



Missouri Board Of Pharmacy

Sterile Compounding: Garbing & Cleaning
August 17, 2016

Katie DeBold, PharmD
Inspector

Webinar Design

- * All participants are muted, “listen only” mode
- * Listen by telephone option



Continuing Education

- * Board-approved for one hour (0.1 CEU) of live pharmacist continuing education
- * Must be officially signed up and logged on via your computer
- * **CE credit will not be issued to those listening via the phone only**
- * Complete post survey within 48 hours
- * Instructions at the end of webinar
- * CE credit is **not** submitted to CPE Monitor



Handouts and Recordings

- Handouts posted on Board's website
- Recording of webinar
 - Videos/Webinars under "Publications/Resources" on the Board's website

Videos/Webinars

- 2015 Legislation and Regulation Update #
- 2015 DEA Update With Scott Collier #
- 2015 Inspector Tips for Your Next Inspection #
- 2014 Pharmacist Administration Regulation Review and Update #
- 2014 RNDD Update #

- No CE credit for watching recording.

How to Ask a Question





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Webinar Objectives

- ❑ Provide guidance on Garbing & Cleaning
- ❑ Answer questions



Definition Review

Buffer Area: ISO Class 7 or better area where the primary engineering control (PEC) is physically located.

Controlled Area: A room or area designated for sterile compounding. The area is separated from other activities/operations by a line of demarcation.

RABS: Restricted Access Barrier System

* New terminology for the types of PECs that people currently refer to as "gloveboxes" and "isolators". Includes CAI & CACI



Garbing: Why is it important?

- * The outer layer of human skin can host up to one million microorganisms per square centimeter
- * A typical person sheds 30,000 to 40,000 dead skin cells from the surface of the skin every minute.
- * There are, on average, four microorganisms per skin cell.
- * There are approximately 1000 different species of bacteria on the human skin.

Most commonly include:

- Actinobacteria (51.8%). Actinobacteria are a group of Gram-positive bacteria with high guanine and cytosine content, such as Micrococci, Corynebacteria and Propionibacteria.
- Firmicutes (22.4%). This includes the genera Clostridia and Bacillus.
- Proteobacteria (16.3%). This is a major phylum of bacteria that includes a wide variety of pathogens such as Escherichia, Salmonella, Vibrio, Helicobacter, and many other notable genera.
- Bacteroidetes (6.3%). The phylum Bacteroidetes is composed of three large classes of Gram-negative, anaerobic, fermenting, anaerobic, and rod-shaped bacteria.

Sandle, Tim, Ph.D. "People in Cleanrooms: Understanding and Monitoring the Personnel Factor | IVT." Institute of Validation Technology, N.p., 16 Dec. 2014. Web. 14 Aug. 2016.

Emergency Rule Garbing Requirements

Risk Level	Current Rule	Emergency/Amended Rule
Risk Level 1	No garbing required	Non-shedding gowns, hair cover, face mask, beard cover and gloves
Risk Level 2	Hair cover, beard cover, gown, mask, & gloves	Non-shedding gowns, hair cover, face mask, beard cover, shoe covers, and sterile gloves
Risk Level 3	Hair cover, beard cover, gown, mask, gloves, & shoe covers	Non-shedding gowns, hair cover, face mask, beard cover, shoe covers, and sterile gloves

* No exemptions for RABS. Garb is donned according to risk level.

* All personnel entering the buffer/controlled area must be garbed

* Location for garbing will differ based upon your facility design

Proper Garbing Procedure

Remove outer garments (coats, jackets, hats, sweaters, etc.), makeup, and jewelry.

Legs/ankles: Covered with pants/socks to ensure no exposed skin

Garbing order should be from dirtiest to cleanest*:

- Hair cover & Beard cover if applicable
- Face mask
- Shoe covers
- Wash hands
- Non-shedding gown
- Best practice: Apply an alcohol based hand rub
- Don gloves (Risk levels 2 & 3: sterile gloves are required)



*This is the preferred garbing order. Depending upon your facility design, it may be appropriate to don shoe covers first (followed by hair cover and then face mask.)

Step 1: Don hair cover & beard cover



* Mirrors are helpful to ensure all hair is covered.

