In Unit 1, you gained an awareness of the historical roots of pharmacy and sterile compounding, exploring how your own training and continued learning, as well as the environment, supplies, label review, and calculations for sterile compounding, may affect patient health and safety. You also performed the “Exploratory Labs” in Part 2 of the Unit’s chapters, which deepened your understanding of the chapter concepts and the central role that USP <797> plays in your compounding work.

In this Unit, you broaden your understanding of the roots and concepts that ground your sterile compounding work and begin practicing the techniques. As you complete the nine “Procedural Labs” contained in Part 2 of this Unit, you may find that they require more traditional lab work than did the “Exploratory Labs” of Unit 1. Indeed, in the Unit 2 labs, you either produce a tangible product (Chapters 8–14) or prepare yourself and your working environment for product preparation (Chapters 6 & 7). The labs are designed to reinforce your sterile compounding training, offering plentiful practice.
to hone your skills toward mastering the work. Your instructor will evaluate your compounded sterile preparation techniques, ensuring they fulfill the revised regulations of USP Chapter <797> that became effective on June 1, 2008.

**Twentieth Century: Sterile Compounding Standards**

Decades before pharmacy implemented these Chapter <797> revisions, early standards evaluated the drugs created and dispensed by pharmacy personnel. The U.S. Congress declared one such standard in 1938 when it passed the Federal Food, Drug, and Cosmetic Act (FD&C Act). The Act “recognized the USP/NF as the official compendia of drug standards.” As the USP developed and evolved, the need for specific procedures for sterile compounding became more evident. Prior to the introduction of regulatory and safety standards, incidences of patient injury or death associated with sterile compounding were relatively commonplace.

During the 1960s and 1970s, many hospital pharmacy departments integrated intravenous (IV) admixture services. In previous decades, most sterile compounds were made by nurses and physicians immediately before patient administration. During the 1980s and 1990s, the increasing demand for specialized parenteral products led to an increasing demand for compounded sterile preparations. These specialized medications are sometimes needed for total parenteral nutrition, pain management, pediatric preparations, and for those patients who require specialized dosing, or formulations, or who are allergic to one or more of the ingredients in a commercially available product.

The need for such preparations continues to build as the number of requests for commercially unavailable medication grows. However, the training of personnel for aseptic technique and sterile product preparation has not always kept up with marketplace demand. Prior to 1995, few guidelines existed for sterile compounding personnel, and standards of practice were not well defined or regulated. The addition of a growing complexity in drug products and the individualized needs of patients has led to increased numbers of medication errors and pharmacy-related nosocomial infections. Given that, “since 1990, the FDA has become aware of more than 55 quality problems associated with compounded preparations, many of which have resulted in recalls, patient injury, and deaths,” it is clear that, even in recent history, these problems are significant. (ASHP Discussion Guide for Compounding Sterile Preparations, pp. 2-3)

In the early 1990s, pharmacy organizations such as the American Society of Health-System Pharmacists (ASHP), United States Pharmacopeia, the National Coordinating Committee on Large Volume Parenterals (NCCLVP), and the National Association of Boards of Pharmacy reviewed policies related to sterile product preparation and eventually issued several recommendations regarding the compounding of sterile preparations. In 1993, ASHP issued the Technical Assistance Bulletin, “Quality Assurance for Pharmacy-Prepared Sterile Products.”

**Twenty-First Century: USP <797> Revised Sterile Compounding Standards**

The 1993 Technical Assistance Bulletin helped to identify and delineate the parameters of information that would eventually be compiled into USP <797> Pharmaceutical Compounding – Sterile Products which was published in 2004. In 1997, the USP revised Chapter <797>, and the revised regulations became effective on June 1, 2008. Because of the recommendations of these groups, USP <797> has become a requirement for all pharmacies that perform sterile compounding. By law, these pharmacies may be inspected for compliance with the standards set forth by USP <797> by state boards of pharmacy, the FDA, and accreditation organizations such as the Joint Commission (formerly known as the Joint Commission on Accreditation of Healthcare Organizations [JCAHO]). (University Pharmacotherapy Associates, LLC (UPA) 2006, www.upa-llc.com USP Chapter 797: Compounding Sterile Preparations: Q and A).
The introduction of USP Chapter <797> wreaked havoc on the world of pharmacy. For decades, pharmacies had viewed the USP as a pharmacy reference guide with little application to everyday pharmacy practice. The changes brought forth in USP <797> presented significant challenges that some pharmacies and sterile compounding personnel struggle with to this day. Those challenges include achieving required alterations to facility design and construction, obtaining adequate funding for USP <797>-compliant equipment and materials, and affording the time and expense to train pharmacy staff and ensure their compliance with <797>. Because the intention of USP <797> is to increase patient health and safety—a goal to which all pharmacy personnel must aspire—the resulting challenges of USP <797>, while significant, can be met with a commitment to excellence in pharmacy.

The most important aspects of USP <797> center on the guidelines that sterile compounding personnel must follow during aseptic technique and sterile compounding procedures. Every aspect of sterile compounding requires a specific technique. For instance, you must follow special procedures when donning sterile garb and completing aseptic hand washing. Specific procedures also apply when your compounding work involves needles, syringes, vials, and ampules. Even more technically advanced and specialized procedures relate to preparing pediatric sterile compounds, total parenteral nutrition (TPN), and chemotherapy products. Clearly, sterile compounding has advanced over the decades, but especially so since the USP <797> changes of 2008: Procedures that were once performed at the patient’s bedside by nurses and physicians with little or no pharmacy training are now performed by specially trained pharmacy personnel using state-of-the-art equipment in USP <797>-compliant facilities.

You learn more about and begin to master the step-by-step procedures for each aspect of aseptic technique and sterile compounding in Unit 2. As you work from Chapter 6 to Chapter 14, you progress from the most basic concepts in aseptic technique to more advanced procedures, such as TPN and chemotherapy preparation. All information and procedures presented in this textbook are based on real-world experience, are considered best practice, and are in full compliance with the current regulatory standards.

