



NHIA Sterile Compounding Guidance for the Home and Specialty Infusion Industry During the COVID-19 Outbreak

These guidelines are intended to help providers assure the quality of sterile compounded products (CSPs) during the COVID-19 outbreak. We have developed these recommendations to assist the industry in protecting employees and patients. Always refer to local and state guidelines in development of internal processes and procedures.

1. General Recommendations:
 - a. Refer to existing standard operating procedures (SOPs) and disaster emergency plans, and update as needed for garb modifications, social distancing, and compounding procedures.
 - b. Establish remote working capabilities for pharmacy staff where possible.
 - c. Refer to United States Pharmacopeia (USP) Response to Shortages of Garb and Personal Protective Equipment for Sterile Compounding During COVID-19 Pandemic⁴
 - i. Refer to state specific recommendations to ensure compliance with local regulations and guidance.
 - d. Wear scrubs for one shift only. Use a professional laundry service or an onsite facility, if possible. Change into scrubs onsite.
2. Masks
 - a. **Until shortages resolve, medical-grade masks should be reserved for personnel with direct patient care responsibilities.**
 - b. Do not reuse disposable masks
 - c. In place of medical-grade masks, use clean, low-linting materials (i.e. polyester fabric, wipe) to cover the nose and mouth.
 - d. Ensure fabric/handmade masks fit securely using straps or elastic bands
 - e. Don a clean fabric/handmade mask each time before entering compounding area.
 - f. If possible, use a professional laundry service or an onsite facility for washing fabric masks. If not available, launder at home to ensure clean face covers are available.
3. Gowns
 - a. **Until shortages resolve, disposable gowns should be reserved for personnel with direct patient care responsibilities.**
 - b. Retain and reuse disposable gowns as long as they are intact and not visibly soiled.
 - c. Reused disposable gowns should be stored on the clean side of the line of demarcation (LOD) in the ante-room area.
 - d. Consider the use of sleeves (non-sterile) with gowns being reused for more than one shift. Do not re-use sleeves.
 - e. Do not reuse disposable gowns if they are used for cleaning.
 - f. Use of clean, washable dedicated buffer room garments (i.e. gowns, lab coats, scrubs). Long sleeves are preferred or use of sleeves is recommended.
 - g. Use a professional laundry service or an onsite facility, if possible, for washing fabric gowns. Launder at home if needed to ensure clean gowns are available.

4. Shoe covers
 - a. Do not reuse shoe covers
 - b. Use dedicated shoes that are cleaned and disinfected prior to entry into the clean room suite or segregated compounding area
 - i. Clean dedicated cleanroom shoes with a germicidal agent prior to entering the cleanroom suite
5. Head and Hair Covers
 - a. If disposable head and hair covers are not available, use shower caps or reusable fabric head and hair cover
 - b. Use a new/freshly laundered head and hair cover each shift.
 - c. Use a professional laundry service or an onsite facility, if possible, for washing fabric head and hair covers. Launder at home if needed to ensure clean head and hair covers are available.
6. Gloves
 - a. Do not discard medical-grade, sterile gloves that are beyond the manufacturer-designated shelf life.
 - b. If medical-grade, sterile gloves are not available, then use nonsterile medical-grade gloves with frequent application of sterile 70% isopropyl alcohol.
 - i. If sterile 70% isopropyl alcohol is not available, use nonsterile 70% isopropyl alcohol.
 - c. The use of hand-sanitizer on gloves is not recommended as it may leave a residue.
7. Hand Sanitizer
 - a. Consider not applying hand sanitizer upon initial entry into the buffer space since hand hygiene was just performed.
 - b. Consider use of hand sanitizer only during the glove change process.
 - c. Consider compounding hand sanitizer per the USP or World Health Organization (WHO) guidance
 - i. https://www.who.int/gpsc/5may/Guide_to_Local_Production.pdf
 - ii. <https://www.usp.org/sites/default/files/usp/document/about/public-policy/usp-covid19-handrub.pdf>
8. Hazardous Drug (HD) compounding
 - a. Do not reuse garb worn to perform HD compounding
 - b. Proactively align work and group all HD compounding together to reduce the amount of garb required to be utilized
 - c. Use closed-system transfer devices for compounding of HDs if essential garb is not available
 - d. Prioritize gowns and chemotherapy gloves for preparing agents in Table 1 of the NIOSH list
9. Cleaning
 - a. When not using standard garb, the frequency of cleaning should be increased.
 - i. Conduct daily cleaning activities at the end of the workday to conserve garb
 - ii. Any garb worn during facility cleaning must be discarded
 - iii. Increase the frequency for cleaning shelves, carts, decks and other areas with a higher potential for contamination, especially when implementing a garb conservation strategy
 - iv. Consider weekly triple clean of the cleanroom suite or segregated compounding areas
 - b. Cleaning and disinfection of the PEC with sterile agents should be performed according to the minimum frequencies in Chapter <797>
 - c. Consider increasing the usage of your sporicidal cleaning agents during garb conservation
10. Environmental Monitoring
 - a. When using non-standard garb, consider weekly surface sampling of the PEC(s)
 - b. Maintain the minimum frequency for conducting air sampling in accordance with the official Chapter <797>
11. Cleanroom Practices
 - a. Maintain a minimum of 6 feet between compounding personnel in the buffer room
 - b. Modify break schedules to keep personnel in the buffer area as long as possible

- c. Modify staging practices to limit personnel access to the cleanroom suite which will result in a reduction of garb use
 - d. Walk slowly and deliberately in the cleanroom suite to reduce particulate matter being dispersed into ISO classified air spaces
 - e. Limit talking in the controlled environment
12. Compounding Practices & Assigning Beyond-Use-Dates
- a. Evaluate use of binary connection devices to reduce aseptic manipulations
 - b. Consider the use of premix IV formulations where possible
 - c. Assign beyond-use-dates (BUDs) conservatively to CSPs made under sub-optimal conditions (i.e. lack of proper garb, shortage of hand-sanitizer)
 - d. Develop a risk-based approach to assigning BUDs that balances risk of contamination to the CSP due to garbing practices, compounding environment, and compounding complexity with risk of exposing delivery personnel and workload burden. The BUD strategy should be incorporated into the facility's current SOPs. Ensure that your facility emergency preparedness plans include pandemic planning and anything that is changed from the normal SOP should be documented and amended for compounding record keeping purposes.

Additional Resources for COVID-19 can be found on our NHIA website at http://www.nhia.org/COVID_19_Resource_Center.cfm

Resources:

1. Critical Point. COVID-19: Downstream Implications for Sterile Compounding. <https://www.criticalpoint.info>
2. Centers for Disease Control and Prevention <https://www.cdc.gov/coronavirus/2019-ncov/index.html>
3. World Health Organization <https://www.who.int/emergencies/diseases/novel-coronavirus-2019>
4. USP Response to Shortages of Garbing and Personnel Protective Equipment for Sterile Compounding During COVID-19 Pandemic
5. 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>
6. USP Compounding Alcohol-Based Hand Sanitizer During COVID-19 Pandemics

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