* Surgical caps are not sufficient

* Hair covers are disposable and must not be re-used



Beard Cover



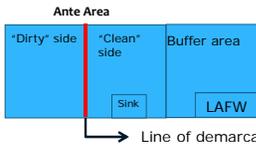
Step 2: Don face mask



- * Mask should be pinched over the bridge of the nose and pulled down to chin
- * Face masks are disposable and must not be re-used
- * Avoid talking while compounding.

Step 3: Don shoe covers

- * NOT required for Risk Level 1 compounders
- * Process for donning shoe covers will depend on your facility's layout
- * Ante area is NOT required per MO law. If you have one, it is best practice to don your shoe covers using a line of demarcation



- If no ante-area, don your shoe covers in your designated garbing area

Donning shoe covers (if you have an anteroom)



- Step 1: On "dirty" side, Don shoe cover without placing your foot down
- Step 2 & 3: Place covered foot onto "clean" side (Repeat with other foot)
- Step 4: Remain on "clean" side with covered shoes

Ante area is NOT required per MO law. If you have one, it is best practice to don your shoe covers using a line of demarcation
Shoe covers are disposable and must not be re-used

Step 4: Wash Hands



Handwashing Process

1. **Scrub hands and forearms for a minimum of 30 seconds under warm running water**

Use a clock to time the 30 seconds. Singing "Happy Birthday" is not sufficient

2. **Remove debris from underneath fingernails.**

Amended rule will require a disposable nail cleaner

Best practice: No artificial nails or polished nails

3. **Dry hands and turn off the faucet using a hands-free procedure (Using a towel or elbow to turn off sink)**

Back

Palm

■ Most Often Missed
■ Often Missed
■ Less Often Missed

*World Health Organization

Step 5: Don Non-Shedding Gown

- * Different closure options: zipper, tie, button, etc.

- * Ensure that gown is closed properly.

- * Inspectors often see gowns that are falling off compounders' shoulders



- * Beware of yellow isolation gowns.

- * Often have open necks, inappropriate cuffs, tear easily and are not made of non-shedding material

- * Gowns are re-usable for one shift only!

- * They should be hung in the buffer/controlled area while not in use



Step 6 (Best Practice): Alcohol based surgical hand rub with persistent activity

- * Used to disinfect your hands after the gowning process
- * If gloves tear while compounding, the persistent activity of the hand rub will help prevent contamination
- * Allow your hands to dry prior to donning gloves

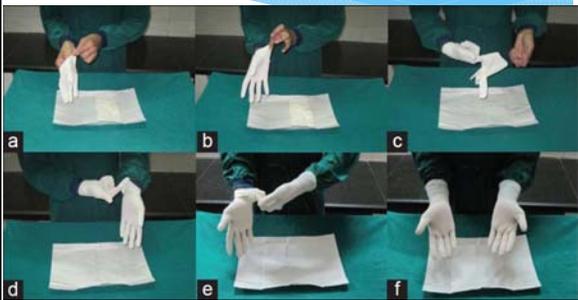


Step 7: Don gloves

- * Gloves must be **sterile** for risk levels 2 & 3
- * See next slide for donning of sterile gloves
- * Gloves should be pulled on over the gown sleeve
- * Be sure to disinfect gloves with sterile alcohol prior to compounding
- * For risk level 2 & 3 compounders:
 - * If using a RABS, sterile gloves must be donned inside the RABS (over the gauntlet gloves)



Donning Sterile Gloves



http://ambjournal.org/temp/ArchMedHealthSci1130-7041463_214654.pdf

Garbing for Cytotoxic Drugs

- * No changes in the emergency rule for cytotoxic garbing
- * Protective apparel shall be worn by personnel compounding cytotoxic drugs which shall include disposable masks, gloves and gowns with tight cuffs

Emergency Rule Cleaning Requirements

Cleaning & Disinfection of controlled and buffer areas shall be performed according to Chapter 797

Site	Frequency
ISO Class 5 - PEC	<ul style="list-style-type: none">Daily cleaning: germicidal agent followed by sterile alcoholFrequent disinfection throughout the day (prior to compounding, between batches and after spills/surface contamination): sterile alcohol
Counters & Work Surfaces	Daily Including pass-through, cart surfaces, and high touch surfaces (phone, door handles etc.)
Floors	Daily
Walls	Monthly
Ceilings	Monthly
Storage Shelving	Monthly

If compounding occurs less often than the specified frequencies, cleaning must occur prior to each compounding session

Cleaning & Disinfection

Cleaning: Mechanical process using soap or detergent and water to remove dirt, debris and germs. It also removes invisible debris that interfere with disinfection

Disinfection: Chemical process that uses specific products to destroy 100% harmful bacteria, viruses and fungi but not necessarily their spores on environmental surfaces.

