Pharmacies: USP <800> Compliance and Hazardous Drugs

Understanding and Planning

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ARRAY architects

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Course Description & Learning Objectives

USP <800> is the current buzzword in clinical pharmacies.

But what exactly does it all mean?

- Learn about the new USP <800> requirements, as they related to facilities, design and construction.
- Learn the specifics on hazardous storage.
- Understand how this impacts pharmacy departments' spaces and air flows.
- Implement proper design of these spaces to meet the requirements.

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Who Regulates Pharmacies?

Pharmacies are complex areas that are highly regulated.

Here are a few:

- United States Pharmacopeia (USP)
  An official public standards-setting authority for all prescription and OTC medications and other health care products manufactured or sold in the United States.
- State Boards Of Pharmacy (BOP)
  Regulatory state agency that oversees the practice of pharmacy in a given state. Clearly defines regulations affecting pharmacy and their roles, duties, and expectations of pharmacists and pharmacy technicians in that state. Has the ability to discipline pharmacies, pharmacists, and possibly pharmacy technicians for improper behavior. ***STATE REQUIREMENTS CAN VARY.***
- Drug Enforcement Agency (DEA)
  Enforces compliance with the Controlled Substances Act. This includes placing medications into the appropriate schedule.
- Food & Drug Administration (FDA)
  Ensures that all pharmaceutical products are pure, safe, and effective. Reviews information supplied on MedWatch forms. Can issue drug recalls if product is adulterated or misbranded. Regulates the distribution of patient package inserts and the repackaging of medications. Reviews new drug applications and investigational new drug applications.
- The Joint Commission
  Formerly known as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), addresses the quality of patient care and patient safety.

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Compliance & Codes

USP <795>	USP <797>	USP <800>
Pharmaceutical Compounding – Non-Sterile Preparations	**Pharmaceutical Compounding – Sterile Preparations**	**Pharmaceutical Storage & Compounding – Hazardous Preparations**
Includes production of solutions, suspensions, ointments & creams, powders, suppositories, capsules & tablets.	Medication intended for injection, infusion or application to eye.	Applies to ALL staff who prepare, compound, dispense, transport, receive & administer hazardous drugs.
	Must maintain cleanliness and monitor sterility.	Describes practice and quality standards for handling hazardous drugs (HDs) to promote patient safety, worker safety & environmental protection.
	Introduced in 2004 and revised in 2008.	Approved February 1, 2016 Compliance required by **December 1, 2019**

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Compounded Sterile Preparations

USP <797> and <800> apply to:

ALL persons who prepare CSP's *(Compounded Sterile Preparations)*

and

ALL places where CSP's are prepared.

This includes hospitals and other healthcare facilities.

Enforcement of USP standards depends on local, state and federal regulatory agencies.

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Compliance & Codes

BOTTOM LINE:

USP <800> *DOES NOT* negate
USP <795> or USP <797>

It is IN ADDITION TO

Added safety measures for those who work with hazardous drugs.

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USP <800> Compliance and Hazardous Drugs

SUMMARY
More safety precautions for those receiving, storing, mixing, preparing, transporting and administering hazardous drugs.
Creating separate spaces for hazardous drugs -Both compounding and storage.
These spaces MUST comply in clinical pharmacies -Both in-patient and out-patient areas.
Released: February 1, 2016.
Implementation: December 1, 2019 for USP <800> compliance

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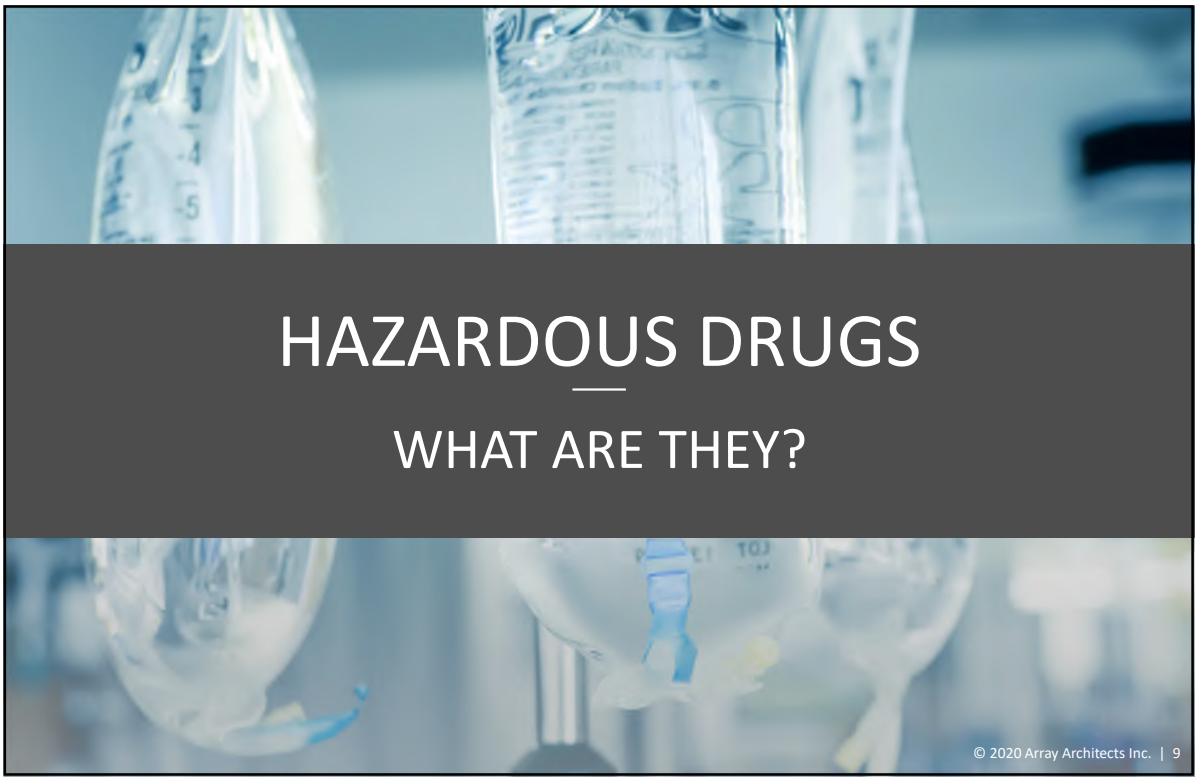

