



**COVID-19: Downstream Implications for Sterile Compounding**  
**CriticalPoint Recommendations**  
**Updated March 16, 2020**

**What follows represents CriticalPoint opinion!**

- These are uncharted waters; and working together, we can be successful.
- Some of these measures are not in compliance with USP 797, so let your state board of pharmacy (or other regulator) know your plans. Send them this information.
- We all must work together to do the best we can!

**Enforce Existing SOPs and Practices**

- Exclude persons that may have a higher risk of contaminating the CSP and the environment from the controlled environment.
- Report to Designated Person (DP).
- Keep a log of these instances, symptoms, and when they returned to work.
- Staff must strictly adhere to established, contamination-control principles, including proper behavior in controlled environments.
- Personnel “must maintain proper personal hygiene.” (USP 797 2019)
  - Shower/bathe daily.
  - Wear freshly laundered clothing.
- “Remove items not easily cleanable and not necessary for compounding.” (USP 797 2019)
- Stage preps and batches outside of the compounding area and transfer into room in a bin that segregates items.
- Perform meticulous material handling using EPA registered one-step sporicidal disinfectant cleaner. Using the sporicidal is mentioned in USP 797 (2019) as an option but is not a requirement. We suggest its use as a best practice.
- Minimize the number of trips crossing the line of demarcation (or perimeter line of SCAs).
- Walk slowly and deliberately in the compounding area.
- Meticulous material transfer into PEC.
- Sanitize deck, staging cart, and other high-touch surfaces frequently (when wiping deck with sIPA, wipe staging cart and computer screen).
- Do not talk while compounding.
- Do not touch mask.
- Frequent resanitization of gloved hands.

**Garb Conservation Through Staffing**

- Limit the number of persons entering the compounding area.
- Instead of 2 compounders entering and each compounding for an hour, send in 1 compounder for 2 hours.
- Whatever your algorithm is, just try to maximize the work for those “inside” by having others stage outside the compounding area.
- Fully utilize pass-throughs to avoid unnecessary entry.

- Have dedicated gowns for different activities. For example, have a tech who completes daily cleaning M-F using one gown, and then compounds M-F and using a different gown. They must be labeled and hung up properly.
- Consider limiting training during a time of shortage.
- Surveyors and inspectors should be respectful of the shortage and perform inspections from the outside of the cleanroom suite, utilizing windows.

## Face Masks

- N95 respirators DO NOT need to be worn for HD compounding. If this is a current practice, stop immediately. For more information on this please visit the [Peer Network](#).
- If N95 respirators are available, but face masks are not, they can be used for both HD and non-HD compounding.
  - They do not need to be fit tested for this type of use, as we are only trying to protect the CSP.
  - They must fit snugly from bridge of nose to around chin without gaps, like a regular face mask.
- Ideally, we would never reuse garb, but pouch-type masks, cleanroom-grade masks, and N95-respirator masks may be more conducive to reuse.
- Must put a process around mask reuse so reuse does not compromise microbial state of control in rooms.
- Suggested reuse process:
  - Write initials on the outside of the mask.
  - Doff the mask on the dirty side of the ante-room or outside of the perimeter line of the SCA without touching the inside.
  - Place each mask for reuse in its own new, small paper bag and initial the outside of the bag (use a new bag each time, discarding the previous when the mask is redonned). [From CDC Pandemic Planning](#)
  - Place all masks in bags in a container located where masks would normally be donned.
- Sink location affects hand hygiene and garbing order:
  - If your sink is on the clean side of the LOD, then put on mask in normal garbing order.
  - If sink is located outside of the ante-room or SCA and mask is donned after hands are washed, use alcohol-based hand rub after donning what is, essentially, a dirty mask.
- How long can the mask be worn before being replaced?
  - Use your best judgment, based on condition, whether it is visibly soiled, and handling technique.
  - Set a procedure and relay to staff.
- If there is a true shortage and you use a CAI in an SCA to compound, masks do not need to be worn.
- Face masks and head covers can be reused after HD compounding.
- Wearing a PAPR or a respirator for compounding is an option, but it might be very uncomfortable for the compounder, resulting in greater distraction during compounding.
- We do not recommend cloth masks.
- Another option is a hood that has an integrated face mask. A head cover must be worn underneath if the hood/face mask combination is going to be reused. These can be found [here](#).

## Shoe Covers

- We don't recommend reuse of shoe covers, nor do we recommend turning them inside out.
- If you are getting close to running out of shoe covers, we suggest implementing "facility-dedicated" shoes (already a best practice recommendation).

