



## COVID-19: BUD and EM for Those Reusing Garb

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# Learning Objectives



At the end of this webinar, you will be able to:

- Evaluate the alternative strategies implemented during the garb shortage to determine appropriate BUDs for CSPs prepared at your location.
- Implement weekly surface sampling of the direct compounding area (DCA) as a tool to evaluate the microbial state of control.

# CDC Coronavirus Disease 2019



## What You Should Know

[How it spreads](#)

[Symptoms](#)

[Prevention & treatment](#)

[Testing](#)

[Frequently Asked Questions](#)

[About COVID-19](#)

## Situation Updates

[Situation summary](#)

[Cases in the U.S.](#)

[Global locations with COVID-19](#)

[Risk assessment](#)

[CDC in Action](#)

[Latest Updates](#)

## Information For

[Communities, schools, and businesses](#)

[Healthcare professionals](#)

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# Other CriticalPoint Resources

## ■ [CriticalPoint Peer Network](#)

- Join as “silver” member (free) and login to access the resources listed below
- Join as “gold” or “platinum” to ask questions in the Ask the Expert forum

## ■ [COVID-19: Downstream Implications for Sterile Compounding](#)

- Webinar recording from 3/4/20
- PowerPoint Slide Deck in PDF updated again on 3/4/20 after the webinar

## ■ [CriticalPoint COVID-19: Strategies to Cope with Garb and sIPA Shortages](#)

- Updated as new ideas and strategies are developed

# What Follows Represents CriticalPoint's Opinion!



- We are providing general guidance
- You determine what will work for your organization
- Information provided is a balance of microbial risk and the need to safely care for patients

A red, slightly wavy banner with a dashed line at the top, giving it the appearance of a torn piece of paper or a sign. The text is in a bold, white, sans-serif font.

**ONE SIZE  
DOES NOT  
FIT ALL**

# Inventory Garb and Sterile Isopropyl Alcohol (sIPA)



- Count your inventory
- Investigate alternate sources
- Do the math
  - Plan to be on shortage until at least June
  - Back into the number you need
  - From there, figure how long you need to reuse garb
- **NOT** okay to work without garb, if you do, ***assign immediate use BUD***





# sIPA Update

- How much inventory
  - Plan to be on shortage
  - Back into the number you need based on what you are going through per day while conserving
- Conserve what you have by using sIPA on only the following (if conservation is necessary)
  - sterile gloves during compounding
  - wiping the direct compounding area (DCA)
  - sanitizing critical sites
- Do not use denatured alcohol (ethanol)



# sIPA Update (continued)

- Domestic companies trying to make more sIPA, but irradiation throughput is the limitation
- If you can't get sIPA, further conservation strategies are found in [CriticalPoint Strategies to Cope with Garb and sIPA Shortages](#)
- Purchase nonsterile filtered (0.2 micron) IPA (the IPA is filtered but placed in a nonsterile bottle)
  - Use this IPA for the DCA and sterile gloves
  - Reserve sIPA for critical sites
- If completely out of sIPA, make your own from the filtered nonsterile



# sIPA Hierarchy of Use



Direct Compounding Area

Sanitizing sterile gloves

Sanitizing critical site



# Making sIPA (continued)

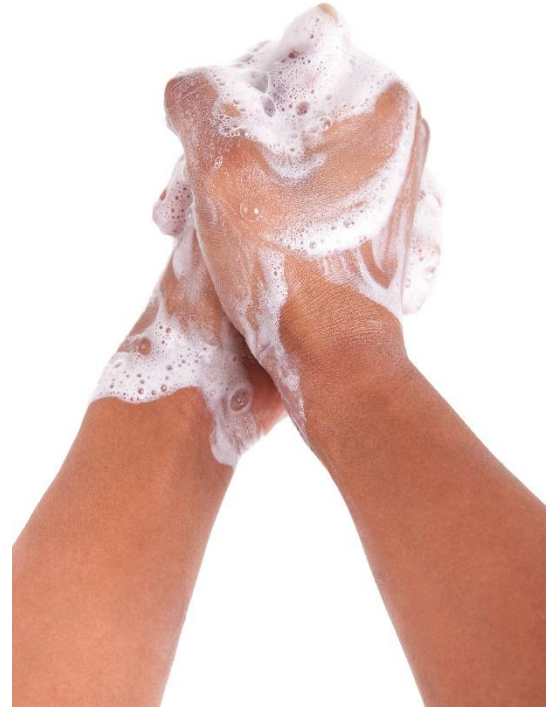


- Current sIPA spray bottles
  - Were they assembled correctly?
  - If so, best bet may be to refill these inside the PEC using aseptic technique
  - Purchase nonsterile filtered IPA that has been filtered. This type of IPA is made for healthcare use.
  - Filter this alcohol using a 0.22-micron sterile, hydrophobic, membrane filter remembering to keep within the filter specifications.
- **If you do not have a mechanism to make sIPA for use on critical sites, go to immediate use!**

