Installation Process for PECs and C-PECs

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Primary engineering controls (PECs) and containment primary engineering controls (C-PECs) are integral to the containment strategy within pharmacy compounding operations. PECs—devices or zones that provide an ISO Class 5 environment for sterile, nonhazardous compounding—use unidirectional airflow to bolster safety and reliability in the compounding area in support of sterility.[1] C-PECs, designed for HD compounding, use unidirectional airflow along with exhaust ventilation or double HEPA filtration to minimize or eliminate drug exposure and support sterility. The installation of new PECs or C-PECs warrants thoughtful preparation, as this equipment requires ample space, engineering assistance, and thorough cleaning prior to use.

Select the Right Engineering Control

The first step is to select controls that fit the pharmacy's current and/or projected operations. The type of compounding being conducted will determine which of the following levels of protection are required:

1. Personnel protection
2. Environmental protection
3. Product protection

Nonsterile Compounding

For nonsterile compounding, personnel and environmental protection are the two key functions of the C-PEC. Nonsterile compounding typically involves manipulation, mixing, and preparation of powder and liquid ingredients, which have a higher likelihood of occupational exposure to the operator.

In the nonsterile environment, the most commonly utilized devices are negative-pressure containment devices, also called containment ventilated enclosures (CVEs) or powder

FIGURE 1

Engineering Control Options

Your facility's compounding needs will inform the choice of engineering control.

containment hoods. These C-PECs pull unclassified room air through the face opening, across the CVE's interior work surface, and out a rear baffle or plenum system, to be finally exhausted through a single HEPA filter (see **Figure 1A**) or redundant HEPA filter (see **Figure 1B**). While CVEs are used for nonsterile compounding of both hazardous and nonhazardous drugs, these activities cannot occur in the same CVE. Although not explicitly stated in USP <800>, facilities that conduct hazardous and nonhazardous nonsterile compounding should physically separate hazardous drug (HD) compounding per Table 2 requirements.[2]

Nonhazardous Sterile Compounding

For compounding sterile nonhazardous drugs, product protection is the main purpose of the PEC. These PECs utilize internal HEPA filters that provide ISO Class 5 clean air across the work surface. Horizontal or vertical laminar airflow workbenches (LAFWs) (see **Figure 1C**) or containment aseptic isolators (CAIs) (see **Figure 1D**) are commonly used as nonhazardous drug compounding PECs.

Hazardous Drug Sterile Compounding

For sterile HDs, all three functions (product, personnel, and environmental protection) are equally key. A biological safety cabinet (BSC) (see **Figure 1E**) or compounding aseptic containment isolator (CACI) (see **Figure 1F**) are the two C-PEC options for sterile HDs such as chemotherapy, as these present a high risk for personnel and environmental exposure.

Exhaust and Ductwork

Given the air handling considerations, installing C-PECs along with additional mechanical equipment during a remodeling effort can be challenging, especially for facilities that have never implemented exhaust configurations. Any pharmacy located on the ground floor will discover that engineer involvement is key, as air handling equipment requires a higher level of technical planning than the average facility's maintenance group may be able to provide.

Ductwork must run from the C-PEC up to the roof, the mapping of which requires the engineer to strategically and mathematically plan the size and scope of the ductwork while also considering the exhaust blower's horsepower and static pressure. Note that implementing a C-PEC, such as a BSC, may require new mechanical equipment on the roof, and therefore a local building permit must be obtained. Proper permits require a set of professionally stamped drawings prepared by an architect or engineer. This step will incur additional costs, so this must be factored into both the budget and the schedule when implementing a C-PEC for hazardous compounding.

Delivery and Installation Considerations

After determining which type of engineering control will best serve the facility's compounding needs, it is wise

to "walk the path" of delivery prior to ordering the equipment. Most PECs or C-PECs will fit through a standard 36" wide door, but some may require larger openings and/or turn clearances. Request the manufacturer's product specification sheet that details the dimensions, and use this as a guide as you walk the path from the loading dock to the installation area.

The pharmacy should also share the equipment specifications with the project design team to avoid the problem illustrated in **FIGURE 2**. This is a real example wherein the pharmacy team did not coordinate with the architect or the modular wall vendor, and the result was a 6' wide BSC that was too large to make the turn through the airlock to the hazardous buffer room. This unfortunate situation could have been avoided with better communication.

