This competency module presents current sterilization techniques used in today's health care environment. Perioperative nurses practice in a variety of settings, including traditional ORs, endoscopy suites, ambulatory surgery units, physicians’ offices, cardiac catheterization units, radiology departments, and other areas where operative or other invasive procedures are performed. This module is intended to provide the basic information necessary for safe and effective sterilization, regardless of the setting in which it occurs.
Sterilization

Competency Assessment Module

3rd Edition

By

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Published by
Competency & Credentialing Institute
2170 South Parker Road, Suite 295
Denver, CO 80231
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3
Overview and Objectives

Overview

Today's health care environment is continually challenged to provide optimal infection prevention modalities. The disinfection and sterilization of instrumentation is an integral component in the provision of safe patient care. This competency assessment module presents current sterilization methods used in today's health care environment. Use of sterile instruments and supplies in the perioperative setting contributes to infection prevention and control and safe patient care. Perioperative registered nurses (RNs) should be knowledgeable of sterilization processes and the various methods of sterilization available to health care settings. These settings may include hospitals, ambulatory surgery facilities, imaging, lab settings (e.g., cardiac, GI, endoscopy), birthing units, physician offices, and any site where operative or other invasive procedures are performed. Perioperative nurses should be knowledgeable of infection prevention and control practices designed to protect both patients and health care workers from potential contamination and/or infection.

This module is designed for perioperative registered nurses and is intended to provide the basic information necessary for safe and effective sterilization, regardless of the setting in which it occurs. The module describes the sterilization process, including preparation for sterilization, various methods of sterilization with examples of instruments and/or devices appropriate to the particular sterilization method, sterilization process monitoring, and documentation of the sterilization process.

Objectives

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

1. Discuss each of the five steps of the sterilization process.

2. Describe the sterilization methods presented in this module.

3. List the types of sterilization monitoring devices used for health care sterilization processes as presented in this module.

4. Discuss monitoring methods and frequency of use for the sterilization methods presented in this module.
Unit 1: Introduction

As health care in general, and operative and invasive procedures in particular, become more complex, the sterilization of essential instrumentation becomes more challenging. Advances in medicine and surgery, and corresponding advances in instruments and technology, have necessitated the development of sterilization specific to complex medical and surgical supplies and instrumentation. Device manufacturers are required by the US Food and Drug Administration (FDA) to provide instructions for cleaning and sterilizing reusable devices and for verifying the efficacy of their recommendations. Health care providers involved with sterilization processes are responsible for reviewing manufacturers’ written instructions and the supporting data and for verifying that the device(s) can be sterilized within the user facility.

The Spaulding classification system, developed by Earle Spaulding and published more than 40 years ago, categorizes devices to be processed for use as 1) critical, 2) semicritical, and 3) noncritical. This classification system continues to be used by infection prevention and control professionals and others to categorize reusable patient care devices. The classification system is based on the potential for infection to occur when the item is used for patient care. According to the Spaulding system, items/devices that enter sterile tissue or the vascular system are categorized as critical items and should be sterilized before use. Examples of critical devices include:

- surgical instruments,
- cutting endoscopic accessories that break the mucosal barrier and the scopes through which they are used,
- cardiac and urinary catheters,
- implants,
- needles, and
- ultrasound probes used in sterile body cavities.
Unit 2:

**Definition of Terms**

For purposes of this competency assessment module, the following definitions apply.

- **Aeration** — Method by which absorbed ethylene oxide is removed from ethylene oxide-sterilized items. \(^2 p^{46}\)

- **Air-removal test (e.g., Bowie-Dick test)** — A diagnostic test to determine the adequacy of air removal from the chamber of a prevacuum steam sterilizer. An air removal test is not a test to determine sterilization assurance. \(^2 p^{65}\)

- **Bioburden** — A population of viable microorganisms on a product and/or package. \(^3 p^{6}\)

- **Biological indicator** — Test system containing viable microorganisms providing a defined resistance to a specific sterilization process. \(^3 p^{6}\)

