



When Is a **Compounding Aseptic Isolator** Right for Your Pharmacy?

When considering the purchase of a compounding aseptic isolator (CAI) or compounding aseptic containment isolator (CACI) for your pharmacy, there are many factors to keep in mind. While these devices are becoming more popular, they are still not as widely used as biological safety cabinets (BSCs) or laminar airflow workbenches. And, as these devices are relatively new to pharmacy, they require a willingness on the part of the user to accept the technology, the new standard operating procedures (SOPs), and the requisite adaptation period. Nevertheless, when used correctly, CAIs can aid pharmacy in the safe and efficient preparation of compounded sterile products (CSPs).

USP <797> Compliance

One common misconception surrounding CAI/CACIs is that using one will automatically guarantee USP <797> compliance. While such tools can greatly assist in this aim, there is no substitution for proper understanding of the chapter to determine compliance requirements for your individual pharmacy. Isolators are considered primary engineering controls and any reputable manufacturer's units should be ISO Class 5, therefore meeting the primary engineering control definition of USP <797>. Even with this classification, a designated space with restricted access is required, as is compliance with all additional USP <797> requirements. Proper understanding of the level of risk of the preparation you are performing, as defined in the chapter, is also important and will dictate the other requirements or standards that must be met.

Motivations for Purchase

It is important to keep in mind your motivations for considering an isolator, as opposed to a more traditional BSC. At Cancer Treatment Centers of America, worker safety was our primary motivation for choosing isolators over BSCs. In each of our hospitals we compound numerous doses of hazardous drugs on a daily basis and ensuring the safety of our staff is of utmost importance.

We also decided to use CAIs for all non-hazardous drug compounding in an effort to maintain consistency across as many of our compounding techniques and procedures as possible. We did not want staff to have to use different procedures based on the type of product being prepared. By increasing exposure to the device, the adoption period for the user is also minimized.

Choosing an Isolator

Once you decide to purchase a CAI, you will then have to determine which one best fits your pharmacy's needs. There are a variety of CAIs in the marketplace at different price points, and as always, cheaper is not necessarily better. When choosing a unit, there are several factors to be conscious of. First, ensure the CAI you select offers unidirectional airflow in all chambers/compartments of the unit. Furthermore, if you are purchasing a unit for hazardous drug compounding, make sure the unit can be vented to the outside, as recommended in USP <797>.



Since compounding aseptic isolators are relatively new to pharmacy, they require a willingness on the part of the user to accept the technology, the new standard operating procedures (SOPs), and the adaptation period.

Another consideration is antechamber functions. Some units offer an integrated locking mechanism, preventing the inner door from being opened while the outer door is open—virtually eliminating exposure by allowing adequate recovery time for the unit to return to ISO Class 5. With this function, the lock time should directly correlate to the time required to clear the air in the antechamber with a unidirectional airflow; this time will vary based on the unit.

Also, keep in mind power and data access within the compounding space when selecting your unit. While it is important to be able to access this data, every access point on the unit must be properly sealed and tested for air leakage so as to not affect the integrity of the CAI.

Safe and easy disposal of waste and sharps is also a concern. The CAI should have a built-in space where the operator can safely dispose of sharps in a secure container. It is just as important that the sharps container can be easily removed with minimal disruption to the compounding process. Check on the compatibility of sharps containers with the unit, as some manufacturers limit the types of containers that can be used with their unit.

An additional consideration is whether you should choose a unit with the ability



Cover Story

to adjust the height of the unit. To maximize the efficiency and comfort of the compounding staff, a hydraulic or mechanical lifting mechanism can be added. Considering the gain in operator comfort with this function, the slight increase in overall cost may be well worth it.

Finally, ask the vendor or manufacturer for references to contact and possibly visit. This can give you the opportunity to see the unit in action and talk to the staff on the frontline regarding product likes and dislikes. Oftentimes staff insight is more valuable than any marketing brochure or pharmacy director's account. If possible, involve your lead or senior technician in this part of the decision process. Technician involvement can provide valuable insight into the best method of making a new unit operational in your pharmacy.

Implementation Considerations

Once the initial selection process is complete, you need to plan for staff training and workflow shifts necessary to accommodate the new technology, especially if you have experienced staff who are accustomed to BSCs or laminar airflow workbenches. Although this may sound like a daunting task, appointing a technician as the champion of the process will simplify matters. Cancer Treatment Centers of America established compounding with CAIs as the standard for all CSP production and still met the demands placed upon us. Robust training and a solid workflow, however, are necessary to accomplish this. Thirty days is a good benchmark for acceptance of and proficiency with the new equipment. Since the actual aseptic compounding technique does not change, it is more a matter of acclimating to the feel of the gloves and the restrictions associated with being in sleeves.

