



COVID-19: CriticalPoint Strategies to Cope with Garb and sIPA Shortages Updated March 19, 2020

A Word About Recommendations

Recommendations are just that. These and other guidances are not requirements. There are many variables attendant to each pharmacy circumstance. You all need to carefully consider the guidance in light of individual events at each location. Work with your state regulators. Many state regulators are writing waivers to our usual garbing requirements, provided each pharmacy puts a formal plan in place. Plans should include specific conservation measures, alternative work practices, and the monitoring being performed. Staff must be knowledgeable about the rationale for such and trained in these new temporary practices. It is expected that each organization will evaluate the success of the strategies and revise their plan if needed. Nothing CriticalPoint or USP has recommended should be considered a requirement. Only your state regulatory authority can put requirements in place. Most regulators are interested in ensuring that you have a plan in place, and they have refrained from promulgating specific requirements since each situation is different, and the consequences of the COVID-19 pandemic are rapidly evolving and changing.

CriticalPoint's thoughts on [USP's Garbing Guidance](#) released March 18, 2020

- Most of USP's guidance is aligned with CriticalPoint's recommended alternative strategies. However, there are some differences of opinion regarding launderable items.
- USP recommends clean, washable, dedicated non-disposable garments (gowns or lab coats) and clean fabric to cover the nose and mouth; however, USP did not provide any statement or guidance about the process of getting these items laundered.
- Some vendors (e.g., like Cintas and Aramark as well as a variety of other providers) supply laundered cleanroom garb. This is a great option! CriticalPoint prefers that the garb used in compounding areas be low-linting since plain cloth gowns and masks shed significantly more particles than the low-linting garb. These operations also have validated laundering, handling, packaging, and distribution processes.
- If you choose to use cloth masks or gowns, we believe pharmacies must put in place a formal process to launder, handle, package, and redistribute these items. We are concerned about the variables that may affect the outcome if staff take launderable items home. What if a family member is ill? What if those who handle the laundry feel fine but are later discovered to have COVID-19 or other infectious diseases. How will the mask, bandanna, or gown be brought back into the facility? We think a disciplined process must be developed.
- The USP Guidance also mentioned the use of lab coats. Regardless of the type of garment used, it must close up to the neck and be closed down to the knees (or at least to below the LAFW deck) and have long sleeves. It is strongly recommended that these items be collarless.
- If your organization chooses to wear bandannas (seen in the USP document and in some other guidances we've seen in the public domain), there must be a sufficient number so that each cloth garment is worn and used once. When it is doffed, it must be put in a container for garb to be laundered (according to the disciplined process you develop). We believe that bandannas will be very difficult to utilize and may take a long time to tie correctly. Whatever you use for a face mask, it must cover the area from the bridge of the nose to the area under the chin without gaps.

What follows represents CriticalPoint opinion!

- These are uncharted waters, and we do not claim to be the authority. Use the "group's genius" at your organization to select the best strategies.
- Some of these measures are not in compliance with USP 797, so you may want to send your state regulator your plan.
- We all must work together to do the best we can! This situation continues to evolve. At some point, even these recommendations may not be possible, and each of you will have to do the best you can to keep both staff and patients safe.

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 or bathe daily.
 - Wear freshly laundered clothing.
- "Remove items not easily cleanable and not necessary for compounding." (USP 797 2019)
- Stage preps outside of the compounding area. Transfer items into the buffer room or inside the perimeter of the SCA 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 your face covering.
- Resanitize your sterile gloved hands frequently...especially any time they re-enter the ISO 5 space, after touching nonsterile items and always, immediately before beginning aseptic manipulations to the critical sites.

Determining the Amount of Garb Needed

- Check your inventory and seek alternate sources.
- Pick a date that you think we may start to see garb more readily available (we're thinking June if we are extraordinarily lucky) and work backwards. This will help you determine how long garb must be reused (based on the number of staff and the inventory you currently have or can get).
- Consider alternative types of garb and garb from different sources.
- Be conservative and make sure you figure in the garb needs during cleaning.