- **Chemical indicator** — Device used to monitor the presence or attainment of one or more of the parameters required for a satisfactory sterilization process, or is used in specific tests of sterilization equipment. \(^3 p^{6}\)

- **Convection** — The transfer of heat by circulation of heated air particles. \(^2 p^{70}\)

- **Decontamination** — The use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or items to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal. \(^4\)

- **Lot control number (load control number)** — Numbers, letters, or a combination of both, by which a particular group of products can be traced to a particular manufacturing or sterilization operation. \(^3 p^{10}\)

- **Pathogen** — Any disease-producing agent or microorganism. \(^2 p^{46}\)

- **Personal protective equipment (PPE)** — Specialized clothing or equipment worn by an employee for protection against a hazard. General work clothing (e.g., uniforms, pants, shirts, blouses) not intended to function as protection against a hazard is not considered to be personal protective equipment. \(^5\)

- **Physical monitor** — Automated devices (e.g., graphs, gauges, printouts) that monitor sterilization parameters for the sterilization method in use. \(^1 p^{478}\)

- **Process challenge device (PCD)** — Item designed to constitute a defined resistance to a sterilization process and used to assess performance of the process. \(^3 p^{12}\)

- **Quality control** — Programs that enhance personnel performance and monitor sterilization efficacy. \(^1 p^{472}\)

- **Spore** — Desiccated, unicellular, microbial structure that is highly resistant to destruction but capable of reproduction when returned to a vegetative state. \(^6 p^{25}\)

- **Sterilization** — The validated process used to render a product free from viable microorganisms. \(^3 p^{13}\)
Since the first century, when it was believed that swampy land contained minute animals, invisible to the naked eye, the study of pathogens has gradually developed into the complex science that exists today. The following is a timeline of landmarks in the history of asepsis, disinfection, and sterilization. These cumulative discoveries by these visionary leaders fostered the present day aseptic practices that we have come to know.

450BC
Hippocrates used wine or boiled water to irrigate wounds. It was found that the use of wine or boiled water decreased the infection rates of wounds.2 p45

Middle Ages
Segregation of lepers, avoiding areas of pestilence, and isolation tactics indicated an awareness of disease transmission.2 p45

1478-1553
Fracastoro published three books on contagion, recognizing three sources of transmission including person-to-person, by foamite or contact with infected material, and airborne.6 p3-18

Mid 1600s
Robert Boyle observed that putrefaction/fermentation and disease were somehow related. Boyle postulated that finding the cause of fermentation would lead to finding the cause of disease.6 p3-18
Van Leeuwenhoek was the first to see microorganisms, which he called “animalcules,” through his microscope. He later examined the film from his teeth and found great numbers of minute objects moving swiftly like eels; this was the first observation of bacteria. Van Leeuwenhoek was the first to use chemicals to kill microorganisms when he added peppered water to the microorganisms and microscopically observed their death. Building on his work, others tested other substances on the animalcules, including sulfuric acid, sodium tartarate, salt, sugar, wine, blood, and ink. All resulted in what appeared to be microbial kill. However, when salt was used, the animalcules recovered when fresh water was applied. Still, these animalcules were not recognized as disease-causing agents.6 p3-18

1700s
Spallanzani wrote about his observations that microorganisms could be killed by heat and that some organisms were more resistant than others.6 p3-18

1774
Scheele discovered chlorine and hypochlorite. This led to a mistaken belief that putrefaction and odors caused disease.6 p3-18
1836

Agostino Bassi demonstrated that a disease of silkworms was contagious and was caused by a fungus. This was the first clear demonstration of a microbial cause of a disease.² p45

Mid 1800s

William Henry attempted to interrupt the spread of plague and found that the cowpox vaccine was inactivated at 140° F (60° C) after 3 hours but was still active at 120° F (49° C). Lister later recommended heating glassware to 150° F (66° C) for two hours to produce sterilization.⁶ p3-18

1859

Ethylene oxide (EO) was first used as a pesticide in agricultural settings.⁷ p178-186

1860s

The mid 1800s was a turning point for the discovery of the prevention of microbial spread with regard to germ theory when researchers described methods that would prevent microorganisms from spreading from one person to another. Among these notable individuals were: Semmelweis, Pasteur and Lister.

