



## **PCAB Guidance to Pharmacies Regarding Hazardous and Potent Substances and Primary Engineering Controls**

This document is designed to provide guidance to pharmacies regarding PCAB requirements for powder and fume containment devices in pharmacies that handle hazardous or potent drugs. Every pharmacy practice is unique and site-specific considerations should be addressed when implementing the suggestions outlined in this guidance document. Please email [CONTACT@PCAB.ORG](mailto:CONTACT@PCAB.ORG) with any questions and recommended improvements to this guidance document.

### **Introduction**

PCAB requirements for protective equipment and procedures for non-sterile compounding are primarily addressed in standard 3.00, Facilities and Equipment.

Standard 3.10 states, “A. The pharmacy demonstrates that the size, type, and quality of facilities and equipment in the pharmacy is adequate to safely and accurately compound preparations in the amount and type relative to the nature of compounding that is performed in the pharmacy. This should include procedures for the control and containment of powders during compounding.”

“C. If the pharmacy handles hazardous materials, it demonstrates that its SOPs are adequate to protect personnel based on volume and scope of compounding performed.”

Standard 3.30 states,

“A. The pharmacy has an area for aseptic compounding of sterile preparations that meets current USP <797> standards.”

“C. The pharmacy demonstrates that it maintains facilities and procedures adequate to avoid cross contamination and contamination by dust and other particulates in the compounding area.”

For sterile compounding, PCAB requires compliance with USP <797> standards that address compounding with hazardous materials. Compliance Indicator F states “If the pharmacy practices aseptic sterile compounding, it has an appropriate area for compounding of aseptic preparations that meets or exceeds USP <797>.”

In order to meet the requirements of the above standards, PCAB requires pharmacies that handle hazardous substances to have appropriate primary engineering controls (Biological Safety Cabinets-BSCs) designed to protect the operator from exposure to the hazardous substance. This requirement is consistent with NIOSH and OSHA standards and recommendations.

### **Non-Sterile Compounding**

For non-sterile compounding, a Class I BSC, a device designed to protect personnel and the environment from hazardous and potent drugs is required. Class I BSCs are available in various sizes and configurations from a variety of vendors. These devices are sometimes called vented balance safety enclosures or powder hoods.

In order to meet PCAB, NIOSH, and OSHA requirements weighing and compounding of hazardous and potent drugs must occur in a type I BSC. Optimally, Class I BSCs should be vented to the outside. However, devices that are designed to recirculate room air are acceptable.

Regardless of whether a pharmacy purchases a class I BSC or designs and constructs a device in-house, PCAB surveyors will ask for documentation that device meets standards for operator protection.

In addition, there are testing protocols for Class I BSCs that include air flow and filter leakage tests. Devices should be tested upon installation and annually to assure they are working correctly.

### **Sterile Compounding**

Sterile portions of the sterile compounding process such as weighing must, at a minimum, be performed in equipment meeting the requirements above for non-sterile compounding. The equipment must be situated in an environment meeting USP 797 standards.

Sterile compounding with hazardous or potent drugs must occur in a Class II BSC or compounding aseptic containment isolator (CACI), devices designed to protect personnel and the environment from the hazardous material, and the product from bacterial or particulate contamination.

For pharmacies that compound a significant amount of hazardous substances, the class II BSC must be located in a minimum ISO Class 7 environment that is physically separate from other preparation areas. This environment should have negative pressure relative to the outside environment of not less than 0.01 inches of water.

A CACI must be located in an ISO Class 7 or 8 environment that is physically separate from other preparation areas. This environment should have negative pressure relative to the outside environment of not less than 0.01 inches

In cases where the pharmacy only prepares a small volume of hazardous drugs, the use of two tiers of containment, for example, a Class II BSC or CACI and the use of closed system transfer devices is acceptable.

ISO environments must be tested every 6 months as required by USP <797>. Protective equipment such as Class I BSCs must be tested upon installation and annually to assure they protect operators as intended.

### **Storage**

Hazardous drugs should be stored separately from other inventory, preferably within a negative pressure room.

### **Frequently Asked Questions**

***Our pharmacy rarely works with hazardous substances; do we need primary engineering controls?***

Yes.

***Our pharmacy provides our staff with masks, respirators and other personal protective equipment to work with hazardous drugs, is this Ok?***

Yes...but PCAB, NIOSH and OSHA all recognize that personal protective equipment is not a substitute for primary engineering controls. PPE is an adjunct to primary engineering controls, and should be available in case of spills or accidents. PCAB will not accept personal protective equipment as a substitute for primary engineering controls.

***Our pharmacy designed its own primary engineering control, is this acceptable?***

Yes, provided that the device has passed appropriate testing by a qualified outside testing service.

***Our pharmacy performs serum/saliva/air or other types of testing for hazardous substances and has never had a problem. Are we exempt from the requirements for primary engineering controls?***

No. PCAB, OSHA and NIOSH require primary engineering controls regardless of any other precautions.

### **Additional Information/Resources**

IACP Hazard Alert: Compounding with Hazardous or Potent Pharmaceuticals.  
[www.iacprx.org](http://www.iacprx.org).

NIOSH: Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Health Care Settings. [www.cdc.gov/niosh/docs/2004-165/](http://www.cdc.gov/niosh/docs/2004-165/)

OSHA: Controlling Occupational Exposure to Hazardous Drugs.  
[www.osha.gov/dts/osta/otm/otm\\_vi/otm\\_vi\\_2.html](http://www.osha.gov/dts/osta/otm/otm_vi/otm_vi_2.html)