By Holly Simmons, RPh

Personnel Hygiene and Gowning Requirements: How the Changes to USP <797> Will Affect Your Practice

The revised USP Chapter <797> was released on December 3, 2007, and will become official on June 1, 2008. It is a dynamic document that will always be subject to revision, but this first revision is significant in that the USP seeks to clarify the original document, as well as provide consistent guidelines that apply to all entities that prepare compounded sterile preparations (CSPs). There is now an expanded definitions section, as well as a summary appendix section. Additionally, the body of the document, arranged in sections, is more organized than the first release. All organizations that prepare CSPs should be familiar with the entire document and stay abreast of resulting enforcement guidelines to be indicated by individual state boards of pharmacy and accreditation bodies. The ultimate goal and purpose of USP <797> is patient safety and consistency in the preparation and dispensing of CSPs. Based on the updated chapter, this article will focus on proper attire and hand hygiene for sterile compounding activities.

The Importance of Appropriate Hand Hygiene and Gowning

To minimize possible contamination of CSPs, it is important to ensure appropriate personnel hand hygiene, garbing, and movement within the cleanroom/sterile compounding areas. Adhering to this portion of <797> does not generally require physical facility renovations and, therefore, could be an important first step toward full compliance. Meeting the physical facility requirements is still necessary for full compliance, but proper hygiene and gowning processes can be implemented in a short period of time and for relatively little money.

It is imperative that compounding personnel follow strict hygiene and aseptic technique requirements. This is the first line of defense to prevent microbial contamination of CSPs and the surrounding work areas and to minimize the introduction of particulate matter into compounding areas. Because particles in the air or on work surfaces provide a vehicle for microorganisms to be introduced into CSPs, it is necessary to cover as many exposed surfaces as possible on compounding employees. With normal movements, the human body sheds squamous cells at a rate of at least 106 per hour[1,2,3], and each particle has the potential to transport microorganisms. Proper garbing and hand hygiene do not totally eliminate all particles, but they can decrease the particulate burden in the compounding environment. Compounding personnel who wear cosmetics or who are experiencing illness, such as a respiratory infection or conjunctivitis, should not be allowed to work in ISO Class 5 or 7 areas until cosmetics are removed or their illness is resolved. Additionally, a severe rash, sunburn, or weeping sore should exclude employees from working in these areas until the condition is resolved.[1]

Garbing Procedure

The following steps constitute a recommended and <797>-compliant garbing procedure:

DEFINITIONS

ISO Class 8 Area – An area that contains no more than 3,520,000 particles 0.5µ or larger per cubic meter. This is the minimum requirement for the environment in the anteroom.

ISO Class 7 Area – An area that contains no more than 352,000 particles 0.5µ or larger per cubic meter. This is the minimum requirement for the air surrounding laminar flow hoods and biological safety cabinets, i.e. the "cleanroom" environment.

ISO Class 5 Area – An area that contains no more than 3,520 particles 0.5µ or larger per cubic meter. This is typically the environment found in the work area of a laminar flow hood, biological safety cabinet (BSC), or compounding aseptic isolator.

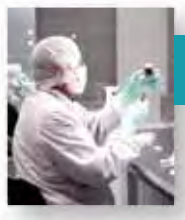
Personal Protective Equipment (PPE) - This is an overall description of the garb worn by compounding personnel.

Compounding Aseptic Isolator (CAI) – Formerly referred to as an "isolator" or "glove-box," this device provides an ISO Class 5 environment and is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material-transfer processes.[1]

Compounding Aseptic Containment Isolator (CACI) – A CAI that provides additional protection to the worker preparing hazardous drugs and is exhausted via properly designed building-ventilation systems if volatile hazardous drugs are prepared.

Closed-System Transfer Device (CSTD) – A device used when compounding hazardous CSPs, which creates a "closed" environment and offers personnel protection in addition to that offered by the BSC or CACI. The CSTD can prevent volatile substances from being released into the work area and provides additional staff protection from sprays or droplets.

