LEARNING OBJECTIVES:

1. Describe the role of the Sterile Processing Department (SPD) within an organizational structure.

2. Describe the various functions of SPD.

3. Understand the professional standards, guidelines, requirements, standards of practice, and ethics that guide sterile processing practices.

4. Identify the health and safety regulations, standards, and guidelines that apply to the processing of medical devices and instrumentation.

5. Identify the federal and state regulatory agencies that have jurisdiction over processing in healthcare facilities.

6. Identify and describe methods of quality assurance.

7. Define the purpose of a procedure manual and the difference between policies and procedures.

8. Outline the training procedures that should be followed to ensure familiarity with and competent performance of sterile processing procedures.

9. Understand the various symbols used in health care and in manufacturing of sterile products.

INTRODUCTION

The effective SPD technician must clearly and thoroughly understand his or her roles and responsibilities. To achieve the necessary level of competence, the technician should study the various functions performed by SPD.

Working in a sterile processing area requires a technician to take on multi-dimensional tasks and responsibilities that require specific knowledge and skills, including an understanding of the following:

- Decontamination, packaging, and sterilization of surgical instrumentation
- Processing and reprocessing of reusable medical devices
- Cleaning, testing, assembly, and distribution of movable patient care equipment
- The facility’s purchasing procedures
- Storage, handling, and distribution of sterile surgical instrumentation and devices, as well as inventory control and cost recovery systems
The nature of the work performed in SPD means that patient and personnel safety is paramount. As will be discussed in more detail later in this chapter, sterile processing practices are highly regulated. A review of the history of the department’s development will enhance understanding of the services of today’s SPD.

A BRIEF HISTORY OF STERILE PROCESSING

The modern era of sterilization began in 1933 when the American Sterilizer Company (later called AMSCO and now part of the STERIS Corporation) developed the first steam sterilizer that allowed temperatures to be measured using a thermometer.

The American College of Surgeons is credited with the birth of sterile processing. That organization recommended standardization of surgical dressings and centralization of the preparation and handling of all surgical supplies into one unit (a “central supply”).

The Sterile Processing Department is defined in Perkins (1982) as “that service area within the hospital which processes, issues, and controls professional supplies and equipment, both sterile and unsterile, for all departments and units of the hospital for the care and safety of the patients.”

W.B. Underwood performed extensive studies of sterile processing (Underwood, 1944, 1945), and his work established the philosophy of centralization, which has proven to be invaluable.

In the early days, when there were comparatively few surgical cases, medical devices and supplies were sterilized primarily in operating rooms (ORs) between cases. OR personnel were considered to be the most knowledgeable about sterilization. As the number of surgeries increased and ORs became busier, sterilization was relocated to a work room within the OR, and the OR supervisor monitored the processing. Surgical dressings, needles, syringes, and surgeons’ gloves were all prepared in this room and then distributed to the various departments.

For many years, sterilization activities were also performed in the areas where the items were used (e.g., nursing units, the nursery, and labor and delivery [L&D]). It was difficult to monitor and standardize the sterilization processes because each department had its own policies and procedures.

Dr. John Perkins, a scientist employed by AMSCO, observed that “sterilization is everyone’s business but no one’s responsibility” (Perkins, 1982). He advocated the centralization of processing in one department so that all procedures could be standardized.

THE ROLE OF STERILE PROCESSING

FUNCTIONS OF SPD

What exactly is the role of the SPD technician? First, one needs to understand what SPD does. SPD is the department that receives, cleans, decontaminates, assembles, disinfects, and/or sterilizes reusable medical and surgical devices for safe and effective patient care. Depending on the healthcare facility, the department might be designated Central Services, Central Supply, Central Sterile Supply, Sterile Processing, Material Services, or another name. It has been recommended by several organizations, including the Certification Board for Sterile Processing and Distribution, Inc. (CBSPD), that the department be called Sterile Processing to reflect the majority of the work done in the present-day department.

In a hospital setting, SPD is usually divided into separate areas according to the functions performed within each area. These areas can include (but are not limited to) the following:
• **Decontamination area**, where soiled items are received and cleaned. In a hospital setting, there might be a dedicated elevator or dumbwaiter used to transport contaminated items from the OR, L&D, and/or nursing units to the SPD decontamination area. If there is not a dedicated system, a transport method must be developed for the safe transport of contaminated items from the using department to the decontamination area.

• **Preparation and packaging area**, where cleaned items are inspected, assembled, and packaged. This area is often within the sterilization area, but it could be separate and distinct. It might also be called a “clean work room.”

• **High-level disinfection room or area**, where cleaned items are high-level disinfected and then passed to the preparation and packaging (clean) area of the department for storage.

• **Sterilization area**, where terminal sterilization is performed. There might be a separate sterilization room or area for ethylene oxide (EO) sterilization. There might also be a segregated area for holding steam sterilizer carts after they have been removed from the steam sterilizer to permit cooling of items away from high-traffic areas.