### Sterile Compounding Area Procedures

#### Anteroom Procedures

**Physical Appearance and Behavior**
- Assess your appearance for any restricted items, including cosmetics, hairspray, nail polish, perfume, jewelry, or artificial nails.
- Abstain from food, drink, and gum chewing.

**Calculations and Supplies**
- Perform calculations prior to gathering supplies.
- Gather supplies at the beginning of the lab to avoid the airflow disturbance caused by entering and exiting the hood frequently.

**Aseptic Garbing, Hand Washing, and Gloving**
- Don correct attire including shoe covers, hair cover, face mask, and beard cover (if necessary).
- Cleanse hands according to aseptic hand-washing procedures. Gloved hands should be frequently rehashed or sterilized using a product such as sterile, foamed 70% isopropyl alcohol.
- Don sterile gown.
- Wipe down all supplies with sterile, foamed 70% isopropyl alcohol.
- Cleanse hands with sterile, foamed 70% isopropyl alcohol and put on sterile gloves.

#### Clean Room Procedures

**Restrictions of Working in the Hood**
- Do not bring potentially septic items such as pens, pencils, calculators, paper supplies, product overwrap, etc. into the hood.
- Avoid touching of the face, hair, eyeglasses, or trash container. If inadvertent touch contamination occurs, perform an aseptic hand washing.
- Avoid talking, sneezing, coughing, and whistling.

**Compounding in the Hood**
- Leave the hood on for at least 30 minutes before using it.
- Clean the hood according to standard protocol prior to making sterile products.
- Perform all manipulations at least six inches inside the outer edge of the hood to maintain good airflow over critical items (the needle, tip of the syringe, vial tops, injection port, etc.). Also, avoid placing these items anywhere on the work surface where they may obstruct horizontal airflow.
Aseptic Garbing, Hand Washing, and Gloving

Learning Objectives

- Gain awareness of the connections between early concepts of germ transmission and current procedures for aseptic garbing, hand washing, and gloving.
- Understand the procedures for aseptic garbing, hand washing, and gloving according to USP <797> guidelines.
- Identify ways that aseptic garbing, hand washing, and gloving protect the patient from infection.
- Recognize and respond appropriately to actions that compromise asepsis during aseptic garbing, hand washing, and gloving procedures.
- Demonstrate excellent technique in aseptic hand washing, garbing, and gloving.

In the 1840s, the work of Hungarian obstetrician Ignaz Semmelweis influenced hospital awareness of infection control. At Vienna General Hospital in Austria, Semmelweis recognized the role that hand cleansing played in reducing infection and mortality among maternity patients. To encourage such results, Semmelweis insisted that all obstetric interns wash their hands with chlorinated lime before they examined patients. By enforcing these antiseptic practices, the Hospital saw mortality rates for new mothers in the maternity ward decline by more than ten percent.

The Bavarian amulet pictured at left comprises three objects meant to protect mothers in childbirth, and is from 1750-1800, well before Semmelweis’s influential work. As in previous centuries, expectant mothers invoked supernatural powers as protection. An amulet’s powers came from its symbols and the organic materials they were made from. This amulet’s white, bone fist is an ancient Roman protective symbol; the circular shell promotes fertility; and the filigree chamber is market with initials of an 8th-century female missionary, symbolizing a container of special bone oil to assist the mother in case of infection or wounds.

By the 1850s, the importance of cleanliness and sanitary conditions to curbing the spread of contagion was slowly building momentum. Notable
English nurse Florence Nightingale observed this connection firsthand as she provided care and treatment for wounded soldiers during the Crimean War. Upon her return to England, Nightingale conducted an exhaustive study of the health of the British Army and provided documented statistics that reinforced the connection between poor hygiene and the deaths of thousands of soldiers. She created a plan for healthcare reform and compiled it into a 500-page report titled *Notes on Matters Affecting the Health, Efficiency, and Hospital Administration of the British Army* (1858). Nightingale submitted this confidential report to the British government. Although the report was poorly received, the document was eventually leaked to the British populace, providing the catalyst for healthcare reform in England. Previously, people with leisure time and extra resources could clean the body using such tools as the child’s silver manicure set from the 1670s pictured. Such a set would have been used for personal hygiene and included implements for cleaning the ears, tongue, fingernails, and cuticles. Yet broader popular association of bodily cleanliness with better health grew stronger over the ensuing 200 years.

The sterile practices set forth by Semmelweis and Nightingale influenced the research of nineteenth-century British surgeon Dr. Joseph Lister. Lister explored the germ theory of disease by building upon the microorganism theories of French chemist Louis Pasteur. Lister’s experiments with sterilization techniques proved that cleansing the hands, donning gloves, and using germicides on surgical instruments greatly reduced the incidence of infection. His sterile practices were met with skepticism by many surgeons, who found the presurgical preparations time-consuming and the caustic disinfecting agents irritating to skin and eyes. However, Lister’s pioneering work in the use of aseptic technique laid the foundation for the importance of gloving and garbing in the healthcare field.

### Emergence of Gloving

Balsam harvesters in the image at the right from the early 1500s wear gloves to gather the tree’s medicinal sap. Other cultures also used the balsam’s needles, inner bark, and branches to treat several concerns. The gloves both protected the harvesters’ hands from the sticky, resinous fluid and helped keep the sap clean. Alchemists and healers used gloves for such practical purposes for centuries, but gloves did not become official garb in the healthcare field until the end of the nineteenth century.

In 1889, Dr. William Stewart Halstead, a physician at Johns Hopkins University, supported Lister’s germ theory and the resulting need for the disinfection of surgical equipment. When his nurse expressed reluctance to using the harsh disinfecting chemicals, Halstead asked the Goodyear Rubber Company in 1890 to make a pair of gloves that would protect the skin. The experimental thin rubber gloves proved so effective that their use spread throughout the healthcare field. By 1905, the Ansell Company developed the first latex medical glove. Practitioners sterilized these early rubber and latex gloves
by dipping them in carbolic acid or steaming them in an autoclave. Sterilizing gloves in this way was labor-intensive and time-consuming, and evidence was growing that glove sterilization methods failed to render the gloves bacteria-free. These concerns wouldn’t be entirely addressed until decades later when, in 1964, the Ansell Company manufactured the first pre-sterilized, disposable, latex medical gloves.