# Making Hand Sanitizer



- Why?
- Does your pharmacy have time to do this?
- Rather spend time ensuring that there is strict adherence to the alternate practices, conservation strategies, aseptic technique, and material handling
- Perform hand hygiene instead!



# Making Hand Sanitizer (continued)



- [FDA Guidance](#) issued this month: Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency
- World Health Organization [Recommendations](#)
- These both have very specific instructions.



# Garbing Conservation and CAIs



- USP 797 (2008) allows the use of this device without garb

performing antiseptic hand cleansing with a waterless alcohol-based surgical hand scrub, and donning sterile gloves upon re-entering the ISO Class 7 (see *Table 1*) buffer area. When CAIs and CACIs are the source of the ISO Class 5 (see *Table 1*) environment, the garbing and gloving requirements for compounding personnel should be as described above, unless the isolator manufacturer can provide written documentation based on validated environmental testing that any component(s) of PPE or personnel cleansing are not required.

- CriticalPoint strongly discourages this practice.
  - Would rather you reuse garb according to the recommendations
  - All PECs have the same inherent risk if ungarbed personnel use them

# Certification of PECs and SECs

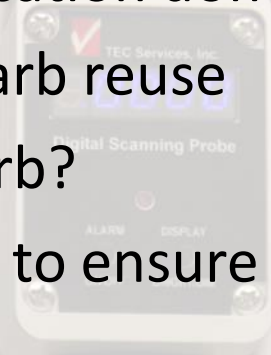




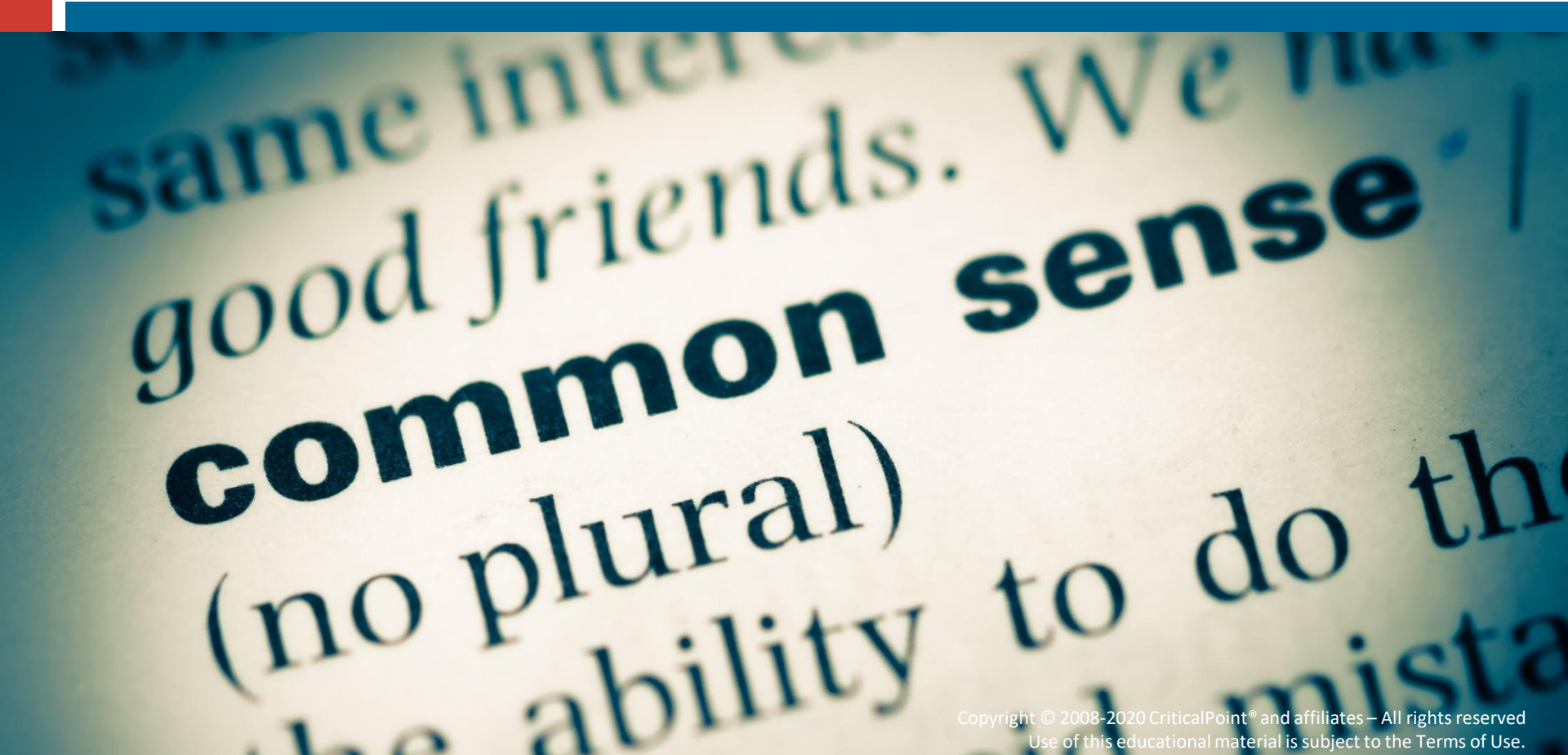


# Certification of PECs and SECs

- Facilities who are due for certification may not be able to get it performed!
  - Many organizations are barring outside vendors from entry
  - Since we are using less than optimum garbing and work practices if you can get your certification done, DO IT!
  - Guide certifier through garb reuse
