USP <797> Compliant Garbing, Material Handling and Cleaning Procedures using Contec® Product Solutions

This resource provides information on garbing, material handling, as well as cleaning and disinfection from the revised USP 797 and marries it with appropriate Contec products and supplies that will facilitate chapter compliance.

USP 797 Basis for Garbing, Material Handling and Cleaning Requirements

The revised USP Chapter 797 (2023) creates new categories for compounded sterile preparations (CSPs) based on environmental conditions, microbial risk and the resulting time period for which they may be stored. Many of the cleaning, garbing, and work practice requirements change based on the category of CSP (Category 1 least strict to Category 3 most strict) compounded by the organization.

Category 1	CSPs compounded under least controlled environmental conditions (e.g., inside a PEC placed in an SCA) and therefore assigned a BUD of ≤12 hours at controlled room temperature or ≤24 hours refrigerated
Category 2	CSPs required more environmental controls and testing than Category 1 CSPs and may be assigned BUDs of >12 hours at controlled room temperature or 24 hours refrigerated but not exceed the limits described in Table 13
Category 3	CSPs undergo sterility testing, supplemented by endotoxin testing when applicable, and have more requirements than Category 2 CSPs for personnel qualification, use of sterile garb, use of sporicidal disinfectants, frequency of environmental monitoring, and stability determination. Category 3 CSPs may be assigned longer BUDs than those set for Category 2 CSPs

Personal Hygiene and Garbing	
Section 3.1 Personal Preparation	All personnel entering a compounding area where Category 1, Category 2, or Category 3 CSPs are prepared must take appropriate steps to minimize microbial contamination of the environment and of the CSPs, including hand hygiene and garbing and consideration of needed materials to be brought into the compounding area. Before entering a compounding area, individuals must remove any items that are not easily cleanable or are not necessary for compounding. At a minimum, individuals must: • Remove all cosmetics because they shed flakes and particles. • Remove personal outer garments • Remove all hand, wrist, and other exposed jewelry, including piercings that could interfere with the effectiveness of garbing (e.g., the fit of gloves, cuffs of sleeves, and eye protection) or otherwise increase the risk of contamination of the CSP. Cover any jewelry that cannot be removed. • Not wear earbuds or headphones • Not bring electronic devices that are not necessary for compounding or other required tasks into the compounding area • Keep nails clean and neatly trimmed to minimize particle shedding and avoid glove punctures. Nail products (e.g., polish, artificial nails, and extenders) must not be worn • Wipe eyeglasses, if worn

Content throughout this document is guidance distilled directly from USP Chapter 797 published 11/1/2022

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Personal Hygiene and Garbing *(continued)*	
Section 3.2 Hand Hygiene	Any person entering a compounding area where Category 1, Category 2, or Category 3 CSPs are prepared must wash hands and forearms up to the elbows with soap and water before initiating compounding activities • Brushes must not be used for hand hygiene. • Hand dryers must not be used. • To minimize the risk of extrinsic contamination, disposable soap containers must not be refilled or topped off. • The order of hand washing & garbing depends on the placement of the sink. • The order of garbing must be determined by the facility and documented in the facility's SOPs. • Hands must be sanitized with alcohol-based hand rub before donning sterile gloves (see Box 4). • Sterile gloves must be donned in a classified room or SCA.
Box 3 Hand Washing Procedure	• Clean underneath fingernails under warm running water using a disposable nail cleaner. • Wash hands and forearms up to the elbows with soap and water for at least 30 seconds. • Dry hands and forearms up to the elbows completely with low-lint disposable towels or wipes
Box 4 Hand Sanitizing Procedure	• Apply an alcohol-based hand rub to dry skin. • Apply product to one hand and rub hands together, covering all surfaces of hands and fingers, until hands are dry. • Allow hands to dry thoroughly before donning sterile gloves
Section 3.3 Garbing Requirements	• Donning and doffing garb should not occur in the same area at the same time. • Garb must be replaced immediately if it becomes visibly soiled or if its integrity is compromised. • Gowns and other garb must be stored in a manner that minimizes contamination (e.g., away from sinks to avoid splashing). • If compounding Category 1 and Category 2 CSPs, gowns may be reused within the same shift by the same person if the gown is maintained in a classified area or adjacent to, or within, the SCA in a manner that prevents contamination. • When personnel exit the compounding area, garb, except for gowns, cannot be reused and must be discarded or laundered before reuse. • Gloves must be sterile and powder free. • Application of sterile 70% IPA to gloves must occur immediately before compounding and regularly throughout the compounding process. • All gloves must be inspected for holes, punctures, or tears and must be replaced immediately if such defects are detected. • The RABS sleeves and gloves and the pharmaceutical isolator sleeves and gloves should be changed per the manufacturer's recommendations and as defined in the facility's SOPs.
Minimum Garbing Requirements for Facilities that Compound Category 1 & 2 CSPs	• Low-lint garment with sleeves that fit snugly around the wrists and an enclosed neck (e.g., gown or coverall) • Low-lint covers for shoes • Low-lint cover for head that covers the hair and ears, and if applicable, cover or facial hair • Low-lint face mask • Sterile powder-free gloves • If using a RABS (i.e., a CAI or CACI), disposable gloves should be worn inside the gloves attached to the RABS sleeves. Sterile gloves must be worn over the gloves attached to the RABS sleeve

