CSI Testing, Inc.
Flowchart of USP 797 Engineering Controls Proposed Changes

Drug Hazard Level	Compounding Volume	Risk Level or Function	Primary Engineering Control	Secondary Control	Room Air Change Requirement	Pressure Differential	Anteroom Secondary Control
Non-Hazardous	All	Low or Medium Risk	LAFW, CAI, BSC, or zone which meets ISO 5 while in operation.	Cleanroom that has HEPA filtered supply airflow and meets ISO 7 in operation.	≥30 room ACPH or ≥15 room ACPH with recirculating Primary Control providing >15 ACPH	0.02 to 0.05 inches water column positive to adjacent 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 positive in relation to the anteroom.
			CAI that conforms to USP requirements such as maintaining ISO 5 during operation and transfer.	None	None	None	None
		High Risk	LAFW, CAI, BSC, or zone which meets ISO 5 while in operation.	Cleanroom that has HEPA filtered supply airflow and meets ISO 7 in operation.	≥30 room ACPH or ≥15 room ACPH with recirculating Primary Control providing 15 ACPH	0.02 to 0.05 inches water column positive to adjacent areas including preparation room to anteroom. 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.
			CAI that conforms to USP requirements such as maintaining ISO 5 during operation and transfer.	None	None	None	None
Hazardous*	≥ 5 per week	Low, Medium, or High Risk	CACI or BSC vented 100% to outside building where feasible. Hazardous drugs shall only be prepared under conditions that protect the healthcare workers and other personnel.	Cleanroom that has HEPA filtered supply airflow and meets ISO 7 in operation.	≥30 room ACPH or ≥15 room ACPH with Primary Control providing 15 ACPH	No less than 0.01 inches water column negative to adjacent 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 negative in relation to the anteroom.
			CACI that conforms to USP requirements such as maintaining ISO 5 during operation and transfer.	Separate room	≥12 room ACPH	No less than 0.01 inches water column negative to adjacent areas. Pressure indicating device must be installed and monitored.	None.
	< 5 per week	Low, Medium, or High Risk	CACI or BSC vented 100% to outside building where feasible. Two-tiered containment must be employed such as CACI or BSC combined with CSTD. CACI must be located in a cleanroom unless it conforms to USP requirements such as maintaining ISO 5 during operation and transfer.	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	Not Applicable	HD's must be stored in a room separate from non-hazardous drug storage and shall have sufficient general exhaust to outside of building. This storage may be in the HD compounding room.	≥12 room ACPH	No less than 0.01 inches water column negative to adjacent areas.	None

*** Note: Hazardous drugs shall only be prepared under conditions that protect the healthcare workers and other personnel.**

Abbreviations:
ACPH = Air Changes Per Hour
BSC = Biological Safety Cabinet
CAI = Compounding Aseptic Isolator
CACI = Compounding Aseptic Containment Isolator
CSTD = Closed System Vial Transfer Devices
FPM = Feet per Minute
ISO = International Standards Organization
LAFW = Laminar Air Flow Workbench

Comments:
Compounding Aseptic Isolators (CAI) and Compounding Aseptic Containment Isolators (CACI) are barrier isolators that conform to the Controlled Environment Testing Association guidance documents CAG-001:2005 and CAG-002:2006 as meeting certain design and performance attributes. USP has determined that specific design and performance attributes must be met to establish whether an isolator is used for sterile compounding and whether it may be used outside a cleanroom and / or used for hazardous drug compounding. These and other performance tests are described within CAG-002:2006.