By the early 1970s, the use of disposable gloves became commonplace in the pharmacy sterile compounding environment. However, pharmacy personnel traditionally used nonsterile, disposable gloves because they were less expensive. Sterile compounders cleaned their gloves by washing them with soap and water or wiping them with isopropyl alcohol. Numerous research studies provided evidence that cleaning gloves in this manner was completely effective in reducing pathogens in the sterile compounding environment. Nonetheless, the revision of USP <797> mandated in 2008 that all sterile compounding personnel wear presterilized, disposable gloves while preparing CSPs.

**Importance of Garbing**

Like gloving, garbing became an important practice in the healthcare field during the twentieth century. In the early decades of the century, documents concerning the Spanish flu epidemic of 1918 reveal that caregivers wore face masks. Building on Lister’s research that infection can be transmitted through airborne microorganisms, some doctors treating victims of the highly contagious disease wore crudely fashioned gauze masks in an attempt to protect themselves. It quickly became apparent that this simple act not only protected the doctors but also helped to reduce the rates of infection among patients they treated. In the workrooms of inventors and early scientists, primitive versions of masks have existed for hundreds of years. Records demonstrate the use of masks for filtering out “bad air” or gases; masks filled with potent, protective herbs and spices; masks made of sap- or wax-coated cloth, of leather, wool, or rubber, and masks that covered the whole face and even the entire head.

For additional protection during the course of their work, early craftspeople, inventors, and healers wore leather or cloth aprons, such as the one shown in the painting at right from the early 1700s. The aprons kept clothes cleaner, held tools or work materials, and provided a surface for wiping sooty or stained hands. In the mid-1930s, evidence mounted that the unsterile lab aprons—or even street clothes—that doctors wore in their healthcare practices harbored bacteria that could spread disease among their patients. As a result, garbing in sterile surgical attire became routine practice by the early 1940s in the United States. Wearing this type of sterile garb drastically reduced the incidence of nosocomial infection in the hospital setting. Sterile compounding pharmacies took the cue from the medical industry and followed suit by garbing in sterile gowns when they prepared CSPs for patient recipients.

Today, aseptic garbing, hand washing, and gloving are fundamental procedures that pharmacy technicians follow in sterile compounding pharmacies around the world. Critical to patient safety, these procedures are regulated by USP <797>, which describes the special requirements for hand-washing supplies and personal protective equipment. The background content and procedural lab of Chapter 6 reflect these directives.
Garbing, hand washing, and gloving are important components of aseptic technique. These procedures help avoid the introduction of pathogens, or disease-causing microorganisms, while you work with sterile compounding products and devices. Maintaining asepsis in product preparation is critical for patients receiving the products: the hospitalized patients who are recovering from surgery, injury, or infection. These patients have compromised immune systems that cannot mount an effective defense against pathogens, putting them at risk for further complications and even death. Thus, in order to minimize the risk of contamination by pathogens, sterile compounding technicians must adhere to strict aseptic technique both in the preparatory steps of garbing, hand washing, and gloving and while performing the sterile compounding procedures.

Correct garbing, hand washing, and gloving are also crucial for those preparing the products: the sterile compounding personnel who need protection from exposure to drugs and hazardous chemicals. In fact, chronic exposure to certain drugs, especially antibiotics, during the sterile compounding process might cause healthcare workers to develop an allergy or immunity to the drugs. As a technician, you must first understand the USP <797> guidelines, practice the procedures, and demonstrate mastery of aseptic garbing, hand washing, and gloving to appropriate personnel in order to ensure the safety of patients and of pharmacy and hospital personnel.

Self-Assessment for Compliance

Before beginning the sterile compounding process, technicians must assess their own physical appearance for any violations that could compromise the sterile compounding procedure. For example, as a technician, you must not wear cosmetics, hair spray, perfume, artificial nails, or nail polish while performing sterile compounding because these substances can flake and contaminate the compounded sterile preparations (CSPs). You must also remove any jewelry, including body piercings not covered by a gown and mask, for these items can harbor microorganisms. You should also keep your fingernails closely trimmed to make it easier to eradicate the bacteria under the nails. Finally, any technicians who have weeping sores, sunburn, rash, or respiratory infection should not work in the sterile compounding room until these conditions have improved.

Use of Personal Protective Equipment

Next, sterile compounding technicians begin the process of donning personal protective equipment (PPE), including shoe covers, a hair cover, and a mask. These items minimize the risk of contamination of the sterile compounding area and the CSPs. Before putting on the last PPE items, a sterile gown and sterile gloves, as a technician you must first perform aseptic hand washing, a hand-washing process that is more stringent than basic hand washing.
Aseptic Garbing, Hand Washing, and Gloving

Aseptic Hand Washing

In aseptic hand washing, you wash the arms (up to the elbow) and hands using an appropriate antimicrobial agent and following a specific sequence. You must pay extra attention to areas that harbor multiple microorganisms, such as under the fingernails and in the creases of skin. In order to become proficient at aseptic hand washing, you need to practice until the steps become second nature. Learning this process is critical because the most common source of contamination in the preparation of parenteral products is touch contamination by a healthcare worker who has not practiced correct aseptic technique in hand washing.

