HFG architecture

PEC PROFESSIONAL ENGINEERING CONSULTANTS, P.A.

Session 3: USP 797 & 800

Oklahoma Association of Healthcare Engineers

2019 Summer Regional Event

August 23, 2019

SPEAKERS

Mark Crane

- Senior Project Manager at HFG Architecture
- Expert in code and regulatory compliance, including USP <795/797/800>, FGI Guidelines, Department of Veterans Affairs best practices, and Department of Defense standards
- Heavily involved in Life Safety Assessments
- Completed Lean Six Sigma Yellow Belt Training through the VA

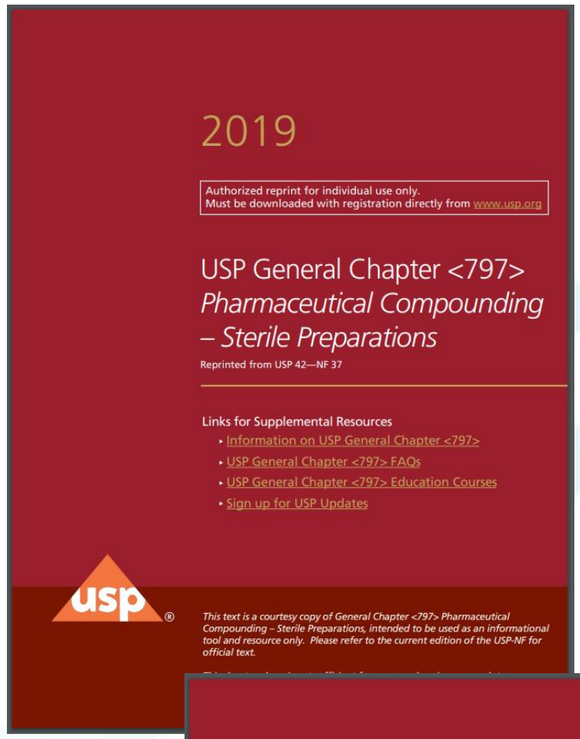
Brian Henry

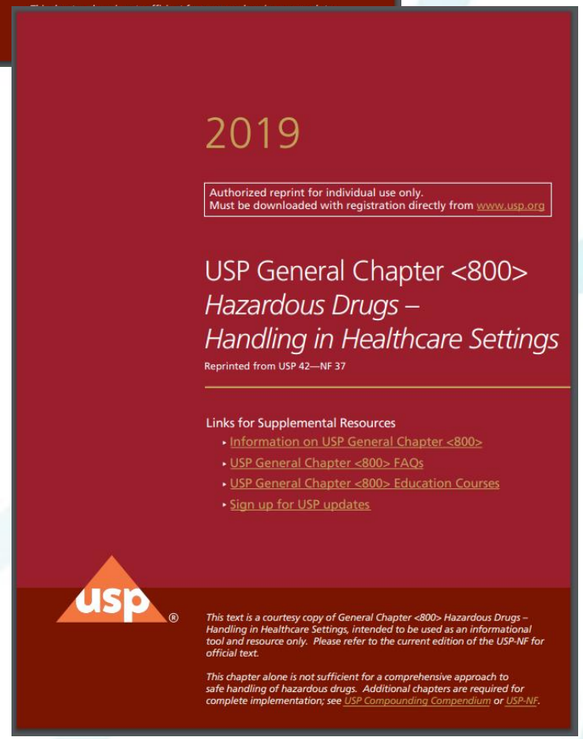
- Associate in Mechanical Division of PEC and Team Leader for PEC Medical Team
- Primary duties include mentoring engineers and designers in the design of plumbing and HVAC systems within medical facilities
- In depth knowledge of codes and guidelines, including USP <795/797/800>, FGI Guidelines, ASHRAE 170, NFPA 99, and NFPA 101
- LEED Accredited in Professional Building Design and Construction

Session 3: USP <797> & <800>

AGENDA

1. BACKGROUND INFORMATION
   - ➢ COMPOUNDING
   - ➢ THE UNITED STATES PHARMACOPEIAL CONVENTION (USP)
2. USP <797> PHARMACEUTICAL COMPOUNDING – STERILE PREPARATIONS
   - ➢ KEY CONCEPTS
   - ➢ FACILITY DESIGN
   - ➢ OWNER RESPONSIBILITIES
3. USP <800> HAZARDOUS DRUGS – HANDLING IN HEALTHCARE SETTINGS
   - ➢ KEY CONCEPTS
   - ➢ FACILITY DESIGN
   - ➢ OWNER RESPONSIBILITIES
4. ENFORCEMENT
   - ➢ OK ADMINISTRATIVE CODE – TITLE 535: OK STATE BOARD OF PHARMACY
   - ➢ CURRENT ENFORCEMENT MECHANISMS