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What is Classified as a Hazardous Drug?

- Hazardous drugs as defined in the **National Institute for Occupational Safety and Health** (NIOSH) publication on *"Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Health Care Settings."*
- NIOSH maintains a list of antineoplastic and other HD's used in healthcare.
- Many pharmacies compound substances, such as chemotherapy drugs, which are referred to as hazardous drugs.
- Extremely toxic and dangerous to staff if not transported, stored and handled properly.

Types of Exposure:

- Dermal
- Mucosal absorption
- Inhalation
- Injection
- Ingestion

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What are the Compounding Environments?

- USP <800> classifies five types of compounding environments:
  1. Low-risk CSPs w/ 12-hour *beyond use dating* (BUD)
  2. Low-risk
  3. Medium-risk
  4. High-risk (hazardous)
  5. Immediate use
- The classification of the compounding environment influences the required characteristics.
- The assessment of risk must list each drug and dosage form individually. Dosage forms of drugs within the same group might not have the same risk of exposure.
- Important for clients to determine their **compounding risk** as part of the initial planning of any **USP <797> or USP <800> compliant project.**

Designated areas must be available for HDs:

- Receipt & Unpacking
- Storage
- Non-sterile compounding
- Sterile compounding

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What is a Clean Room?

- An environment free from dust and other contaminants.
- Clean Rooms have **ISO Classification**, **air change** and **pressurization** requirements.
- HEPA (high-efficiency particulate air) is the key to effective engineering controls.
- HEPA filters can remove **MOST** particulate contamination, but are **NOT** effective in filtering gases and vapors.
- This is why hazardous drug storage and preparation are required to be externally vented.

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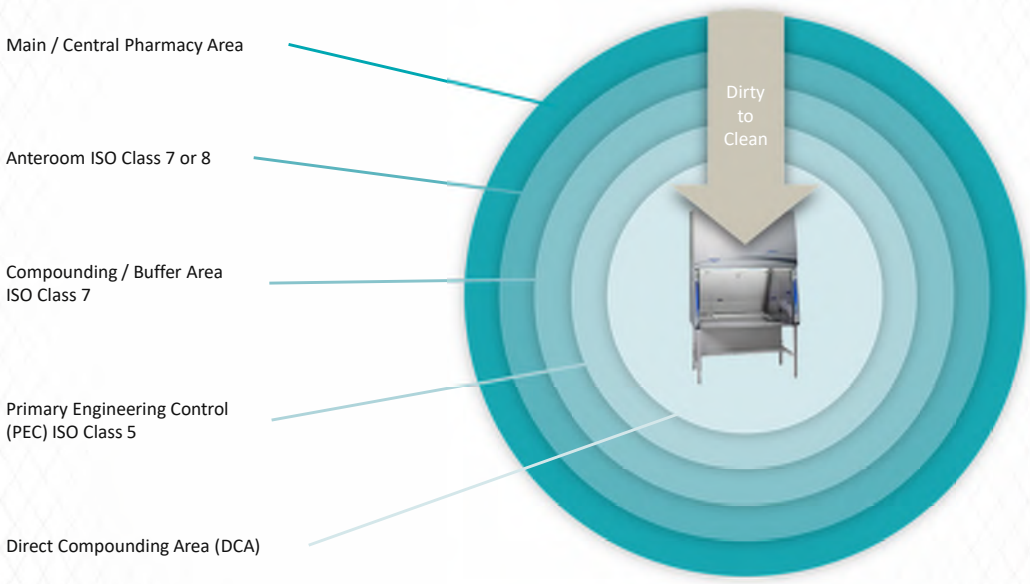
Air Flow



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ISO Classifications

ISO Classification of Particulate Matter in Room Air

Class Name		Particle Count		Example
ISO Class	U.S. FS 209E	ISO (m^3)	FS 209E (ft^3)	
5	Class 100	3,520	100	Laminar Flow workstation, BSC or CACI
7	Class 10,000	352,000	10,000	Buffer / I.V. Compounding and Anteroom: <800>
8	Class 100,000	3,520,000	100,000	Anteroom: <797> (unless anteroom also off haz sterile)

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Clean Rooms & ISO Classifications