Adjusting to the CAI's gloves is one of the most significant challenges during isolator implementation. Initially, staff will likely feel awkward and complain about the lack of tactile sensation with the gloves. Experimenting with different types and sizes of gloves can minimize this experience. If you have a dual-operator unit, installing two different sized gloves can be beneficial. This way flexibility is increased and physical differences among staff can be accommodated.

Also, it is a misconception that sterile glove changes occur less frequently with CAIs. CAI gloves must be maintained and changed regularly. In fact, they need to be changed just as often as you would with BSCs. While there is a system on the market that provides assistance with changing the non-sterile glove—Germfree Rapid Exchange Glove System—at this point, there is no such system to assist with the sterile glove changes as required by USP <797>. Currently, sterile gloves must be applied over the attached non-sterile CAI gloves. This is a challenging, but necessary task.

In CAI training and in the SOPs, location of clean or first air within the unit should be stressed. Since these devices are unidirectional (top to bottom), positioning of product in the unit is important as is hand position and aseptic technique. The use of smoke tubes can be helpful in illustrating this change in airflow, creating a strong visual effect for training staff. Smoke in the hood creates a visual of the airflow patterns that are created. This allows the trainer to clearly show a technician how his/her process affects airflow around a CSP, thereby increasing the adoption of proper sterile aseptic technique.

At Cancer Treatment Centers of America, we take an extra step and use a vial transfer device within the CAI. This process does increase the cost per dosage, and slightly increases the time to prepare each dose, but we feel the improvement in staff safety justifies this added cost.

Cleaning and Maintenance

Hood cleaning and maintenance procedures for CAIs are similar to those used with other hooded products; the cleaning process should be top to bottom and back to front. The protocol for cleaning and disinfecting agents remains the same as well. Cleaning the inside front glass may pose a slight challenge based

on the glove configuration/location, but there are quite a few devices on the market that facilitate this process. For example, ITW Texwipe makes a product called the Mini AlphaMop System and IsoTech Design has the Telescopic Mop 70-E004.

Anytime the CAI is opened, adequate time must pass after closing the unit before resuming compounding activities. The amount of time necessary is contingent on the unit type and should be easily attained from the unit manufacturer, but a generally accepted timeframe is two complete airflow cycles. This will allow the air to be scrubbed of any particles that may have been introduced when the unit was opened, returning the CAI to ISO Class 5. When cleaning a CACI in which hazardous products are compounded, the use of a respirator is recommended, as the chance of vapor release exists even with a vented unit.

With regards to maintenance, the USP <797> standards apply. Units must be routinely cleaned and maintained, including pre-filters, if applicable. It is a good idea to have your hood certification company change these for you as part of regularly scheduled visits by the company. It is also important that the certification company you use is familiar with and capable of certifying your type of CAI in dynamic conditions. This may be as simple as asking if they have such experience, checking references, or putting them in touch with the manufacturer and/or providing the technical specifications that came with your unit. Also, it is a good idea to oversee the initial inspection/certification to ensure all proper steps and measurements are being performed.

Conclusion

CAIs can be a valuable tool in the safe and efficient preparation of CSPs. Dedicating the time and energy to review purchasing considerations will help you decide if a CAI is right for your pharmacy as well as ensure you are choosing a unit that best fits your pharmacy's needs. ■



Joseph W. Coyne, RPh, is the director of pharmacy at Cancer Treatment Centers of America at Eastern Regional Medical Center in Philadelphia, Pennsylvania. Joe obtained his BS in pharmacy from the Philadelphia College of Pharmacy and Science where he is currently an adjunct senior clinical professor with the department of pharmacy practice. He serves as a co-diplomat to Temple University's School of Pharmacy for the Academy of Managed Care Pharmacy, and is a member of ASHP, HOPA, and ISOPP.



**WHERE TO FIND:
Compounding Aseptic
Isolators/Compounding Aseptic
Containment Isolators**

www.findit.pppmag.com

Vendor	Reader Service Number
Comecer	111
GERMFREE	112
Gallipot	113
IsoTech Design USA	114
Innovative Technology, Inc	115
Labconco Corporation	116
NuAire, Inc	117
Terra Universal	118
The Baker Company	119