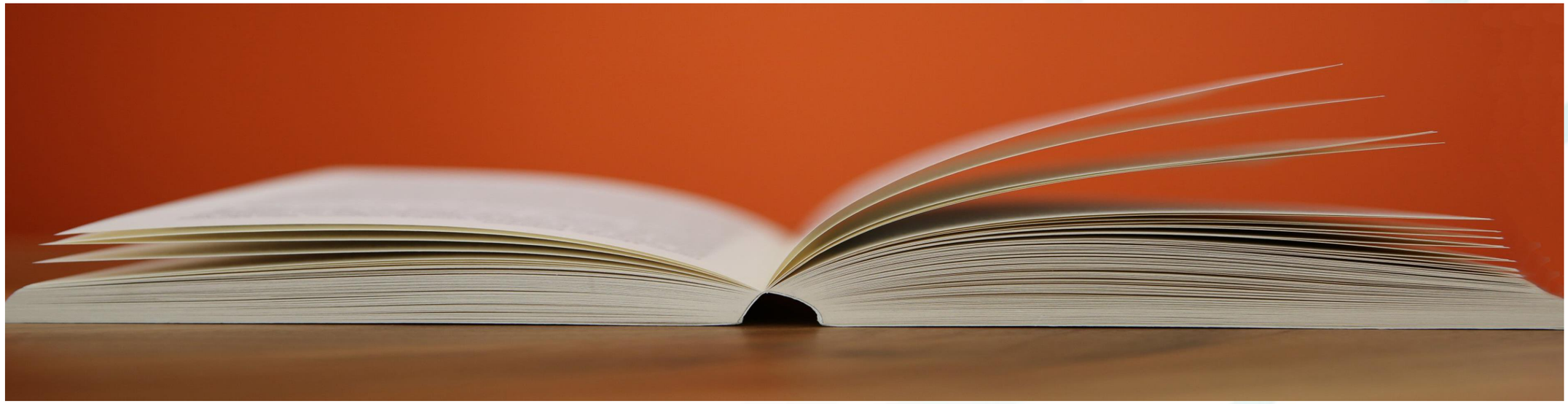




LEARNING OBJECTIVES

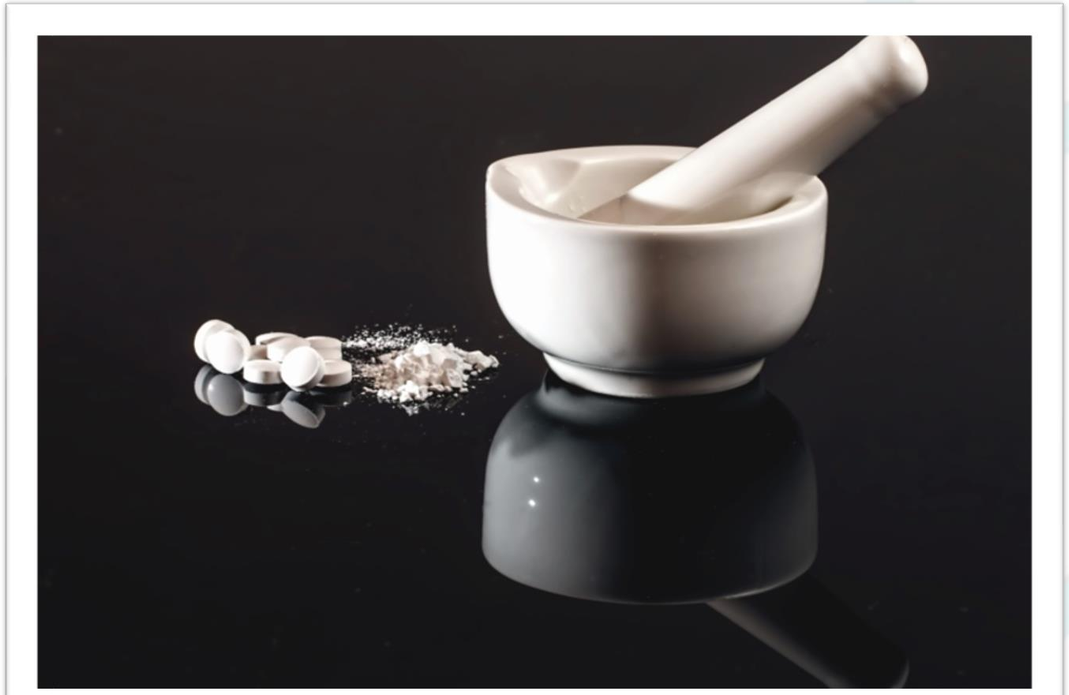
USP <797> & <800> Learning Objectives

1. APPRECIATE BROADER REGULATORY CONTEXT SURROUNDING USP <797> AND <800>.
2. UNDERSTAND FACILITY DESIGN COMPONENTS REQUIRED BY USP <797> AND <800>.
3. RECOGNIZE RELEVANT ENFORCEMENT MECHANISMS IN PLACE FOR USP <797> AND <800>.
4. DISCUSS POTENTIAL RESPONSIBILITIES OF A FACILITY ENGINEER RELATED TO USP <797> AND <800>.



What is a compounding pharmacy?

- **Compounding:** "The process of combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug or bulk drug substance" (USP).
- Drugs are compounded when a desired dosage form or potency of a medicine is not available from a manufacturer.