• **Sterile storage area**, where sterile items are stored until needed. This area is used to store sterile items received from outside vendors, sterile items processed on site, or both. The location of the area where sterile medical/surgical supplies are stored and distributed varies with the facility.

• **Sterile stores**, where items for patient care from outside manufacturers are stored. This area might be a completely separate area, or it might be within the sterile storage area, depending on the size of the facility. “Sterile stores” is sometimes referred to as Medical Supply Distribution, Central Supply, or a similar designation.

• **Case cart area**, where sterile supplies (trays and/or sterile items from outside manufacturers) are kept and picked for surgical cases. This area might be within the sterile storage area.

• **Dispatch**, where sterile and clean items are dispensed. There is usually a window through which the items are dispatched to the transporter.

• **Loaner area** for the receipt and return of instruments borrowed for specialty procedures. Although such an area is not a requirement, many SPDs are now providing a separate room or space for loaner instruments.

• **Patient care equipment clean-up area**, where patient care equipment is cleaned and disinfected. There might be a separate area designated for this purpose. There is usually a separate area for storage of cleaned and disinfected equipment.

Depending on the facility, SPD can provide a variety of services, including decontamination, preparation and packaging, sterilization, and supply distribution. (Each of these functions will be discussed separately in later chapters.) Regardless of the specific scope of its work in a given facility, SPD is responsible for providing dependable, reliable services to enhance the quality of patient care. In other words, instrument sets, patient care equipment, and other medical devices must be processed and distributed in an accurate and timely manner so that patient care is not adversely affected. The important work performed in SPD permits surgeons to perform surgery and patients to heal. It has been said that the department is “the heart of the hospital.” Any healthcare facility would find it difficult to function even for a few hours without SPD.
In an ambulatory surgery facility, the setup is usually similar to, but smaller than, a hospital setting. The decontamination area is separate from the preparation and packaging area. The sterilizers are usually located in the preparation and packaging area. There is usually a separate sterile storage area, but sterile trays and sets are sometimes stored in closed cabinets within the operating rooms (ORS) or the preparation and packaging area.

Many photos of the various areas of SPD are included in this textbook to better acquaint you with the physical layout of this important department/area.

**WORK FLOW, PEOPLE FLOW, TRAFFIC CONTROL**

Several basic concepts affect the work in SPD. The first is **work flow**: how the work progresses through the department or processing area. As depicted in Figure 1-1, everything begins in the decontamination area (soiled), where medical devices are cleaned. Then work progresses to the clean preparation and packaging area, where high-level disinfection might take place (depending on the device and its intended use). After packaging, the medical devices are sterilized, then stored or distributed. The dirty-to-clean flow should never be circumvented.

![Figure 1-1 — Steps in sterile processing](image)

**People flow** refers to how people move through the department or processing area. Technicians working in the decontamination area must remove all their personal protective equipment (PPE) (including head cover and shoe covers) and wash their hands before proceeding to the clean areas. If a technician needs to go to the decontamination area, he or she must don PPE, which is then removed when he or she leaves the area. Anyone visiting the department or processing area should start in the clean areas (sterile storage, sterilization) and complete his or her tour in the decontamination area (soiled).
Traffic control means controlling access to SPD. Because the department contains contaminated items and because it prepares sterile product, traffic should be restricted to departmental employees and authorized personnel, such as equipment service representatives. It is the responsibility of the sterile processing technician to make sure that all visitors abide by the required dress code for the department and that cover garments (e.g., jumpsuits), head covers, and shoe covers are available for visitors.

DISASTERS

In many facilities, SPD is responsible for providing supplies and equipment for disaster response. The Joint Commission (JC) (formerly called the Joint Commission for Accreditation of Healthcare Organizations [JCAHO]) requires that facilities be prepared for internal disasters (e.g., a sewer back-up in SPD) and external disasters (e.g., a train accident with multiple injured patients who must be cared for at the same time). It is important for SPD technicians to understand their role in the facility’s disaster preparedness plan. For example, where are disaster-related supplies located in the department (a disaster cart is sometimes used to store and transport supplies), where are the supplies to be delivered (in the facility, there will be a designated area where patients will be “triaged” or evaluated for treatment), and what types and quantities of patient care equipment (e.g., intravenous [IV] pumps) is the department responsible for providing? Disaster plans should be routinely reviewed, and all equipment and supplies should be routinely inventoried and maintained in readiness.

TRAINING AND CERTIFICATION

In recent years, the profession of sterile processing has been increasingly recognized for its importance. The majority of training is on-the-job. Many individuals do not have access to a formal training program. By studying textbooks like this one, SPD personnel can help educate themselves in the principles and best practices of the profession. However, it is important to get hands-on experience within an SPD so that the principles learned from this book can be applied to practice.

Some companies and organizations offer on-line training. It is important to look at who developed the educational program and the content of the program. You should also confirm that the program is awarded continuing education credits from an accrediting organization (e.g., CBSPD).

Another change taking place in the United States is certification. The sterile processing profession has certification programs that recognize those individuals who have met professional standards. Attaining certification is an important personal and professional goal. In August 2004, New Jersey became the first state to require certification of all sterile processing professionals. In 2015, New York and Connecticut became the second and third states, respectively, to require certification. Other states are attempting to do the same. Many countries around the world also recognize certification for sterile processing personnel.