- * For a disinfectant to work effectively, "soil" (such as grease and dust particles) must be removed first using a suitable cleanroom grade detergent.
- * Many cleanroom products are a cleaner/disinfectant combination
- * Proper dilution and contact time are essential for ensuring disinfectant effectiveness

Types of Disinfectants

Common disinfectants used in health care settings

- Sterile isopropyl alcohol 70%
- Accelerated hydrogen peroxide 0.5%
- Quaternary ammonium 0.4-1.6%
- Phenolics 0.4-1.6%
- Chlorine 100-5000 ppm
- All above disinfectants are effective against bacteria, lipophilic viruses and fungi
 - Variable effectiveness against hydrophilic viruses and spores
- Contact time is essential for micro-organism inactivation
 - Can range from <1 minute to 10 minutes
 - Refer to manufacturer
- Corrosive and residue properties will differ between agents

Cleaning Primary Engineering Controls

Pre-Cleaning: Apply sterile water to heavily soiled areas if needed

Step 1: Apply a germicidal detergent to all surfaces within the PEC

- If the germicidal detergent requires dilution, sterile water MUST be used

Type of Water	CFU/mL	Pyrogens
Tap Water	500	100 EU/mL
Purified Water	100	0.25 EU/mL
Water for Injection	<10 CFU/mL	<0.25 EU/mL

Step 2: Apply sterile 70% Isopropyl alcohol (IPA) to all surfaces within the PEC

Use low lint wipes (NO brown or household paper towels or cotton gauze)

- Presaturated wipes are OK.
- Sterile wipes are considered best practice for ISO Class 5 areas but not required.

Optional: Rotate a sporicidal agent into the cleaning schedule weekly or monthly



Cleaning Primary Engineering Controls

Order of cleaning surfaces within the PEC: (Cleanest to dirtiest, top to bottom, back to front)

1. Ceiling →
2. Back →
3. IV pole/hooks
4. Sides
5. Anything in PEC (Sharps container, compounding etc)
6. Work Surface

Common myth: The "filter" cannot be touched or cleaned. The filter is protected by a metal grate. The grate needs to be cleaned/disinfected. However, cleaning agents should not be sprayed into the filter.

- * All surfaces cleaned first with a germicidal detergent and then disinfected with sterile IPA
- * Use overlapping strokes (No circular motions)
- * Use a new wipe for each surface

Cleaning CAI & CACI

- * OK to open them for cleaning purpose. Must be fully garbed
- * Clean/Disinfect the main chamber followed by the ante chamber



Cleaning CAI & CACI

- * Isolator Cleaning tools are helpful
 - * Need to replace the mop head often
- * Additional things to clean within CAI/CACI
 - * Sleeves
 - * Front panel
 - * Spill tray under the work surface



Cleaning Controlled/Buffer Areas

Cleaning tools must be dedicated for use in the controlled or buffer area and be composed of nonshedding material