Semmelweis advocated hand washing between patients as a method to reduce infection.² p45

Pasteur advocated for passing surgical instruments through a flame before use to eliminate dust harbored on the instruments. He encouraged use of a heat process for preparing dressings applied to open wounds.² p45

Lister’s contribution to antiseptic surgery is considered a major event in the evolution of asepsis. Lister used phenol in surgery to clean wounds. Phenol killed vegetative bacteria, and Lister used it on all parts of the wound and on the room’s walls and floor. Lister later found that a phenol dilution of 1:40 was as effective as full strength phenol and much less toxic to tissue.⁶ p3-18

Late 1800s

Robert Koch worked on the use of hot air and steam as a sterilizing agent.⁶ p3-18 Concepts developed by Semmelweis and Lister were implemented in hospital settings as surgeons gradually transitioned their practice from homes and open areas. Preoperative skin preparation was introduced; surgical teams also wore gowns, gloves, and masks.

1886

Ernst von Bregmann introduced the first steam sterilizer, although it was soon discovered that steam alone was not sufficient to kill heat-resistant microorganisms. Steam under pressure was necessary to raise the temperature to effectively kill resistant spores. This was the catalyst for the vacuum type and dry heat sterilizers that followed.⁸ p297

1933

EO was patented for use with carbon dioxide (CO₂) to destroy both insects and microorganisms. It was then used for the next decade as a fumigant for hospital rooms, as well as foods such as gums, cereals, and spices.

1940–50s

EO was further refined to be used with CO₂ concentrations to sterilize heat sensitive items, which allowed for the development of heat sensitive instrumentation.
Microorganisms, also known as microbes, are microscopic or submicroscopic organisms. Most of the microbes people come in contact with are harmless, having no effect on healthy people. Harmful microorganisms are disease-producing and are called pathogens. Microorganisms cannot be strictly classified as harmless or harmful. A microorganism that is nonpathogenic to one person may be harmful when transferred to another person. A nonpathogenic microorganism may become pathogenic to the original person when conditions change.

Microbes exist in water, air, and dust; on uncooked foods; on the skin and hair of people; and in decaying matter. Healthy people harbor millions of bacteria and continually shed them into the environment. Microorganisms are necessary for sewage treatment, the decay process, fermentation, and other processes.

Types of Microorganisms

Types of microorganisms include

- bacteria,
- fungi,
- protozoa,
- algae,
- viruses, and
- prions.

Bacteria

Bacteria are single-celled plant-like microbes that reproduce by splitting; some cause diseases (pathogens, also called germs). Bacteria are classified by shape, spore-forming capabilities, biochemical and physiological characteristics, staining properties, and pathogenicity (i.e., ability to produce disease). Bacteria in their active state are known as vegetative. Many bacteria can become dormant when the environment becomes unfavorable (e.g., dry). Sunlight may be detrimental to the vegetative (i.e., active growth) state of some bacteria. The cell shrinks until moisture is again available.

Some bacteria develop a highly resistant protective structure called a spore. A spore is dehydrated protoplasm that is so resistant it can survive prolonged exposure to drying, heat, and chemical disinfectants. Some species form spores to survive in extreme hot, dry, or cold environments. When the cell forms a spore, it forms a new, thicker wall inside the old one. As long as environmental conditions are adverse to the growth of the bacterium, the spore will remain a spore. Given the proper conditions for growth, the wall splits, a vegetative cell emerges, and the bacterial cell begins to reproduce. Some spores have been shown to survive for thousands of years in a dormant state.
Sterilization is a process by which all forms of microbial life, including bacteria, viruses, spores, and fungi, are completely destroyed. Sterilization is expressed as the probability of any organism surviving the sterilization process. This is known as the sterility assurance level (SAL). For steam sterilization processes, $10^{-6}$ (ten to the negative sixth power) is the recommended probability of survival for microorganisms on a sterile device. This represents the probability that only one microorganism in a million will remain alive.