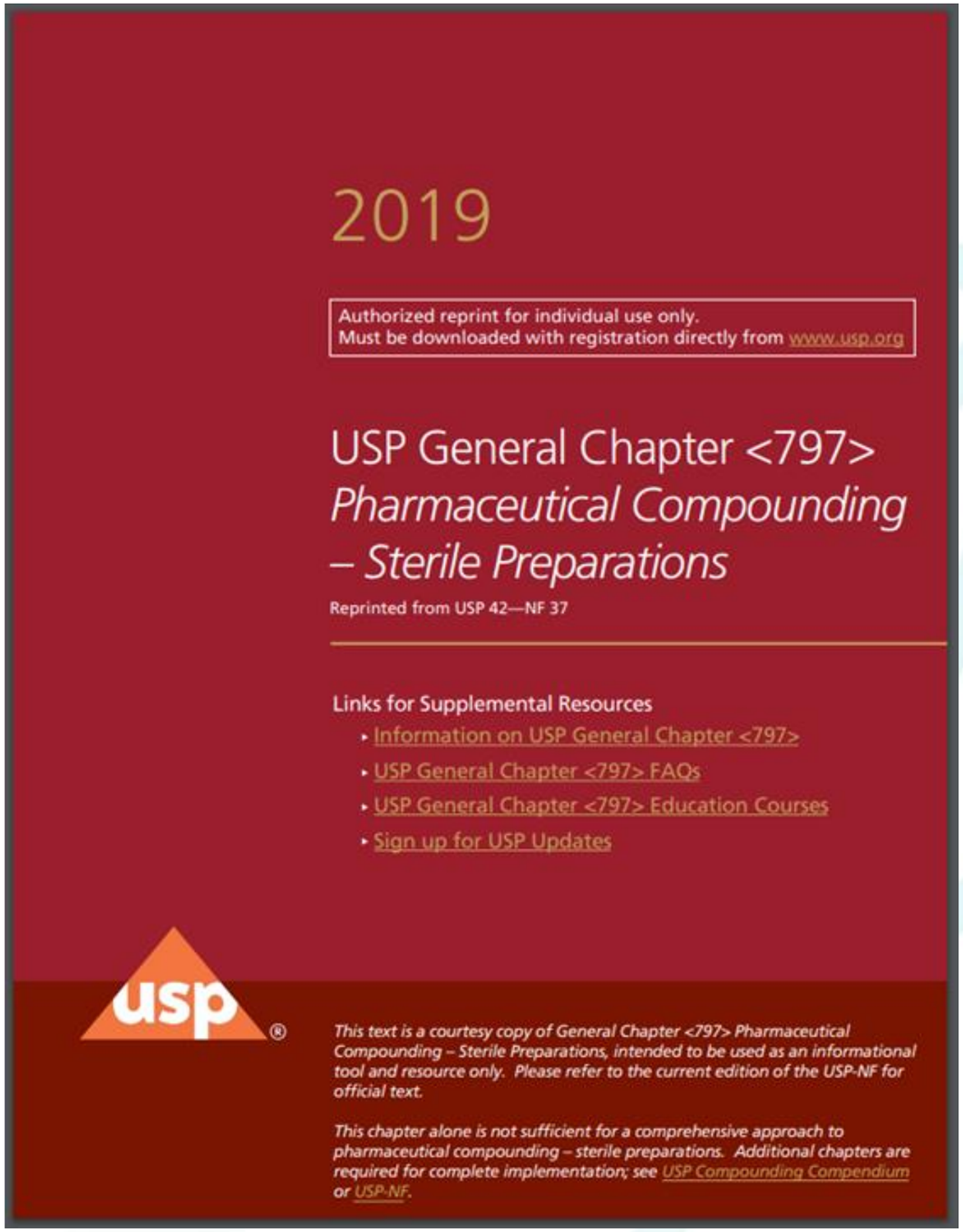


The United States Pharmacopeial Convention (USP)

- USP is an "independent, science based, standards setting organization" that publishes general and specific best practices for drug preparations in its United States Pharmacopeia – National Formulary (USP-NF).
- Within the USP-NF, four General Chapters comprise the USP Compounding Compendium:

1. USP <795> Pharmaceutical Compounding – Nonsterile Preparations
   - Existing. No pending changes.
2. **USP <797> Pharmaceutical Compounding – Sterile Preparations**
   - Existing. Substantial revisions take effect December 1, 2019.
3. **USP <800> Hazardous Drugs – Handling in Healthcare Settings**
   - New Chapter. Takes effect December 1, 2019.
4. USP <825> Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging
   - New Chapter. Takes effect December 1, 2019.

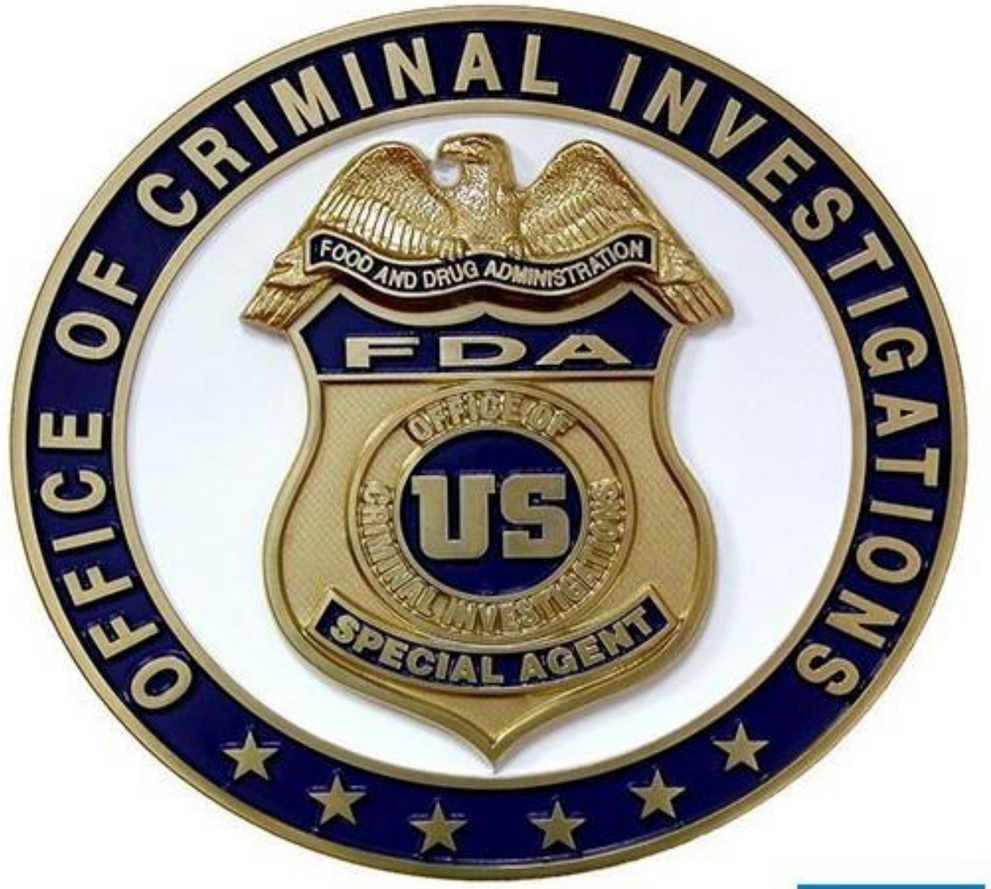
USP General Chapter <797> *Pharmaceutical Compounding – Sterile Preparations*



Only 36 pages!

Why has USP <797> been revised?

