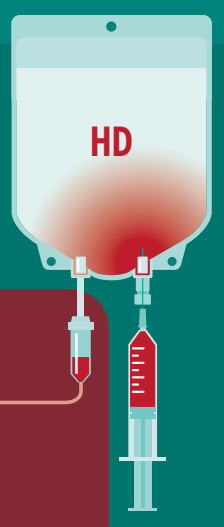
FLOW CHART FOR **USP 797** AND **USP 800** PEC REQUIREMENTS



NON-HAZARDOUS DRUG PREPARATION

STERILE

CATEGORY 1
Beyond Use Date (BUD)
BUD ≤ 12 hrs
≤24 Hrs if Refrigerated

CATEGORY 2
Beyond Use Date (BUD)
BUD > 12 hrs
>24 Hrs if Refrigerated

SECONDARY ENGINEERING CONTROL (SEC) CONFIGURATION

SEGREGATED COMPOUNDING AREA
UNCLASSIFIED
NO AIR CHANGES NEEDED

ISO CLASS 7 CLEAN ROOM
30 AIR CHANGES / HOUR
POS. PRESSURE ≥ 0.02" WC

PRIMARY ENGINEERING CONTROL (PEC) REQUIREMENTS

Vertical Airflow

Horizontal Airflow
Style: Bench Top

Horizontal Airflow
Style: Console

LAMINAR AIRFLOW WORKSTATION (LAFW)

— OR —

Type A2
70% Recirculated / 30 % Exhausted
No Requirement to Externally Vent

CLASS II BIOSAFETY CABINET (BSC)

— OR —

Compounding Aseptic Isolator (CAI)
Positive Pressure Recirculating

RESTRICTED ACCESS BARRIER SYSTEM (RABS) OR ISOLATOR

HAZARDOUS DRUG PREPARATION

STERILE

CATEGORY 1
Beyond Use Date (BUD)
BUD ≤ 12 hrs
≤24 Hrs if Refrigerated

CATEGORY 2
Beyond Use Date (BUD)
BUD > 12 hrs
>24 Hrs if Refrigerated

CONTAINMENT SECONDARY ENGINEERING CONTROL (C-SEC) CONFIGURATION

CONTAINMENT SEGREGATED COMPOUNDING AREA
12 AIR CHANGES / HOUR
NEG. PRESSURE 0.01" - 0.03" WC

ISO CLASS 7 CLEAN ROOM
30 AIR CHANGES / HOUR
NEG. PRESSURE 0.01" - 0.03" WC

NON-STERILE

CONTAINMENT SECONDARY ENGINEERING CONTROL (C-SEC) CONFIGURATION

CONTAINMENT SEGREGATED COMPOUNDING AREA
12 AIR CHANGES / HOUR
NEG. PRESSURE 0.01" - 0.03" WC

CONTAINMENT PRIMARY ENGINEERING CONTROL (C-PEC) REQUIREMENTS

Type B1
30% Recirculated / 70% Exhausted
Hard Connection
External Vent

Type B2
0% Recirculated / 100% Exhaust
Hard Connection
External Vent

Type A2
70% Recirculated / 30 % Exhausted
Canopy Connected
External Vent

CLASS II BIOSAFETY CABINET (BSC)

— OR —

Compounding Aseptic Containment Isolator (CACI)
Negative Pressure Recirculating
Canopy Connected External Vent

Compounding Aseptic Containment Isolator (CACI)
Negative Pressure Total Exhaust
Hard Connection External Vent

RESTRICTED ACCESS BARRIER SYSTEM (RABS) OR ISOLATOR

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CONTAINMENT PRIMARY ENGINEERING CONTROL (C-PEC) REQUIREMENTS

Canopy Connected Exhaust

Exhaust into Room through Redundant HEPA Filters

CLASS I CONTAINMENT VENTILATED ENCLOSURE (CVE)
EXTERNALLY VENTED OR REDUNDANT HEPA FILTER EXHAUST INTO ROOM

— OR —

Type B1
30% Recirculated / 70% Exhausted
Hard Connection
External Vent

Type B2
0% Recirculated / 100% Exhaust
Hard Connection
External Vent

Type A2
70% Recirculated / 30 % Exhausted
Canopy Connected
External Vent

CLASS II BIOSAFETY CABINET (BSC)
EXTERNALLY VENTED

— OR —

Compounding Aseptic Containment Isolator (CACI)
Negative Pressure Recirculating
Canopy Connected External Vent

Compounding Aseptic Containment Isolator (CACI)
Negative Pressure Total Exhaust
Hard Connection External Vent

RESTRICTED ACCESS BARRIER SYSTEM (RABS) OR ISOLATOR

Glossary

ACPH	-	Air Changes per Hour
BUD	-	Beyond Use Date
BSC	-	Biosafety Cabinet
CACI	-	Compounding Aseptic Containment Isolator
CAI	-	Compounding Aseptic Isolator
C-PEC	-	Containment Primary Engineering Control
C-SCA	-	Containment Segregated Compounding Area
C-SEC	-	Containment Secondary Engineering Control
CSP	-	Compounded Sterile Preparation
CVE	-	Containment Ventilated Enclosure
LAFW	-	Laminar Airflow Workstation
PEC	-	Primary Engineering Control
RABS	-	Restricted Access Barrier System
SCA	-	Segregated Compounding Area
SEC	-	Secondary Engineering Control

Sources

USP General Chapter <800>
Hazardous Drugs– Handling in Healthcare Settings. (2017).
The United States Pharmacopeial Convention.

General Chapter <797>
Pharmaceutical Compounding – Sterile Compounding. (n.d.).
The United States Pharmacopeial Convention.

ISOLATOR VS. RESTRICTED ACCESS BARRIER SYSTEM (RABS)

ISOLATOR

Provides isolation from the surrounding area and maintains ISO Class 5 air quality during typical operating conditions.

The following standards must be met to qualify as an isolator:

- High-integrity transfer ports are used to move supplies, Ingredients, components, and devices into and out of the isolator.
- The isolator is decontaminated using a generator that distributes a sporicidal chemical agent throughout the isolator chamber.
- The isolator maintains constant overpressure of at least 0.05-inch water column.
- The manufacturer has provided documentation that the isolator will continuously meet ISO Class 5 conditions, including during material transfer.
- A CAI or CACI is not an isolator.

RESTRICTED ACCESS BARRIER SYSTEM (RABS)

Glove ports are used to provide physical separation between the surrounding area and the aseptic manipulations. If used to prepare Category 2 CSPs, the area surrounding the RABS must meet ISO Class 7 or better air quality.

All transport ports on the RABS must be closed during compounding. When a RABS is used, the recovery time after opening to achieve ISO Class 5 air quality must be documented, and internal procedures must be developed to ensure that adequate recovery time is allowed after opening and closing the RABS, both before and during compounding operations.

TYPES OF RABS

COMPOUNDING ASEPTIC ISOLATOR (CAI)

A CAI is designed for compounding non-HD CSPs. It is designed to maintain an ISO Class 5 environment throughout the compounding and material transfer processes. Air exchange into the CAI from the surrounding environment must not occur unless the air has first passed through a HEPA filter.

COMPOUNDING ASEPTIC CONTAINMENT ISOLATOR (CACI)

A CACI is designed to provide worker protection from exposure to undesirable levels of airborne drug throughout the compounding and material transfer processes, and to maintain an ISO Class 5 environment for compounding sterile HD preparations. Air exchange with the surrounding environment must not occur unless it is first passed through a HEPA filter capable of containing airborne concentrations of the physical size and state of the drug being compounded.

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