

CETA Flowchart of Engineering Control Requirements for Non-Hazardous Drugs

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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	
Non-Hazardous	All	Low or Medium Risk	LAFW, BSC, or zone which meets ISO Class 5 while in operation. CAI/CACI	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 recirculating Primary Engineering Control (PEC) providing >15 ACPH	0.02 to 0.05 inches water column positive from buffer room to pharmacy areas. If line of demarcation is used, displacement airflow at a rate of at least 40 FPM from clean to less clean space.	ISO Class 8 cleanroom with positive pressure to adjacent areas except to the preparation room. Preparation room should be <u>positive</u> in relation to the anteroom. HEPA filtered supply air with adequate ACPH required.	
			CAI / CACI that maintain ISO 5 particle levels during dynamic operating conditions within the main chamber, and during transfers in and out of the main chamber	None	None	None	None	
		Low Risk with ≤12 hour BUD (or less based upon drug manufacturer requirements) before commencing administration to patient.	If CAI or CACI does not maintain ISO Class 5 during dynamic operating conditions and / or during transfers, it must be located within the ISO Class 7 cleanroom. If located outside the ISO Class 7 cleanroom, the preparation is limited to ≤ 12 hour BUD or less per drug manufacturer requirements. If LAFW or BSC must be located outside the ISO Class 7 cleanroom, the preparation is limited to < 12 hour BUD or less per drug manufacturer requirements.	Segregated compounding area restricted to sterile compounding activities. It may not have unsealed windows or doors that connect to the outdoors, or high traffic flow, or be adjacent to construction sites, warehouses, or food preparation areas. Sinks may not be located adjacent to the PEC.	None	None	None	None
		High Risk	LAFW, CAI, CACI, BSC, or zone which meets ISO 5 while in operation.	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 recirculating Primary Engineering Control (PEC) providing >15 ACPH	0.02 to 0.05 inches water column positive from buffer room to pharmacy areas. No line of demarcation is permitted.	ISO Class 8 cleanroom with positive pressure to adjacent areas except to the preparation room. Preparation room should be positive in relation to the anteroom. HEPA filtered supply air with adequate ACPH required.	
			CAI / CACI that maintain ISO Class 5 during dynamic operating conditions with-in the main chamber, and during transfers in and out of the main chamber.	None	None	None	None	

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.