  - Can certifiers use own garb?
  - Especially important now to ensure that PECs and SECs are working properly!



# BUDs and EM is all about...



# Determining BUD



- You need to decide and be comfortable with the rationale for determining BUD based on your situation.
- The Pharmacist in Charge (or Designated Person) is responsible to assign beyond-use dates (BUDs).
- Normally we assign BUDs according to USP 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.

# Determining BUD (continued)



- The reality is that we must use our best judgement. CriticalPoint has proposed many 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.***
- This sampling occurs at the end of the compounding shift or day provides data on the state of control of the DCA in each PEC.



# Implementing Surface Sampling

- Get plates either from a lab or another supplier
- Do NOT rely on your certifier, if a hospital they may not be allowed to enter
- We may see labs or shipping companies shut down, be prepared to incubate the samples yourself
  - Purchase 2 incubators and calibrate, if it's an option
  - Talk to your organization's clinical lab, they may incubate for you
  - Last option, which is better than nothing, leave the plates at room temperature and count them after 48 hours and 5 days

# Implementing Surface Sampling (continued)



- Below action level, counts only
- Exceeded action level, identification if it is an option
  - Based on contract lab availability
  - Expect “people” bacteria anyway since we are reusing garb
  - Cleaning with EPA registered one-step *sporicidal* disinfectant cleaner will remediate those organisms

Regulators must be understanding of incubation and identification capabilities during this time.





