal aorta).

reusable (inventory) Assets that are relatively inexpensive, such as medical devices and sterilization containers, that can be reused as healthcare services are provided to patients.

reusable medical device Devices intended for repeated use on different patients, with appropriate decontamination and other processing between uses.

reusable surgical textile Drape, gown, towel or sterilization wrapper intended to be used during surgery or to assist in preparing for surgery; made from a fabric (usually woven or knitted), fabric/film laminate, or non-woven material intended to be used more than once, with appropriate reprocessing between uses.

reverse osmosis (RO) A water purification process by which a solvent, such as water, is removed of impurities after being forced through a semipermeable membrane.

rhinitis Inflammation of the mucous membrane of the nose.

rib spreaders Retractor used to expose the chest.

rigid container system Instrument containers that hold medical devices during sterilization and also protect devices from contamination during storage and transport

ribonucleic acid (RNA) One of two types of nucleic acids; found in nucleus and cytoplasm and involved in protein synthesis.

risk management The methods used to assess the risks of a specific activity and to develop a program to reduce risk.

rod Straight, slim mass of substance related to microorganisms. Example: rod-shaped bacteria.

roentgenogram Film produced with of x-rays.

rongeurs Surgical instruments to cut or bite away at bone and tissue.

root cause analysis (RCA) Process that "looks backwards" at an event to help prevent its future occurrence.

root (word element) Tells the primary meaning of a word; also called base word element.

rubeola Measles.

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REFERENCES

1) Hoffbrand's Essential Haematology, A. Victor Hoffbrand, Eighth Edition
2) Essentials of Haematology, Shirish M Kawthalkar, First Edition
3) District Laboratory Practice in Tropical Countries Part 2, Monica Cheesbrough, Second Edition
4) Medical Parasitology, Rohela Mahmud Yvonne Ai Lian Lim • Amirah Amir, first edition
5) Website of Institute of Blood Transfusion Service Punjab.gov.pk. https://ibts.punjab.gov.pk
6) website punjab blood transfusion authority.https://pbta.punjab.gov.pk › sop for blood bank, 2014