- Remove outer garments (including coats or jackets, hats, scarves, and sweaters), cosmetics, and visible jewelry, prior to entry into the cleanroom or compounding area. Scrubs are not required, but donning clean scrubs will likely increase employee comfort during the compounding process, since scrubs are generally cooler and lighter than street clothes. An additional best practice suggestion is to change into the scrubs after entering the compounding facility to reduce the chance of introducing bacterial and fungal contamination.
- Artificial nails or extenders are prohibited and should not be worn. Natural nails must be kept neat and trimmed.[1]
- Garbing order should be dirtiest to cleanest (as detailed below) and based on current facility layout for storage of supplies and entries into anteroom and cleanroom areas.
  - Don dedicated shoes or shoe covers. If dedicated shoes are used, they should be resistant to disinfectants and stored in the anteroom or chang-



ing area. They should be cleaned on a regular basis and should not be worn outside the cleanroom/anteroom area. Shoe covers are should be worn only once and removed after exiting the cleanroom.

- Don head cover and facial hair cover, if applicable.
- Don face mask and eye shield. An eye shield is optional, except during cleanroom disinfection activities and preparation of hazardous drugs.
- Cleanse hands. (See sidebar on page 9 for detailed recommendations.)
- Don non-shedding gown with sleeves that fit snugly around the wrists and an enclosure at the neck. Compounding personnel generally prefer gowns that snap or button in the front, for ease of use, but USP Chapter <797> does not specify a required gown type. It is preferable to use a disposable gown, which may be stored in the anteroom and reused for one shift, if not visibly soiled or ripped. If reusable gowns are worn, they should be laundered appropriately for cleanroom use.
- Enter the cleanroom or segregated compounding area.
- Use a waterless alcohol-based surgical hand scrub to further cleanse hands.[1,4] Allow hands to dry prior to donning sterile gloves. For more information on this requirement, please refer to the CDC website (www.cdc.gov/handhygiene).
- Don sterile, powder-free gloves.
- Sterile gloves should be disinfected by wiping or rubbing sterile 70% isopropyl alcohol (IPA) on all surfaces of the gloves after they make contact with non-sterile surfaces, as well as routinely throughout the compounding process. The IPA should be allowed to fully dry before compounding duties are resumed. Continue to inspect gloves for holes or tears throughout the compounding process.
- After compounding is complete and personnel exit the cleanroom/compounding area, all garb items, except the gown, must be disposed of.
- For re-entry into the cleanroom/compounding area, don new garb (except the gown as previously mentioned) and perform hand hygiene.

Additional Provisions for High-Risk Compounding

For facilities that perform compounding using terminal sterilization of non-sterile initial ingredients, the weighing of all non-sterile ingredients should occur with the employee fully garbed and gloved. The weighing activities should occur in the ISO Class 7 area, and employees should re-garb and perform hand hygiene if they need to leave and re-enter the area or are exposed to worse than ISO Class 7 air.

Additional Provisions for CAIs and CACIs

Personnel preparing CSPs in either a CAI or CACI should perform the full garbing and hand hygiene procedure described above, unless the isolator manufacturer can provide written documentation, based on validated environmental testing, that any components of PPE or personnel cleansing are not required.

Additional Provisions for Hazardous Compounding

Preparation of hazardous drugs requires all of the same garbing requirements for preparations of non-hazardous drugs, with the following additional requirements:

- Handle all hazardous drugs with chemotherapy-rated gloves. This rule applies to all contact with hazardous drugs and hazardous drug containers, including contact made when unpacking and receiving the order from the wholesaler, as well as during stocking and physical inventory activities.
- Chemotherapy gloves must also be worn during the preparation and disposal of hazardous drugs.
- In addition to standard garb, eye shields should be worn when preparing hazardous CSPs in a BSC or CACI, even when using a closed-system drug transfer device.
- Double glove with sterile gloves.

Assessment of Hand Hygiene, Garbing, and Gloving Competency

Documented visual observation of hand hygiene, garbing, and gloving technique should occur during initial orientation training of compounding personnel and at least once annually, for low- and medium-risk level facilities, and at least semi-annually for facilities that prepare high-risk CSPs. It is also a best practice suggestion for supervisory personnel to observe these processes on an ongoing basis. The USP has included a Sample Form for Assessing Hand Hygiene and Garbing Related Practices of Compounding Personnel on page 59 of the Revision Bulletin.[1] This checklist can be used to document that each step of the process is properly performed.