Sterile compounding technicians need to know not only the aseptic hand-washing process but also the circumstances under which the process must be performed or repeated. The following situations require the completion of aseptic hand washing:

- When first entering the sterile compounding area
- When reentering the sterile compounding area
- After eating
- After using the rest room
- After sneezing or coughing
- After a major contamination, such as a needle stick or a drug spill with a volume greater than 5 mL
- After the hands touch any item that is obviously contaminated, such as the floor, the trash or sharps container, or a visibly soiled item

In certain situations, sterile compounding personnel may cleanse their hands with foamed sterile 70% isopropyl alcohol. The following scenarios allow the use of these products:

- After using a calculator or pen
- After spilling a few drops of liquid on the hand
- When there is potential for minor hand contamination such as after adjusting eyeglasses or handling labels or medication orders

Sterile Gloves

After hand washing has been completed, sterile compounding technicians put on the last two PPE items: a sterile gown and a pair of sterile gloves. These items minimize skin exposure in the compounding area, an important safeguard given the fact that a human sheds more than one million skin cells every hour. These skin cells harbor multiple organisms that could contaminate the sterile products, endangering patient recipients.

Although it may seem odd to don sterile gloves after completing aseptic hand washing, this last PPE item provides an additional barrier or backup against product contamination. Technicians who have aseptic hands inside sterile gloves have compensated for two possible scenarios: First, the ripping or puncturing of gloves by a needle or glass shard; and second, the growth of microorganisms on poorly cleansed hands enclosed in the warm, moist environment of gloves. These microorganisms could then seep through the micropores of the gloves, contaminating the CSPs. Either situation could ultimately put the patient recipient at risk for infection, but both are less likely when you apply gloves over aseptically washed hands.
Check Your Understanding

Write your answers on a separate sheet of paper, as modeled in these examples: 1d; 2c; 3b; etc. Check your answers using the Answer Key in Appendix A.

1. What is the most common source of microbial contamination in CSPs?
   a. poor hand washing
   b. torn gloves
   c. circulating air
   d. soiled shoe covers

2. Which of the following situations requires a complete aseptic hand washing?
   a. entering the sterile compounding area after your lunch break
   b. being cut by a broken ampule
   c. spilling 10 mL of intravenous penicillin on your hand
   d. all of the above

3. Which antimicrobial agent is most commonly used after minor hand contamination?
   a. povidone-iodine
   b. triclosan
   c. chlorhexadine gluconate
   d. foamed, sterile 70% isopropyl alcohol

4. Why is it important that sterile compounding personnel don sterile gloves before preparing products?
   a. to protect long fingernails
   b. to provide added protection against pathogen transmission
   c. to avoid any potential drug interaction with nail polish
   d. to protect wrist and hand jewelry from corrosive chemicals

5. Which physical condition precludes pharmacy technicians from working in a sterile compounding facility?
   a. gastric reflux
   b. cardiac arrhythmia
   c. osteoarthritis
   d. weeping sores

Expand Your Knowledge

Write your answer to this question on a separate sheet of paper, taking the time to create a thorough and thoughtful response and use complete sentences. Check your answer against the “Possible Answer” provided in the Answer Key in Appendix A.

Scenario: Given the demands of aseptic technique, what personal qualities might be important for a sterile compounding technician?
Examine the Resources and Supplies

**Foot and Head Garb**

Personnel who work in the sterile compounding room must don appropriate footwear for safety and comfort. Technicians should wear close-toed shoes because of the potential for injury by needles or broken glass. Clean, well-fitting walking or running shoes are a safe option and can provide technicians with the comfort and increased stamina they need for standing for hours in front of the laminar airflow hood. Technicians place disposable shoe covers over the shoes to keep dirt and other substances from contaminating the clean room floor. Personnel remove these shoe covers and throw them away upon leaving the *anteroom*.

Personnel in the sterile compounding area must also wear head covers. The several options for hair covers include disposable caps and washable caps. Disposable surgical caps, or bouffant caps, are the most common type of hair cover for pharmacy personnel, who must remove and throw them away upon leaving the sterile compounding room. Washable caps are available in both surgical and bouffant styles and must be cleaned in the hospital laundry after each use. In general, surgical caps tie behind the head, and bouffant caps have a band of elastic that secure them to the head. No matter which style technicians choose, the most important consideration is that the selected head cover completely cover all of the hair.

Lastly, pharmacy personnel wear face masks to catch the bacteria held in the liquid droplets and aerosols that emanate from the mouth and nose. Masks may have ties or elastic to secure them to the face and most masks are made from paper or other non-woven material and are discarded after each use. Technicians with facial hair should also wear beard covers, which are similar to face masks but cover all visible facial hair, including beards, moustaches, and sideburns.
Hand Cleansers
Several cleansing agents are available for aseptic hand washing in the sterile compounding environment. Each commonly used type of hand cleanser has benefits and well-defined uses, and compounding facilities choose the types that suit them. To help prevent the formation of microbes that are resistant to a specific cleansing agent, facilities should occasionally change their hand cleanser type.

- **Chloroxylenol** is an effective, common cleansing agent appropriate for aseptic hand washing.
- **Chlorhexidine gluconate** is also a common and appropriate cleansing agent for aseptic hand washing.
- **Isopropyl alcohol** rinses, gels, or foams are frequently used between aseptic hand-washing procedures when there is minor hand contamination from handling labels or medication orders or adjusting eyeglasses. Whenever your hands touch anything that is potentially contaminated, use this cleansing agent to quickly re-clean the hands or gloves, provided that you have already performed a complete aseptic hand washing.
- **Iodophors** (such as povidone-iodine) have very effective antimicrobial properties, but they irritate the skin. Thus, sterile compounding technicians typically use this cleansing agent only if nothing else is available.
- **Triclosan**, common in household soaps, is appropriate for general hand washing in other areas of the pharmacy, but not acceptable for aseptic hand washing.

Aseptic Hand-washing Equipment and Supplies
USP <797> regulations describe the features and location of a sink designated for aseptic hand washing. The sink should be used only for aseptic hand washing by pharmacy personnel who are preparing to enter the sterile compounding room. This specialized and restricted-use sink is designed to minimize splashing and reduce the possibility of contamination during the hand-washing procedure.

The sink must be located in the anteroom or just outside the door of the sterile compounding area. It should be deep and have a gooseneck faucet and hot and cold running water. Preferably, foot pedals are used to turn the water on and off. If a sink with foot pedals is not available, personnel must let the water run throughout the entire scrub and rinse procedure and then turn off the faucet with clean, lint-free paper towels. The sink must be clean and free of any items that might cause splashing, such as sponges or intravenous bags.

