Hand washing and Garbing

Best Practices for the Cleanroom

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What is Garbing?

The act of donning PPE

Personal Protective Equipment?

Is it protecting you or the product?
Generally, garbing is performed from dirtiest to cleanest

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.  USP<797> June 1, 2019

What are the reasons for a particular order in your facility?

Step 1:
Begins at home with your choice of clothing.
NO
• Ripped jeans
• Sequins, beads, or fringe
• Shorts
• Shoes without socks
YES
• closed toed shoes
Scrubs are a good choice.
If possible, leave the jewelry at home

Step 2: In the General Pharmacy:
Remove all outer garments including
• Hoodies, coats, jackets, and vests
• Sweaters, especially fuzzy sweaters
• Hats, bandanas and scarves
• Jewelry, watches, hair clips, Fitbits
**USP<797> Section 3.1 Personnel Preparation**  June 1, 2019

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.
- Wipe eyeglasses, if worn.

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

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**Corrective eyewear**

Policy on washing?

**Hijabs**

Policy?

Disposable hijab
What We Teach at UConn

Don Shoe Covers one at a time, on bench, while swinging over the line of demarcation.

Don head cover, using mirror to ensure all hair is under bonnet

Beard Cover then Facemask- if Tie-on style, put on next. If using ear loop style, put on before head cover

Hand Hygiene

Don low shedding gown or coverall

Perform hand sanitizing with waterless alcohol-based hand rub with persistent activity

Allow hands to dry- without waving them around

Don Sterile Gloves – (Either before or after entering buffer area if both areas are ISO 7)

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Written Test on Handwashing and Garbing Order

Name __________________________

Instructions

Insert into the first column, the area in which the activity should be performed (G = general pharmacy, A = ante-room, or B = buffer room). Indicate the order (1-18) in which the activities should be performed by inserting numbers into each box.

<table>
<thead>
<tr>
<th>Area</th>
<th>Step</th>
<th>Action/Activity</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td>Applies sterile 70% isopropyl alcohol to the gloves and allows it to dry without waving hands.</td>
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<td>Allows hands to dry thoroughly.</td>
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<td>Disinfects hands using a suitable alcohol-based hand rub with sustained antimicrobial activity. Keeps hands wet for the specified application time.</td>
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<td>Dons head cover assuring that ears and hair are completely covered.</td>
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<td>Dons shoe covers one at a time, placing only the covered shoe on the clean side of the ante-room.</td>
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<td></td>
<td>Pulls both gloves up to form a seal over the sleeves of the gown/lab coat.</td>
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<td></td>
<td></td>
<td>Dons beard cover if necessary.</td>
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<td></td>
<td>Pulls up the second glove by slipping the first gloved hand in the cuff.</td>
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<td>Dons face mask to cover from bridge of nose down to and including chin.</td>
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<td>Washes hands and forearms up to the elbows with soap and water for at least 30 seconds</td>
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<td>Dries hands and forearms using low-linting wiper.</td>
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<td>Turns off water supply with used low-linting wiper.</td>
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<td>Under warm running water, uses nail pick to remove any debris from under nails.</td>
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<td>Allows rinse water to run from fingertips to elbows only.</td>
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<td></td>
<td>Examines gloves ensuring that there are no defects, holes, or tears.</td>
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<td></td>
<td>Enters the buffer room without touching the door.</td>
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<td></td>
<td></td>
<td>Pulls up and dons the first glove without touching the outside of the glove.</td>
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<tr>
<td></td>
<td></td>
<td>Dons gown and ensures full closure, including the top clap.</td>
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</table>
A majority of Americans are getting caught dirty-handed when it comes to their handwashing habits. A survey by SCA, a global hygiene company, uncovered that consumers understand the importance of hand hygiene but their practices may be greatly exaggerated.

- 58% have witnessed others leaving a public restroom without washing their hands.
- 35% have witnessed co-workers not washing their hands after sneezing, coughing or after handling money.
- 39% do not wash their hands after riding public transportation.
- 20% wash their hands after cleaning equipment or handling money.
- 33% wash their hands.

On average, you come in contact with 300 surfaces every 30 minutes, exposing you to 840,000 germs.

*According to the study, residents are at risk of catching 1,400 viruses on their hands, which could result in a lifetime of disease. A study by the CDC found that.