Certification for sterile processing is available through two organizations. The Certification Board for Sterile Processing & Distribution, Inc. (CBSPD) is located in Lebanon, New Jersey, and offers five levels of international certification: technician, management, ambulatory surgery, surgical instrument specialist, and gastrointestinal (GI) flexible endoscope reprocessor. Information about this certification program can be found at http://www.sterileprocessing.org. The International Association of Healthcare Central Service Materiel Management (IAHCSMM) is located in Chicago, Illinois, and offers technician, surgical instrument specialist, and leadership certifications. Information about the IAHCSMM certification program can be found at http://www.iahcsmm.org.
**ORGANIZATIONAL STRUCTURE**

Within healthcare facilities, like most organizations, there is an “organizational structure,” which is often referred to as an organizational chart. The department to which SPD reports varies with the facility. It might be the Operating Room, Material Management, Infection Prevention, or, sometimes, Nursing. The departmental organizational chart details the reporting and accountability mechanisms for the titles within the department, and the facility organizational chart details the reporting mechanism for administration. See Figure 1-2 for an example.

![Sample organization chart](image)

**ETHICS**

**DEFINITIONS**

The following definitions relate to the important subject of ethics:

- **Ethics** is the discipline dealing with what is good and bad and with moral duty and obligation.
- **Ethical actions** are actions that conform to accepted and professional standards of conduct.
- **Morals** deal with or relate to principles of right and wrong behavior (e.g., a set of moral principles or values).
- **Unethical professional conduct** is the failure to conform to moral standards or policies.
- **Professional ethics** are principles of conduct governing an individual or group.

What we do and how we do it affects the lives of everyone. There is no individual or group that is untouched. We need to reaffirm our moral obligation to **DO THE RIGHT THING** in a healthcare profession that can be ambiguous, difficult, and conflicted!
CODES OF ETHICS

Steven Coughlin, author of “Ethical Issues in Epidemiologic Research and Public Health Practice,” asserts that healthcare professionals might face ethical issues such as conflicts of interest, distortion of medical facts, exorbitant or inconsistent billing, poor privacy and security of patient records and information, and compliance with local, state, and federal health regulations. (Coughlin, 2006)

Because noncompliance with healthcare legislation related to ethics can directly result in harm to patients, healthcare employers provide ethics training and policies for their workers. These courses and policies explain the ethical issues that healthcare workers might encounter, why they exist, and how to deal with them. The penalties for not following the guidelines set in these training courses and policies are sometimes severe: workers could face suspension, fines, loss of their medical license (if they have one), or lawsuits and jail time, depending on whether the worker violates employer or licensing body ethics policies or ethics legislation. (Coughlin, 2006)

Ethical actions are those that conform to accepted and professional standards of conduct. Deciding what is ethical can be complicated by an individual’s beliefs, knowledge base, and work ethic. Behaving ethically is important for the sterile processing worker.

Codes of Ethics have been established for many healthcare professionals, including healthcare executives, dental hygiene practitioners, and nurses, to name a few. Where is the SPD Code of Ethics? One cannot be found. The following is a suggested Code of Ethics for SPD:

- Always act in the best interests of the dignity, reputation, and good standing of the SPD profession, applying professional judgment and acting responsibly in all matters related to patient care.
- Always act with courtesy and consideration to all those with whom you have to deal, including fellow professionals.
- Always comply with regulations and professional standards with regard to safety and processing issues.
- Communicate clearly and concisely; remember that communication is a two-way process and that listening is critical to the process.
- Always strive for the highest standards of excellence; never assume. Make sure that all devices are reprocessed as if they would be used on you or a family member.
- Practice competently. When in doubt, ask for advice from a qualified co-worker.
- Take responsibility for your work and make sure that it is completed on time and accurately.
- Identify safety and/or risk management issues and report them immediately.
- Never disclose confidential information about a patient.
- If you make a mistake, try to minimize the damage or harm that could result by owning up to it as soon as you realize a mistake has been made so that corrective action can be taken.
- Seek total quality management for all stages of a process.
• Maintain your continuing education and certification by attending continuing education programs.
• Report any instances of hospital property damage or theft and do not participate in it.
• Treat co-workers with dignity and respect as you would like to be treated.
• Accept constructive criticism as part of your professional growth.
• Accept changes in work schedules when they are dictated by patient needs.

ETHICAL ISSUES
Many types of ethical issues can arise in SPD:

• Work ethic
• Patient confidentiality
• Hospital property
• Sales representatives
• Employee behavior
• Employee safety

**Work ethic:** The SPD is a diverse workplace; people from many cultures work together. Differences in cultural beliefs or behaviors can create misunderstandings. Part of a good work ethic is to learn as much as possible about how cultural differences affect work practices and incorporate those differences into departmental functions without compromising the products that are produced. Understanding these differences promotes the teamwork needed for a properly functioning department.

