

CETA Flowchart of Engineering Control Requirements for Hazardous Drugs

USP <797> June 2008

Drug Hazard	Compounding Volume	Risk Category	Primary Engineering Control (PEC) <i>PEC shall have unidirectional airflow (an airflow moving in a single direction in a robust and uniform manner and at sufficient speed to reproducibly sweep particles away from the critical processing or testing area)</i>	Secondary Control	Room Air Change Requirement	Room Pressure Differential	Anteroom Secondary Control
Hazardous*	Greater Than Low Volume	Low, Medium, or High Risk	CACI or BSC. CACI must maintain ISO Class 5 during dynamic operating conditions within the main chamber and during transfers. CACI and BSC optimally should be vented 100% to outside building where feasible.**	Cleanroom that has HEPA filtered supply airflow introduced at the ceiling, and that meets ISO Class 7 while in operation.	≥30 room ACPH or ≥15 room ACPH with Primary Control providing 15 ACPH	Optimally, no less than 0.01 inches water column negative in relation to adjacent ISO Class 7 areas. Pressure indicating device must be installed and monitored.	ISO Class 7 cleanroom with positive pressure to adjacent areas including the preparation room. Preparation room should be <u>negative</u> in relation to the anteroom. HEPA filtered supply air with adequate ACPH required.
			CACI must maintain ISO Class 5 during dynamic operating conditions within the main chamber and during transfers. CACI optimally should be vented 100% to outside building where feasible.**	Separate room	≥12 room ACPH	Minimum negative pressure of 0.01 inches water column to adjacent areas.	None
	Low Volume	Low, Medium, or High Risk	CACI or BSC. CACI must maintain ISO Class 5 during dynamic operating conditions within the main chamber and during transfers. The CACI or BSC optimally should be vented 100% to outside building where feasible.** Two-tiered containment must be employed; CACI or BSC combined with CSTD.	Separate room	≥12 room ACPH	No negative pressure requirement if two tiers of containment (BSC and CSTD, or CACI and CSTD) are used.	None
	All	Storage	NA	HD's must be stored separately from other inventory in a manner to prevent contamination and personnel exposure.	The storage areas should have sufficient general exhaust ventilation and ≥12 room ACPH	Preferably within a negative pressure room.	NA

Hazardous Drug Preparation

* Hazardous drugs shall only be prepared under conditions that protect the healthcare workers and other personnel. *All hazardous drugs shall be prepared in a BSC or a CACI that meets or exceeds the standards for CACI in USP Chapter 797.*

** The use of 100% building exhaust is recommended where the hazardous drugs volatilize.

Abbreviations:

ACPH = Air Changes Per Hour
 BSC = Biological Safety Cabinet
 BUD = Beyond-Use Date
 CAI = Compounding Aseptic Isolator
 CACI = Compounding Aseptic Containment Isolator

CSTD = Closed System Transfer Devices
 FPM = Feet per Minute
 ISO = International Standards Organization
 LAFW = Laminar Air Flow Workbench
 PEC = Primary Engineering Control

Isolators:

- Compounding Aseptic Isolators (CAI) and Compounding Aseptic Containment Isolators (CACI) are definitions of isolators established by the Controlled Environment Testing Association (CETA) in guidance documents CAG-001:2005 and CAG-002:2006 as meeting certain design and performance attributes.
- The United States Pharmacopeia established specific operational performance tests that must be carried out on isolators used for sterile drug compounding, to determine whether the isolator may be located outside the cleanroom (buffer room), or whether the isolator can be used for hazardous drug compounding.