Garb Conservation Through Staffing

- Limit the number of persons entering the compounding area. Example: 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 and cart exchange (dirty to clean) to avoid unnecessary entry to the buffer room or inside the perimeter line of the SCA.
- Try dedicating a gown to an activity. 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. Just ensure that gowns used for cleaning cannot be used for compounding.
- Consider limiting training during a time of shortage. This is not a good time to introduce new staff to the controlled environments.
- Surveyors and inspectors should be respectful of the shortage and perform inspections from the outside of the cleanroom suite, utilizing windows, if they inspect at all. TJC and NABP have announced that audits and surveys are postponed until further notice.

Face Masks, Head Covers and Beard Covers

- N95 respirators are NOT needed for HD compounding provided you are compounding in a properly functioning and certified C-PEC. If this is your current practice, stop immediately.
- If N95 respirators are available, but face masks are not, they can be used in place of a face mask.
 - 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 the 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 than simple tie surgical masks.
- You may consider the use of launderable surgical masks or other launderable low-linting materials. If so, we strongly recommend a process around laundering, handling, packaging, and deployment.
- If you are reusing masks, put a process around this activity, so the risk of compromising the microbial state of control in rooms is reduced.

- 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. Do not touch the inside of the mask.
 - Place each mask for reuse in its own new, small white 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.](#)
 - Do not use plastic sandwich bags or other plastic containers which do not "breathe" and may encourage microbial growth.
 - 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 the mask in the normal garbing order.
 - If the sink is located outside of the ante-room or SCA and mask is donned after hands are washed, use alcohol-based hand rub (if available) after donning what is, essentially, a dirty mask. If alcohol hand sanitizer is not available, you may need to consider changing your garbing order.
- 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 ensure that staff understand and comply.
 - If you use a CAI in an SCA to compound, according to USP 797 (2008) masks (and gowns) are not required if the device manufacturer can provide written documentation (based on validated environmental testing) that any component(s) of PPE or personnel cleansing are not required.
 - According to USP 797 (2008), you are permitted to assign full dating as described in that chapter.
- Face masks, beard covers, head covers can be reused after HD compounding as long as that compounding is performed in a C-PEC. If CriticalPoint HD doffing practices are followed, then the inside shoe covers are also not contaminated and may be reused.
- 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.
- Another option is using a hood that has an integrated face mask. A head cover should be worn underneath if the hood/face mask combination is going to be reused. These can be found [here](#).
- There are additional types of hair covers available, such as full hoods.
- We 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](#)

Shoe Covers

- We do not recommend the reuse of shoe covers, nor do we recommend turning shoe covers 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 that they are dedicated to the interior of the pharmacy office, not "hospital dedicated." They can be stored in the general pharmacy area.
 - We prefer shoes that are washable or cleanable and suggest you put some type of 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.

Gowns

- For those who do not reuse gowns during a shift (a best practice recommendation), start reusing immediately. This applies to cleanroom suites and SCAs.
- Reuse for 1 shift/day if you have or can get sufficient inventory.
 - Reduce the compounding personnel that enter the buffer room or inside the perimeter of the SCA, reducing the number of gowns needed.
 - If reusing gown, do so for no longer than a week (this is just a guess...use your own judgement).
 - If a gown is being reused, then add disposable nonsterile or sterile sleeves (whatever you can get).
- 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 headcover must still be worn underneath the hood.
- Disposable jackets that are a shorter length than a gown is an option, if it covers clothing that is exposed to the opening of the LAFW.

HD Gowns

- HD gowns **MUST NOT** be reused. If you are running very low, remove them in the HD buffer room or inside the perimeter line. Do so very carefully and ensure the outside of the gown does not contact the nonhazardous gown worn below (buffer room) or your clothing (C-SCA). Understand that by doing this, you increase the potential that HD residue is not contained and that workers are exposed.
- Conserve HD garb for those preparing antineoplastic agents in Table 1 of the NIOSH list. Remember, you may need to update your Assessments of Risk.