SUMMARY
Clean Room: An environment free from dust and other contaminants
ISO class 5: Where the work is directly performed & within a room
ISO Class 7: USP <800> required for hazardous sterile compounding
ISO Class 8: USP <797> anteroom required for non-hazardous sterile compounding

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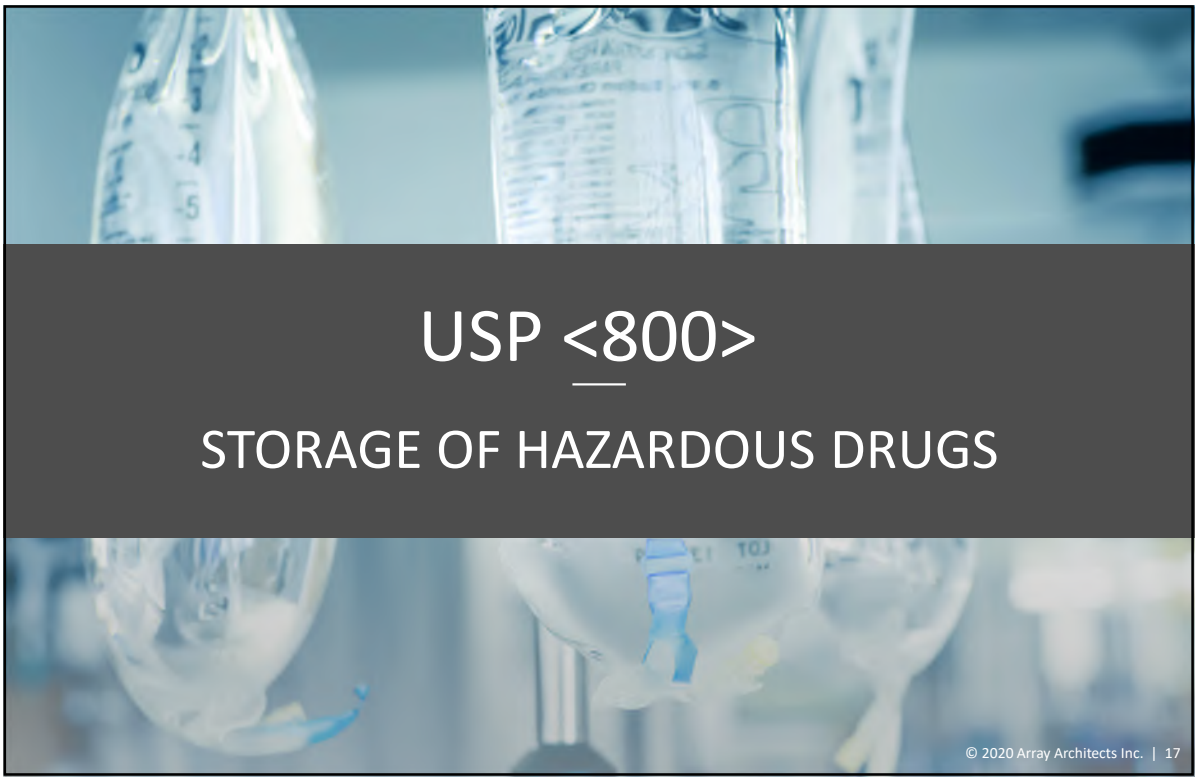

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Handling of Hazardous Drugs

- Hazardous Drugs (HDs) shall be handled to promote patient safety, worker safety, environmental protection, and infection prevention.
- Manipulation of HDs requires appropriate administrative controls, PPE, engineering and environmental controls, and work practices.
- Restricted areas for HDs storage and preparation – for authorized staff only.
- To reduce risk of exposure, HD compounding area shall be located away from break rooms and refreshment areas for staff, patients, or visitors.
- Prominently displayed hazard signage before entry into the HD area.

Separate designated areas to be available for:

- Unpacking HDs
- Non-sterile HD compounding
- Sterile HD compounding

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Delivery & Storage of Hazardous Drugs

Hazardous Drug Path

1. Labeled HD received directly from vendor or supplier by Pharmacy Storeroom or IDS staff. **Chain of command**.
2. Designated and segregated HD handling areas. Unpacking HDs from external shipping containers shall **NOT** occur in an area used for sterile compounding.
3. HD stored in a USP <800> compliant storage room *(negative air pressure w/ at least 12 ACPH).*
4. Drugs for compounding brought into the Anteroom.
   a. Passed or walked in by trained pharmacy staff.
5. Drugs then brought into the Hazardous Compounding Room *(negative air pressure).*
   a. Passed or walked in by trained pharmacy staff.

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Delivery & Storage of Hazardous Drugs

- All hazardous drugs *(both room temperature and refrigerated)* to be unpacked and stored separately from non-hazardous drugs in:
  - Negative pressure rooms
  - Externally vented
  - Minimum of 12 air changes per hour.
- This includes all hazardous drugs *(sterile and non-sterile)*, except for unit-dose or unit-of-use packaging *(if not altered)*.
- Must be taken to the designated hazardous storage room immediately after unpacking.
- Hazardous drug returns can be stored near hazardous drug storage in a negative pressure room if segregated in a designated area.