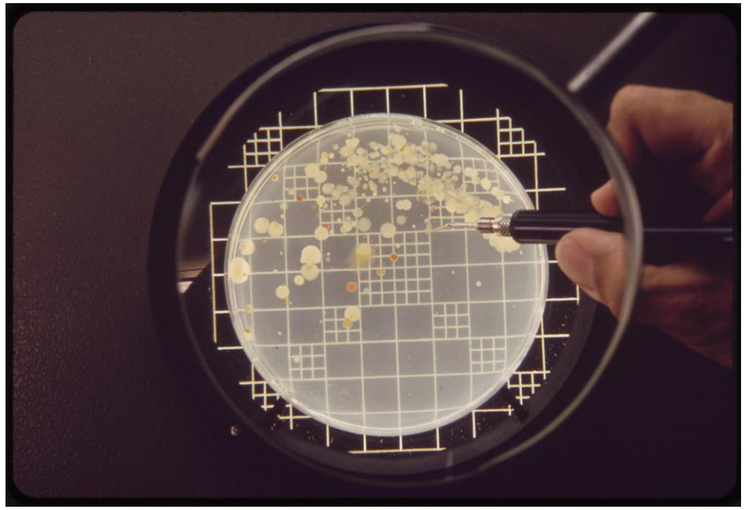
- In the last decade, unsanitary conditions at compounding pharmacies have resulted in repeated public health crises caused by contaminated compounded drugs.
  - In 2012, the New England Compounding Center (NECC) shipped medicine tainted with fungal meningitis across the country, resulting in over 100 deaths, over 750 injuries, and thousands of exposure incidents.
- Many outbreaks were caused by larger actors who exploited an FDA loophole in order to remain classified as a compounding pharmacy, instead of as a drug manufacturer.
- However, the public scrutiny resulting from these incidents has contributed to a climate of stricter regulation and enforcement for compounders of all sizes.

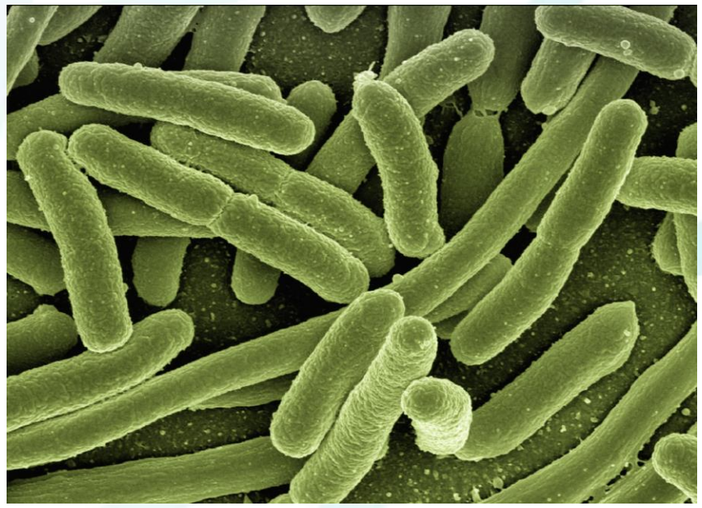


FDA

Contamination Risk

- The OLD <797> designated compounds as “Low,” “Medium,” or “High” risk according to the characteristics of the drug or the compounding procedure.
- The NEW <797> designates compounds as **Immediate Use** (Lowest Risk), **Category 1** (Lower Risk), or **Category 2** (Higher Risk) based on multiple factors, including the length of time between compounding and administration to the patient.



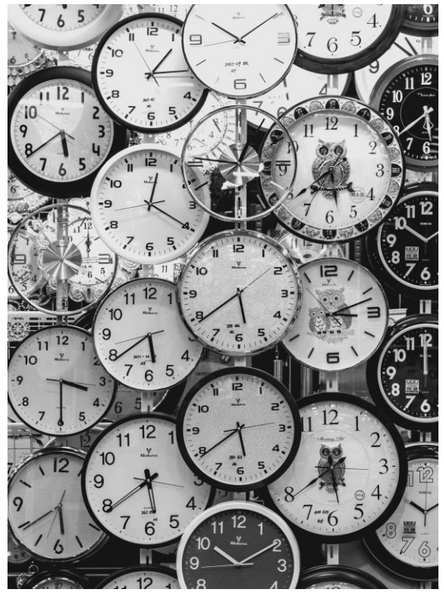


Contamination Risk

- **Immediate Use Certified Sterile Preparations:** CSPs compounded for direct and immediate use that are NOT subject to Category 1 and 2 requirements because all the following are met:
  1. Aseptic processes.
  2. Evidence-based physical and chemical compatibility of drugs.
  3. Three or fewer sterile products.
  4. Single-dose starting components discarded. One patient per single-dose container.
  5. Administration within four hours of preparation start time.
  6. Proper labeling unless administered by or in the presence of the original preparer.

Contamination Risk

- **Beyond Use Dates (BUDs):** "The date or time beyond which a compounded preparation cannot be used and must be discarded. The date or time is determined from the date or time when the preparation was compounded" (USP).
  - **Category 1 (Lower Risk):** A Certified Sterile Preparation with a BUD of 12 hours or less at room temperature or 24 hours or less if refrigerated.
  - **Category 2 (Higher Risk):** A Certified Sterile Preparation with a BUD of greater than 12 hours at room temperature or 24 hours if refrigerated.