- 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.
- The adoption of USP 800 is recommended but since the chapter is currently official but not compendially applicable, follow the requirements in your state.

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).
- Per USP 797 (2019), hang gowns on the 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.

Disposable Sleeves

- We recommend the use of sleeve covers, which do not have to be sterile.
- 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 disposable sleeves over the gown sleeves.
 - Don sterile gloves, pulling up over the additional sleeve.
- If there is shortage of sleeves, consider using sleeves for one shift. If you opt to do this, you must have a process on how to remove them and store them between use.

Alcohol-Based Hand Rub

- FDA released [Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency](#) on March 14, 2020, and [USP released Compounding Alcohol-Based Hand Sanitizer During COVID-19 Pandemic](#) on March 18, 2020.
- 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 before donning fresh gloves.
- We don't recommend the application of sterile IPA directly to hands. We are concerned that the direct application of alcohol will dry out workers' hands, resulting in increased shedding and potentially, cracking of skin. You might consider making hand sanitizer for home use and bringing in commercially made sanitizer for pharmacy use.

- There is no need to place an expiration or "BUD" on hand rub unless that is part of the manufacturer's instructions.
- Any type of alcohol-based hand sanitizer is acceptable, foam, or gel as long as it contains 60% IPA.

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. Use of UV light sanitizers, 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 the following strategies.

- **Always use sIPA on sterile gloves during compounding to wipe the direct compounding area (DCA) and on critical sites.**
- Consider the 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, but that is up to you.
- If you are entirely out of sIPA, then make some for use on the surfaces on which we think 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 (usually 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 frequently touched if an IV-workflow system is used

Beyond Use Dating

- The Pharmacist in Charge (or Designated Person) is responsible for assigning 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 must use our best judgment.
- Our general recommendations are listed below:
 - If you are following some or all of our recommendations and performing the recommended weekly surface sampling in the DCA (see the environmental monitoring section), then keep full dating.
 - If you have exceeded action levels in the DCA, reduce BUD to 12 hours room temperature/24 hours refrigerated. This applies to all risk levels.
- In their garbing guidance, USP recommended limiting anticipatory compounding. We strongly agree with this recommendation.

Environmental Monitoring (EM)

- We DO NOT recommend increasing the frequency of your routine viable air and surface sampling. If you are doing monthly sampling and can maintain that frequency, please do. Be sure to check the expiration date of your sampling media and order, if needed.
- In addition to your routine monitoring (whether it be monthly or every six months), if you are following our garbing and sIPA conservation strategies, we recommend **WEEKLY surface sampling in the DCA of every PEC** during dynamic operating conditions.

- We do not see a need for additional surface sampling in the rooms or any additional air sampling.
- If your certifier does your routine air and surface sampling, they can continue to perform the sampling if they are allowed into your facility based on organizational policies.
- DO NOT rely on your certifier to perform weekly surface sampling for you. They will not be able to meet the demand.
- The following is what is required to maintain your weekly surface sampling:
 - Purchase sampling devices. We prefer contact plates, but in the event that contact plates are not available, paddles are an acceptable alternative. Check the paddles before use to be sure they are not desiccated (dried out).
 - The sampling devices must contain sterile TSA with lecithin and polysorbate 80. If you cannot get sterile sampling devices, nonsterile are acceptable. Still, you **MUST** allow them to sit at room temperature (in their packaging) for at least 48 hours after receipt, even if they are to be stored refrigerated.
 - After the 48 hours, they can be placed in the refrigerator, if required for storage. This is a "preincubation," and in the event, the nonsterile plates are contaminated, you should see growth within 48 hours.
 - When you go to use the plates, check each one for contamination before you use it to sample. If the plate is contaminated, it must be discarded according to local regulations.
 - We recommend the following incubation parameters: 30 to 35 C for 48 to 72 hours and then transfer the samples to 20 to 25 C for 5 to 7 days.
 - USP 797 (2008) provides recommended incubation parameters and states that other suitable incubation can be used.
 - One of the shortfalls of the 2008 version is that only one incubation temperature was provided for TSA. Best practice (and common in GMP operations that use only TSA to sample) is to transfer the samples to the lower temperature to help recover a wider variety of microorganisms. Therefore, we recommend using the incubation parameters from the 2019 version of the chapter, because it does not conflict with the 2008 version.
 - Incubation is based on facility capability. The following list ranks incubation from the most ideal to least ideal
 - Internal incubation using 2 calibrated and qualified incubators set at 30 to 35 C and 20 to 25C **OR** outsource to a contract pharmaceutical microbiology lab that specializes in the incubation of EM
 - Use the organization's clinical laboratory (if possible), if they have incubators set at the necessary temperatures
 - Internal incubation using 1 calibrated and qualified incubator at 30 to 35 C and after 48 to 72 hours remove the samples from the incubator and leave at room temperature for 5 to 7 days
 - No access to incubation capability, leave the samples at room temperature for 5 to 7 days