With the complexities of both surgical instruments and the sterilization methodologies available in today's health care environment, medical and surgical devices require a specific regimen of care and processing prior to sterilization processes. Although the basic principles of sterilization originating from the early work of John Perkins, Robert Koch, and Ernst von Bregmann are still apparent, there have been significant changes in the complexity of instrumentation and processes.

The sterilization process consists of several steps that must be performed in sequence to render medical devices safe for use. These steps are:

- disassembly, decontamination, cleaning, and lubrication;
- inspection and assembly of items;
- packaging;
- sterilization; and
- storage.

**Decontamination**

The first and most important step in the sterilization process is decontamination. All instrumentation opened on a sterile field, whether used or unused, require decontamination. The first step in decontamination begins with the scrub personnel reducing the amount of bioburden by wiping off the instruments on the field using a sponge soaked in sterile water. Sodium chloride and bleach are not appropriate, because the chloride ions may cause pitting, rusting, and corrosion of metal instruments. In addition, lumens should also be flushed with sterile water to prevent obstruction with biodurden.

Physical decontamination may be accomplished manually, mechanically, or by a combination of both methods. Cleaning methods for each item depends on the characteristics of the item and should be accomplished in accordance with that specific device manufacturer's written recommendations. All reusable device manufacturers have the responsibility to provide validated reprocessing instructions in their labeling of the device (e.g., in the instruction manual).

Chemical decontamination refers to use of chemical agents such as enzymatic detergents to neutralize or arrest microbial proliferation on items.
Sterilization processes used in health care facilities can be categorized as either thermal or chemical processes. Thermal processes involve high temperatures, and chemical processes typically involve lower temperatures. High temperature processes include steam and dry heat sterilization. Chemical processes include ethylene oxide gas, hydrogen peroxide, ozone, and liquid peracetic acid sterilization. Other liquid chemical sterilization is possible using submersion in liquid chemical sterilants/disinfectants (e.g., gluteraldehyde compounds) for a prolonged period of time. This latter process is not practical in the health care environment and will be addressed only briefly in this module.

Steam Sterilization

Steam sterilization is the oldest, most economical, most reliable, and best understood method of sterilization. It is the method of choice for heat- and moisture-stable items such as metal items, most rubber goods, surgical instrument sets, fabric packs, glassware, solutions, and some hard plastic items. Steam is the sterilization method most frequently used in health care facilities.  

Steam is vaporized water; one of the physical states of water. It is nontoxic, readily available, and easily generated. The term “steam quality” is used to describe the amount of water contained within the steam. Steam should contain 2% to 3% liquid water. Excessive liquid water will result in wet loads and a need for increased drying times. Superheated steam, or steam containing less than 2% water, can result in a lack of heat transfer to the items in the sterilizer load. For steam sterilization to occur, saturated steam at an appropriate temperature must contact all surfaces of each item to be sterilized for a sufficient length of time to achieve microbial kill. If saturated steam at the proper temperature is not present, microbial kill will not occur regardless of how long the items are exposed to the lower temperature steam.

As liquid water is heated, the water temperature rises until it begins to vaporize at 212° F (100° C). At this point, the liquid and the steam are at the same temperature, which is known as the “saturation temperature.” The steam has more energy (i.e., heat) than the liquid water; and this energy is known as the latent heat of vaporization. When a cool object is placed in the steam, steam gives up some of this latent heat, and in doing so, a small amount of liquid water known as condensate is formed. The heat is transferred to the items to be sterilized, and the condensate reforms into steam when it again reaches the saturation temperature. This process is continuous until the entire sterilizer load reaches the desired temperature.