Delivery Options

Once the order for the equipment is placed, it is time to plan for the delivery. Moving these devices is not an easy process as a CVE for nonsterile compounding weighs anywhere between 250 to 650 pounds, while a BSC can weigh upwards of 850 pounds. This equipment is typically shipped via tractor trailer directly to the facility, so a plan for unloading must be established. Some trailers offer a lift gate, which lowers the equipment from the truck; it is important to specify this option at the time of order, because it may carry an extra charge. Without a lift gate, a forklift or other equipment picker will be necessary for unloading.

For facilities unable to manage the unloading process, a white glove delivery service may be hired to take possession of the PEC or C-PEC from the manufacturer on the facility's behalf and store it. These service providers are essentially furniture movers who also handle medical equipment. They will schedule a time for delivery, provide the staffing to move the equipment, complete a basic setup of the equipment (eg, assemble the base stands), and remove the dunnage (eg, cardboard and packaging materials). The manufacturer may have existing relationships with such vendors.

If the new PEC or C-PEC is being implemented as part of a larger remodeling project, utilizing a service that can house this valuable equipment offsite may be advantageous. Storing a PEC or C-PEC on an active construction site can be challenging, as construction schedules are subject to change without notice, often resulting in delays.

Engineering Requirements

Most PECs and C-PECs are configured to pull air from the compounding room, and then clear that air via air foils, grilles, barriers, supply and/or exhaust HEPAs, or exhaust the air externally (eg, C-PECs). In addition to sharing the engineering requirements for each PEC or C-PEC with the project design team, it is important to detail how the PEC or C-PEC influences the air handling of the compounding room.

Nonsterile PECs

For nonsterile compounding of nonhazardous drugs, both the single HEPA and redundant HEPA CVE can safely recirculate exhausted air back into their respective rooms. Recirculation of CVE air is considered room neutral

SIDEBAR

The Right C-PEC for the Job

It is important to understand the distinctions between C-PECs as not all options are appropriate for nonsterile compounding. USP chapter <800> *Table 2. Engineering Controls for Nonsterile HD Compounding* lists Class II BSC cabinets as an acceptable example of a C-PEC for nonsterile compounding.[2] However, given that a BSC has a downflow of HEPA filtered air (for ISO Class 5 conditions), this can create turbulence inside the C-PEC with the potential for analytical balance instability and difficulty in accurately weighing powders. As such, consider utilizing a redundantly filtered CVE for nonsterile HD compounding as these low-flow containment devices are designed specifically for powder handling.

FIGURE 2

Plan for Installation and Placement

Walk the path of installation prior to receiving new equipment to avoid scenarios such as this one, where the BSC did not fit into the buffer room.

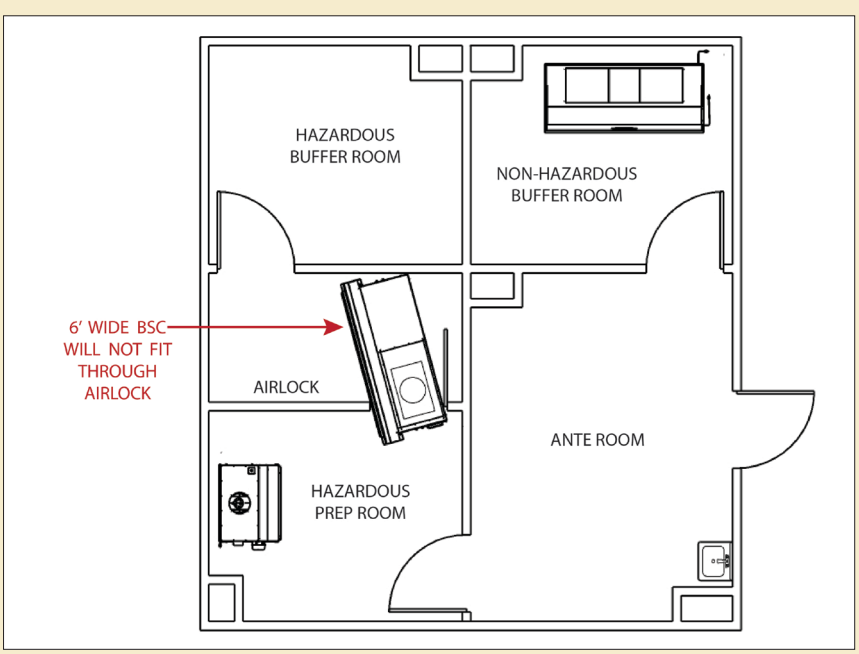
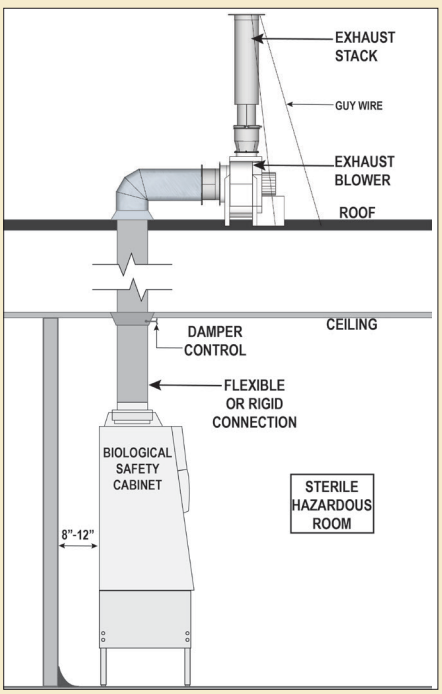


