

New Revision of USP<797>: Key Changes in Cleaning, Disinfecting, and Garbing-Related Activities

Section 2.1 Demonstrating Proficiency in Core Competencies

The original chapter did not have annual competency requirements.

The revised chapter states:

Before beginning to prepare CSPs independently, all compounding personnel must complete training and be able to demonstrate knowledge of principles and proficiency of skills for performing sterile manipulations and achieving and maintaining appropriate environmental conditions. Competency must be demonstrated every 12 months.

- Hand Hygiene
 - Garbing
 - Cleaning and Disinfecting
 - Principles of materials and personnel within the compounding area
- All compounding personnel must complete written or electronic testing every 12 months.

Contec Healthcare Comments: Contec offers a network of personnel and videos to help with training. Appropriate resources will be applied to meet increasing demands.

Section 3.2 Hand Hygiene

The chapter required use of a "*waterless alcohol-based surgical hand scrub with persistent activity*" before donning of sterile gloves.

The revised chapter removed the requirement for "*persistent activity*" and only requires use of an "*alcohol-based hand scrub*."

Contec Healthcare Comments: The removal of the requirement for persistent activity will benefit pharmacies by broadening the portfolio of products available for use by facilities.

Section 3.3 Garbing Requirements

The original chapter had a specific donning sequence listed for all PPE.

The revised chapter states:

"The order of hand washing and garbing depends on the placement of the sink" and "The order of garbing must be determined by the facility and documented in the facility's SOP."

Contec Healthcare Comments: Contec will suggest donning sequences which are based upon sink location and on the recommendations of noted industry experts. Contact your Contec representative for a copy of these suggested donning sequences.

The revised chapter states:

Donning and doffing garb should not occur in the ante-room or the SCA at the same time.

Contec Healthcare Comments: This will impact flow of personnel in and out of the cleanroom.

The revised chapter states:

When personnel exit the compounding area, garb except for gowns cannot be reused and must be discarded. Gowns may be re-used within the same shift if the gown is maintained in a classified area or inside the perimeter of an SCA.

Contec Healthcare Comments: Gowns are still allowed to be reused for one shift.

Section 4.4 Water Sources

The original chapter did not address cleaning and disinfecting the sink.

The revised chapter states:

"Surfaces of sink(s) must be cleaned and disinfected at least daily and a sporicidal agent must be applied at least monthly."

Contec Healthcare Comments: Contec Healthcare can assist with updating SOPs and training the staff on the cleaning and disinfecting sinks.

Section 7: Cleaning, Disinfecting and Applying Sporicidal Agents in Compounding Areas

The revised chapter contains several new guidelines for the frequency of cleaning and disinfecting the PEC.

The original chapter required the cleaning and disinfecting the PEC at the *"beginning of each shift"*.

The revised chapter (see Table 8 in section 7) requires to clean all interior surfaces of the PEC daily (once per day).

The original chapter required the entire PEC to be disinfected "before each batch, not longer than 30 minutes following the previous surface disinfection." *Additionally, the original chapter did not specify use of a sporicidal disinfectant in the PEC."*

The revised chapter states:

"Apply sterile 70% IPA to the horizontal work surface at least every 30 minutes if the compounding process takes 30 minutes or less. If the compounding process takes more than 30 minutes, compounding must not be disrupted, and the work surface of the PEC must be disinfected immediately after compounding."

Contec Healthcare Comments: The key change is that the requirement only applies to the horizontal work surface (deck), not the entire PEC. The revised chapter also will require monthly application of a sporicidal disinfectant on every surface in the cleanroom (PEC and SEC). Also note the footnote "c" regarding the ceilings of the SCA.

Table 8. Minimum Frequency for Cleaning and Disinfecting Surfaces and Applying Sporicidal Agents in Classified Areas and within the Perimeter of the SCA^a

Site	Cleaning	Disinfecting	Applying Sporidical
PEC(s) and equipment inside the PEC(s)	Equipment and all interior surfaces of the PEC daily and when surface contamination is known or suspected.	<ul style="list-style-type: none"> Equipment and all interior surfaces of the PEC daily and when surface contamination is known or suspected. Apply sterile 70% IPA to the horizontal work surface at least every 30 minutes or less. If the compounding process takes more than 30 minutes, compounding must not be disrupted the work surface of the PEC must be disinfected immediately after compounding. 	Monthly
Removable work tray of the PEC	<ul style="list-style-type: none"> Work surface of the tray daily All surfaces and the area underneath the work tray monthly 	<ul style="list-style-type: none"> Work surface of the tray daily All surfaces and the area underneath the work tray monthly 	<ul style="list-style-type: none"> Work surface of the tray daily All surfaces and the area underneath the work tray monthly
Pass-through(s)	Daily	Daily ^b	Monthly
Work Surface(s) outside the PEC	Daily	Daily ^b	Monthly
Floor(s)	Daily	Daily ^b	Monthly
Wall(s), Door(s), and door frame(s)	Monthly	Monthly ^b	Monthly
Ceiling(s)	Monthly	Monthly ^b	Monthly
Storage shelving and bins	Monthly	Monthly ^b	Monthly
Equipment outside the PEC(s)	Monthly	Monthly ^b	Monthly

^aCleaning of sinks is described in 4.4 Water Sources

^bMany disinfectants registered by the EPA are one-step cleaning and disinfecting agents, which means that the disinfectant has been formulated to be effective in the presence of light to moderate soiling without a separate cleaning step.

