

# **The Pandemic has Affected Sterile Compliance. How are you doing?**

Scherra Bartoli, CPhT, RPhT, PRS

Pharmacy Regulatory Specialist

Integrated Medical Systems

March 4, 2021

Covid19 hit the world like a tornado and took PPE availability with it. Products were diverted to frontline healthcare workers caring for patients. Manufacturers and distributors changed their priorities to help wherever they could. This left compounders scrambling for the appropriate sterile garb to protect their patients. Many Governors stepped up and wrote executive orders to assist pharmacies allowing the temporary use of non-sterile garb for USP<797> practices during these exigent circumstances, asking that Pharmacists maintain the integrity of their practice. The purpose of this webinar is to raise the question, one year into the public health emergency, “How are you doing?”

# Objectives

- Identify vital cleanroom products that became unavailable to sterile compounding pharmacies
- Examine what procedures were necessary to maintain patient safety
- Compare executive orders and BOP waivers from different states during COVID-19 peaks
- Prepare for another year and be as prepared as we can be

## Chief Product Backorders

### Non-Sterile Garb

N95 Masks, Ear loop Masks

Isolation Gowns

Chemo Gowns – due to a shortage of raw SMS material.

### Sterile Garb

As sterilizers across the country were being mandated by the government to sterilize specific products, they fell behind on consumer orders.

Filters

Sterile Gowns, coveralls

Gloves

### Cleaning Products

As the panic of Covid19 grew, the availability of necessary cleaning and disinfecting agents disappeared.

Wipes

Sprays

IPA – sterile and non-sterile

# Temporary Policy Regarding Non- Standard PPE Practices for Sterile Compounding by Pharmacy Compounders not Registered as Outsourcing Facilities During the COVID-19 Public Health Emergency

## Guidance for Industry

April 2020 Updated May 14, 2020

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/temporary-policy-regarding-non-standard-ppe-practices-sterile-compounding-pharmacy-compounders-not>



[This Photo](#) by Unknown Author is licensed under [CC BY-SA](#)

Webinar brought to you by



# Preserving PPE Supply and Obtaining Alternative Equivalent or Better PPE

**If the PPE a compounder relies on is in limited supply, we recommend the compounder modify its practices as follows:**

- Preserve the supply of available PPE by:
  - Limiting the number of personnel conducting sterile compounding activities.
  - Reducing sterile compounding activities, considering the risks and need for the compounded product intended to be sterile.
  - If obtainable, use other PPE that confer equivalent or better protection for the compounded product intended to be sterile.

### ***Contains Nonbinding Recommendations***

1.(1) The compounder is unable to obtain sufficient supply of PPE that it typically relies on (or PPE that is equivalent or better) to assure compliance with the insanitary conditions provision for its compounding activities (referred to as *standard PPE*). If PPE is not appropriate to assure compliance with the insanitary conditions provision (e.g., if a mask is beyond the manufacturer's shelf life or is reused) it is not considered standard PPE for purposes of this guidance.

2.(2) The drugs compounded meet the conditions in section 503A of the FD&C Act (21 U.S.C. 353a) and applicable FD&C Act requirements.

3.(3) The compounder:

1. employs the mitigation strategies as described below to reduce the risk of product contamination related to compounding when compounding is performed without standard PPE; or

**2. employs terminal sterilization where standard PPE is not used, as long as basic garbing expectations (e.g., hairnet, clean garment, non-sterile gloves, other appropriate coverings) are followed.**

4.(4) The compounder:

1. **keeps a record** when compounding is performed without standard PPE;

2. **keeps a record** when there are changes in the sterilization approach (e.g., from

