



COVID-19: Downstream Implications for Sterile Compounding
CriticalPoint Recommendations
Updated March 12, 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 that 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 facemasks 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 shoes 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.
- HD gowns MUST NOT be reused.
- 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.

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 hand 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.