ISO Air Quality Standards

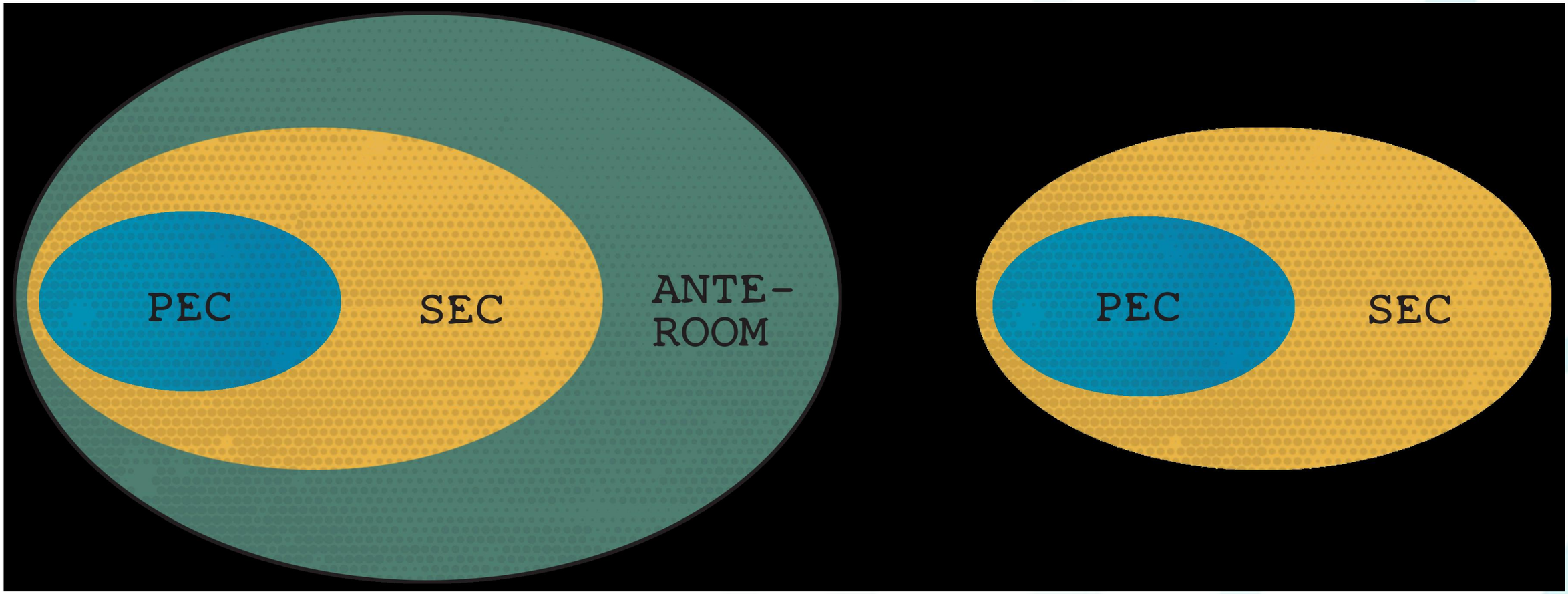
- The International Organization for Standardization (ISO) classifies air quality based on the metric of particle count per cubic meter.
  - Class 1 – Class 9 (+ unclassified environments)
  - Lower Number = Fewer Particulates / Cleaner
- ISO Classes most relevant to <797> and <800> include:
  - Class 8: 3,520,000 0.5-micron particles / cubic meter
  - Class 7: 352,000 0.5-micron particles / cubic meter
  - Class 5: 3,520 0.5-micron particles / cubic meter

Designing a USP <797> Compliant Pharmacy

Isolation Concepts

Clean Room Suite (Buffer Room + Ante-room) = Category 2

SCA = Category 1



PEC (Primary Engineering Control)

- **PEC (Primary Engineering Control):** "A device or zone that provides an ISO Class 5 air quality environment for sterile compounding" (USP).
  - ISO Class 5 PEC required for both Category 1 and Category 2 CSPs.
  - Maintains unidirectional airflow with HEPA-filtered air
  - Placement must enable cleaning around the PEC
  - If the PEC's air flow contributes to the ISO classification of the Buffer Room and Ante-Room, then the PEC can only be turned off for maintenance.

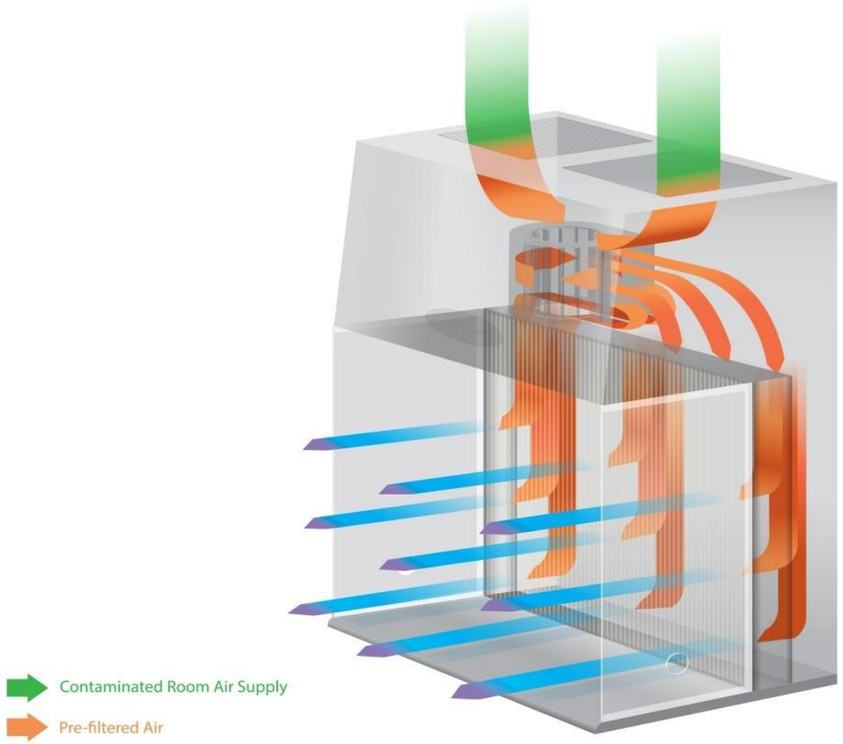
Types of PECs (Primary Engineering Control)

- Laminar Airflow Systems (LAFS)
  - Laminar Airflow Workbench (LAFW)
    - Category 1: SCA / Category 2: Buffer Room
  - Integrated Vertical Laminar Flow Zone (IVLFZ)
    - Category 1: Buffer Room / Category 2: Buffer Room
  - Class II Biological Safety Cabinet (BSC)
    - Category 1: SCA / Category 2: Buffer Room
- Restricted-Access Barrier System (RABS)
  - Compounding Aseptic Isolator (CAI)
    - Category 1: SCA / Category 2: Buffer Room
  - Compounding Aseptic Containment Isolator (CACI)
    - Category 1: SCA / Category 2: Buffer Room
- Pharmaceutical Isolator: Category 1: SCA / Category 2: ISO Class 8 Positive Pressure Room

Example of an unapproved hood design.