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Delivery & Storage of Hazardous Drugs

- **Can store sterile and non-sterile hazardous drugs together.**
- HD's can be stored within the hazardous sterile compounding room.
- Limit HD storage in a hazardous sterile compounding area to those used for sterile compounding.
- Refrigerated HD's to be stored in a dedicated refrigerator in the HD storage room, buffer room, or containment segregated compounding area (C-SCA).
  - In negative pressure room, an exhaust located adjacent to the refrigerator's compressor and behind the refrigerator is recommended.
- Allowed to store small quantities of hazardous drugs in dedicated medical dispensing units in hazardous sterile compounding.

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Delivery & Storage of Hazardous Drugs

- **Do not use sterile compounding or positive pressure areas for hazardous drugs.**
- Best practice: Do not store hazardous ointments and pills with sterile I.V.'s in areas designated for sterile compounding to minimize traffic into the sterile compounding area.
- Do not store HD's on the floor. Should be stored at or below eye level.
- Do not transport HD's via pneumatic tubes.

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Delivery & Storage of Hazardous Drugs

SUMMARY
All hazardous drugs are to be stored separately from non-hazardous drugs.
Limit hazardous drug storage in the hazardous sterile compounding area to immediate use.
In negative pressure rooms: HD can be stored in a dedicated refrigerator next to a low air exhaust. Small quantities of HD can be stored in medical dispensing units.
Do not use sterile compounding or positive pressure areas for hazardous drugs.

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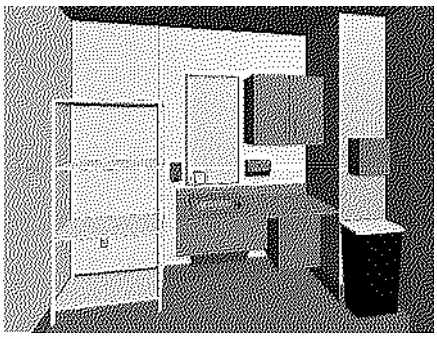
What is an Anteroom?

- Part of the clean room area.
  - The transition point from *"dirty"* to *"clean"* to mitigate contamination.
  - Clean rooms are classified by the number and size of particles permitted per volume of air.
- Provides assurance that pressure relationships are constantly maintained.
- Reduces the need for the HVAC control system to respond to large disturbances.



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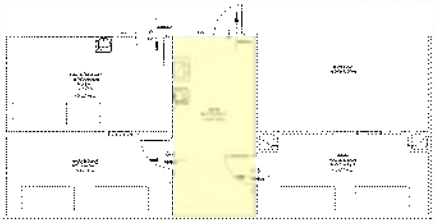

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What is an Anteroom?

An **ISO Class 8** *(or better)* area where personnel perform:

- Hand hygiene and garbing procedures
- Staging of components
- Order entry
- CSP labeling
- Other high-particulate generating activities.

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Anteroom Requirements

For USP <797>:

- Adjacent to a **POSITIVE** pressure room to be a minimum of **ISO Class 8** compliant.
  - Example – Sterile compounding (non-haz)
- **ISO Class 8**:
  - Previously Class 100,000

For USP <800>:

- Adjacent to a **NEGATIVE** pressure room to be **ISO Class 7** compliant.
  - Any anteroom serving a hazardous buffer area must be a minimum of ISO 7 *(because the air from the anteroom is being drawn into the hazardous buffer area).*
- **ISO Class 7**:
  - Previously Class 10,000

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Anteroom Design Requirements

For both USP <797> *and* <800>:

- Adjacent to buffer / compounding room
- Creates a physical separation between the buffer area and ante area in high-risk environments.
  - At minimum: recommend walls.
- Require a sink with eyewash for handwashing.
- Requires PPE area with changing bench, waste receptacle and a line of demarcation.
  - **Demarcation Line:** Defines the boundary of a buffer zone or area of limitation.

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Anterooms

SUMMARY
Part of the clean room area.
Separate room recommended to maintain pressure differentials.
Adjacent to the buffer / compounding room.
For any high-particulate generating activities.
Requires specific items and layout.
Must be ISO Class 7 compliant if adjacent to a NEGATIVE pressure room.

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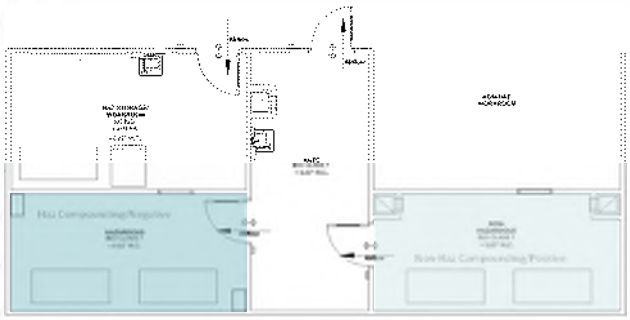
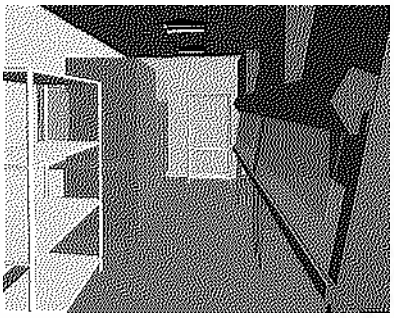
Buffer / Compounding Rooms

- Access through an anteroom due to the required pressure differentials and air changes.
- Must be a separate, designated ISO 7 compliant room for all hazardous drug compounding.
- Compounding spaces must have an eyewash nearby.
- Provide low air returns and/or exhaust grilles installed in the direction of air flow.