A steam temperature of 212° F (100° C) is not sufficient to kill microorganisms. The temperature of the steam is increased by containing the steam within a sealed container known as the sterilizer chamber. As the volume of steam increases, pressure builds in the sealed chamber. As pressure increases, the temperature of the steam rises. A steam temperature of 250° F (121° C) or higher is necessary for sterilization to occur.

To achieve steam penetration and contact with all surfaces to be sterilized, air must be evacuated from the sealed sterilization chamber. This is accomplished by means of a drain and steam trap in the bottom of the chamber. This allows excessive condensate to drain away, but prevents large amounts of steam from exiting the chamber with the condensate. Air can leave the sterilizer chamber passively (using a natural displacement process, steam pushes air out the chamber) or actively (with the use of a mechanical air removal method).
Unit 7:

Quality Control for the Sterilization Process

A quality control program must be in place in any facility where sterilization takes place. This program should address sterilizer performance and all aspects of the sterilization process including work practices, personnel performance, and adherence to established infection prevention and control principles. To help achieve and maintain the sterility of processed items, health care personnel must possess the knowledge of the sterilization process and general infection prevention and control practices. Orientation and ongoing education will optimize staff understanding and compliance.

Product Identification and Traceability

Product identification and traceability are important parts of the quality control process wherever sterilization takes place. In many facilities, sterilization is primarily accomplished in the Sterile Processing Department (SPD). The same guidelines are followed regardless of whether sterilization takes place in the SPD or the OR.

Each package sterilized in the health care facility should be labeled with a lot control identification label. This identification label should designate the sterilizer identification number or code, the date of sterilization, and the cycle number (run) of the sterilizer. Lot identification enables retrieval of items in the event of a recall, and also is helpful when tracing sterilization problems (e.g., wet packs) to their source. Lot identification labels can be affixed to a package either immediately before sterilization or at the conclusion of sterilization after items have cooled.

Detailed sterilization records should be maintained. In addition to the lot control identification label, the following should be recorded for each sterilization cycle:

- lot number, including sterilizer identification and cycle number;
- date and time;
- specific load contents;
- exposure time and temperature (if not recorded by the sterilizer);
- name or initials of the operator;
- aeration time and temperature (for EO sterilization);
- results of sterilization process monitoring (e.g., Bowie-Dick test, mechanical, chemical, biological); and
- reports of nonresponsive or inconclusive indicators found at a later time when packages are opened.

Each item in a load should be labeled with a control date for stock rotation. The item also should contain a statement regarding the expected shelf life of the item. If an event-related shelf life system is used in the facility, the statement should indicate that the package contents are sterile unless the package is opened or damaged. If a facility uses a time-related shelf life system, a specific expiration date should be placed on each package. Regardless of which shelf
Unit 8:

**Perioperative Nursing Data Set**

One of the responsibilities of the perioperative registered nurse is to prevent hospital-acquired infections by ensuring the cleanliness and sterility of instrumentation, supplies, and equipment within the perioperative setting. Though many of the steps to achieve this expectation are delegated to unlicensed assistive personnel, the accountability to ensure practice policies and standards are followed remains with the perioperative registered nurse. The nurse’s responsibility includes obtaining information on sterilization processes from both manufacturers of the sterilizer and the device being sterilized.\(^{18,64}\)

The *Perioperative Nursing Data Set* (PNDS) is a clinically relevant interface terminology that provides uniformity to perioperative nursing documentation and provides a common language for the documentation of clinical care. PNDS Outcome O.280 states, “Patient is free from signs and symptoms of infection is the area specific to sterilization.”\(^{19}\) In preventing infections in the operating room, as well as a myriad of other patient outcomes, we must look at this process within a professional nursing framework and develop outcomes and indicators specific to the patient. The outcome for prevention of hospital-acquired infection is as follows:\(^{19}\)

**Outcome**

The patient is free from signs and symptoms of infection.

**Outcome Definition**

The patient is free from signs and symptoms of surgical site infection such as pain, induration, foul odor, purulent drainage, and/or fever through 30 days following the operative procedure.