- “Facility dedicated” means inside the pharmacy offices not “hospital dedicated.” They can be stored in the general pharmacy area.
- Maybe shoes that are washable or cleanable, then put a process around that.
- Another option is purchasing construction-grade shoe covers.
- For HD, wearing facility-dedicated shoes, don one pair of waterproof, seamless shoe covers.
  - There is no way around not wearing at least one pair of shoe covers for HD compounding. If facility-dedicated shoes are not implemented, two shoe covers must still be donned.

## Head Covers

- Not expected to be on shortage
- There are additional types of hair covers available, such as full hoods.
- We really like these two head covers as alternatives to the traditional bouffant cap.
  - This one is great for keeping all hair contained and for men with beards. [Medline NONSH700W](#)
  - This is another option that ties. [Medline 620105](#)

## Gowns

- For those who do not reuse gowns during a shift (a best practice recommendation), start reusing immediately.
- Reuse for 1 shift/day only, until there is a true shortage.
  - First cut down on the compounding personnel that enter, reducing the number of gowns needed.
  - If reusing gown, do so for no longer than a week.
  - If gown is reused, then add nonsterile sleeves (not in short supply).
- Gowns must be discarded if visibly soiled or used during cleaning activities.
  - Consider having pharmacy do the daily clean if it is currently outsourced to EVS. This will conserve garb.
- Coveralls or bunny suits are an option for use, but they must be donned properly and must not be dragged on the floor. Also, if a bench is not already available to don shoe covers, we strongly recommend that a bench is added. Donning garb must not be a test of balance.
- If the coverall has a hood, a head cover must still be worn underneath the hood.
- We do not recommend using laundered cloth gowns, as they will shed significantly more particles than the low-linting garb we are required to use.
- Some vendors like Cintas and Aramark provide laundered cleanroom garb. This is an option as long as it is low linting.
- Disposable jackets that are shorter length than a gown is an option, as long as it covers clothing that is exposed to the opening of the LAFW.

## HD Gowns

- HD gowns MUST NOT be reused.
- Only if you MUST, consider temporarily discontinuing the USP 800 required chemo gown change "per the manufacturer's information on permeation of the gown" or every 2-3 hours if no information exists.

## Disposable Sleeves

- If gown supply dwindles and reuse is required, we recommend use of sleeve covers.

- They do not have to be sterile if they are intended for use in cleanroom environments.
- Examples of sleeve cover materials are Tyvek and microporous film products with enclosed elastic.
- Don sleeves in buffer room or inside perimeter line of the SCA
  - Remove the outer package from both the sterile gloves and sleeves. (Sleeves may come single or double wrapped.)
  - Apply alcohol-based hand rub to hands and wrists and allow to dry.
  - Don sleeves over the gown sleeves.
  - Don sterile gloves, pulling up over the additional sleeve.

### **Alcohol-Based Hand Rub**

- If hand rub is affected, conserve for applying during the glove change only.
- If completely unavailable, those changing gloves return to the ante-room, remove and hang their gown, and wash hands prior to donning fresh gloves.
- Do not apply sterile IPA directly to hands. We are concerned that the direct application of alcohol will dry out workers hands so much they will be shedding more particles and could experience cracking of skin. You might consider making hand sanitizer for home use and bringing in commercially made sanitizer for pharmacy use.
- We are evaluating other sanitizers (other than alcohol based and will be back with more information if we get it).
- There is no need to place an expiration or "BUD" on hand rub unless that is part of the manufacturer's instructions.
- We do NOT recommend the use of chlorhexidine, as it has been shown to interfere with the ability of alcohol to work properly. It can also be very irritating to the skin.

### **Doffing Gowns**

- Remove gowns slowly and carefully, as they are laden with particles on the skin side.
- Try to remove gown standing near a return (if the return is not located next to a sink that is in use).
- As per USP 797 (2019), hang gowns on clean side of ante-room. The ante-room can be ISO Class 7 or 8.
- Hang far away from the sink, so that persons performing hand hygiene will not splash the gowns with water.
- Do not turn gowns inside out to hang them. This releases more particles.

### **Use of UV Light on Garb**

- There are a variety of hand-held UV-light sanitizers on the market. We were not able to find any data about their effectiveness for this use. We would still follow the recommendations made in the webinar and then potentially add the use of the sanitizer to them; but use of the sanitizer, in our opinion, would not facilitate increased garb reuse.

**Sterile IPA (sIPA)** - If your pharmacy has enough sIPA or can purchase more, do NOT employ these strategies.

- **Always use sIPA on sterile gloves during compounding to wipe the direct compounding area (DCA) and on critical sites.**
- Consider use of presaturated sterile low-lint wipes, presaturated sterile critical site wipes, sterile alcohol prep pads, or aerosol spray sIPA.

