Hand washing and Garbing

Best Practices for the Cleanroom

Laura Nolan, CPhT, CSPT
Robin Bogner, PhD

What is Garbing?

The act of donning “PPE”

Is it really
Personal Protective Equipment?

The term “PPE” is no longer used in USP<797> -- only in <800> (see section 7).

Is it protecting you or the sterile preparation?

Garb described in <797> is worn to protect the compounded sterile preparation from YOU.
The order of garbing is no longer specified in proposed USP<797>

Garb must be donned and doffed in an order that reduces the risk of contamination.

The order of hand washing and garbing depends on the placement of the sink (see 4.4 Water Sources). The order of garbing must be determined by the facility and documented in the facility’s SOP.

Proposed USP<797>

Do you know the justification for the order of garbing in your facility?

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Garbing Requirements

Proposed USP<797> Section 3.3

- Any person entering the compounding area must be properly garbed
- Donning and doffing garb should not occur in the ante-room or SCA at the same time
- The order of garbing must be determined by the facility and be documented in SOPs
- Garb must be replaced immediately if it is visibly soiled or compromised
- Garb must be stored in a manner to minimize contamination
If the facility does not require dedicated cleanroom clothing – scrubs and cleanroom shoes

**Step 1:**
Begins at home with showering and your choice of clothing.

NO

- Ripped jeans or shorts
- Sequins, beads, or fringe
- Shoes without socks

YES

- closed toed shoes

**Step 2:**
In the General Pharmacy:
Remove all outer garments including

- Hoodies, coats, jackets, and vests
- Sweaters, especially fuzzy sweaters
- Hats, bandanas and scarves
- Removable jewelry, watches, hair clips, Fitbits

Wedding rings?
Jewelry that doesn’t interfere with garbing?

Before Garbing

Before entering a compounding area, individuals must remove any items that are not easily cleanable or that are not necessary for compounding. At a **minimum**, individuals must:

- Remove personal outer garments.
- Remove all cosmetics because they shed flakes and particles.
- 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 ear buds 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 polish, artificial nails, and extenders must not be worn. **(no longer a 2 mm nail length specification)**
- Wipe eyeglasses, if worn.

The designated person(s) may permit accommodations as long as the quality of the CSP and environment are not affected.
Corrective eyewear

“Wipe eyeglasses, if worn.”
When, where and with what?

Hijabs

USP is silent on religious clothing in the cleanroom

Does your facility have a policy?

What We Teach at UConn

Don shoe covers one at a time, on bench, while swinging leg over the line of demarcation.

Don facemask, beard cover, and head cover, using mirror to ensure all hair is covered.

Hand hygiene using particular technique for at least 30 seconds on the clock.

Don low shedding gown or coverall.

Perform hand sanitizing with waterless alcohol-based hand rub.

Allow hands to dry without waving them around.

Don Sterile Gloves in ISO 7 room.
Area | Step | Action/Activity
---|---|---
Picks up and dons the first glove without touching the outside of the glove. |  |  
Turns off water supply with used low-linting wipe. |  |  
Allows hands to dry thoroughly. |  |  
Dons head cover, face mask, and beard cover (if necessary) assuring that ears and hair are completely covered by the head cover, bridge of nose down to and including chin are covered by the face mask, and all beard and sideburn hair is covered by the beard cover, using the mirror to check and adjust. |  |  
Push thumbs through sleeves near cuffs of gown. |  |  
Dries hands and forearms using low-linting wipe from fingertips to elbows only. |  |  
Wipes down garbing packages using sterile 70% isopropyl alcohol and discard gloves. |  |  
Pulls gloves up to form a seal over the sleeves of the gown/lab coat. |  |  
Dons gown and ensures full closure, including the top clasp. |  |  
Dons shoe covers one at a time, placing only the covered shoe on the clean side of the ante-room. |  |  
Applies sterile 70% isopropyl alcohol to the gloves and allows it to dry without waving hands. |  |  
Selects garbing supplies. |  |  
Picks up the second glove by slipping the first gloved hand in the cuff. |  |  
Allows rinse water to run from fingertips to elbows only. |  |  
Under warm running water, uses nail pick to remove any debris from under nails. |  |  
Remembered to discard all packaging correctly along the way. |  |  
Select correct size of gloves and open package. |  |  
Enteres the buffer room without touching the door. |  |  
Disinfects hands using a suitable alcohol-based hand rub with sustained antimicrobial activity. |  |  
Examines gloves ensuring that there are no defects, holes, or tears. |  |  
Washes glasses and/or safety glasses. |  |  
Washes hands and forearms up to the elbows with soap and water for at least 30 seconds |  |  
Dons non-sterile gloves. |  |  

VIDEO ON GARBING AND HANDWASHING
Hand Hygiene

- Remove visible debris from 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.
  - Wash from finger tips downward to elbows
  - Avoid using overly hot water (reduce the risk of dermatitis)
  - Rinse hands with fingertips upward
  - Keep a clock within view of the sink
- Dry hands and forearms to the elbows completely with low-lint disposable towels or wipers.
  - Use a non-linting wipe to shut off water faucet if not handsfree
- A closed system of soap (i.e., nonrefillable container) to minimize the risk of extrinsic contamination must be readily available or in close proximity to the sink.
- Brushes must not be used
- Hand driers must not be used
Hand Sanitizing Procedure

- Apply an alcohol-based hand rub to dry skin following the manufacturers instructions for the volume of product to use.
- 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.

**Professional hand sanitizer that has persistent anti-microbial activity is no longer specified.**
GLOVES

- Must be sterile and powder free
- Must be donned in a classified room or SCA
- Gloves must NOT be donned or doffed in the ISO 5 PEC exposing bare hands
- Application of sterile 70% IPA to gloves must occur regularly throughout the compounding process and whenever nonsterile surfaces are touched.

How often must gloves be changed during compounding?

7. Place fingers of gloved hand into cuff ‘pocket’ of glove in wallet.
Key steps for gloving

Don’t forget to examine gloves for defects, holes or tears.
The minimum garbing requirements include:
• Low-lint garment with sleeves that fit snugly around the wrists and that is enclosed at the neck (gown or coverall)
• Low-lint disposable covers for shoes
• Low-lint disposable covers for head that cover hair and ears
• Low-lint disposable cover for facial hair of needed
• Face mask
• Sterile powder-free gloves
• When personnel exit the compounding area, garb except for gowns cannot be reused.
• Gowns may be reused within the same shift if the gown is maintained in a classified area

Questions to Consider

Is there a set order for doffing?

What should the order be?

In what location?

Reusable versus single-use garb?

New garb after cleaning?