FIGURE 3

External Exhaust

For sterile HD compounding, the C-PEC must be externally exhausted.



and does not influence air changes per hour (ACPH) or room pressurizations. As such, the project team simply has to account for the appropriate electrical requirements for the PECs, which typically contain energy efficient motors pulling less than 5 amps of electrical power.

Nonsterile HD C-PECs

C-PECs used for nonsterile HD compounding can incorporate either a single or double (redundant) HEPA filter. C-PECs equipped with a single HEPA filter must be externally vented using the manufacturer's thimble or canopy connection. If the C-PEC is equipped with two HEPA filters, then according to *Table 2. Engineering Controls for Nonsterile HD Compounding,* air can safely recirculate back into the HD compounding room.[2]

Although there are no special installation requirements for CVEs that recirculate back into the nonsterile compounding rooms, it is advised to confirm this approach with your state board of pharmacy. Certain states may require that a CVE in a nonsterile HD room be externally vented, which is one of the subjective implications of USP <800> Table 2. It is important to review the state board's position on redundant HEPA CVEs during the design phase, as connecting CVEs to exhaust systems after ordering or installing the mechanical equipment may significantly complicate the HVAC design. Note that CVEs that recirculate air are room neutral; however, with CVEs that are externally exhausted, the impact on the room's airflow dynamics must be considered as discussed in the Sterile Hazardous C-PECs section below.

Sterile Nonhazardous PECs

Much like the nonsterile, room neutral CVEs, the PECs used in the sterile nonhazardous rooms should also be considered room neutral in terms of measuring room pressurization. The LAFW and CAI pull room air in from the top or bottom of the unit and push that air through a HEPA filter and then over the work surface. Because the amount of air pulled in by these PECs equals the amount of air pushed back into the room, the only installation requirements are electrical.

Sterile Hazardous C-PECs

For pharmacies compounding sterile HDs, the C-PECs directly influence the engineering requirements of the compounding room and the building. The BSC and CACI must be externally exhausted out of the building, which requires ductwork routed to the roof to an exhaust blower (see **FIGURE 3**). The BSC has an internal blower but does not have ample leverage to push the air out of the building without the assistance of another external blower to pull the differential.

Exhausted air must be replaced with new air introduced into the building. Because the BSC in a sterile cleanroom contributes to the ACPH and negative pressure of the room, it is never powered off. A typical BSC will continually exhaust around 400 to 500 cubic feet per minute (CFM) of air 24 hours a day, and if that exhausted air is not balanced with intake air, then eventually the cleanroom and quite possibly the entire pharmacy will see negative air handling challenges.

Cleaning Prior to Installation

Because the PECs or C-PECs will consume most of the floor space in the cleanroom, it is important to clean and remove bulk dust prior to move-in. Construction dust is not always visible to the naked eye, and because the air handling system is typically turned on before the end of construction, this dust will have been introduced. Following installation, cleanroom staff should engage in a deep clean in preparation for the certification process. This includes environmental sampling and an aerosol challenge of all HEPA filters, both in the ceiling and within the PECs or C-PECs.

Conclusion

Just as PECs and C-PECs contribute invaluable safety to the compounding processes in the pharmacy, safety must also be incorporated throughout the planning phases for new engineering control implementations. Product selection, delivery planning, engineering requirements, and initial cleaning comprise a deliberate process that can reduce risk and ultimately help ensure a smooth installation.

References

1. United States Pharmacopeial Convention. USP General Chapter <797> Pharmaceutical Compounding—Sterile Preparations. www.usp.org/compounding/general-chapter-797. Accessed March 21, 2023.
2. United States Pharmacopeial Convention. USP General Chapter <800> Hazardous Drugs—Handling in Healthcare Settings. www.usp.org/compounding/general-chapter-hazardous-drugs-handling-healthcare. Accessed February 17, 2023.