Types of PECs (Primary Engineering Control)

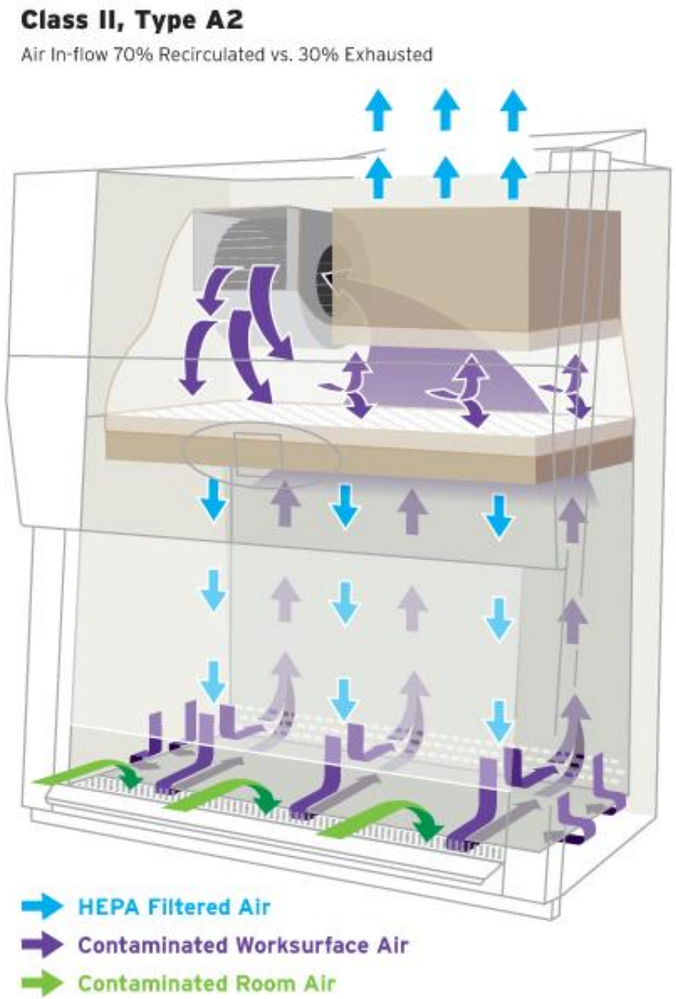
- Laminar Airflow Systems (LAFS)
  - Laminar Airflow Workbench (LAFW) [NOT suitable for <800>]
    - Category 1: SCA / Category 2: Buffer Room



Images from NuAire

Types of PECs (Primary Engineering Control)

- Laminar Airflow Systems (LAFS)
  - Class II Biological Safety Cabinet: Type A2
    - Category 1: SCA / Category 2: Buffer Room

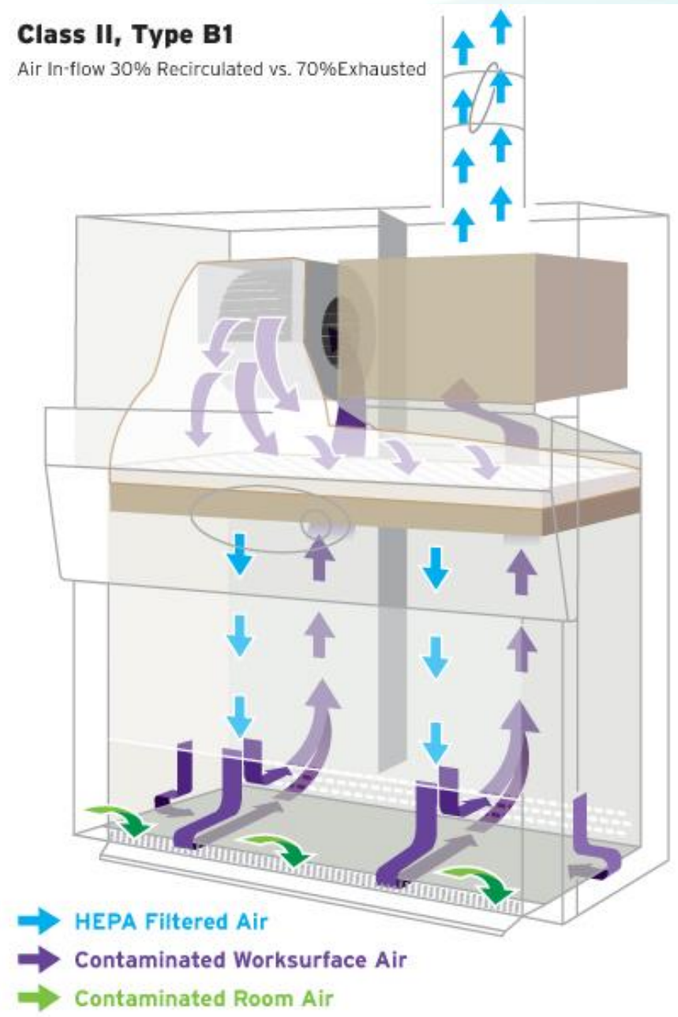


Images from NuAire

<797> PHARMACY DESIGN

Types of PECs (Primary Engineering Control)

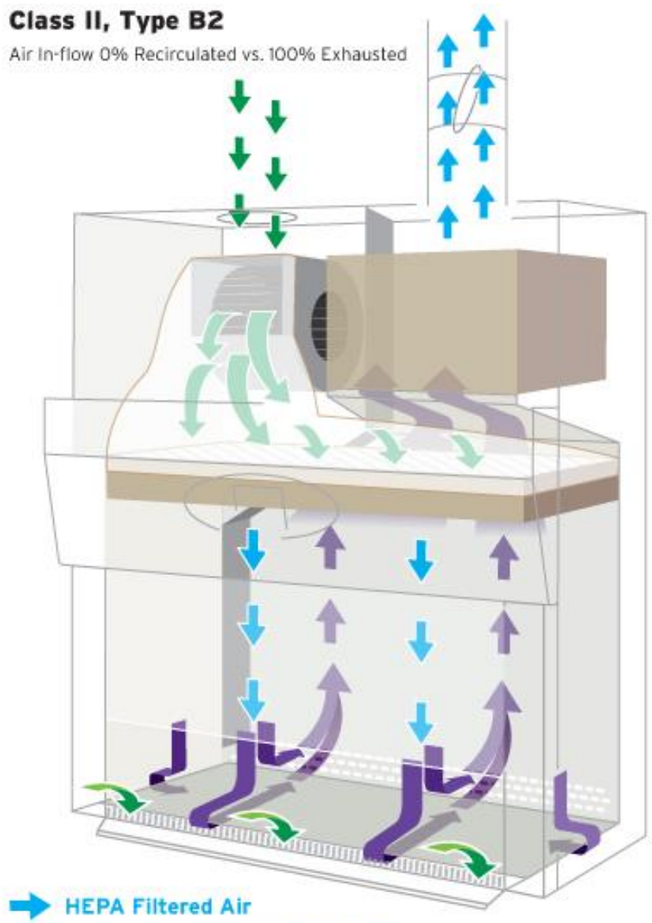
- Laminar Airflow Systems (LAFS)
  - Class II Biological Safety Cabinet: Type B1
    - Category 1: SCA / Category 2: Buffer Room