**Patient confidentiality:** The SPD technician has access to confidential patient information through the OR schedule, computerized records, the issuing of equipment, and charge systems. All patient information is highly confidential and should never be discussed with anyone at any time unless it is required for the direct care of the patient. All healthcare facilities must comply with the Health Insurance Portability & Accountability Act (HIPAA), which provides for the confidentiality and security of health information. Each facility has procedures regarding the destruction of confidential records.

**Hospital property:** Stealing or damaging hospital property is also an ethical issue. Sometimes when personnel witness such activity, they do not want to “get involved.” Ethically, however, the right thing to do is to report it.

**Sales representatives:** When sales representatives provide inaccurate information about their products, it is an ethical issue. Did the representative not really know, or was the sale more important than patient safety?

**Employee behavior:** Sometimes employees feel that they “do not want to get involved” so they do not report problems such as a staff member leaving the workplace for several hours or not reporting for work at all but getting paid because he or she “forgot” to punch in or punch out.
**Employee safety:** Ethics also involves reporting noncompliance with wearing PPE, failure to adhere to all decontamination protocols, and any other instances of noncompliance with policies and procedures. These issues relate to employee and patient safety and must be reported. Each facility has a corporate compliance policy; some facilities have a hot-line that can be used to anonymously report any compliance issues.

SPD personnel should be knowledgeable about the various signs and symbols used in packaging of medical/surgical devices. This information helps ensure employee safety as well as the safety of the device or products contained in the package. Please refer to Appendix A for a listing of common signs and symbols.

The guiding principle of healthcare ethics is the Hippocratic Oath, the ideal of doing no harm to another person. This means that ethical arguments related to health care revolve around whether the beliefs or actions of the healthcare worker affect any patient in a negative way. It is important to remember that ethics means doing the right thing.

**REGULATIONS, STANDARDS, AND RECOMMENDED PRACTICES**

Because of the nature of SPD’s work, the safety of patients, device users, and SPD personnel is of paramount importance. The SPD is subject to many regulations, standards, and recommended practices:

- **A regulation** is a principle, rule, or law designed to control or govern behavior. Compliance with a regulation is mandatory (i.e., required by law). Examples of agencies that issue regulations are the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), the Occupational Safety and Health Administration (OSHA), and individual state health departments.

- In the context of SPD, a **standard** is an established norm determined by opinion, authority, research, and/or theory. Examples are the American National Standards developed by the Association for the Advancement of Medical Instrumentation (AAMI). Although compliance with AAMI standards is not legally required (except when an individual state health department adopts these standards as regulations), AAMI standards for steam sterilization, EO sterilization, chemical disinfection, flexible endoscope processing, and other types of sterile processing activities are recognized as the primary measure of good practice in SPD. The Centers for Disease Control and Prevention (CDC) also publishes standards for infection control that include information on SPD practices.

- **Recommended practices** are statements of sound principles of practice that are based upon scientific data and the opinions of experts. Again, compliance is not legally required, but recommended practices reflect accepted professional practices. Examples of recommended practices are the documents developed by IAHCSMM, the Society for Gastroenterology Nurses and Associates (SGNA), and the Association of periOperative Registered Nurses (AORN).

**GOVERNMENT AGENCIES**

**ENVIRONMENTAL PROTECTION AGENCY (EPA)**

The EPA’s regulations affect several aspects of sterile processing. First, the EPA registers and regulates environmental disinfectants (disinfectants used on nonliving things, such as tables and floors). Second, the EPA controls emissions into the air (under the Clean Air Act) and into
the water (under the Clean Water Act) of such substances as ethylene oxide. The EPA also regulates the manufacture and sale of EO gas.

According to the EPA website (http://www.epa.gov), “before a pesticide can be marketed and used in the United States, EPA must evaluate the pesticide to ensure that it meets federal safety standards for human health and the environment. Such evaluation is particularly important for antimicrobial pesticides (disinfectants, sterilants, and sporicides) which are used to reduce or eliminate microbial contamination. Once EPA determines that a pesticide meets federal safety standards, the Agency grants a license or ‘registration’ permitting its distribution, sale, and use according to approved label instructions.” Instructions for the disposal of pesticides must be followed in order to abide by the Clean Water Act.

In December 2008, the EPA issued additional regulations for EO emissions. See Chapter 10, “Sterilization,” for more information about these regulations.

**FOOD AND DRUG ADMINISTRATION (FDA)**

**FDA’s Mission and Scope:** The FDA’s mission is “to promote and protect the public’s health by helping safe and effective products reach the market in a timely way, to monitor products for continued safety after they are in use, and to help the public get the accurate, science-based information needed to improve health” (http://www.fda.gov). The FDA website provides helpful information on medical products and devices.

The FDA originated in 1906, when the Food and Drugs Act was passed and President Theodore Roosevelt assigned implementation of the law to the Bureau of Chemistry of the U.S. Department of Agriculture. The Bureau eventually became the FDA, an agency residing in the U.S. Department of Health and Human Services. In 1938, Congress passed the Federal Food, Drug and Cosmetic Act, which, for the first time, required companies to prove the safety of new drugs before putting them on the market. It also provided for the regulation of foods, cosmetics, and therapeutic devices and generally updated existing laws to improve consumer protection.