Policies and procedures regarding the use of scrub sponges or scrub brushes in the aseptic-hand-washing process vary slightly among sterile compounding facilities. You
perform a very basic aseptic hand washing by vigorously washing both hands and forearms for at least 30 seconds with an appropriate antimicrobial agent. You must focus extra attention on areas that harbor multiple microorganisms, such as under the fingernails and in the creases of skin, and must wash your arms up to the elbow. Compared to doing a complete aseptic hand washing, you perform the basic hand washing procedure more quickly and without using a surgical scrub sponge or brush. However, the two types of hand-washing are otherwise the same.

Many facilities, especially those that prepare high-risk CSPs, such as total parenteral nutrition solutions and parenteral products compounded from nonsterile ingredients, prefer to perform the hand-washing procedure using a sterile, prepackaged, surgical scrub sponge/brush presaturated with an approved antimicrobial soap. The sterile surgical scrub sponge/brush is a very effective tool for ensuring a correct aseptic hand-washing process. Use the sponge side of the tool to cleanse the skin; use the brush side to scrub under the fingernails and around the nail cuticles. Perform the rinse procedures so that soapy water runs off toward the elbow. This arm position helps to maintain the cleanliness of the fingertips, which will come in direct contact with the CSPs. Dry the hands and forearms with aseptic, lint-free, disposable towels or an aseptic hand dryer. The towel container must be designed so it does not compromise the cleanliness or integrity of the towels.

**Scrub, Gowns, and Gloves**

Keep in mind that the airflow hood generates a certain amount of heat when on. Thus, when dressing to enter the sterile compounding area, layer your attire to be both appropriate for the warmth level and comfortable and practical for the tasks at hand. Technicians should don clean scrub uniforms (available in most hospitals or uniform supply stores) that should only be worn when preparing sterile products. If scrubs are not available, preparers should dress in clean, lightweight clothing that is not prone to shedding and that has not been exposed to pet hair.

Sterile compounding technicians must wear, as the outer layer of clothing, either a sterile, lint-free, disposable gown, or a gown that has been freshly laundered and sterilized by the hospital’s laundry department. The gown should completely cover the front of the preparer, have a secure neck closure, tie in the back, and fit snugly around the wrists.

Technicians should also don sterile, powder-free gloves. (Synthetic, nonlatex gloves are available for people with latex allergies.) As a general rule, note that size six gloves are size small, size seven gloves are size medium, and size eight gloves are size large. Gloves should be close-fitting to allow for maximum finger dexterity but not so tight that they compromise circulation or cause discomfort. Experiment until you find the size that fits best. Gloves are for one-time use only; you should discard them when leaving the sterile compounding area or anteroom.

Sterile gloves are recommended for use in sterile product preparation. If sterile gloves are not available, you can use nonsterile gloves, such as vinyl or nitrile gloves, but must wash these gloves by completing an additional aseptic hand washing once you’ve put them on. Powdered gloves are not recommended for use in the sterile compounding area due to their high potential for shedding particulates.
Part 2: Training

Preview the Lab Procedure

The following material provides a detailed description of each part of the lab procedure that you will perform. First, read the technique’s description carefully, visualizing every action. Next, reinforce your understanding of the procedure by watching the demonstration video. Once you are in the lab, your instructor will demonstrate the procedure, and then you will perform the procedure by following the steps in the Procedure section of the lab. Practice the lab procedure multiple times. After sufficient practice, you will complete the lab procedure for process validation by your instructor.

Garbing

When you enter the anteroom, you first remove any outer garments that you are wearing, such as a coat, sweater, jacket, or hat. If you are not already wearing appropriate lab attire, you change into a clean scrub uniform, or other lightweight clothing.

Next, you put on a clean pair of shoe covers. Once your shoe covers are in place, you put a hair cover on your head, making sure that all hair is tucked under the cap. Sterile compounding technicians with long hair may find it helpful to put hair in a ponytail or otherwise tie it back before putting on hair covers.

Once the shoe and hair covers are in place, you position a face mask over the nose and mouth. The face mask should cover the entire face, from below the chin to the bridge of the nose. If you position the top tie of the mask above the ears, the mask won’t slip down on your face. Men with visible facial hair should also wear a beard mask.

Aseptic Hand Washing

Once you are appropriately garbed, proceed to the sink for aseptic hand washing. Because fingertips directly contact the sterile product, aseptic hand washing is designed to move dirt from the fingertips toward the elbows. Thus, the hand-washing procedure repeatedly alternates between the hands and gradually works toward the elbows. The average acceptable aseptic hand washing takes a minimum of thirty seconds, but a careful and thorough job requires two to four minutes.

The surgical scrub sponge/brush is for one-time use only and should be thrown away immediately after using. Take caution not to contaminate the fingers, hands, arms, or the scrub sponge/brush at any time by inadvertently touching the sink or faucet. Should this happen, you must repeat the entire hand-washing procedure with a new sterile scrub sponge/brush.
**Gowning**

After the aseptic hand washing, you don a clean gown. When opening the gown or removing it from the hanger, be sure that the gown does not touch the floor or other surface at any time. You should pull the gown up the arms and onto the shoulders. Secure the neck closure at the nape and then wrap the waist ties around your body and tie them in the back.

If you need to remove your gown and your shift is not yet over, you may store disposable gowns that are not visibly soiled and reuse them. Turn the gown inside out to reduce the chance of exposure to airborne contaminants, and store it in the anteroom. Throw away the gown at the end of the shift. Non-disposable gowns may also be hung up, inside out, in the anteroom during the shift. At the end of each shift, place the used gowns in the laundry hamper that should be located just outside the anteroom. The gowns will then be picked up and taken to the hospital's laundry department where they will be washed like other sterile linens.