3. aseptic processing to terminal sterilization); and

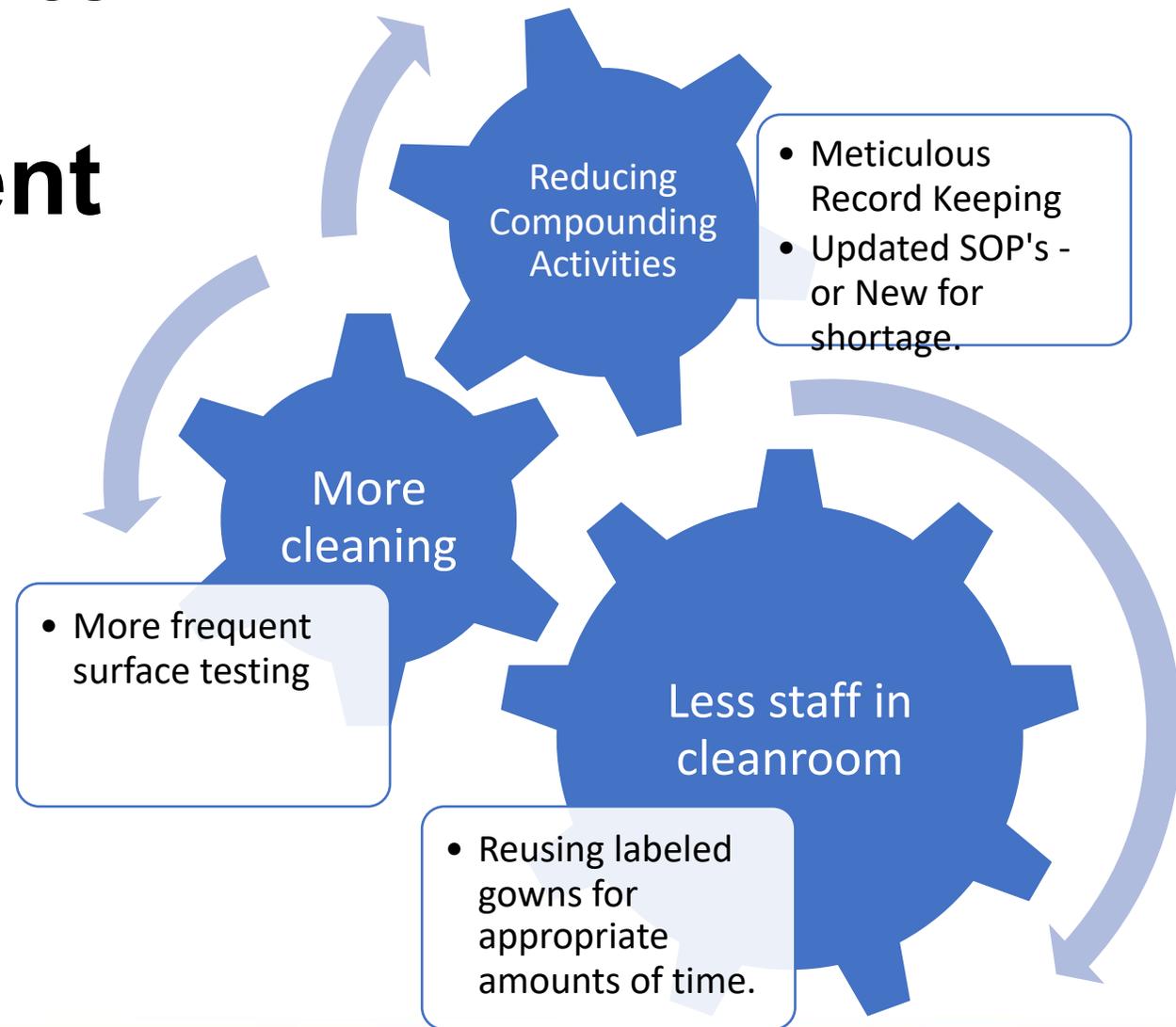
4. **documents** mitigation strategies in a **new or updated standard operating procedure.**

**Records of compounding without standard PPE may be essential to allow follow-up if quality issues or adverse events are reported for the products the compounder has released.**

## At the bottom of the page..

- FDA understands that due to the exigencies of the COVID-19 public health emergency, compounders may consider alternate risk mitigation strategies when standard PPE is unavailable. Compounders should consider such alternate approaches carefully and on a case- by-case basis to evaluate whether they provide protection to the drug product that is comparable to that provided by the risk mitigation strategies described above. FDA does not intend to object to the use of approaches that provide such comparable protection, provided the other circumstances described above<sup>12</sup> are present.
- <sup>12</sup> I.e., the circumstances described in items 1, 2, and 4 in this guidance.

