



USP 797: Insights and Resources for Small and Rural Hospitals Frequently Asked Questions with Clyde Buchanan, M.S. R.Ph.

This document is based on information in United States Pharmacopeia (USP) Chapter 797 and the USP <797> Guidebook to Pharmaceutical Compounding-Sterile Preparations, as well as the author’s interpretation of the information.

1. Q: How can I justify the cost of building a buffer room and anteroom?

A: This first issue to resolve is whether you actually need a buffer room and anteroom. If the affected pharmacy is a satellite or ambulatory infusion center, you might be able to set up a segregated compounding area – an area that does not require HEPA filtered air and pressure differentials – to compound low risk sterile preparations that do not need longer than a 12 hour BUD. If you make low and medium risk non-hazardous sterile preparations that require longer than a 12-hour BUD, you might consider using a qualified compounding aseptic isolator – another option that does not require a buffer room and anteroom. Be sure to read USP Chapter 797 carefully before selecting either of these options. If you do have to justify building a buffer room and anteroom, the best justification may be a requirement of your state board of pharmacy to implement USP Chapter 797. Board inspectors can be your advocates for this approach. You may have other supporters within your organization, i.e. infection control officer, risk manager, legal counsel. Be sure to conduct a careful request for proposal (RFP) from several cleanroom builders, including modular cleanroom companies and pharmacy fixture companies.

2. Q: Is it better to have an “open” cleanroom or a “closed” cleanroom?

A: You must have a closed cleanroom, i.e. buffer room and anteroom separated by a wall, if you compound high risk sterile preparations. If you never compound high risk sterile preparations you can choose an open cleanroom that does not have a physical wall between the buffer room and cleanroom. Open cleanrooms have the advantages of easier personnel and cart movement between the anteroom and buffer room. Closed cleanrooms have the advantages of lower air handling costs and capability of high risk compounding should that become necessary.

3. We don't have space for an anteroom. Are there any alternatives in USP Chapter 797?

Besides the segregated compounding area and the qualified compounding aseptic isolator (mentioned in Question 1.), another alternative is to combine several approaches, such as premixed IVs from manufacturers, putting proprietary bags and vials into unit-based dispensing cabinets, using a closed-system vial transfer device (e.g. PhaSeal®) in a biological safety cabinet for hazardous drugs and outsourcing TPNs and batch preparations. STAT compounding of non-commercially available medium and high risk preparations will still be a problem unless the STATs can be made under the immediate-use exemption. One must be very familiar with USP Chapter 797 and have the right injectable drug usage patterns to avoid having to have an anteroom and buffer room, even in a small pharmacy.

4. Q: Will I have to add staff to comply with USP Chapter 797?

A: Few small hospital pharmacies will have to add staff to comply with USP Chapter 797. Compliance may require more time in quality assurance activities, hand hygiene, gowning and gloving but the actual time to compound each sterile preparation should not change. One key to saving time is to buy commercially available ready-to-use products whenever possible, and some time-consuming CSPs like total parenteral nutrition and cardioplegia solutions might be outsourced.

5. Q: We have a small OR satellite. What is the best way to bring it into compliance with USP Chapter 797?

A: Since space is an issue, you can set up a segregated compounding area which is defined as “a designated space, either a demarcated area or room, that is restricted to preparing low-risk level CSPs with 12-hour or less beyond use dates. Such area shall contain a device that provides unidirectional airflow of ISO Class 5 air quality for preparation of CSPs and shall be void of activities and materials that are extraneous to sterile compounding.”¹ The ISO Class 5 device (i.e. the primary engineering control) may be a horizontal laminar airflow workbench, a biological safety cabinet or a compounding aseptic isolator. Note that batches of syringes, cardioplegia solutions and TPN compounding may not fit the definition of low-risk CSPs. Should these medium risk sterile preparations be needed in the OR, perhaps they can be made in the central pharmacy buffer room.

6. Q: Can we do hazardous and non-hazardous drug compounding in the same buffer room?

A: No. It is virtually impossible to have negative pressure around the hazardous compounding BSC or CACI and to have positive pressure around the non-hazardous compounding laminar airflow hood both in the same buffer room (i.e. ISO Class 7). The

separate buffer rooms for hazardous and non-hazardous buffer rooms can both be served by the same ISO Class 7 anteroom.

7. Q: Our hospital is converting a nursing floor to an ambulatory cancer suite. What is the best approach to compounding chemotherapy for the new cancer suite?

A: The best approach is to have a negative pressure buffer room (ISO Class 7) with an ISO Class 7 anteroom. The BSC or CACI must be located in the negative pressure buffer room. If you are also compounding non-hazardous sterile drugs for cancer patients, the best approach is to have a separate positive pressure buffer room (ISO Class 7). Both buffer rooms can be accessed through the same anteroom. This arrangement gives the most flexibility in compounding low, medium and high risk sterile preparations, all with full USP 797 standard beyond use dates.