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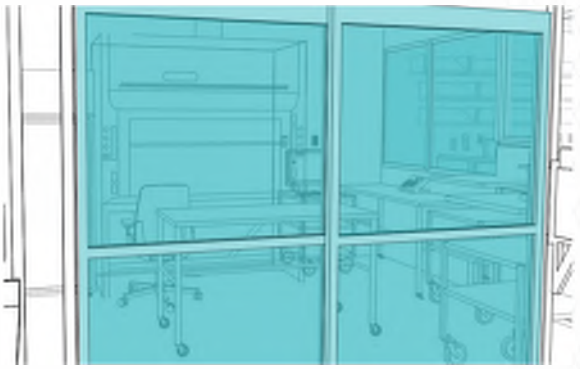
Buffer / Compounding Rooms – Best Practices

- No sinks or floor drains allowed.
- Visibility is key! Install windows, glass doors and cameras for staff safety.
- Automatic sliding/break-away doors; interlocked and gasketed for all clean room doors.
- Install pressure monitors at entrance of ante and buffer rooms.
- Provide access for cleaning the sides and back of all major equipment (BSC's, refrigerators, etc.)
- All HD storage (refrigerated and non) to be stored in either the HD compounding room or a separate HD storage room.



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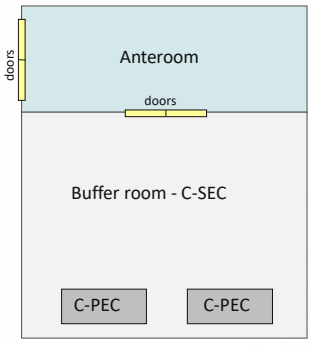
Containment Engineering Controls

- If the preparation is intended to be sterile, engineering controls are required to protect the preparation from cross-contamination and microbial contamination during **ALL PHASES** of the compounding process.
- Engineering controls for containment are divided into three categories:

1. **Primary** levels of control
   - Containment Primary Engineering Controls (**C-PEC** *or PEC)*
2. **Secondary** levels of control
   - Containment Secondary Engineering Controls (**C-SEC**)
3. **Supplementary** levels of control



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Containment Engineering Controls

STERILE IV HAZARDOUS DRUG COMPOUNDING

Containment Primary Engineering Controls (C-PEC or PEC)

- A ventilated device designed to minimize worker and environmental HD exposure.
  - ***Examples:*** Compounding aseptic containment isolator (CACI) or Class II Biological Safety Cabinet (BSC), where the actual aseptic compounding activities are performed.
- Must be 100% exhausted; externally vented to the outside through (HEPA) filtered exhaust.
- Internal work chamber within that equipment must equal ISO 5 and must operate continuously.
- Must be within a restricted access room.
- Place devices out of the traffic flow & in a manner to avoid disruption from the HVAC system and room cross-drafts.

Containment Secondary Engineering Controls (C-SEC)

- HD compounding activities to occur within C-SEC.
- The room where the C-PEC is placed.
  - ***Example:*** Buffer or compounding room
- Must be physically separated.
- Must be externally vented through (HEPA) filtration.
- 30 ACPH of HEPA-filtered supply air.
- Must be negative pressure between 0.01 and 0.03 inches water column between anteroom and buffer room.
- Consider power outage plan. Loss of power requires all activities must be suspended immediately.

Supplementary Engineering Controls

- Closed System Transfer Devices (CSTD) transfers the HD into an IV bag or syringe.
- Offer additional levels of protection.

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Containment Engineering Controls

NON-STERILE HAZARDOUS DRUG COMPOUNDING

Containment Primary Engineering Controls (C-PEC or PEC)

- Must provide personal and environmental protection (recommend Class I or II BSC).
- Must be dedicated equipment.
- Must be externally vented to the outside (preferred) or redundant- HEPA filtration in series.
- C-PEC required for manipulations.
  - Cutting, crushing
- C-PEC *not required* for final dosage.
  - Counting
  - Repackaging

Secondary Engineering Controls (C-SEC) Containment

- HD compounding activities to occur within C-SEC.
- The room where the C-PEC is placed. Should be in a physically separate room from the preparation area.
- Externally vented.
- Minimum 12 ACPH.
- Maintain a negative pressure between 0.01 and 0.03 inches water column compared to all adjacent spaces such as corridors and above ceiling.
- Smooth, impervious, seamless surfaces are required to ensure adequate cleaning.
- Does not need to be ISO 7 or have HEPA filtration.

Supplementary Engineering Controls

- Closed System Transfer Devices (CSTD) transfers the HD into an IV bag or syringe.
- Offer additional levels of protection.
- Avoid manipulation such as crushing, splitting, opening capsules, etc.

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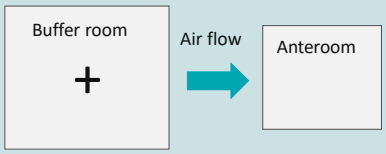
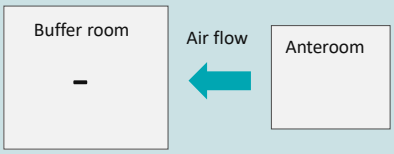
Room Pressurization

POSITIVE PRESSURE ROOM	NEGATIVE PRESSURE ROOM
Air flows out of or toward adjacent rooms, resulting in a positive pressure in the room	Air flows into the room and away from adjacent rooms, resulting in a negative pressure in the room
Pressurized positively relative the anteroom --> The air should flow from the buffer area to the ante area. The cleaner buffer area environment is not contaminated by the less clean ante area environment.	Pressurized negatively relative the anteroom --> The air should flow into the buffer area from the ante area. The potentially more hazardous air of the buffer area is contained and it does not contaminate the cleaner ante area environment.
	

