



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

May 6, 2020

This document is for informational purposes only for compounders and is intended to address the garb and personal protective equipment (PPE) shortages caused by the COVID-19 pandemic. This does not reflect the Compounding Expert Committee's opinions on future revisions to official text of the *USP-NF*. Parties relying on the information in this document bear independent responsibility for awareness of, and compliance with, any applicable federal, state, or local laws and requirements. USP is actively monitoring the evolving situation and will update this document accordingly.

Summary of updates:

- ▶ **May 6, 2020:** Recommendations were added to respond to stakeholder input to allow reuse of certain garb or PPE. References to the [USP Operational Considerations for Sterile Compounding During COVID-19 Pandemic](#) were added. The title of the document was changed to clarify that the scope of this document applies to low- and medium-risk compounding.¹

Background and Introduction

USP General Chapter <797> *Pharmaceutical Compounding – Sterile Preparations* provides official standards for compounding quality sterile preparations. In addition to addressing personnel, facility, and monitoring requirements, the chapter sets forth garb requirements to minimize the microbial contamination risk for compounded sterile preparations (CSPs).¹ For compounding sterile hazardous drugs (HDs), General Chapter <797> requires PPE to minimize the exposure of healthcare workers to HDs.

Additionally, USP General Chapter <800> *Hazardous Drugs – Handling in Healthcare Settings* is an official and informational chapter on handling HDs and includes PPE recommendations for compounding and other activities.²

In light of the rapidly evolving COVID-19 pandemic, the demand for garb and PPE is expected to continue to outpace available supply. During this pandemic, USP supports State Boards and other regulators using **risk-based enforcement discretion** related to the implementation of USP compounding standards.

The USP Compounding Expert Committee (CMP EC) provides the following garb and PPE conservation strategies for consideration and potential use during shortages for healthcare organizations and personnel during the COVID-19 pandemic. In light of the public health emergency posed by COVID-19, this document was developed without a public comment period. This document is not a USP compendial standard; rather, it reflects potential options developed by the USP CMP EC, based on their scientific and professional expertise, and with input from regulatory agencies at the federal and state level.

Implementing the strategies described below may not be aligned with provisions in General Chapter <797>. Reuse of garb and lack of garb may increase the risk of microbial contamination of the CSP and the environment. Facilities should carefully consider the impact on the CSP and the environment and implement risk-mitigating strategies to help ensure quality CSPs. Engineering controls are essential and must remain in effect to minimize the risk of contamination to the CSP and the environment. USP recommends that compounders also check with State Boards or regulatory bodies to determine the existence of waivers or interim requirements.

¹ Free digital access to <797>: <https://www.usp.org/compounding/general-chapter-797>

² Free digital access to <800>: <https://www.usp.org/compounding/general-chapter-hazardous-drugs-handling-healthcare>



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.³
- ▶ 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.

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.

³ For example, NIOSH has become aware of counterfeit respirators or those misrepresenting NIOSH approval on the market (See www.cdc.gov/niosh/nppt/usernotices/counterfeitResp.html).



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.⁴
- ▶ 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.

If Facilities are Not Able to Obtain Garb or PPE

- ▶ 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.

⁴ NIOSH List of Antineoplastic and other Hazardous Drugs in Healthcare Settings, 2016 at <https://www.cdc.gov/niosh/docs/2016-161/pdfs/2016-161.pdf>