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Personal Hygiene and Garbing *(continued)*	
Minimum Garbing Requirements for Facilities that Compound Category 3 CSPs	If the facility compounds Category 3 CSPs, additional garbing requirements must be continuously met in the buffer room in which Category 3 CSPs are prepared. The following additional garbing requirements must be followed in the buffer room where Category 3 CSPs are prepared for all personnel regardless of whether Category 3 CSPs are compounded on a given day: • Do not allow any exposed skin in the buffer room (i.e., face and neck must be covered). • All low-lint outer garb must be sterile, including the use of sterile sleeves over gauntlet sleeves when a RABS is used. • Disposable garbing items must not be reused, and laundered garb must not be reused without being laundered and resterilized with a validated cycle. • The facility's SOPs must describe disinfection procedures for reusing goggles, respirators, and other reusable equipment

Contec® Healthcare Product Solutions for Garbing Sterile Compounding Operations

- Contec® Healthcare Low-lint Hand Drying Wipes
- Contec® CritiGear™ Sterile Nitrile Gloves
- Contec® CritiGear™ Cleanroom Frock *(not appropriate for Cat 3 compounders)*
- Shoe covers *(not appropriate for Cat 3 compounders)*
- Bouffants *(not appropriate for Cat 3 compounders)*

DAILY ACTIVITY: Disinfecting Supplies Prior to Use (Material Handling)	
Section 8.1 Introducing items into SEC	Before any item is introduced to clean side of anteroom(s), placed into pass-through chamber(s), or brought into SCA, providing that packaging integrity will not be compromised, it must be wiped with a sporicidal disinfectant, EPA-registered disinfectant, or sterile 70% IPA using low-lint wipes by personnel wearing gloves. If an EPA-registered disinfectant or sporicidal disinfectant is used, agent must be allowed to dwell for minimum contact time specified by manufacturer. If sterile 70% IPA is used, it must be allowed to dry. The wiping procedure should not compromise the packaging integrity or render product label unreadable.
Section 8.2 Introducing items into PEC	Just before any item is introduced into the PEC, it must be wiped with sterile 70% IPA using sterile low-lint wipes and allowed to dry before use. When sterile items are received in sealed containers designed to keep them sterile until opening, sterile items may be removed from the covering as the supplies are introduced into the ISO Class 5 PEC without the need to wipe the individual sterile supply items with sterile 70% IPA. The wiping procedure must not render the product label unreadable.
Section 8.3 Use of Sterile 70% IPA on Critical Sites	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. Sterile 70% IPA must be allowed to dry before personnel enter or puncture stoppers and septums or break the necks of ampules.

Contec® Healthcare Product Solutions for Material Handling

- Contec® Sterile 70% IPA (Available in 16 oz. and 32 oz. bottles)
- Amplitude™ EcoCloth™ Wipes
- Sanotex® Environmental Surface Wipes
- PeridoxRTU® Sporicide, Disinfectant and Cleaner
- Contec® Critical Site® Sterile Wipes
- Contec® Healthcare TB1-3300™ Disinfectant
- PREempt® Plus Disinfectant

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DAILY ACTIVITY: Cleaning of ISO 5 Laminar Flow Hoods, Biological Safety Cabinets, and other PEC (Primary Engineering Controls)	
Section 7	• In a PEC, sterile 70% IPA must be applied after cleaning and disinfecting, or after the application of a one-step disinfectant cleaner or sporicidal disinfectant, to remove any residue. • Sterile 70% IPA must also be applied immediately before initiating compounding. • During the compounding process sterile 70% IPA must be applied to the horizontal work surface, including any removable work trays, of the PEC at least every 30 mins if the compounding process takes 30 mins or less. • If the compounding process takes more than 30 mins, compounding must not be disrupted, and the work surface of the PEC must be disinfected immediately after compounding.
Table 10	• PECs and equipment inside the PEC must be cleaned daily on days when compounding occurs. For daily cleaning an EPA-Registered Disinfectant is acceptable • Work surfaces outside of the PECs and equipment inside the PEC have a sporicidal disinfectant applied monthly for entities compounding Category 1 & 2 CSPs; and weekly for entities who compound Category 3 CSPs
Section 7.1.1 Agents	• Cleaning, disinfecting and sporicidal agents used within the PEC must be sterile. When diluting concentrated cleaning and disinfecting agents for use in the PEC, sterile water must be used.
Section 7.1.2 Supplies	• Cleaning, disinfecting and sporicidal agents used within the PEC must be sterile. When diluting concentrated cleaning and disinfecting agents for use in the PEC, sterile water must be used.