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Negative Pressure Rooms

- For staff safety:
  - Hazardous compounding and storage rooms to be negative air pressure.
  - Keeps germs from entering the general airflow and infecting staff.
- Hazardous buffer room to be externally vented.
- A specially designed ventilation system keeps contaminated air from escaping.
- Windows, light fixtures, outlets and conduits are sealed so that air only exits the room through a filtered ventilation system
- In a properly functioning negative pressure room, air is drawn into the room only through a half-inch gap under the door.

Reminder: Primary Engineering Controls (PEC's) used for sterile compounding of hazardous drugs must be vented to the outside.

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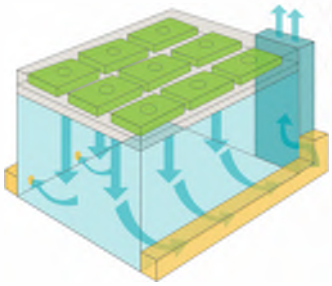
Negative Pressure Rooms

In Hazardous Sterile Rooms: Unidirectional airflow design.

- HEPA-filtered air is distributed from supply grills in the ceiling and returned through return grills mounted low in the wall.
  - Exhaust system removes air
  - Supply system delivers less
  - Room pressure is negative
  - Infiltration makes up the difference
- Low Air Exhaust:
  - Recommend multiple distributed low wall exhausts
  - Minimum of two per room
  - Exhausts at each refrigerator, by the coils.



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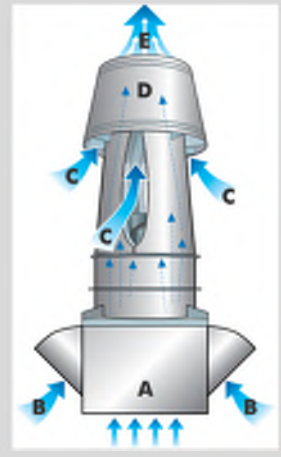
HVAC Air Flow – Best Practices

- Correct ISO Class spaces / Proper Air Changes
  - A minimum of 30 air changes per hour (ACPH) in an ISO 7 space supplied by HEPA-filtered air.
    - For non-haz rooms: The number of air changes could be split between the PEC contributing no more than 15 ACPH and the HEPA-filter supply air to the area at least 15 ACPH.
    - Compounding processes that generate a significant amount of particles may increase the ACPH requirements.
- Proper Air Flow and Redundancy:
  - Dedicated roof exhaust fan (redundant) for each ducted BSC with continuous negative pressure.
  - Hazardous exhaust systems = no fire dampers
  - Dedicated air handling unit(s) with redundant fans



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HVAC Controls – Best Practices

- Maintain required pressures, temperature and humidity
  - Fully automated DDC controls to actively maintain set points.
  - Fully automated communication (BAS or BMS) between all HVAC components: *supply, return or exhaust* via terminal boxes at supply and returns.
  - Continuous monitoring of alarms, diagnostics and fully automating adjustments at BAS or BMS to avoid down time or shut downs.
  - Generate reports for temp, humidity, pressurization, and air changes for each space.
- Minimize service disruption

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Electrical – Best Practices

- Lighting in Cleanrooms
  - Fully gasketed, cleanroom grade and perimeter sealant.
- Devices in Cleanrooms
  - Cleanable, no ledges or surfaces to collect dust.
  - Sealed conduits and any penetrations.
- Emergency Power
  - At a minimum, any critical equipment should be on emergency power.
    - Exhaust fans
    - Biosafety Cabinets
    - Refrigerators
  - Consider UPS for Biosafety cabinets and exhaust fans in event of a power outage.

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Engineering Controls & Air Flow

SUMMARY
Positive room pressure drives air and contaminants out. Air flows out of or toward adjacent rooms. *Example: USP <797>*
Negative room pressure draws air and contaminants in. Air flows into the room and away from adjacent rooms. *Example: USP <800>*
Neutral room pressure exchanges air and contaminants in both directions.
Fully automated controls and redundancy.

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Equipment Requirements

Types of Devices for Compounding Hazardous Drugs

TYPE OF COMPOUNDING	TYPE OF DEVICE	CLASS DESCRIPTION
Non-sterile	Containment Ventilated Enclosure (CVE) or Class I Biological Safety Cabinets (BSC) NOTE: Class II BSCs or Compounding Aseptic Containment Isolators (CACIs) may be used for nonsterile compounding if they are dedicated for nonsterile compounding.	Class I provides personnel and environmental protection, but no product protection.
Sterile	Class II Biological Safety Cabinets (BSC) or CACI (Compounding Aseptic Containment Isolator)	Class II provides protection to the user, the experimental material and the environment.

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Non-Hazardous Sterile Compounding Pharmacy Equipment

Photo credit: www.bakerco.com

Laminar Flow Workstation:

- Most basic
- Provides an ISO 5 environment
- No venting required
- Must be certified every 6 months.