**Sterile Gloving**

The last part of the garbing, hand-washing, and gloving procedure involves the donning of sterile, powder-free gloves. First, you clean the hands with a small amount of foamed, sterile 70% isopropyl alcohol. Next, you open the outer packet of the gloves to reveal the inner, sterile packet containing the gloves. You then unwrap the sterile packet carefully so that the gloves do not come into contact with any non-sterile surface. You then carefully pull each glove onto the hand and over the wrist cuff of the gown, until it is firmly seated on the forearm, just above the cuff. This placement ensures that the gloves will not slip down below the gown's cuffs.

Gloves may be re-cleaned with sterile 70% isopropyl alcohol as needed, provided that they are fully intact and have not experienced major contamination. Inspect the gloves regularly throughout the shift. Immediately replace gloves when you noticing a hole or tear. Sterile gloves are for one-time use and must be disposed of immediately upon leaving the sterile compounding area.

**Removal of PPE Items**

Upon completion of sterile compounding procedures and prior to leaving the anteroom, sterile compounding personnel must correctly remove the PPE items worn. Remove PPE items in the reverse order from how they were donned, starting with glove removal and ending with shoe covers.

**Watch the Demonstration Video**

Watch the Chapter 6 lab demonstration video, which shows the step-by-step aseptic garbing, hand-washing, and gloving procedures.
Part 2: Training

Procedural Lab

Before performing this lab, review the Sterile Compounding Area Procedures listed on page X at the end of the Unit 2 opener, and preview the accompanying process validation checklist in Appendix E.

This lab walks you through the step-by-step actions that you must follow for aseptic garbing, hand washing, and gloving. Take your time. Work through each step methodically and with close attention to detail.

Supplies

- Shoe covers
- Hair cover
- Face mask and beard mask (if necessary)
- Surgical scrub sponge/brush packet
- Sink appropriate for aseptic hand washing
- Aseptic, lint-free, paper towels
- Sterile gown
- Foamed, sterile 70% isopropyl alcohol
- Packet of sterile gloves

Procedure

Garbing

1. Remove any outer garments and jewelry.

2. Don shoe covers, one at a time. Slip the longer end over the toe of the shoe. Pull the cover around the bottom of the shoe and onto the heel. The cover should completely envelop the shoe.

3. Put on the hair covering. Gather or tie back loose hair and place the bouffant cap over your head so that most of the hair is at the back. Position the back elastic against the back of your neck. Pull the front over your head until the elastic is against your forehead. Tuck any loose hair under the cover. All hair must be covered.

4. Don a face mask. Place the top of the mask on the bridge of the nose and gently pinch the thin aluminum strip woven into the top of the mask. Tie the upper ties behind the head, just above your ears. Tie the lower ties behind the neck. Position the mask securely over the nose, mouth, and chin. If you have facial hair, don a beard cover as well.

Aseptic Hand Washing

5. Proceed to the sink and prepare for aseptic hand washing. Before opening the surgical scrub sponge/brush, squeeze the packet several times to activate the soapsuds. Then open the packet, remove the sterile sponge/brush, and hold it in your dominant hand. Use your other hand to dispose of the wrapper. Press the foot pedals to begin the flow of water. Allow the water to run until it is warm.
6. Wet your hands and arms. Still holding the scrub sponge/brush, use the nail pick (found loosely embedded in the sponge side of the tool) to clean under each of your fingernails. When you have finished, throw the pick away.

7. Apply a **small amount** of water to the scrub sponge/brush and squeeze the tool several times to form an ample lather.

8. Using the **brush side** of the tool, scrub under the fingernail of the thumb of the left hand. Move to the other fingers, one by one, in order from thumb to pinkie. Repeat with the right hand.

9. Using the **sponge side** of the tool, clean each of the four surfaces (top, side, bottom, side) of the thumb of the left hand. Clean the webbing between the thumb and forefinger. Next, clean all four surfaces of the forefinger. Continue cleaning the remaining fingers of the left hand sequentially, cleaning the webbing in between each finger before moving on to the next finger. Repeat the cleaning pattern while cleaning the thumb and fingers of the right hand.

10. After cleaning the thumb and fingers of the left hand and the right hand, you now return to the left hand and clean the left palm with the sponge. Then clean the right palm with the sponge.

11. After cleaning the palm of the right hand, return to cleaning the left hand and clean the back of the hand with the sponge. Then clean the back of the right hand with the sponge.

12. Next, clean the left forearm, moving gradually, and in a circular pattern, around and around the arm, proceeding from the wrist up to the elbow. Then clean the right forearm using the same technique.

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**POINTER**

Squeeze the scrub sponge/brush with a gentle pumping motion and use only a small amount of water. This technique helps to prevent too much soap from being wasted down the drain. Squeeze and dampen as needed so that you have a good soapy lather throughout the entire procedure.

**BE AWARE**

Remember to use the brush side of the surgical scrub sponge/brush should only to clean the fingernails. Use the sponge side for the rest of the aseptic hand-washing procedure.

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After cleaning the palm of a hand, do not go back and clean the fingers again. USP guidelines stipulate that the cleaning process should not be reversed.
13. Having completed the cleaning process, you now throw the scrub sponge/brush away without touching the trash can or its contents.

14. Press the foot pedals on the sink so that you have a nice flow of warm water. Rinse the left hand and forearm, holding your arm with fingertips pointing up so you rinse the fingers first and the water runs down toward the elbow. Then rinse the right hand and forearm. If the sink does not have a foot pedal, use an aseptic, lint-free, paper towel to turn the faucet on and off.

15. Using an aseptic, lint-free, paper towel, dry both hands, and then dry the forearms, moving toward the elbow. Keep your fingers pointing up throughout the drying procedure. Throw the paper towel away when finished drying (Once they are dry, your fingers may point downward).

**Gowning and Gloving**

16. Carefully open the package containing the sterile gown. Don the gown, making sure it does not touch a contaminated surface, such as the floor or a work surface. Insert one arm into the open sleeve and then pull it up onto the shoulder. Insert the other arm into the other sleeve and pull the gown up to the neck. Secure the neck closure of the gown at the nape. Wrap the waist ties around your body and tie them in back.
17. Sterilize your hands with foamed isopropyl alcohol. Hold a can of foamed alcohol so the tip is pointed down into the palm of the opposite hand. Press against the tip with the index finger of the hand holding the can, releasing into the palm a small amount of alcohol, approximately the size of a quarter or a golf ball. Rub your hands together making sure that the alcohol coats the palms, the backs of the hands, and each finger. The alcohol will evaporate.

