

Q&A from 6/9/09 Webinar: “Use of Isolators in Compliance With USP 797”

Q: Which is better, cleaning within the hood or opening the front window? We clean daily by opening the front window and then allowing the hood to operate for 30 minutes before compounding.

A: Follow the manufacturer’s recommendations for cleaning. To the extent possible, it is better to clean with the front view screen closed.

Q: You discussed placement of the hood outside of an ISO 7 room. If this is done, how should the room itself be cleaned, i.e. mopping the walls and floors, etc?

A: Cleaning for rooms other than ISO class 7 should be done as described in the chapter for segregated compounding areas.

Q: When you refer to cleaning work surface every 30 minutes are you referring only to the horizontal bottom work surface?

A: yes

Q: Would you address the disinfecting of products being introduced into the entry lock of the isolator?

A: The intent is to reduce the bioburden as much as possible on the outside of the packages. This should include a wipe down with the appropriate disinfectant as the materials are placed in the pass-through.

Q: When will the USP FAQ re: USP 797 be avail?

A: <http://www.usp.org/audiences/pharmacist/797FAQs.html>

Q: If hand washing and gowning must be available in room with isolator, what if isolator is in a Class 7 cleanroom? Can't have sink and should already be gowned prior to entry to class 7 room.

A: If you are placing an isolator outside of a cleanroom, you need to take into consideration where you will gown and garb. Hand hygiene and garbing are done in the ante room for a cleanroom.

Q: Please comment on how one uses sterile gloves (as required by USP 797) when working in an isolator.

A: One method is to place the sterile gloves in the isolator and to place the sterile glove over the top of the isolator glove.

Q: Should paper wrappers be removed prior to placement in the pass-through?

A: Paper wrappers should only be removed after they are in ISO class 5 unidirectional airflow. If the pass-through is unidirectional airflow and can accommodate careful unwrapping, then the wrapping can be taken off in the pass-through. Otherwise the wrapping should be taken off inside the isolator.

Q: WHAT TYPE OF REQUIRED DOCUMENTATION IS NEEDED FOR ISOLATOR CLEANING?

A: There is no difference in documentation practices for an isolator than there are for a cleanroom operation.

Q: what is your feeling on using sterile alcohol vs. non sterile?

A: USP recently provided a list of FAQ that clarifies this question
<http://www.usp.org/audiences/pharmacist/797FAQs.html>

Q: What garbing requirements apply when working in a CAI (both hazardous and non-hazardous)?

A: Garbing requirements are the same as for a cleanroom operation unless the manufacturer validates otherwise. For hazardous operations, NIOSH recommendations should be taken into account.

Q: What are your recommendations for fingertip testing in a CAI?

A: Same as in a cleanroom operation

Q: We missed what you said about unwrapping syringes in the pass through? Can you cover that again? Thanks

A: Paper wrappers should only be removed after they are in ISO class 5 unidirectional airflow. If the pass-through is unidirectional airflow and can accommodate careful unwrapping, then the wrapping can be taken off in the pass-through. Otherwise the wrapping should be taken off inside the isolator.

Q: Make-up, if the manufacturer does not exclude can it be worn?

A: USP is clear on this issue. Makeup is not to be worn while compounding. I am not aware of an exception for isolators.

Q: If the isolator is located in a clean room, could the wrappers be removed before or as the product is placed in the ante chamber?

A: The opening of the sterile wrapping when using an isolator should be handled the same in a cleanroom as outside of a cleanroom unless the cleanroom is ISO class 5. Sterile components should only be exposed to ISO class 5 unidirectional airflow.

Q: Jim, do you recommend opening the front shield when performing routine cleaning & decontamination of a CACI used for compounding Hazardous Substances, or should the isolator remain closed and the inside cleaned with wipes?

A: Only as part of a thorough cleaning program that will include a thorough cleaning after the front access is closed.

Q: Please have Jim answer the question about the room spec differences for Type A2/B1 and Type B2 hoods. We're building a cleanroom in the near future and cost is a major consideration.

A: There is a big difference between the amount of air exhausted by an A2 cabinet and a B1 cabinet or a B2 cabinet. This will affect the amount of air exhausted and supplied to the room but it will not affect the fact that the room must be ISO class 7.

Q: Please comment on one manufacturer that states "Perfect solution for hazardous/chemo compounding - Gas tight, No venting required, no negative pressure clean room needed.

A: This does not meet the recommendations of either NIOSH or USP. There is no precedent that I am aware of for this type of solution.

Q: Is there any circumstance that compounding volatile hazardous drugs in a recirculating negative pressure isolator is acceptable?

A: The exhaust should be vented from the building and not recirculate back into the room if volatile drugs are being compounded.

Q: Is there a list of VOLATILE hazardous drugs?

A: Cisplatin and ifosfoamide two examples in the literature. There is no aggregated list of drugs that volatilize to my knowledge.

Q: is sterile alcohol sufficient to clean both + and - isolators daily and every 30 minutes?

A: You need to address the disinfectant materials for your specific operation. Remember that alcohol does not kill spores so this will need to be accounted for.