Photo credit: www.bakerco.com

Biological Safety Cabinets (BSC):

- Similar turbulent air flow as a chemical fume hood, but w/ HEPA filter in the exhaust system to provide containment and environmental protection.
- Provides an ISO 5 environment
- Class I or II
  - Class I: provides personnel and environmental protection, but no product protection.
  - Class II: provides protection to the user, the experimental material and the environment. HEPA filtered.
- No venting required
- Must be certified every 6 months.

Photo credit: www.nuaire.com

Compounding Aseptic Containment Isolator (CACI):

- An isolator cabinet designed to contain all contaminants
- Prevents contaminants from escaping IVs and being transferred to surrounding area
- Provides an ISO 5 environment
- Class II
- No venting required
- No anteroom required
- Not ergonomic
- More time consuming
- Requires approval of National Pharmacy
- Must be certified every 6 months.

Allowed in non-hazardous – USP <797>

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Hazardous Sterile Compounding Pharmacy Equipment

Photo credit: www.labconco.com

Biological Safety Cabinet (BSC):

Class II, Type A2 or B2 recommended

- The Class II biosafety cabinet provides protection to the user, the experimental material and the environment.
- Class II BSC's are HEPA filtered and make up about 90% of BSC's.
- Type A2: Negative pressure plenum
- Type B2: Total exhaust and expensive to operate; no air is recirculated within.
- Type C1: Controls infectious material, chemical hazards, reduces operating costs and adds flexibility.
  - Added in 2016.

Photo credit: www.nuaire.com

Compounding Aseptic Containment Isolator (CACI):

- An isolator cabinet designed to contain all contaminants
- Prevents contaminants from escaping IVs and being transferred to surrounding area
- Class II
- Must exhaust to outside
- Not ergonomic
- More time consuming
- Requires approval of National Pharmacy

Required in hazardous to meet USP <800>

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PHARMACIES

INTERIOR FINISHES / FF&E

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Clean Rooms – Interior Finishes

Description	ISO Class 7
Type of Gasketed Ceiling	1-1/2" Aluminum T-grid
Ceiling	Mylar or Vinyl Rock (wrapped) lay-in ceiling tiles, gasketed with hold down clips OR fully caulked. Perimeter of ceiling at wall needs caulked in both ISO 7 and 8 spaces. Drywall ceiling with epoxy paint recommended for all ISO Class 7 spaces.
Lighting Type	2x4 Cleanroom Gasketed Fixture
Wall System	Modular
Wall Panels	Smooth FRP panels or similar plastic protection panels; floor to ceiling and sealed / caulked at all seams
Floor Covering	Welded seamless sheet vinyl or rubber (w/ 6" integral coved base)
Casework	Stainless steel or approved pharmacy vendor storage solutions (for all shelving, racks, etc.) No plastic laminate.
Countertops	Stainless steel w/ integral stainless sinks

Description	ISO Class 8
Type of Gasketed Ceiling	1-1/2" Aluminum T-grid
Ceiling	Mylar or Vinyl Rock (wrapped) lay-in ceiling tiles, gasketed with hold down clips OR fully caulked. Perimeter of ceiling at wall needs caulked in both ISO 7 and 8 spaces.
Lighting Type	2x4 Cleanroom Gasketed Fixture
Wall System	Modular or Drywall
Wall Panels	Smooth FRP panels or similar plastic protection panels; floor to ceiling and sealed / caulked at all seams
Floor Covering	Welded seamless sheet vinyl or rubber (w/ 6" integral coved base)
Casework	Stainless steel or approved pharmacy vendor storage solutions (for all shelving, racks, etc.) No plastic laminate.
Countertops	Stainless steel w/ integral stainless sinks

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Clean Rooms – Interior Finishes

Ante Rooms and Buffer Room (Compounding) spaces:

- Non-porous and easily cleanable materials are a must.
- All surfaces (e.g., ceilings, walls, floors, fixtures, shelving, counters and cabinets) to be "smooth, impervious, free from cracks and crevices, and non-shedding."
- Junctures of ceilings to wall "shall be coved or caulked."
- Wall construction can be either epoxy-coated gypsum board, or heavy gauge polymer panels locked together and sealed.
- Work surfaces should be made of smooth, impervious materials
  - Typical materials = stainless steel or molded plastic.

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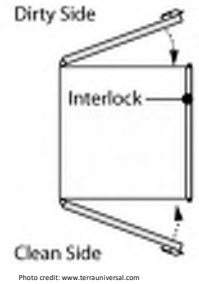
Clean Rooms – Interior Finishes

Ante Rooms and Buffer Room (Compounding) spaces:

Pass throughs:

- Best practice to install between a sterile HD negative pressure buffer room into the anteroom; another classified air space with interlock. Consider HEPA filtration.
- Confirm with the State Board of Pharmacy to install between a sterile HD negative pressure buffer room into a non-classified air space such as the general pharmacy or receiving/breakdown room.
  - If allowed, it must be HEPA filtered purged pass-through when used between negative-pressure HD buffer room and general pharmacy.
- Pass-through refrigerators between a negative-pressure buffer room and any space are prohibited.