# What is necessary to survive and not compromise patient safety?



# USP Response to Shortages of Garb and Personal Protective Equipment (PPE) for Low- and Medium-Risk Sterile Compounding During COVID-19 Pandemic



Webinar brought to you by



# Conserve Garb and PPE

- Facilities should prioritize conservation of garb.
- **Garb for direct patient care personnel should take priority.**
- **Prioritize availability of sterile gloves above other garb for sterile compounding activities because direct contact**
- contamination is the highest risk to the CSP.
- Inventory supply of garb to prepare and implement a temporary garb and PPE action plan. Ensure staff are properly trained to implement changes in garbing procedures. Check with suppliers on expected availability.
  - Be aware of counterfeit garb and PPE that may be falsely marketed and may not be capable of performing as represented.
- Limit staff performing sterile compounding.
  - Schedule staff to maximize compounding time and limit number of compounders per day or shift.
  - **Modify staging activities to minimize passage into and out of the compounding areas.**
- If necessary, establish and document deviations from existing Standard Operating Procedures (SOPs).

# For Shortages of Garb Used for Sterile Non-HD Compounding

- Store garb in a manner that minimizes contamination of that garb and surrounding garb.
- Maintain garb **inside of the classified area or within the perimeter of the segregated compounding area (SCA)**.
- There are **no data to support effectiveness of sterilizing garb for reuse with hand-held UV lights**.

## Face mask

- If face masks are in short supply, they may be reused and BUDs described in the [\*USP Operational Considerations for Sterile Compounding During COVID-19 Pandemic\*](#) may be applied if the face masks are:
  - Re-donned and reused by the same employee during the same work shift in the classified area or within the perimeter of the SCA.
  - Not visibly soiled or known to be contaminated.
- If face masks are not available, use clean fabric (e.g., polyester) to cover nose and mouth (e.g., washable face mask). Don a clean, freshly laundered or sterilized face cover each time before entering the buffer room or SCA.
- Do not enter the buffer room or the perimeter of the SCA without a face cover.

# For Shortages of Garb Used for Sterile Non-HD Compounding

## Gown

- Use **clean, washable, dedicated non-disposable garments (e.g., gowns, lab coats)**. Long-sleeved garments are preferred, and if not available, wear sleeve covers. Preferably, **wash garments after each shift or sooner when visibly soiled.**
- Retain and **reuse disposable gowns as long as they are intact and not visibly soiled.** Preferably, **discard used disposable gowns each day.**

## Head and hair cover

- Use **clean fabric to cover head and hair.** Preferably, **wash after each shift or sooner when visibly soiled.**

## Shoe cover

- Implement **dedicated shoes for the compounding area.** Preferably, **dedicated shoes should be cleaned regularly.**

# For Shortages of Garb Used for Sterile Non-HD Compounding

## Gloves

- Sterile gloves may be used beyond the manufacturer-designated shelf life.
- If sterile gloves are not available, nonsterile gloves may be used and the BUDs described in the [\*USP Operational Considerations for Sterile Compounding During COVID-19 Pandemic\*](#) may be applied if they are:
  - Saturated with sterile 70% isopropyl alcohol immediately after donning, and sterile isopropyl alcohol is frequently reapplied. Allow to dry thoroughly.
  - If sterile 70% isopropyl alcohol is not available, use nonsterile 70% isopropyl alcohol.
  - Visibly inspect the gloves prior to use and throughout use, and discard if there are discolorations, tears, punctures, or other defects.

# For Shortages of PPE Used for Sterile HD Compounding

- PPE is designed to minimize exposure of healthcare personnel to HDs.
- Prioritize the use of unworn gowns and chemotherapy gloves for preparing antineoplastic drugs in Table 1 of the NIOSH list over other types of HDs
- Gloves used for HD compounding should not be reused.
- Preferably, gowns shown to resist permeability by HDs should not be reused. If they are reused due to shortages:
  - Use only in the HD compounding area.
  - Store and maintain away from non-HD garb inside of classified area or within the perimeter of the containment segregated compounding area.
  - Re-don and reuse by the same employee during the same work shift in the HD compounding area only.
  - Inspect prior to use, throughout use, and discard if there are tears or other visible soiling or defects.
  - Consider the use of closed-system drug-transfer devices (CSTDs) if appropriate for the HD and dosage form, or disposable sleeves to protect from contamination.