Images from NuAire

Types of PECs (Primary Engineering Control)

- Laminar Airflow Systems (LAFS)
  - Class II Biological Safety Cabinet: Type B2
    - Category 1: SCA / Category 2: Buffer Room



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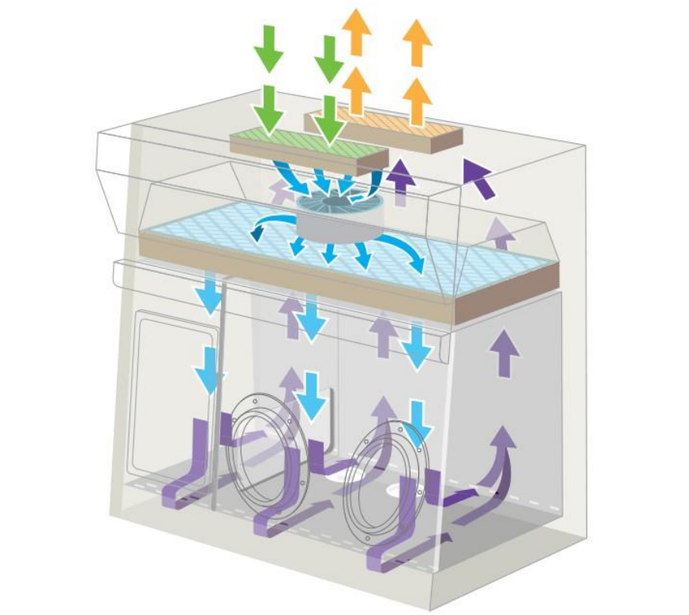
Types of PECs (Primary Engineering Control)

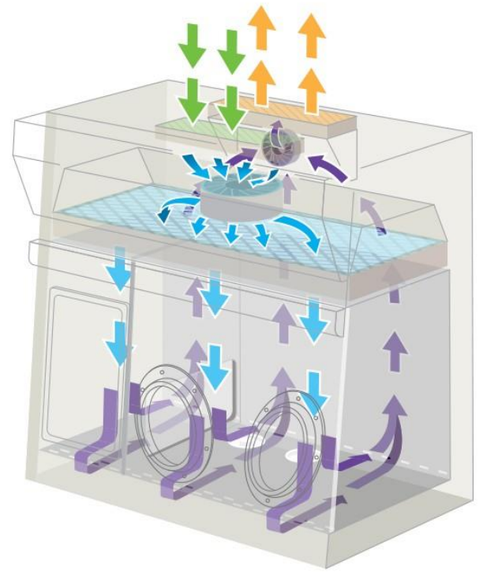
- Restricted-Access Barrier System (RABS)
  - Compounding Aseptic Isolator (CAI) [NOT suitable for ·
    - Category 1: SCA / Category 2: Buffer Room



Images from NuAire

Types of PECs (Primary Engineering Control)

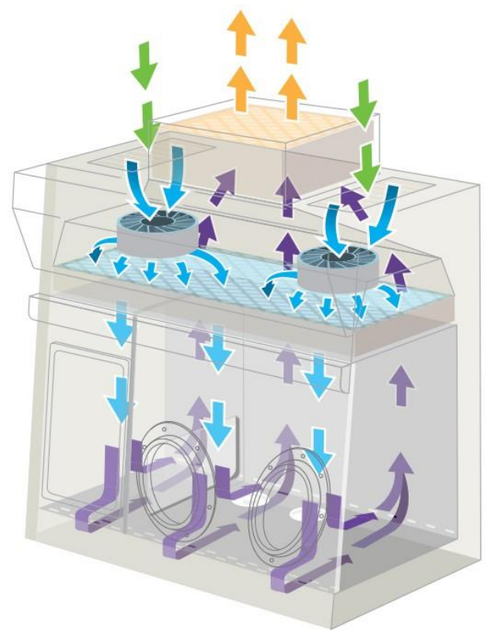
- Restricted-Access Barrier System (RABS)
  - Compounding Aseptic Containment Isolator (CACI) – Recirculation Unit
    - Category 1: SCA / Category 2: Buffer Room



Images from NuAire

Types of PECs (Primary Engineering Control)

- Restricted-Access Barrier System (RABS)
  - Compounding Aseptic Containment Isolator (CACI) – Total Exhaust Unit
    - Category 1: SCA / Category 2: Buffer Room



Images from NuAire

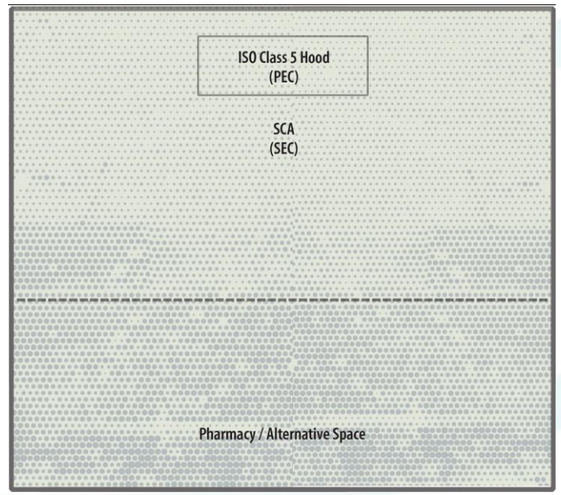
SEC (Secondary Engineering Control)