^cCeilings of the SCA are required to be cleaned, disinfected, and applied with sporicidal agent only when visibly soiled and when the surface contamination is known or suspected

Section 7.2 Cleaning Supplies

The revised chapter requires that mop handles be disinfected before and after each use: *“Reusable cleaning tools must be made of cleanable materials (e.g., no wooden handles) and must be cleaned and disinfected before and after each use.”*

Contec Healthcare Comments: Contec Healthcare offers cleaning hardware that can be effectively cleaned and disinfected.

Section 7.3 Cleaning, Disinfecting and Applying Sporidical Agents in the PEC

The original chapter did not indicate a clear procedure for cleaning and disinfecting the PEC.

The revised chapter establishes a clear procedure for **cleaning and disinfecting** and for **applying a sporidical agent** in the PEC. See Boxes 7-1 and 7-2.

Box 7-1. Procedures for Cleaning and Disinfecting the PEC

- Remove visible particles, debris, or residue with an appropriate solution (e.g., Sterile Water for Injection or Sterile Water for Irrigation) using sterile, low-lint wipers.
- Using a low-lint wiper, apply a cleaning agent, followed by a disinfecting agent, or apply an EPA-registered (or equivalent) one-step cleaner or equipment and all interior surfaces of the PEC.
- Ensure the contact time specified by the manufacturer is achieved.
- Using a low-lint wiper, apply sterile 70% IPA to equipment and all interior surfaces, in the PEC.
- Allow the surface to dry completely before beginning compounding.

Box 7-2. Procedures for Applying a Sporidical Agent in the PEC

- Remove visible particles, debris, or residue with an appropriate solution (e.g., Sterile Water for Injection or Sterile Water for Irrigation) using sterile, low-lint wipers.
- After cleaning and disinfecting (Box 7-1), apply the sporidical agent using a low-lint wiper to all surfaces and the area underneath the work tray. If the sporidical agent is EPA-registered (or equivalent) one-step disinfectant sporidical cleaner, separate cleaning and disinfecting steps are not required.
- Ensure the contact time specified by the manufacturer is achieved.
- Using a low-lint wiper, apply sterile 70% IPA to equipment and all interior surfaces, including underneath the work tray.
- Allow the surface to dry completely before beginning compounding.

Contec Healthcare Comments: contec’s epa-registered, one-step disinfectants combined with wipers are considered “*appropriate solutions*” for removal of visible particles, debris and residue as described in the first bullet points of both boxes 7-1 and 7-2. Use of these products to accomplish all the cleaning and disinfection steps will simplify the process.

Section 8.1 Introducing Items into the Cleanroom Suite and SCAs

The original chapter, suggested, but did not require the use of a suitable disinfecting agent on items being taken into the cleanroom.

The revised chapter states: “*Before any item is introduced into the clean side of ante-room(s), placed into pass-through(s), or brought inside the perimeter SCA and when packaging integrity will not be compromised, it must be wiped with a sporidical agent, EPA-registered disinfectant, or sterile 70% IPA using low-lint wipers by personnel wearing gloves. If an EPA-registered disinfectant or sporidical agent is used, the agent must be allowed to dwell for the minimum contact time specified by the manufacturer. If sterile 70% IPA is used, it must be allowed to dry. The wiping procedure must not render the product label unreadable.*”

Contec Healthcare Comments: Contec offers appropriate EPA-registered disinfectants for wiping items before introduction into the cleanrooms. We recommend the use of a sporidical disinfectant to wipe supplies when removing them from shipping containers. This is considered best practice due to the risk of spore contamination associated with cardboard and paper packaging materials.

Section 8.3 Use of Sterile 70% IPA on Critical Sites within the PEC

The original chapter did not address this issue with its own section.

The revised chapter calls attention to the importance of this issue by creating a new section (8.3): *“Critical sites (e.g., vial stoppers, ampule necks, and intravenous bag septums) must be wiped with sterile 70% IPA in the PEC to provide both chemical and mechanical actions to remove contaminants. The sterile 70% IPA must be allowed to dry before entering or puncturing stoppers/septums or breaking the necks of ampules.”*

Contec Healthcare Comments: Use of wipes specifically developed for Critical Site applications will alleviate challenges associated with individually-packaged alcohol prep wipes that were designed for skin antisepsis.

GLOSSARY

The original chapter did not provide a definition of a *“low-linting wipe.”* It referenced the term *“low-shedding wipes,”* but did not give a definition.

The revised chapter defines a low linting wiper as: *“A wiper exhibiting few, if any, fibers or other contamination, visible without magnification, which is separate from, or easily removed from, the wiper material in a dry condition.”*

Contec Healthcare Comments: This definition brings USP <797> in line with the Institute of Environmental Sciences and Technology (IEST)-recommended practice (IEST-RP-CC004.4, Evaluating Wiping Materials Used in Cleanrooms and Other Controlled Environments, pending publication).