8. Q: We use sterile 70% isopropyl alcohol to clean hoods and counters. What is the best disinfectant for cleaning floors, walls and ceilings?

A: Floors, walls and ceilings will collect more soil than hoods and counters; so they should be both cleaned and disinfected. Quaternary ammonium disinfectants can be obtained that have both cleaning and disinfecting properties. Work with your director of housekeeping to select the best product for your anteroom and buffer room floors, walls and ceilings.

9. Q: USP Chapter 797 specifies “routine” testing for surface microbes. So how often should we do surface microbial testing?

A: I recommend that surface testing for microbes as described in USP 797 be done whenever cleaning personnel change or when cleaning procedures change. If surface microbial testing with agar plates or swabs show the presence of pathogenic microorganisms like molds, yeasts and bacterial spores, then periodic (e.g. weekly or monthly) cleaning with a sodium hypochlorite solution may be warranted. Be sure to include the advice of your hospital microbiologist when pathogenic organisms are encountered.

Q10: USP Chapter 797 recommends sampling of surfaces for contamination with hazardous drugs. How often should this be done and who should do this sampling?

A: Especially if you compound relatively large amounts of chemotherapy or other hazardous drugs (e.g. hormones, some antivirals), you should do surface swab sampling as described in USP Chapter 797 to determine whether your cleaning, handling and venting procedures are working to minimize personnel exposure to these drugs. USP Chapter 797 recommends that surface sampling for hazardous drug contamination be done initially and at least every 6 months or more often to verify containment. Your environmental testing company may be able to do your testing or may be able to

recommend a surface testing company to you. It is possible that your group purchasing organization has an agreement with a hazardous drug surface sampling company to do this sampling.

11. Q: Will we have to buy a microbial air sampler?

A: Since USP 797 only requires viable (i.e. microbial) air sampling every six months, I recommend that you have an outside environmental testing company do this. Many companies that verify the ISO Classification of your primary and secondary engineering controls can also do microbial air sampling. Microbial air sampling requires expertise and is time-consuming.

12. Q: There is only one pharmacist (and no technician) on evening and weekend shifts. How can one pharmacist answer the phone, enter orders, compound admixtures and so on if they have to garb every time they compound an admixture?

A: One solution is to install a compounding isolator that is validated by its manufacturer not to require full garbing with gown, facemask, shoe and hair covers. Such compounding isolators can be used quickly for STAT sterile compounding. You would have to install such an isolator outside of the buffer room, perhaps in the anteroom, because you don't want regular foot traffic in your buffer room. In other words, full garb is always required to enter a buffer room.¹

13. Q: If we don't have a cleanroom yet, do we need to do viable and non-viable air sampling or surface microbial sampling or fingertip glove microbial sampling or even media fill testing?

A: USP 797 specifies that a certified testing company certify primary engineering controls semi-annually. Microbial air and surface sampling should be done for primary engineering controls as well. Often the same certified testing company will be able to do this microbial air sampling and perhaps the surface sampling. It is permissible for the hospital pharmacy or microbiology lab to do microbial air and surface sampling but this requires special equipment and expertise. I recommend that microbial air and surface sampling be done in the work area outside the primary engineering control even if you don't have a cleanroom – in order to detect pathogenic microbes. According to USP 797, if you use a segregated compounding area where you make only low-risk CSPs with beyond use dates of ≤ 12 hours, viable and non-viable sample testing must be followed as described in the Chapter.

Fingertip testing and media fill testing are required to verify the competency of personnel for garbing/hand hygiene and aseptic technique, respectively. This is true whether you have a cleanroom or not.

14. Q: Who should be doing the “housekeeping” for the pharmacy cleanroom?

A: USP 797 requires that any person who cleans and disinfects a cleanroom be trained and observed during the process of actual cleaning and disinfecting. Observations should be organized and documented for personnel competency records. USP 797 Appendix V gives an example of such an observation document. Whether pharmacy personnel do all the cleaning or just hoods and counters, all personnel who do cleaning must be competency tested including housekeeping personnel who may participate in cleaning and disinfecting floors, walls and ceilings. Each hospital must decide whether pharmacy personnel or housekeeping personnel do the regular cleaning of floors, walls and ceilings.

15. What should be done about caulked ceiling tiles in the IV rooms?

A: First, ceiling tiles should be the right type – smooth surfaced and hydrophobic. These tiles should then be caulked into place to enable cleaning of the ceiling every month as specified in USP 797. Some experts have said that clipping ceiling tiles into place may be as good as caulking them into place. However, full-caulking around ceiling tile edges will keep cleaning water from getting above the ceiling where microbial growth can take place.

References

2009 USP NF. Rockville, MD: The United States Pharmacopeial Convention; 2008.

USP <797> Guidebook to Pharmaceutical Compounding-Sterile Preparations. Rockville, MD: The United States Pharmacopeial Convention; 2008.