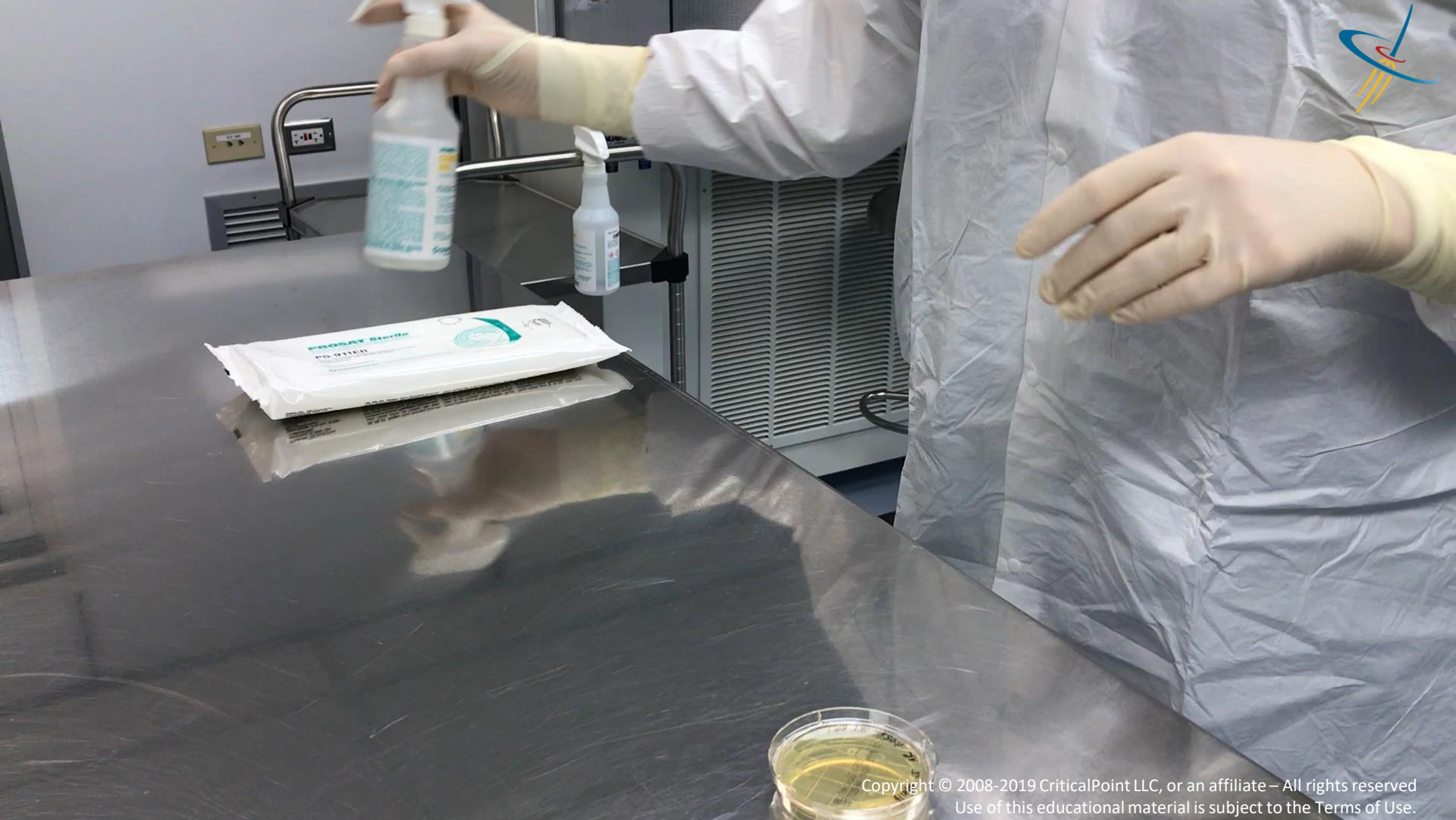
# Surface Sampling Technique

## ■ Contact Plates

- Media plate which has a convex surface
- General growth medium such as TSA with lecithin and polysorbate 80 which neutralize cleaning agents and prevent false negatives
- Only used to sample smooth, flat, and nonporous surfaces

## ■ How to use

- Gently roll the plate over the surface to be sampled
- Media residue will be left behind
- Wipe the sampled area thoroughly with sIPA





# Handling an Exceeded Action Level

- 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 SIIPA

# Handling an Exceeded Action Level (continued)



- Ensure that SIPA is always used to wipe the DCA, and sanitize gloves and critical sites (remember the algorithm presented earlier for severe shortages)
- Ensure that ***meticulous and vigilant*** aseptic technique and material handling is observed 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

# Advice for Consecutive Exceeded Action Levels



- If the results again exceed the action level, do the following:
  - Decrease BUDs to 12 hours room temperature/24 hours refrigerated
  - Evaluate garb conservation and alternative work practices
  - Since there were different staff members working when action levels are exceeded, it's reasonable to assume that this is a pharmacy-wide problem.
  - If you haven't begun to use sterile sleeves, do so immediately. Gowns may be reused but sleeves are NEVER reused.

# Advice for Consecutive Exceeded Action Levels (continued)



- 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
- 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.

# Summary



- Discuss options with your state board of pharmacy or other regulatory authority
- If you are not using garb, you fall under immediate-use.
- Develop a plan for surface sampling now.
- Maintaining a state of microbial control is still the goal, so additional contamination control measures may be necessary.

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topics related to  
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