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Pharmacy Departments - Programs

IV Compounding Rooms (Non-Hazardous and Hazardous)

Important to understand proper special needs, including, but not limited to:

- Work space and flow
- Equipment needs & sizes
- Circulation
- Door clearances
- Special requirements & connections
  - Mechanical, electrical, plumbing, structural, etc.
- Chases - exhausts & returns

Example program

Room or Space	Qty.	Area	Total	Comments
Sterile IV Preparation & Compounding				USP <797> and <800> compliant Clean Rooms
IV Anteroom:				Positive Pressure ISO Class 7, Shared with Hazardous IV Prep Room. Low Air Returns.
Single Person Scrub Sink	1	20	20	Eye Wash
Gowning Bench	2	20	40	Clean Storage; gowns, masks, caps and shoe covers on shelves above bench
Gowning Supply Storage	2	15	30	Clean Storage; - 3' wide units. gowns, masks, caps and shoe covers
Computer Workstation	4	25	100	Workstation w/ barcode scanner & label printer
Worktable	1	25	25	30" x 60" Mobile Table
Pass Through Cabinets	4	20	80	Located between "Main Pharmacy" & Anteroom with interlocking doors
Cart Pass Through	1	20	20	with interlocking doors
Pass Thru Refrigerator (2-Door)	2	30	60	Located between "Main Pharmacy" & Anteroom with interlocking doors
Door Clearance	3	25	75	Glass; sliding door
IV Compounding Room (Non-Hazardous) (High Risk) ("Clean Room" or "Buffer Area")				Positive Pressure ISO Class 7; 65 -68 Degrees, 40% Relative Humidity, Low Air Returns, Intercom Accessed thru Anteroom, 8'-6" ceiling min.
Pass-thru cabinet	3	12	36	Located between "Clean Room" & Ante-Room; with interlocking doors
6' Laminar Flow Biosafety Cabinet	3	50	150	Recirculating Biosafety Cabinet
6' Laminar Flow Biosafety Cabinet	1	50	50	Dedicated for TPN's
Supply cart	5	15	75	Mobile Stainless Steel Cart, one at each Compounding station
Worktable	3	30	90	30" x 60" Mobile Table
Sterile Gloves & Alcohol Hand Cleaner	2	12	24	
Door Clearance	1	30	30	Glass; sliding door
Low Air Return	3	8	24	
Hazardous IV Prep Room: ("Clean Room" or "Buffer area")				Negative Pressure Room, ISO Class-7; Accessed through Anteroom. 65-68 Degrees, 40% Relative Humidity.
Pass-thru cabinet	3	12	36	Located between "Clean Room" & Anteroom
Refrigerator (Single-Door)	3	15	45	Low Air Exhaust Located Adjacent to Ref
4' Laminar Flow Biosafety Cabinet	4	30	120	Class II / B2 Direct Exhausted Hood
Robotic IV - Apoteca	1	50	50	Direct Exhausted
Supply cart	3	12	36	Mobile Stainless Steel Cart
Wire Shelving Units	4	25	100	All Cytotoxic Drugs must be stored inside a negative pressure room
Door Clearance	1	30	30	Glass; sliding door
Low Air Exhaust	1	8	8	
Subtotal Sterile IV Prep & Compounding			1,354	
			1.20	Multiplier
Total Sterile IV Prep & Compounding			1,625	

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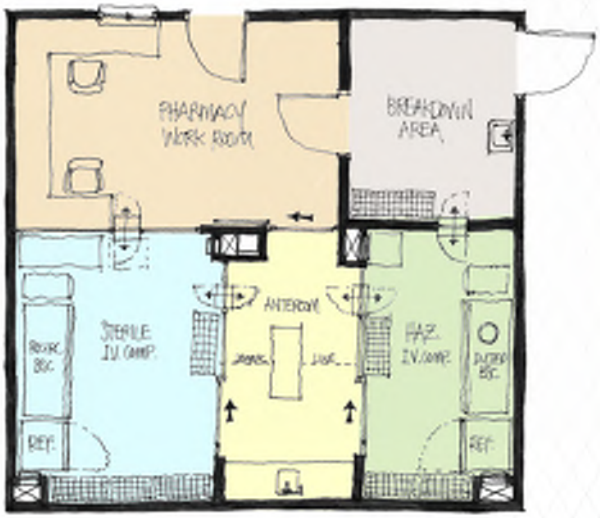
Planning Layouts / Adjacencies

1. Breakdown
2. Pharmacy Work Room
3. Anteroom
4. Sterile IV
5. Haz IV



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Planning Layouts / Adjacencies

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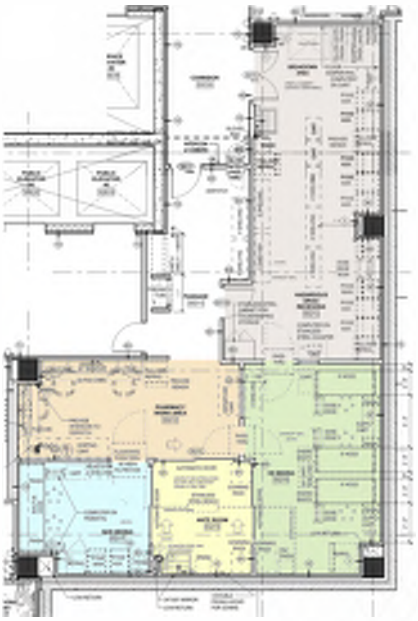

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Q&A

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