“FDA’s regulatory approaches are as varied as the products it regulates. Some products—such as new drugs and complex medical devices—must be proven safe and effective before companies can put them on the market. Other products—such as x-ray machines and microwave ovens—must measure up to performance standards. And some products—such as cosmetics and dietary supplements—can be marketed with no prior approval. These differences are dictated by the laws we enforce and by the relative risks that the products pose to consumers.” (http://www.fda.gov)

“The FDA safeguards the nation’s food supply by making sure that all ingredients used in foods are safe, and that food is free of contaminants—like disease-causing organisms, chemicals, or other harmful substances. The agency must approve new food additives before they can be used in foods. The FDA also monitors the safety of dietary supplements and the content of infant formulas and medical foods. Meat and poultry products, however, are regulated by the USDA [U.S. Department of Agriculture].”

In addition, FDA regulates all medical devices, from very simple items like tongue depressors or thermometers to very complex technologies such as heart pacemakers and dialysis machines. The Medical Device Amendments of 1976, the Safe Medical Devices Act of 1990, and the Food and Drug Administration Modernization Act of 1997 progressively expanded and clarified FDA’s authority over medical devices.
FDA Regulation of Medical Devices: It is important to note that, in general, FDA does not directly regulate healthcare facilities; rather, it regulates the manufacturers of medical devices. There are two exceptions to this rule:

- The medical device reporting (MDR) regulation (FDA, 1996) requires medical device manufacturers and distributors to report patient deaths, serious injuries, and serious device malfunctions to FDA. It also requires healthcare facilities to report device-related patient deaths to both FDA and the device manufacturer and to report device-related serious injuries to the manufacturer. Healthcare facilities must also submit semiannual reports to FDA, summarizing all device-related patient deaths and serious injuries.

- In 2000, FDA began regulating the reprocessing of single-use devices by healthcare facilities (hospitals) and third-party reprocessors (FDA, 2000). Essentially, such facilities are regulated in the same manner as medical device manufacturers and must submit to FDA the same kinds of information that device manufacturers do when they seek FDA clearance for introducing a new or modified device to the market. At this time, FDA does not regulate the reprocessing of opened but unused devices, pacemakers, or hemodialyzers (pacemakers and hemodialyzers are covered by other regulations), nor do the reuse regulations apply to ambulatory surgery facilities.

Sterilizers, sterilization monitoring devices such as chemical indicators (CIs) and biological indicators (BIs), chemical sterilants, and chemical high-level disinfectants (HLDs) are all within FDA’s area of control and experience. All such products must be cleared by FDA, based on applications submitted by the manufacturer, before they are marketed for the first time. The FDA maintains a list of cleared liquid chemical sterilants (LCSs) and high-level disinfectants that can be used to reprocess heat-sensitive medical devices, such as flexible endoscopes (FDA, 2009). This list is available at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofSingle-UseDevices/ucm133514.htm.

Instructions for Use: The FDA also requires that medical device manufacturers provide end-users in healthcare facilities with specific instructions for use (IFU) on how to clean and sterilize their products. This information should be obtained for every device processed at the facility and maintained in a binder. (It is advisable for SPD to have two binders, one for the decontamination area and one for the preparation/packaging/sterilization area.) If a manufacturer fails to provide this information, the healthcare facility should document and report the problem using FDA’s MEDWATCH program (http://www.fda.gov/medwatch/).

The sophistication of today’s medical devices makes it critical that IFUs be obtained and available for all devices being reprocessed, regardless of how long a device has been in use. Many manufacturers regularly update their IFUs; therefore, to ensure the safety of the device, it is essential that SPD technicians have the most current information. The best approach is to obtain the IFU before a device is purchased so that it can be verified that the processing equipment and cycle parameters recommended by the device manufacturer are available at the facility.

If the device is new (has never been used in your facility before), it is important to ensure that the staff is in-serviced in the cleaning, disinfection, or sterilization of the device according to the IFU. Thereafter, the IFU should be required each time the device is purchased. When the device is received, the IFU should be reviewed and compared to the information on file. If the IFU has been updated, SPD personnel should be in-serviced in the changes and the new IFU dated and placed in the reference binders. If the IFU is the same, no action need be taken.
It is the responsibility of SPD management to obtain manufacturers' IFUs and to ensure that the most current IFU information is available for use. Manufacturers should be contacted for their IFUs at least every two years; manufacturers of orthopedic and loaner sets (e.g., spinal and total joint sets) should be contacted at least annually. This recommendation is based on the fact that manufacturers constantly update IFUs. It is recommended that a policy and procedure be established for routine review of this information. The IFU should be dated when received to document when the company should be contacted for updates.