In addition to the documented observation, organizations that prepare CSPs are required to conduct gloved fingertip/thumb sampling. Immediately after all garbing and gloving is complete (and prior to spraying gloves with sterile 70% IPA), the compounding employee should lightly press each fingertip into a nutrient agar plate (trypic soy agar with lecithin and polysorbate 80). Use one plate per hand. Label the agar plates and place in an incubator at 30° to 35°C for 48 to 72 hours. After the incubation period, count any colony forming units (CFUs) that grow on the plates and document the results. The desired result is zero CFUs, which is considered a "negative" result. A "positive" result would be any growth on the agar plate during the incubation period. During initial orientation, compounding personnel must complete a minimum of three "negative" gloved fingertip samples prior to preparing CSPs for human use. Thereafter, gloved fingertip sampling should be conducted at least annually for low- and medium-risk compounding, and semi-annually for

findit
findit.pppmag.com

WHERE TO FIND IT
www.findit.pppmag.com

Sterile Gloves

Vendor	Reader Service Number
Ansell Healthcare	38
Baxter Healthcare Corporation	41
Best Manufacturing Company	43
Cardinal Health	45
Cypress Medical Products	46
Kimberly-Clark Professional	48

Sterile Alcohol

Decon Labs, Inc.	50
ITW Texwipe	52
Miller Products Company, Inc.	58
STERIS Corporation	55

Gowns/Garb

Acute Care Pharmaceuticals	59
Innotech Products Inc.	61
Terra Universal, Inc.	62
Ultrapure Technology, Inc.	63
Value-Tek	65

Hand Hygiene Procedure

After donning head cover, shoe covers, and facemask, careful and thorough hand cleansing is next. The first steps of hand hygiene should be performed in the anteroom and prior to donning the non-shedding gown. Because tap water can be a source of microbial contamination, the gown should be donned after hand washing, thus minimizing the chance of water-borne bacteria splashing on the gown.

1. Remove debris from underneath fingernails with a nail cleaner and warm water.
2. Wash hands and forearms to the elbow for at least 30 seconds with non-antimicrobial or antimicrobial soap and water. Hand washing should be vigorous and thorough.
3. Do not use antimicrobial scrub brushes on the skin, as they can damage the skin and increase skin shedding.
4. Completely dry the hands and forearms using lint-free disposable wipes or an electronic hand dryer.
5. Continue with garbing process.

high-risk compounding. Any "positive" results require re-training of the compounding employee, and re-evaluation of garbing, hand hygiene, and gloving technique.

Conclusion

Proper hand hygiene and garbing are an essential part of the sterile compounding process and truly are your first line of defense to prevent patient harm from contaminated CSPs. Compounding supervisors that maintain a diligent training and observation program will assure that their facility meets and exceeds the guidelines established in USP Chapter <797>. Include employees in the quality assurance process and keep them informed of positive and negative results. Their feedback regarding policies and processes can be an instrumental part of assuring patient safety. ■

Holly Simmons, RPh, is the president of Impact Solutions Group (www.impactsolns.com), offering consulting services for general pharmacy operations, USP <797> compliance, proper aseptic technique, and accreditation survey preparation. She is also a pharmacy surveyor for the Accreditation Commission for Healthcare. She can be reached at hwsimmons@verizon.net.

References

1. The United States Pharmacopeia (USP) General Chapter <797> Pharmaceutical Compounding – Sterile Preparations Revision Bulletin. www.usp.org/pdf/EN/USPNF/generalChapter797.pdf. Accessed December 15, 2007.
2. Agalloco J, Akers JE. Aseptic processing: a vision of the future. *Pharmaceutical Technology*. 2005(suppl). Aseptic Processing. s16.
3. Eaton T. Microbial risk assessment for aseptically prepared products. *Am Pharm Rev*. 2005;5:46-51.
4. Guideline for hand hygiene in health care settings. *MMWR*. 2002;51:16.