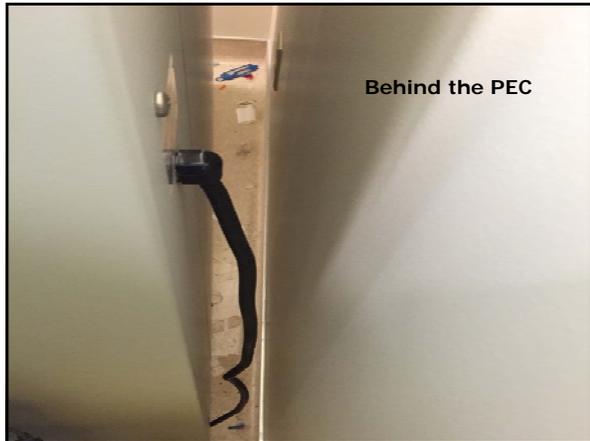
- * Mops with disposable mop heads are best. Cellulose (spongy) mop heads harbor micro-organisms.
- * Mopping should be done at a time when no sterile compounding is occurring
- * If using buckets, it best to have a dedicated bucket for each area. (Ex- a walls/ceiling bucket, a floor bucket, etc.)
- * Cleaning agent for floors, work surfaces, walls/ceilings and storage shelves: Germicidal detergent
- * Steam is OK. Must be followed with germicidal detergent

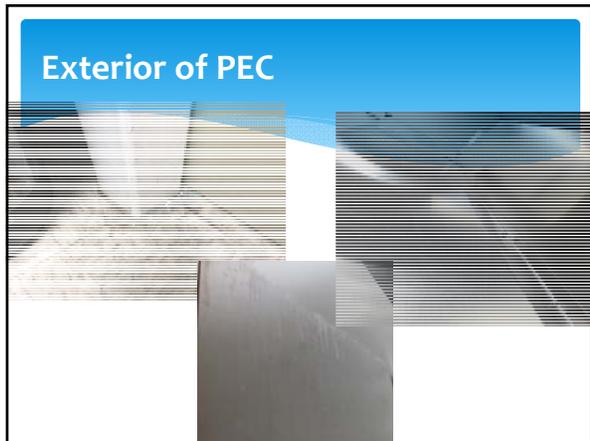
Common places that people forget to clean

- * Behind the PEC
- * Top & Exterior of PEC
- * Under the tray of PEC, if applicable
- * Underneath automated compounding devices
- * Return air vents
- * Wheels of carts/storage shelves
- * Storage bins
- * Sharps bin
- * Exterior of trash cans
- * Under fatigue mats



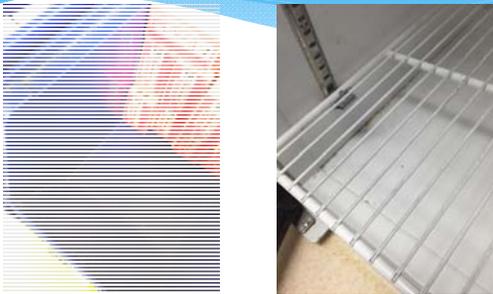








Storage Shelves & Fridges



Material Handling

For pharmacies with buffer areas:

- * Furniture, carts, supplies and equipment shall be removed from shipping cartons/containers and properly disinfected with sterile alcohol or an equivalent non-residue disinfectant before entering any ISO classified area.

For all pharmacies (controlled or buffer area):

- * All supplies, equipment, vials, and ampules must be wiped prior to placement in PEC (with sterile alcohol or an equivalent non-residue disinfectant)
- * If you have an ISO classified buffer area, items are wiped down TWICE! Prior to entry into the ISO classified area and prior to placement in the PEC
- * If you have a controlled area, items are wiped down ONCE. Prior to being placed in the PEC

Cleaning/Disinfection Competency

- All personnel (including non-pharmacy personnel) that perform cleaning in a controlled/buffer area need to be trained and demonstrate cleaning/disinfection competencies
- All personnel performing cleaning need to be fully garbed and are required to demonstrate garbing and hand hygiene competencies

Cleaning Competencies

- Create cleaning competencies specific to your own pharmacy
 - Example competencies:
 - Demonstrates proper dilution of cleaning/disinfectant solutions
 - Demonstrates proper cleaning tool selection (dedicated tools/buckets)
 - Demonstrates proper cleaning methods (cleanest to dirtiest, overlapping strokes etc.)
 - Allows disinfectant to dwell for the recommended contact time
 - Performs the appropriate daily cleaning activities (PEC, floor, work surfaces)
 - Performs the appropriate monthly cleaning activities (walls, ceilings, storage shelving)

Next Webinar

August 25th, 2016 10 am: Aseptic Technique Skill Assessment & Media Fills

Questions

Enter a question for staff

Ask Question

Answer

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Webinar ID: 571-638-438
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