18. Open the outer wrapper of a packet of sterile gloves. Place the inner packet on a clean surface, such as a table or countertop that has been recently cleaned with 70% isopropyl alcohol. Open the inner glove packet. Do not touch the fingertips of the glove at any time during the donning process. Note that the gloves are labeled “left” and “right.” Place the glove on the right hand by grasping the inner part of the cuff (it will be folded over for easy access) with the left hand and carefully pulling the glove onto the right hand, up to the wrist, and over the cuff of the gown. Repeat with the other hand.

**Removal of PPE upon Leaving Anteroom**

19. Remove one glove by grasping the cuff and pulling it down and off the hand. The glove should now be inside out. Continue holding this glove in the hand that remains gloved. Grasp the cuff of the glove on the other hand and pull it off of the hand. One glove is now inside the other glove. Dispose of this glove bundle in a standard waste receptacle.

20. Untie the strings of the gown and then remove the gown by pulling it off at the shoulders. As you pull it toward the fingers, the gown turns inside out. Make sure that the gown never touches the floor or any other potentially contaminated surface. At the end of your shift, throw away your disposable gown or place your reusable gown in a designated laundry hamper outside the anteroom. Reusable gowns will be picked up and taken to the hospital’s laundry facility for cleaning.

21. Remove your face mask, hair cover, and shoe covers, in that order. Discard them in a standard waste receptacle.

**Process Validation by Instructor**

Your instructor will use the process validation checklist provided in Appendix E to evaluate your technique for this lab. To pass the evaluation, you must correctly perform each component of the lab procedure. Review the Chapter 6 lab and thoroughly practice each of the steps prior to your evaluation.
**Chapter Summary**

- To maintain infection control, sterile compounding technicians must follow the strict aseptic procedures outlined in USP <797> and in their pharmacies’ policies and procedures manual.
- All components of sterile compounding and aseptic technique play an important role in preventing contamination of the CSP, thus ensuring patient health and safety.
- Correct garbing, hand washing, and gloving are important components of aseptic technique and reduce the introduction of pathogens into the sterile environment.
- IV technicians must assess their own physical appearance and health condition prior to preparing for work in the clean room.
- Donning PPE items such as shoe covers, a hair or beard cover, a face mask, a sterile gown, and gloves is required for sterile compounding personnel.
- Correct removal, storage, and disposal of used PPE items also help to maintain aseptic technique protocol.
- Sterile compounding requires aseptic hand washing with an antimicrobial agent.

### Key Terms

- **aerosols** small liquid or solid particles that are temporarily suspended in air or in another gaseous medium
- **anteroom** a room or designated area that is located just outside the clean room and used by sterile compounding personnel to prepare themselves and their supplies prior to entering the clean room
- **antimicrobial agent** a cleansing product that is designed to either slow the growth of, or kill, microbes and bacteria
- **asepsis** a state or condition in which the sterile compounding area and the CSP remain free from pathogenic microorganisms
- **bacteria** a single-celled microorganism that may contaminate the CSP and lead to a serious infection in the patient recipient
- **basic aseptic hand washing** a type of hand washing that lasts approximately thirty seconds, using an antimicrobial soap but no scrub/sponge tool; may be performed after minor glove contamination (such as after using a calculator) but is most often done after removing sterile garb just prior to exiting the anteroom
- **chlorhexidine gluconate** an antimicrobial agent that is widely effective against contaminants that may be encountered in sterile compounding; commonly used in the surgical scrub sponge/brush products utilized in aseptic hand washing
- **chloroxylenol** a chlorine-based phenol derivative that is used as an antiseptic cleansing agent in pharmacy and presurgical hand washing
- **compounded sterile preparations (CSPs)** the mixing of one or more sterile products using aseptic technique
- **garbing** the process of donning aseptic shoe covers, hair covers, a facial mask, and a sterile gown and gloves in preparation for working in the clean room
- **germ theory** The theory that all diseases are caused by microorganisms, and that these germs can be transmitted among humans.
- **iodophors** anti-infective, antimicrobial agents used for presurgical cleansing
- **isopropyl alcohol** a cleansing agent commonly used to clean and prepare surfaces in the sterile compounding environment
- **Lister, Dr. Joseph** determined in 1867 that hospital deaths would decrease significantly if personnel thoroughly cleaned surgical instruments and environments before using them; influenced the development of the procedures and techniques of “modern” pharmacy
micropores  microscopic holes inherent in manufactured membranes, such as those used to create gloves

Nightingale, Florence  A celebrated British nurse and writer who is well-known for her pioneering work in nursing techniques and medical cleanliness

nitrile gloves  synthetic gloves that have a higher resistance to puncture than standard rubber gloves

Pasteur, Louis  French chemist and biologist whose 1870s research and work with germ theory led doctors to realize the importance of hand washing and thorough sanitizing in preventing the transmission of disease; influenced the development of the procedures and techniques of “modern” pharmacy

pathogens  disease-causing microorganisms

personal protective equipment (PPE)  specialized clothing and equipment worn by sterile compounding personnel to protect them from hazardous chemicals and to protect the CSP from contaminants

povidone-iodine  an anti-infective, antimicrobial agent used for presurgical cleansing

powdered gloves  medical gloves that contain a fine powder to decrease friction between the glove surface and the hand, thereby making them easier to put on

Semmelweis, Dr. Ignaz  A Hungarian obstetrician who observed that hand washing drastically reduced the transmission of disease; considered an early germ theorist

surgical scrub sponge/brush  a dual-sided tool that is typically presaturated with chlorhexidine or another similar anti-infective solution and used in aseptic and presurgical hand washing

touch contamination  transmission of contaminants through the touching of nonsterile surfaces or a break in aseptic technique; the most common and potentially dangerous form of CSP contamination

triclosan  a cleansing agent present in many household soaps

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**Check the Basics**

*On a separate sheet of paper, write your answers as modeled in these examples: 1d; 2c; 3b; etc.*

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1. What should you do if you accidentally drop the sterile scrub sponge/brush in the sink while hand washing?
   a. Pick up the scrub sponge/brush and resume hand washing per lab protocol.
   b. Pick up the scrub sponge/brush, rinse it off, and resume hand washing.
   c. Discard the dropped scrub sponge/brush, open a new scrub sponge/brush packet, remove the tool, and begin the hand-washing procedure again.
   d. Discard the dropped scrub sponge/brush, open a new scrub sponge/brush packet, and resume scrubbing wherever you left off on the original hand scrub.