- We don't think you should use nonsterile IPA.
- If you are completely out of sIPA, then make some for use on the surfaces on which it must be used:
  - If you have sIPA spray bottles that were assembled correctly (the bottle and sprayer were manipulated correctly and assembled inside ISO 5), then consider reusing these to refill in the ISO 5 using aseptic technique.
  - Purchase nonsterile IPA that has been filtered. This type of IPA is made for healthcare use.
  - Filter this alcohol using a 0.22-micron sterile, hydrophobic, membrane filter remembering to keep within the filter specifications.
- During material handling
  - Continue to use an EPA registered one-step sporicidal disinfectant cleaner to wipe all items before they enter the buffer room
  - *Instead of wiping all surfaces with sIPA immediately before they are placed into the PEC, wipe these items with a low-residue EPA registered one-step **sporicidal** disinfectant cleaner*
- During daily cleaning
  - Use EPA registered one-step **bactericidal** disinfectant cleaner to clean and disinfect all surfaces inside the PEC as usual
  - *Instead of wiping all surfaces with sIPA as the second step (done to remove residues and further sanitize), substitute a low-residue EPA registered one-step **sporicidal** disinfectant cleaner (check with the manufacturer).*
  - When using any sporicidal agent, your staff must strictly adhere to vapor-containment and vapor-limiting strategies
  - Information on these strategies (which you probably already use during monthly cleaning) is available [here](#).
- Where to use sIPA
  - At the beginning of the compounding day, after the PEC surfaces have been wiped with the EPA registered one-step sporicidal disinfectant cleaner, *wipe the DCA with sIPA.*
  - *Sanitize sterile gloves with sIPA* at the regular intervals if hands leave ISO 5, after touching nonsterile items and immediately before beginning sterile manipulations.
  - *Sanitize all critical sites with sIPA* (and allow to dry).
  - Between batches and patient preps (as well as if you suspect contamination), wipe the entire deck with an EPA registered one-step sporicidal disinfectant cleaner and allow to achieve dwell time.
  - Wipe only the area of the DCA with sIPA.
- Alternative actions (Instead of Using sIPA)
  - Daily before compounding begins, wipe these surfaces (normally wiped with sIPA) with a low-residue EPA registered one-step sporicidal disinfectant cleaner
    - all surfaces inside the PECs
    - the top surface of the "staging cart" (the cart each employee keeps by the PEC)
    - the screen or other objects touched frequently if an IV-workflow system is used

## Beyond Use Dating and EM

- The Pharmacist in Charge (or Designated Person) is responsible to assign beyond-use dates (BUDs). In normal circumstances we assign BUDs according to USP Chapter 797 standards, however if your organization is following our garb and sterile IPA (sIPA) conservation and reuse guidelines then you are already not compliant with USP 797. The reality is that we have to use our best judgement. CriticalPoint

has proposed a large number of garb and sIPA conservation measures as well as alternative garbing, cleaning and material handling work practices.

- If you are following all or some of them, then we strongly recommend that your pharmacy perform **WEEKLY surface sampling in the direct compounding area (DCA) of all PECs under dynamic conditions.** Should the results of the sampling exceed the action level, do the following:
  - Note the staff member who was working in the PEC when the sample was taken
  - Take steps to ensure that garb that is reused is being reused according to the instructions at your pharmacy
  - Ensure garb is discarded as required by your pharmacy
  - Ensure that an EPA registered one-step sporicidal cleaner disinfectant is being used as proposed by CriticalPoint's guidance if you are running low of sIPA
  - Ensure that sIPA is always used to wipe the DCA, to wipe critical sites and to sanitize gloves
  - Ensure that meticulous and vigilant aseptic technique and material handling is being complied with by every single compounder
  - Observe staff to ensure this is occurring.
  - Resample the DCA with a different staff member working inside the PECs that exceeded the level. If the results again exceed the action level do the following:
    - Decrease BUDs to 12 hours room temperature/24 hours refrigerated
    - Evaluate your garb conservation strategies and alternative work practices. Since you had 2 different staff members working when action levels are exceeded, it's safe to assume that this is a pharmacy wide problem. Something needs to change. If you haven't begun to use sterile sleeves, do so immediately. Gowns may be reused but sleeves are NEVER reused.
    - Systematically evaluate, make appropriate modifications, one at a time, sampling each time a change is made.
    - Perform surface sampling daily as changes are made to evaluate if DCA is becoming cleaner.
    - After 3 days of surface sampling that are below the Action Level, return to regular BUDs
- If repeat surface sampling in the DCA that exceeded the level is below the action level (on the repeat), work with the staff member who may need additional help to improve their technique. Repeat surface sampling daily in the PEC where the "failing" staff member is working to ensure effective remediation.
- At the end of the day, it's about vigilance during material handling and using consistent aseptic technique. Even with all the garb conservation and alternative work practices, pharmacies should be able to keep their surface sampling in the DCA below the action level and therefore keep 797 BUDs.