Contec® Healthcare Product Solutions

- Contec® Sterile 70% IPA
- SterileSorb™ Wipes
- PROSAT® Sterile Presaturated Wipes
- Sterile PeridoxRTU® Sporicide, Disinfectant and Cleaner
- Contec® Healthcare TB1-3300™ Sterile Disinfectant

All Contec's sterile products are validated sterile at 10^{-6} Sterility Assurance Level (SAL).

DAILY ACTIVITY: Cleaning and Disinfecting Floors	
Table 10	• Floors must be cleaned daily on days when compounding occurs. For daily cleaning and EPA-registered disinfectant is acceptable. • A sporicidal disinfectant must be applied monthly for entities compounding Category 1 & 2 CSPs and weekly for those who compound Category 3 CSPs
Section 7 General	• Cleaning must be performed in the direction of clean to dirty • Same floor mop may be used in both buffer and anteroom but only in that order
7.1.1 Agents	• In classified areas outside the PEC, sterile cleaning and disinfecting agents should be used.
7.1.2 Supplies	• Reusable cleaning tools must be made of cleanable materials (e.g., handles should not be made of wood or any other porous material) and must be cleaned and disinfected before and after each use.

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Contec® Healthcare Product Solutions for Daily Floor Cleaning and Disinfection

- MicroCinch™ Mop & Klean Max™ Mopping Systems
- PeridoxRTU® Sporicide, Disinfectant and Cleaner
- PREempt® Plus Disinfectant
- Contec® Healthcare TB1-3300™ Disinfectant

DAILY ACTIVITY: Cleaning and Disinfecting Work Surfaces Outside of the PEC	
Table 10	• Work surfaces outside of the PEC must be cleaned daily on days when compounding occurs, and an EPA-registered disinfectant is acceptable for daily cleaning.
	• Work surfaces outside of the PEC have a sporicidal disinfectant applied monthly for entities compounding Category 1 & 2 CSPs; weekly for entities who compound Category 3 CSPs.

Contec® Healthcare Product Solutions for Cleaning and Disinfecting Work Surfaces Outside of the PEC

- Amplitude™ EcoCloth™ Wipe
- Contec® Sterile 70% IPA
- PeridoxRTU® Sporicide, Disinfectant and Cleaner
- PREempt® Plus Disinfectant
- Contec® Healthcare TB1-3300™ Disinfectant
- Sanotex® Environmental Surface Wipes

MONTHLY ACTIVITY: Cleaning and Disinfecting Walls, Ceiling and Storage Shelving and Bins*	
Section 7.1.1 Agents	• In classified areas outside of the PEC, sterile cleaning and disinfecting agents should be used. • Note: using nonsterile disinfectants in the SEC is acceptable per Contec best practice – provided the pharmacy conducts environmental monitoring to ensure they are maintaining a microbial state of control.
Section 7.1.2 Supplies	• All cleaning and disinfecting supplies (e.g., wipes, sponges, pads, and mop heads) with the exception of tool handles and holders must be low lint. • Wipes, sponges, pads, and mop heads should be disposable. If disposable cleaning supplies are used, they must be discarded after each cleaning activity. • **Reusable cleaning tools must be made of cleanable materials** (e.g., handles should not be made of wood or any other porous material) and must be cleaned and disinfected before and after each use.
Table 10	• Walls, ceilings, storage shelves and bins, and equipment outside of the PEC be cleaned monthly. • Walls, ceilings, storage shelves and bins, and equipment outside of the PEC have a sporicidal disinfectant applied monthly for entities compounding Category 1, 2 & 3 CSPs.

Contec® Healthcare Product Solutions for Monthly Cleaning for Category 1 & 2 Compounders; Weekly for Category 3

- Amplitude™ EcoCloth™ Wipe
- MicroCinch™ Mop
- Klean Max™ Mop
- PeridoxRTU® Sporicide, Disinfectant and Cleaner
- Sanotex® Environmental Surface Wipes

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