At the time of receipt, the IFU should be reviewed to ensure the following:

- The decontamination recommendations provide for thorough cleaning and defined microbial lethality.
- The procedures can be performed in the healthcare facility using commonly available chemicals, supplies, and equipment.
- The procedures can be duplicated by healthcare personnel.
- The procedures can be easily understood by the user. (For example, diagrams and step-by-step instructions are helpful to personnel.)
- The procedures are in alignment with the recommendations of professional organizations and with OSHA regulations for minimizing occupational exposure to bloodborne pathogens (21 CFR 1910.1030).
- The instructions include a method by which users can verify effective decontamination.
- The instructions for use for the cleaning agent include the dilution/concentration that should be used, the temperature, the water quality (e.g., pH, hardness), and the exposure time (soaking or contact).
- The type and necessary quality of the water are specified (e.g., distilled water, deionized water, water treated by reverse osmosis, filtered water, hard or softened tap water).
- The type and quality of cleaning agents and cleaning accessories that should be used are specified.
- There are instructions for the handling and preparation of the device for cleaning.
- Instructions are provided for the manual or mechanical method that should be used for cleaning, rinsing, and drying.
- The time-at-temperature and water pressure parameters for mechanical cleaning equipment are specified.
- Instructions are provided for any necessary testing of function and cleanliness that should be performed after the decontamination process.
- Any necessary additives (e.g., lubricants) that should be used in reassembly are specified.
- The compatibility of packaging with device materials is described.
- Instructions are provided on the use of packaging materials commercially available to healthcare facilities.
• The compatibility of the packaging technique with existing packaging practices is described.

• The compatibility of the wrapped device with the planned sterilization process is described.

Healthcare personnel are responsible for ensuring that the cleaning, packaging, and sterilization methods recommended by the device manufacturer can be duplicated in their environment and that the manufacturer’s instructions are followed correctly. Healthcare personnel should follow regular and documented preventive maintenance and calibration procedures for the equipment used in sterilization.

Some healthcare facilities use an on-line service for IFUs. However, what happens when the system is down or when power is lost? Do staff members know how to access the information? If a manual system is used (e.g., placing the IFUs in a binder), how does staff locate the information? Who reviews the IFUs to ensure that they comply with AAMI standards for minimum exposure times and temperatures? How is compliance with IFUs monitored? Noncompliance is not an option.

It is important that sterile processing professionals remember that the device manufacturer’s IFU must be followed exactly as written, each and every time the device is processed. Noncompliance with IFUs creates patient safety, standard-of-care, and legal issues for the healthcare facility.

There are two important terms that sterile processing professionals need to understand: validation and user verification. AAMI TIR12 (Designing, Testing, and Labeling Medical Devices for Reprocessing in Health Care Facilities: A Guide for Medical Device Manufacturers) defines these terms as follows:

• “Validation: Documented procedure for obtaining, recording, and interpreting the results required to establish that a process will consistently yield product complying with predetermined specification. Validation is performed by MANUFACTURERS, not end users.” [emphasis added]

• “User verification: Documented procedures, performed in the user environment, for obtaining, recording, and interpreting the results required to establish that predetermined specifications have been met.” (Users are facility personnel who reprocess or use the device.)

The FDA requires medical device manufacturers to validate their product label claims of reusability and to provide complete and comprehensive written instructions for cleaning, disinfection, testing, packaging, sterilization, drying, and aeration (if applicable).

Although the device manufacturer is responsible for qualifying the sterilization process for the device, healthcare personnel are responsible for demonstrating that they can replicate that process exactly and consistently. See Chapter 10 for information about AAMI standards for sterilization.

If the IFUs are not consistent with recommended sterilization protocols (e.g., the specified exposure time is less than the AAMI minimum, the cleaning instructions are insufficient or unclear), the device manufacturer should be contacted to reconcile the discrepancy. The device or set should not be processed until all discrepancies are resolved.
SPD personnel should work proactively with vendors and manufacturers of medical devices to ensure that IFUs are current and to provide training for processing personnel. Training should

- be on-site (preferred),
- be hands-on,
- provide for return demonstration, and
- provide for competency verification.

Recalls: Sometimes manufacturers must recall a product because of a problem. Healthcare facilities are usually notified by FAX, e-mail, or other method. It is important for SPD technicians to understand the importance of their role in a manufacturer’s recall. All recalled products (which are usually identified by item name, catalog number, and lot number) must be located, retrieved, and documented. This type of recall differs from the recall of sterilized items processed within the facility (see Chapter 10, “Sterilization”).

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION (OSHA)

OSHA greatly affects SPD through its regulation of occupational exposure to airborne contaminants, occupational exposure to bloodborne pathogens, and communication of workplace hazards. The relevant OSHA standards must be communicated to employees on their first day of work in the department, and copies of the standards must be made available to employees. In addition, as continuing education to update staff on current regulations, in-services on all OSHA standards must be provided to the staff at least annually. All training must be documented (see Chapter 4, “Infection Prevention”).