**Outcome Indicators (sterilization specific)**

- **Skin condition (surgical wound):** incision well approximated and free from heat, redness, induration, swelling, or foul odor; drains covered with sterile dressing and/or connected to continuous drainage; wound class identified.
- **Clinical documentation:** wound classification and infection prevention interventions and measures documented according to facility policy.

**Examples of Interim Outcome Statements**

- The patient is afebrile and free from signs and symptoms of infection.
- The patient’s wound is intact and free from signs of infection 30 days following surgery.
- The patient’s wound is free from signs or symptoms of infection and pain, redness, swelling, drainage, or delayed healing at time of discharge.


References


Additional Resources


Ethylene Oxide Sterilization Association, Inc.
www.eosa.org

International Association of Healthcare Central Service Materiel Management
www.iahcsmm.org

Occupational Safety and Health Administration
www.osha.gov

US Food and Drug Administration
www.fda.gov/MedicalDevices

US Environmental Protection Agency
www.epa.gov
Case Studies Response Guide

For each case study on page 73, list the interventions that the RN care provider should consider. List the rationale for the interventions.

**Case Study #1 — DP**

*Interventions:

*Rationale:

**Case Study #2 — BK**

*Interventions:

*Rationale:

**Case Study #3 — LT**

*Interventions:

*Rationale:

**Case Study #4 — TS**

*Interventions:

*Rationale:
## Competency Assessment
### Sterilization

<table>
<thead>
<tr>
<th>Name: _______________________</th>
<th>Title: _____________</th>
<th>Unit: ________</th>
<th>Date of Validation: _______</th>
</tr>
</thead>
</table>

Type of Validation:  [ ] Initial  [ ] Annual  [ ] Bi-annual

**Competency Statement:** The following are general competencies for all RNs and other health care personnel.

**Performance Criteria**

<table>
<thead>
<tr>
<th>Performance Criteria</th>
<th>Met</th>
<th>Not Met</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>•</strong> Understands and practices the principles of sterilization techniques when caring for all patients, especially those undergoing surgical procedures.</td>
<td>☐</td>
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<tr>
<td><strong>•</strong> Verbalizes an awareness of the relationship between sterilization practices and the risk of infection to patients.</td>
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<tr>
<td><strong>•</strong> Demonstrates the ability to recognize proper sterilization indicators on processed items.</td>
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<tr>
<td><strong>•</strong> Demonstrates the ability to recognize correct wrapping for sterilized items.</td>
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<td>☑</td>
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<tr>
<td><strong>•</strong> Demonstrates the ability to identify the correct use of a rigid container for sterilized items.</td>
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</tr>
<tr>
<td><strong>•</strong> Demonstrates the correct method to prepare items for flash steam sterilization.</td>
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<td>☑</td>
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<tr>
<td><strong>•</strong> Demonstrates the ability to initiate the correct cycle parameters for flash steam sterilization.</td>
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<td>☑</td>
</tr>
<tr>
<td><strong>•</strong> Demonstrates the ability to use and read chemical and biological indicators.</td>
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<td>☑</td>
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<tr>
<td><strong>•</strong> Demonstrates the ability to correctly operate a low-temperature peracetic acid sterilizer.</td>
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<td>☑</td>
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<tr>
<td><strong>•</strong> Demonstrates the ability to transport sterilized items from the sterilizer to a sterile field.</td>
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<td>☑</td>
</tr>
<tr>
<td><strong>•</strong> Plans appropriate nursing interventions concerning item sterility.</td>
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</tr>
</tbody>
</table>

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**Validator’s Signature**  
**Employee’s Signature**

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**Validator’s Printed Name**
This competency module presents current sterilization techniques used in today’s health care environment. Perioperative nurses practice in a variety of settings, including traditional ORs, endoscopy suites, ambulatory surgery units, physicians’ offices, cardiac catheterization units, radiology departments, and other areas where operative or other invasive procedures are performed. This module is intended to provide the basic information necessary for safe and effective sterilization, regardless of the setting in which it occurs.