Q: Are sterile gloves required when a pharmacist is checking a compounded sterile product or only when it is being compounded?
A: As long as the pharmacist is not performing any aseptic manipulations, non-sterile gloves disinfected with sterile alcohol can be worn while checking the compounded sterile preparation. The pharmacist should also be properly garbed while checking CSPs if that activity occurs in the buffer area.

Q: Are there any good training videos for the use of CAIs?
A: Check with your isolator manufacturer for any training videos on the use of their CAI. I am not aware of any commercially available educational products at this time.

Q: Are you aware of any continuing education programs for USP 797?
A: There are several CE programs for USP 797. If you Google “USP 797 Training” you will find lots of options.

Q: Could you comment on Training requirements for nurses who prepare urgent/emergent preparations?

Q: Do you have any examples for competency test/checklist for aseptic technique with or without limited review of select topics?
A: Appendix IV of the current USP Chapter <797> has a sample form that can be used to assess aseptic technique.

Q: Do you know of any video formats that are in the process of being produced that reflects the new revisions?
A: ASHP updated their Compounding Sterile Preparations video in 2008. I am not aware of any other videos at this time.

Q: Do you need to do glove testing on the gloves in an isolator and the person compounding?
A: Yes, non-sterile supplies and components must be brought into the isolator and there is still a risk on surface and glove contamination. USP 797 requires the use of sterile gloves for all compounding activities in all types of primary engineering controls.

Q: Does the 30 ACPH requirements apply to ISO-8 Ante-rooms or just an ISO-7 Clean Room?
A: USP states that “Adequate HEPA-filtered airflow supplied to the buffer area and ante-area is required to maintain cleanliness classification during operational
activity through the number of ACPHs.” It does not state a minimum ACPH rate for the ante area. I generally recommend at least 30 ACPH to maintain ISO class 8 when no HEPA filtered primary engineering control is present to aid in room scrubbing.

Q: Does the usage of a closed system transfer device when compounding chemotherapy from a single use vial prolongs the beyond use date or must it be used once and discarded?
A: Excellent question. I am aware of a study currently in-process looking at extending the BUD of single-dose vials when used with CSTDs.

Q: Does USP 797 require pharmacists who only check CSPs have the same training as the technician making it? i.e. Media fill tests, Gloved finger tip testing. Etc
A: In the Responsibility of Compounding Personnel section of the chapter, it states: “Qualified licensed healthcare professionals who supervise compounding and dispensing of CSPs shall ensure that the following objectives are achieved:…” Pharmacists should be as qualified as the staff they are supervising.

Q: Gowning process-shoe covers-before or after hand washing?
A: Shoe-covers are dirty and shall be donned prior to hand washing.

Q: Have you any experience with and what are your thoughts on the Baxter Training Manual for IV Admixture Personnel computer based training program?
A: I like web-based education programs. Each training program has their strengths and weaknesses. The Baxter program is good introduction to the basics of sterile compounding in my opinion.

Q: How do you know if your department is doing more than is required for 797? Is there a check list?
A: The easiest way is to conduct a gap analysis of your existing operation. A web-based gap analysis is available at http://797gaptool.797compoundingiq.com/

Q: How often do you have to do the didactic training?
A: Please refer to Training matrix that will be available for download as part of the follow-up to the webinar.

Q: Is double gloving still required if Chemo approved sterile gloves are used?
A: Double gloving is recommended by both USP and ASHP in order in minimize the transfer of hazardous drug contamination to other surfaces and employees.

Q: Is TJC (The Joint Commission) looking for USP 797 compliance?
A: Based on 2009 survey conducted by Pharmacy Purchasing and Products Magazine reports that 58% (n=262) of facilities surveyed by TJC in the past two years report being questioned about their compliance to USP Chapter <797>.

Q: Please tell me exactly when and how often finger tip testing should be done.
A: The chapter is very specific. All personnel need to perform a gloved fingertip sampling procedure three times with zero CFUs. Once the employee is proficient, at the conclusion of their annual or semi-annual media fill, a gloved fingertip sampling can be incorporated as part of their revalidation.

Q: Are staff that prepare immediate use preps (i.e. Nurses, etc) exempt from the USP 797 training requirements?
A: If nurses prepare urgent/emergent preparations, a hand-hygiene and aseptic technique assessment program should be established. You can download a primer article here: http://www.pppmag.com/pp-p-april-issue-2009/spread-the-word-aseptic-technique-prevents-infection

Q: What are proper policies for compounding personnel with dermatologic issues (i.e. hand dermatitis from excessive hand washing, etc.)
A: Consider consulting with your organization’s Infection Preventionists for more guidance.

Q: What is the best way to train media fill?
A: Practice, practice, practice

Q: When air and surface samples are taken on clean rooms and isolators and a bacterial or fungal growth occurs does the microorganism need to be identified or can a second sample be taken after extra cleaning be done?
A: The chapter requires the identification of any CFU. A second cleaning is always helpful. You can resample the site in question after cleaning.

Q: When conducting practical media-fill tests for high-risk products, must they be done at 6 month intervals or can they be done two consecutive times annually?
A: The intent is to have the employee demonstrate proficiency throughout the year. The frequency for high-risk level media fills is semi-annual.

Q: In a glove box (CAI/CACI), do you need to put sterile gloves over the gloves of the box when you compound?
A: Yes

Q: Do employees need to remove all make up when we have CAI in a room for compounding, not a clean room?
A: Makeup can be a source of particles and contamination. Ideally, no makeup should be worn while compounding in a CAI.

Q: For a CAI, how do you do finger tip testing?
A: You need to sample the gauntlet gloves that have been donned with sterile gloves.