Occupational Exposure Limits for Ethylene Oxide and Other Chemicals in the Workplace: OSHA has established occupational exposure limits for numerous chemical agents found in gaseous and liquid sterilants and high-level disinfectants. Separate standards have been issued for ethylene oxide and formaldehyde, and a general Air Contaminants Standard covers such sterilants and HLDs as glutaraldehyde, hydrogen peroxide, and ozone. All facilities using such agents must implement engineering and work-practice controls to ensure that employees are not exposed to these agents at levels above the “permissible exposure limits” (PELs). See Chapter 10, “Sterilization,” for a more detailed description of OSHA regulation of occupational exposure to ethylene oxide.

Occupational Exposure to Bloodborne Pathogens: In 1991, OSHA issued a standard limiting occupational exposure to bloodborne pathogens. This standard was the first action that OSHA had taken concerning a microbiological hazard to workers. The provisions of this standard will be discussed in more detail in Chapter 4, “Infection Prevention.”

Hazard Communication: The Hazard Communication Standard (HCS) (29 CFR 1910.1200(g)), revised in 2012, requires that the chemical manufacturer, distributor, or importer provide a Safety Data Sheet (SDS) (formerly MSDS or Material Safety Data Sheet) for each hazardous chemical to downstream users to communicate information on these hazards. The information contained in the SDS is largely the same as that in the MSDS, except that now the SDSs are required to be presented in a consistent, user-friendly, 16-section format.

Updated SDSs should be routinely requested from the chemical manufacturer. On their first day at work, new SPD technicians should review all SDSs in the department to familiarize themselves with the safety precautions that should be observed when they use the chemicals in
the department. All staff should participate in subsequent reviews of new SDS information and in annual reviews of SDSs and other safety information.

According to the Occupational Safety & Health Administration: “New changes to the Occupational Safety and Health Administration's (OSHA) Hazard Communication Standard are bringing the United States into alignment with the Globally Harmonized System of Classification and Labeling of Chemicals (GHS), further improving safety and health protections for America's workers. Building on the success of OSHA's current Hazard Communication Standard, the GHS is expected to prevent injuries and illnesses, save lives and improve trade conditions for chemical manufacturers. The Hazard Communication Standard in 1983 gave the workers the ‘right to know,’ but the new Globally Harmonized System (2012) gives workers the ‘right to understand.’” (https://www.osha.gov/dsg/hazcom/HCSFactsheet.html)

“The new hazard communication standard still requires chemical manufacturers and importers to evaluate the chemicals they produce or import and provide hazard information to employers and workers by putting labels on containers and preparing safety data sheets. However, the old standard allowed chemical manufacturers and importers to convey hazard information on labels and material safety data sheets in whatever format they chose. The modified standard provides a single set of harmonized criteria for classifying chemicals according to their health and physical hazards and specifies hazard communication elements for labeling and safety data sheets.” (https://www.osha.gov/dsg/hazcom/HCSFactsheet.html)

“The SDS includes information such as the properties of each chemical; the physical, health, and environmental health hazards; protective measures; and safety precautions for handling, storing, and transporting the chemical. The information contained in the SDS must be in English (although it may be in other languages as well). In addition, OSHA requires that SDS preparers provide specific minimum information as detailed in Appendix D of 29 CFR 1910.1200. The SDS preparers may also include additional information in various sections.” (https://www.osha.gov/Publications/OSHA3514.html)

“Sections 1 through 8 contain general information about the chemical, identification, hazards, composition, safe handling practices, and emergency control measures (e.g., fire fighting). This information should be helpful to those that need to get the information quickly. Sections 9 through 11 and 16 contain other technical and scientific information, such as physical and chemical properties, stability and reactivity information, toxicological information, exposure control information, and other information including the date of preparation or last revision. The SDS must also state that no applicable information was found when the preparer does not find relevant information for any required element.” (https://www.osha.gov/Publications/OSHA3514.html)

“The SDS must also contain Sections 12 through 15, to be consistent with the UN Globally Harmonized System of Classification and Labeling of Chemicals (GHS), but OSHA will not enforce the content of these sections because they concern matters handled by other agencies.” (https://www.osha.gov/Publications/OSHA3514.html)

The major changes to the Hazard Communication Standard are as follows:

- **Hazard classification:** Chemical manufacturers and importers are required to determine the hazards of the chemicals they produce or import. Hazard classification under the new, updated standard provides specific criteria to address health and physical hazards as well as classification of chemical mixtures.
- **Labels:** Chemical manufacturers and importers must provide a label that includes a signal word, pictogram, hazard statement, and precautionary statement for each hazard class and category.

- **Safety Data Sheets:** The new format requires 16 specific sections, ensuring consistency in presentation of important protection information.

- **Information and training:** To facilitate understanding of the new system, the new standard requires that workers be trained by December 1, 2013, on the new label elements and safety data sheet format, in addition to the current training requirements.

OSHA has updated the requirements for the labeling of hazardous chemicals under its HCS. As of June 1, 2015, all labels are required to have pictograms, a signal word, hazard and precautionary statements, the product identifier, and supplier identification. Supplemental information can also be provided on the label as needed. Figure 1-3 shows a sample label.