Q: Is a respirator mask required for cleaning of isolators?

A: Not if the front access is closed

Q: If you only compound one hazardous drug per week do you need to vent to the outside?

A: A low-volume exemption exists if a closed system transfer device is used in the primary engineering control. One preparation per week would qualify and therefore external venting would not be required.

Q: If not working continuously in the CAI or CACI, is the every 30 minute surface cleaning or glove changing necessary? For example if 45-90 minutes elapse between IV preps, when should clean & change gloves, before or after each prep?

A: Every 30 minutes is for continuous operations. You are ultimately responsible for your operation. Ideally, you should clean the work surfaces between batches and/or drugs. You will be responsible to validate that an alternative time frame is adequate.

Q: If I have an isolator inside a "clean as possible" room with an anteroom, do I need to have a pressure gauge that is easily readable to show positive pressure from isolator to buffer zone to ante room? Can you recommend a product?

A: The isolator is most likely equipped with a gauge to monitor pressure from the isolator to the room. A magnehelic gauge is an inexpensive and simple to install instrument to measure pressure from room to room. As an alternative, a digital manometer is a little more expensive but easier to read.

Q: is a 797 clean room is a mask necessary or required

A: The garbing level when using an isolator is the same as for a cleanroom unless the manufacturer has validated otherwise.

Q: How often should the sleeves be replaced?

A: A number of variables will affect the service life of the sleeves including the type of sleeve, the environment it is used in, the amount the isolator is used, etc. For the most part, semi-annual replacement is a reasonable starting point until you have an opportunity to judge based on experience. Regardless of replacement cycle, the sleeves should be inspected daily.

Q: How often should the gloves be replaced for non chemo compounding?

A: This will be based on usage and input from the glove manufacturer.

Q: How often do you recommend changing gloves in a positive-pressure isolator?

A: This will be based on usage and input from the glove manufacturer. Regardless of the change cycle, regular inspection is a must. These gloves must be routinely disinfected with sterile 70% IPA.

Q: We currently use alcohol to sterilize the inside surface between batches and upon twice daily cleaning. Do you recommend using hydrogen peroxide for one week out of the month instead of alcohol (this was the recommendation from our isolator's manufacturer)?

A: Disinfection agents used in an isolator should be based on the same factors as any other engineering control. Regular usage of an agent with sporicidal capabilities is good practice.

Q: For non-hazardous preparations, would changing gloves every shift comply with the "frequent" changing requirement?

A: This would seem reasonable in a low-volume application but most likely inadequate for a large volume user.

Q: Do you recommend vented isolation

A: External venting of the isolator is recommended for applications where drugs with a potential for volatilization.

Q: Do compounders still need to gown during IV preparations if using a barrier isolator while the unit is sealed? Also, the photo shows cleaning with the unit sealed. Is it acceptable to gown, glove, mask, etc and clean while the unit is open? Work surfaces need to be cleaned every 30 minutes or just between batches when not in constant use?

A: These are all variables that need to be addressed based on your particular isolator. If the manufacturer has validated reduced garbing for their isolator, then you do not need gowning when using it. Follow the manufacturer's recommendations for cleaning. To the extent possible, it is better to clean with the front viewscreen closed.

Q: Still confused about how to incorporate STERILE GLOVES requirement into CAI workflow? Comment?

A: One method is to place the sterile gloves in the isolator and to place the sterile glove over the top of the isolator glove.

Q: Can you use a closed system transfer device (i.e. PhaSeal) in addition to the isolator?

A: A CSTD can be used in addition to the isolator but not as a replacement to the isolator.

Q: Can you speak to glove tip sampling required by USP 797 and how you do this in an isolator?

A: Glove tip sampling in an isolator would be done the same as when using a BSC. In this case, place the plates on the work surface and touch with fingertips. Note that the gloves will need to be replaced after the test. This test is less onerous if you use the sterile glove over top of the isolator glove.

Q: Can compounder be placed in the CAI?

A: The size and design of the isolator must be taken into account. A visual airflow smoke pattern test must be performed with the isolator in place to assure the compounder does not negatively affect the unidirectional airflow.

Q: What are your recommendations for disinfecting the outside of the CAI unit?

A: Should be treated like any other surface in a segregated compounding area.

Q: CACI must be located INSIDE a negative pressure room?

A: yes

Q: Are there vendors that supply externally-vented storage compartments for hazardous drugs?

A: I am not aware of any. Consider a volatile chemical storage cabinet.

Q: Are sterile gloves required for CAI/CACIs?

A: yes

Q: Are gowns really necessary while using a barrier isolator?

A: Garbing requirements are the same as for a cleanroom operation unless the manufacturer validates otherwise. For hazardous operations, NIOSH recommendations should be taken into account. Most isolators do not require gowning.

Q: Are closed system transfer devices needed when compounding in a CACI?

A: Not unless you are using the low-volume exemption to justify not venting outside. There is no specific number associated with low volume. At one point, USP suggested less than 5 because that would be less than one per day for a normal work week.