2. Which statement most accurately describes the rinsing procedure?
   a. The water should run off toward the fingertips.
   b. The water should run off toward the elbow.
   c. The water should run toward the elbow, and then the hands should be shaken into the sink to remove excess water.
   d. It makes no difference how you rinse your hands since they are already clean.

3. How long should it take to complete a correct aseptic hand washing?
   a. a minimum of thirty seconds and up to four minutes
   b. exactly thirty seconds
   c. a minimum of two minutes
   d. at least ten minutes

4. What should you do if your hand accidentally touches the sink or faucet during the aseptic hand-washing procedure?
   a. Rinse your hand with water and continue the hand washing procedure from the point where you left off.
   b. Repeat the entire procedure with a new, sterile scrub sponge/brush.
   c. Provided that the sink and faucet have been cleaned recently, you do not have to do anything.
   d. Spray alcohol on your hands and start over with the same scrub sponge/brush.
5. Which statement is accurate regarding the use of a sterile scrub sponge/brush?
   a. A sterile scrub sponge/brush should never be used because this tool causes skin damage and skin cell shedding.
   b. The brush side of the sterile scrub sponge/brush should be used during the entire hand-washing procedure.
   c. The brush side of the sterile scrub sponge/brush should be used to clean the fingernails; the sponge side of the sterile scrub should be used to clean the skin.
   d. The sponge side of the sterile scrub sponge/brush should be used during the entire hand-washing procedure.

6. Which of the following items may be reused, provided that it is not visibly soiled and does not leave the sterile compounding area or anteroom?
   a. gown
   b. gown and shoe covers
   c. gown and hair cover
   d. gown, hair cover, shoe covers, and face mask

7. What is the correct order of preparation for sterile compounding?
   a. shoe covers, hair cover, face mask, hand washing, gown, gloves
   b. gown, shoe covers, face mask, hand washing, gloves, hair cover
   c. hand washing, gloves, gown, shoe covers, hair cover, face mask
   d. shoe covers, hair cover, gown, face mask, hand washing, gloves

8. Which type of gloves is most appropriate for use in compounding sterile products?
   a. vinyl gloves
   b. nitrile gloves
   c. sterile, nonpowdered gloves
   d. sterile, powdered gloves

9. What is the correct order of cleaning the fingers and hands during an aseptic hand washing?
   a. palm, fingers, and nail scrub of the left hand—and then repeat the process on the right hand
   b. nail scrub, fingers, and palm of the left hand—and then repeat the process on the right hand
   c. fingers, palm, and nail scrub of the right hand—and then repeat the process on the left hand
   d. nail scrub, palm, and fingers of the right hand—and then repeat the process on the left hand

10. Which is the correct method for cleaning the forearms during an aseptic hand washing?
    a. Scrub in an up-and-down motion, gradually working around the arm
    b. Scrub in a back-and-forth motion, gradually working around the arm
    c. Scrub in a circular motion, gradually working around the arm
    d. none of the above

Make Connections

On a separate sheet of paper, write your answers to the following three questions, using complete sentences and making sure your answers are thorough and thoughtful. Note that the third question requires Internet access.

1. Process validation involves the instructor's observation, critique, and grading of each aspect of the pharmacy technician's aseptic technique. In what ways might the process validation experience benefit the pharmacy technician?

2. What rationale might you offer for using a sterile, antimicrobial, saturated scrub sponge/brush while performing aseptic hand washing rather than washing your hands without a sponge/brush?
3. Visit the home page of the Web site for the Centers for Disease Control and Prevention (CDC). In the CDC search bar, type in Hand Hygiene Basics to obtain general hand hygiene information for healthcare personnel. In what ways does this basic hand hygiene information differ from aseptic hand washing? Note that both procedures are designed to prevent nosocomial infections and improve patient health and safety.

**MEET THE CHALLENGE**

**Scenario**
This “illuminating” class activity requires the product GloGerm and a handheld black light. The hand cleansing testing kit is available from the manufacturer’s Web site or other Internet websites related to hand washing training and testing.

**Challenge**
Perform this “mini lab” using the supplies and following the procedure listed below.

**Supplies**
- GloGerm
- Hand-washing supplies

**Procedure**
- Gather with your classmates around a hand-washing sink.
- Apply a liberal amount of the product GloGerm to the hands and forearms, scraping the fingernails across the palms to force the substance under the nails.
- Wash your hands and forearms vigorously (as done in a “basic” aseptic hand washing) for at least thirty seconds with an approved antimicrobial soap, and then dry your hands and forearms with sterile, lint-free paper towels.
- Turn off the lights in the lab and, under a black light, look for glowing, white specks on your hands. The GloGerm illuminates surface microbes. Where are they most evident? What does this result indicate about this type of hand washing?
- Reapply a liberal amount of GloGerm to the hands.
- Perform a complete aseptic hand washing, as detailed in this lab, with a sterile scrub sponge/brush.
- View the hands under a black light and compare the results to those of the regular hand washing.

**Additional Resources**
Go to the Paradigm Internet Resources Center at www.emcp.net/sterilecomp to access live links related to these Chapter 6 topics:
- sterile compounding
- hand washing and prevention of infection