In conclusion, handwashing is crucial to maintaining good hygiene habits and preventing the spread of germs.
Key Points to Handwashing in a Cleanroom Setting

- Use a disposable nail pick under running water
- Wet hands with water, then apply the manufacturer’s recommended amount of soap from a hands-free dispenser
- Wash hands for at least 30 seconds
- Keep a clock within view of the sink
- Wash from finger tips downward to elbows
- Avoid using overly hot water (reduce the risk of dermatitis)
- Rinse hands with fingertips upward
- Dry hands with non-linting wipe from fingertips down to elbows
- Do not refill partially used soap dispensers
- Keep fingernails trimmed and neat
- Use a non-linting wipe to shut off water faucet if not handsfree
USP <797> Section 3.2 Hand Hygiene  
June 1, 2019

- Personnel must wash hands and forearms up to the elbows with soap and water before initiating compounding activities.
- Brushes must not be used (because of the potential for skin irritation/shedding)
- Hand driers must not be used (because of the risk of creating air turbulence and circulating contaminated air in the compounding area)
- 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.

USP <797> Box 3-1 Hand Hygiene Procedures  
June 1, 2019

- Remove 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.
- Dry hands and forearms to the elbows completely with low-lint disposable towels or wipes.
USP<797> Box 3.2 Hand Sanitizing Procedure
June 1, 2019

- Apply an alcohol-based hand rub with persistent antimicrobial activity to dry skin following the manufacturer’s 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 is longer acting is no longer specified.**
GLOVES

Must be sterile and powder free

Must be donned in a classified clean 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.

Key steps for gloving

a  b  c  d  e  f
Don’t forget to examine gloves for defects, holes or tears.

OBSERVATION 2
Clothing of personnel engaged in the of drug products is not appropriate for the duties they perform.

Specifically,

During production on 10/29/2018 of Glutathione Sterile 100MG/ML Solution, Lot: 10292018@17, formula ID: 10586, with a BUD of 01/27/2019, the following was observed:

-The Pharmacist in charge was observed to don a previously worn, non-sterile gown hanging on the wall of the ISO 8 classified anteroom that was ill fitting, exposing both skin (unshaven neck and eyes without cover) and personal clothing inside the ISO5 classified LAFH during production.

- The Pharmacist in charge was observed leaning into the ISO5 classified LAFH during aseptic processing with other non-sterile garbing such as gloves, face mask and hairnet.
OBSERVATION 1

Personnel engaged in aseptic processing were observed with exposed hands and exposed hair.

Specifically, your Pharmacy Technician was observed to have exposed hands in the ISO 5 zone. An example includes, but is not limited to, the instance that occurred on the date listed below.

11/27/2018—During sterile drug compounding procedures, your Pharmacy Technician(b)(6) entered the ISO 7 Compounding Room with ungloved hands. He proceeded to don sterile gloves under the ISO 5 “Hood #1” with ungloved hands exposed in this ISO 5 zone.

OBSERVATION 2

Personnel donned gowning apparel improperly, in a way that may have caused the gowning apparel to become contaminated.

Specifically, current sterile gowning components can expose hair and operators touch gowning on the floor. Examples include, but are not limited to, the items listed below.

A.) 11/26/2018—During (b)(4) facility cleaning procedures located in the ISO 7 Compounding Room that (b)(4) , your Pharmacy Technician (b)(6) had hair exposed from her bouffant cap.

OBSERVATION 1

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established and followed.

Specifically, the sterile drug technician demonstrated inadequate aseptic technique during non-sterile to sterile drug production operations on 12/10/2018. For example:

A. Mixing drug components in non-depyrogenated equipment.
B. Disinfecting equipment (vial,(b)(4) and rubber vial stopper) with non-sterile (b)(4) using a non-sterile wipe.
C. Jewelry not removed prior to donning sterile gloves.
D. Donning sterile gloves with gloved fingertips in contact with the non-sterile area of the inside cuff.
E. No disinfection of the ISO5 classified LAFH prior to production.
F. The operator was observed leaning into LAFH during production with facial protection that was not worn appropriately during production to provide an adequate seal.
G. Crimping equipment was used outside the ISO5 classified zone with a vial cap and crimping tool that had not been disinfected prior to use and gloves that were not disinfected prior to vial being sealed.
H. Media fills are conducted but do not include the most challenging process performed as described by the Pharmacist in charge and the sterile drug technician.
I. Dynamic smoke studies have not been conducted to demonstrate airflow during production.
USP<797> Section 3.3 Garbing Requirements

Any person entering the compounding area must be properly garbed

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

The order of garbing must be determined by the facility and be documented in SOPs

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

Garb must be replaced immediately if it is visibly soiled or compromised.

Garb must be stored in a manner to minimize contamination

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 all garb except for gowns cannot be reused.
- Gowns may be reused within the same shift if the gown is maintained in a classified area
Is there a set order for doffing?

What should the order be?

In what location?

Reusable versus single-use garb?

New garb after cleaning?