- Count the samples after the first 48 to 72 hours, transfer and read again after the second incubation. If you do not have access to incubation, count the samples after 48 to 72 hours and again after 5 to 7 days.
- Identify only the growth that exceeds the action level, if identification is an option.
 - We DO NOT agree with the 2008 version of USP 797 requirement to identify all recovered microbial growth. Even the 2019 version does not require identification if the count was below the action level.
 - To identify recovered growth, samples must be sent to a clinical lab or a contract lab.
- We are more focused on proper cleaning with EPA registered one-step sporicidal disinfectant cleaner will kill anything present on the surface than we are on the identification of the organisms.
- For those who normally perform their own monthly sampling, keep your routine sampling plan for as long as you can, but plan for a shortage of plates as well. You have a lot of options for how to reduce your sampling plan. We recommend the following:
 - Keep your regular monthly PEC sampling for as long as you can.
 - Reduce your monthly viable air sampling to locations posing the most significant risk, like right outside of the PECs. If you have a small buffer room, one sample may be enough. Ante-room, one sample. Same thing for surfaces, do a risk assessment.
 - You will still want to have a full routine sampling session every six months as required by the chapter, whether you do it or your certifier does it.
- 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 the garb is discarded as required by your pharmacy
 - Ensure that an EPA registered one-step sporicidal cleaner disinfectant is being used on targeted areas, if you are running low of SIPA
 - Ensure that SIPA is always used to wipe critical sites and to sanitize gloves and to wipe the DCA.
 - 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 likely that this is a compounding staff work practice issue rather than an issue with one staff member. 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 and weekly sampling.
- 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.
- As is true before this crisis, it comes down to 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 USP 797 BUDs.

Cleaning

- We have been asked what to do in the event of a COVID-19 diagnosis of a sterile compounding employee. If the individual was garbed properly, there should be little risk; however, there is more risk in the ante-room where they entered ungarbed.
- The virus is highly contagious and does live for significant periods on hard surfaces. The daily cleaning with an EPA registered one-step bactericidal disinfectant cleaner should be sufficient.
- Still, you **must confer with the infection preventionists** in your organization to determine the best course of action. They will review the exact behaviors at the pharmacy (including which garb conservation and alternative work practices you are using) and advise you accordingly.
- Certainly the risk to other staff is reduced since they are also garbed and working in ante-rooms where the air is changed at least every 3 minutes (20 ACPH) and more frequently in the buffer room.
- If you are having issues getting your usual cleaning agents, consider temporary alternatives. Discuss options with the infection preventionists, keeping in mind dwell times that are reasonably achievable in a cleanroom suite (not longer than 3 minutes).

Staff Competencies

- Tenured staff can be tested as part of daily operations.
- Evaluate hand hygiene and garbing as they enter to compound. If you are adopting alternative garbing practices at this time, have them verbally explain how what they normally do is different than what they are doing now.
- Media-fill testing can be performed at the end of the compounding day, along with gloved fingertip samples.