Employers must ensure that the SDSs are readily accessible to employees for all hazardous chemicals in their workplace. This may be done in many ways. For example, employers may keep the SDSs in a binder or on computers, provided that the employees have immediate access to the information without leaving their work area and a back-up is available for rapid access to the SDS in the case of a power outage or other emergency. Furthermore, employers might want to designate a person(s) to be responsible for obtaining and maintaining the SDSs. If the employer does not have an SDS for a particular product, the employer or a designated person(s) should contact the manufacturer to obtain one.

**Emergency Eyewash Stations:** OSHA requires that eyewash units be available for emergency use, and ANSI/AAMI ST79 states that “suitable eyewash/shower equipment must be available, with unobstructed access, for immediate emergency use in all locations where potentially damaging chemicals (e.g., instrument cleaning solutions and disinfectants, EO) are used.” The American National Standards Institute has set minimum standards for eyewash stations (ANSI Z358.1). They should provide at least 0.4 gallons of water per minute continuously for at least 15 minutes. They should permit hands-free operation, have a stay-open feature, and have the ability to flush both eyes at the same time. The eyewash unit should be connected to tepid—not hot—water (60°F to 100°F [15.5°C to 37.7°C]) to prevent burns to the eyes. It should be tested regularly to verify that it is operating properly; the prescribed frequency of testing is usually weekly, but the instructions of the eyewash unit manufacturer should be followed. This testing should be documented. The temperature of the water should also be documented when the eyewash unit is tested; water that is too cold or too hot can cause eye damage.

It should be noted that drench hoses and eyewash bottles are not acceptable according to the ANSI standard. If an eyewash unit is installed on a sink, it should be a handwashing sink, not a sink used for decontamination purposes. All emergency eyewash stations should be located within 10 seconds’ travel time (approximately 56 feet) of all chemicals used in SPD (ANSI Z358.1). They must be placed immediately adjacent to strong chemicals, on the same level as the hazard, and the path of travel must be free from obstructions. A door is considered an obstruction. If the chemical is non-corrosive, one door can be present, provided that it opens in the same direction of travel as the person requiring the use of the flushing station. Eyewash and drench shower stations must be installed in a well-lit area and identified with a highly visible safety sign. The SPD staff must know where eyewash stations are and how to use them.

Figures 1-4 and 1-5 show examples of acceptable emergency eyewash units and unacceptable emergency eyewash units, respectively.
PRODUCT IDENTIFIER

CODE ______________________________

Product Name _____________________

SUPPLIER IDENTIFICATION

Company Name _____________________
Street Address ______________________
City __________________________ State____
Postal Code __________ Country ______
Emergency Phone Number __________

PRECAUTIONARY STATEMENTS

Keep container tightly closed. Store in cool, well ventilated place that is locked.
Keep away from heat/sparks/open flame. No smoking.
Only use non-sparking tools.
Use explosion-proof electrical equipment.
Take precautionary measure against static discharge.
Ground and bond container and receiving equipment.
Do not breathe vapors.
Wear protective gloves.
Do not eat, drink or smoke when using this product.
Wash hands thoroughly after handling.
Dispose of in accordance with local, regional, national, international regulations as specified.

In Case of Fire: Use dry chemical (BC) or Carbon dioxide (CO2) fire extinguisher to extinguish.

First Aid
If exposed call Poison Center.
If on skin (on hair): Take off immediately any contaminated clothing. Rinse skin with water.

HAZARD PICTOGRAMS

SIGNAL WORD
Danger

HAZARD STATEMENT
Highly flammable liquid and vapor.
May cause liver and kidney damage.

SUPPLEMENTAL INFORMATION

Directions for use _______________________________
____________________________________________
Fill weight: __________ Lot Number ______
Gross weight: __________ Fill Date: ______
Expiration Date: __________

Figure 1-3 — Sample label for chemical

**STATE AND LOCAL AGENCIES**

In addition to federal regulations, there might be state and local regulations as well. Many states and communities have health, safety, and “right-to-know” regulations and ordinances that might apply to SPD activities, especially in regard to hazardous chemicals. If an applicable federal regulation is stricter than the corresponding state regulation, then it takes precedence. If the state regulation is stricter, it takes precedence. For example, California prohibits the release of EO into the air; therefore, any facility in California that uses EO must have an EO abatement system that, at the end of a sterilization/aeration cycle, converts EO into non-toxic gases.
**NFPA Diamonds:** The National Fire Protection Agency (NFPA) is not a government agency, but its standards are commonly cited in state and local regulations. For hazardous chemicals, NFPA specifies a labeling code for types and severity of hazards. Hazards are color-coded:

- Blue diamond = health hazard
- Red diamond = flammability
- Yellow diamond = instability
- White diamond = special hazard information

A numerical rating is also provided in the blue, red, and yellow diamonds. This number indicates the severity of the hazard, with a 0 indicating no hazard and a 4 indicating the most severe hazard. All chemicals should be labeled with an NFPA diamond.

This is the end of Module 1.

**NOTE: The Quiz for this topic is given AFTER you complete Module 2.**