- Adopt a **risk-based approach and limit anticipatory compounding.**
- **Storage times** should be assigned **conservatively using a risk-based approach and based on patient need** and the type of **garb mitigation strategy that is used.** Use the **shortest feasible beyond-use dates (BUDs)** while giving **consideration to avoiding drug shortages and maintaining patient access to essential medications** (See USP Operational Considerations for Sterile Compounding During COVID-19 Pandemic).
- Where feasible, **increase cleaning and disinfecting frequency.**
- Consider **increasing frequency of surface sampling in the primary engineering control to determine effectiveness of cleaning procedures and work practices.**
- If any changes are needed, **promptly remediate and consider assigning shorter BUDs.**

# If Facilities are Not Able to Obtain Garb or PPE

# For low- and medium-risk level compounded sterile preparations

- (CSPs) prepared in a segregated compounding area, apply BUDs conservatively, not to exceed:
  - 12 hours at controlled room temperature
  - 24 hours in a refrigerator
- For low- and medium-risk level CSPs prepared in a cleanroom suite, apply BUDs conservatively, not to exceed:
  - 4 days at controlled room temperature
  - 10 days in a refrigerator for medium-risk level CSPs
  - 14 days in refrigerator for low-risk level CSPs
  - 45 days in a solid frozen state at  $-25^{\circ}\text{C}$  to  $-10^{\circ}\text{C}$  or colder (see <659> Packaging and Storage Requirements)

# For low- and medium-risk level compounded sterile preparations

If a single-dose container is entered or punctured only in ISO Class 5 or cleaner air, it may be used up to:

- 12 hours after initial entry or puncture, as long as the storage requirements during that 12-hour period are maintained.
- Opened single-dose ampules must not be stored for any time period.

When assigning these BUDs, considerations should be given to:

- Ensuring personnel monitoring (e.g., gloved fingertip and thumb sampling) is successfully completed every 6 months.
- Increasing frequency of surface sampling in the primary engineering control to determine effectiveness of cleaning procedures and work practices.

If compounding using nonsterile components, containers or devices, follow the requirements for high-risk compounding.

# State to State Differences in COVID-19 Policies

- **Virginia** – Adopted the FDA GFI but added weekly surface sampling inside ISO 5 mandate if not able to comply with USP standards.
- **Tennessee** – Adopted the FDA GFI with continuing executive orders from the Governors office continuing the authority.
- **Kansas** – Adopted USP, FDA GFI and a private entity's guidance for pharmacies.
- **Ohio** – Adopted the FDA GFI
- **New Mexico** – Encouraged best practice and adopted the USP, and a private entity's guidance.

\*\*Data changes daily contact BOP for your state's information

# March 4, 2021

**It's a year later, How are you Doing?**

**Have you completed this checklist?**

- Designated reduced compounding staff?
  - Do they understand the procedures of how to conserve garb within your pharmacy?
  - Do you have your garb conservation policies posted?
- Adjust SOP's accordingly to all new actions.
- Document every time a drug is made with alternative garb. Keep records of all changes made and lot #'s.
  - If you have designated a lab director/manager/PIC to do this, have you checked it for completion lately?
- Revise environmental monitoring policies
- Assign new BUD's when you have alternative compounding practices in place.

# Thank You

**Scherra Bartoli, CPhT, PRS**  
**Pharmacy Regulatory Specialist**  
**Cell: 708-653-6828**  
[SBartoli@integratedmedsys.com](mailto:SBartoli@integratedmedsys.com)

# Slider header, Arial Bold, 44pt

- Arial Regular, 18 pt is the preferred font style and weight to use for the primary text content in your presentation.
- Lorem ipsum dolor sit amet, eu causae omnium vel. Exerci iisque debitis eum ea. Stet assum populo pri ad, cu sea idque aliquip graecis. Eos no odio commune, vim utroque blandit cu. Exerci eloquentiam mel cu, suscipit assentior pro at, harum vituperata quo ei.
- Est erat aperiam singulis id, epicuri platonem delicatissimi te pro. In ullum perfecto deterruisset sit. Congue sententiae eum at, at duo debitis officiis sententiae.

Thank you to IMS for your generous  
Sponsorship of this Webinar



# IMS

INTEGRATED MEDICAL SYSTEMS, INC.

Webinar brought to you by