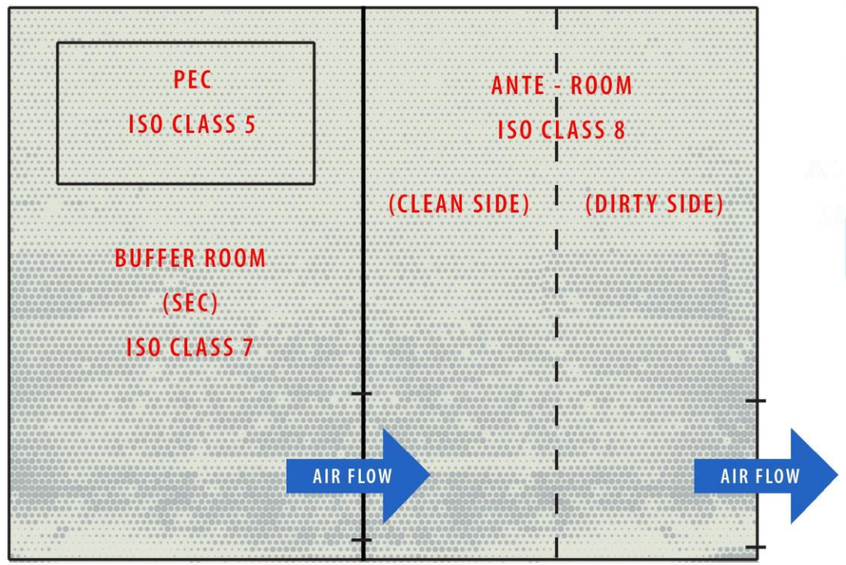
- **SEC (Secondary Engineering Control):** "The area where the PEC is placed (e.g., a cleanroom suite or SCA). It incorporates specific design and operational parameters required to minimize the risk of contamination within the compounding area" (USP).
- Temperature/Humidity monitored each day, either manually or automatically.
  - 20 degrees Celsius (68 degrees Fahrenheit) or cooler
  - Relative humidity below 60%
  - NO free-standing humidifiers/dehumidifiers or air conditioners

Not this SEC!

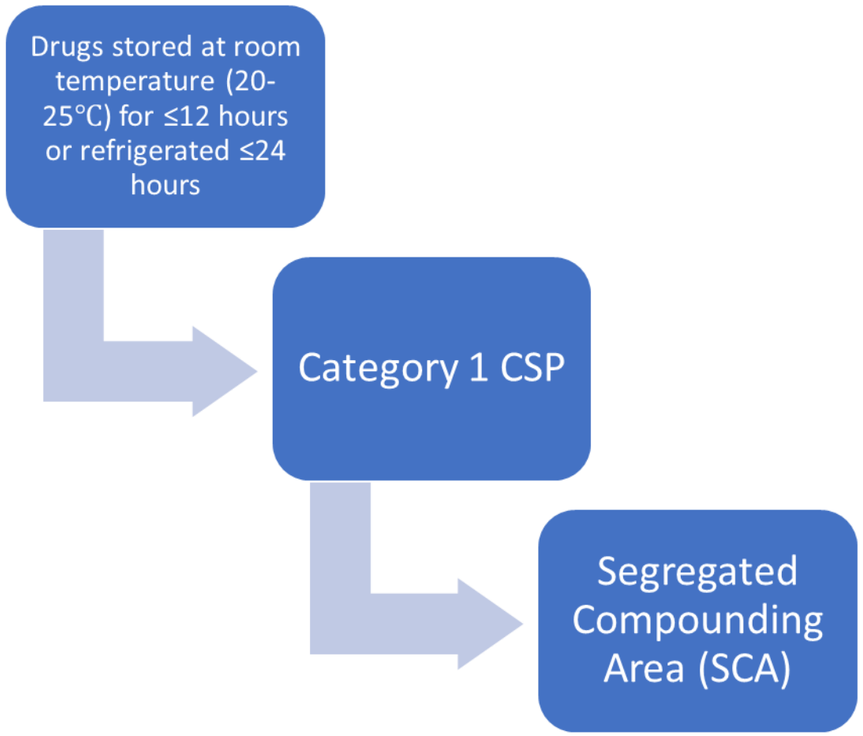
Types of SECs (Secondary Engineering Control)

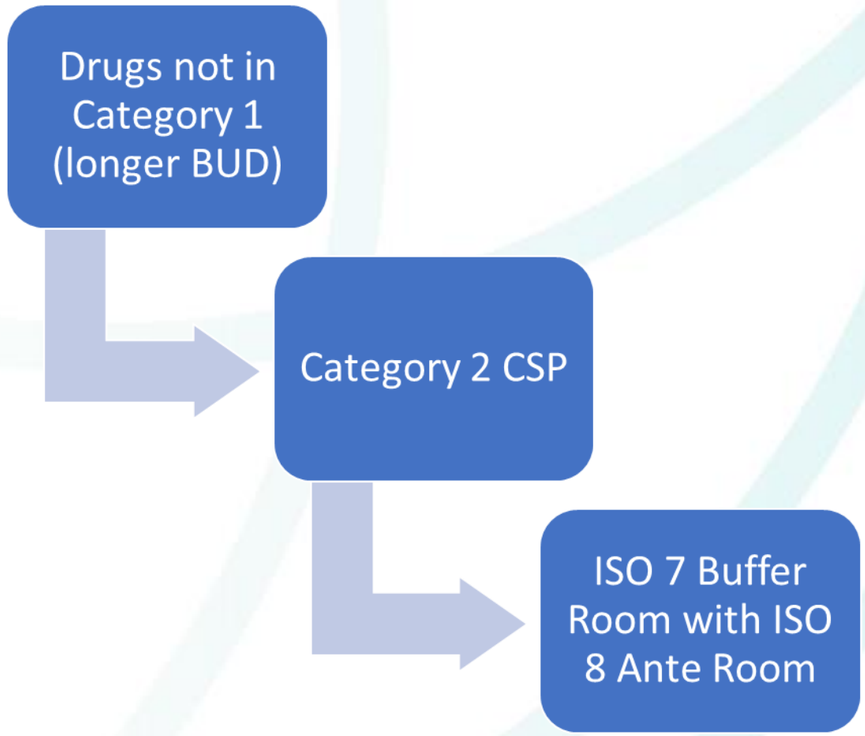
- **SCA (Segregated Compounding Area):** "A designated, unclassified space, area, or room with a defined perimeter that contains a PEC and is suitable for preparation of Category 1 CSPs only" (USP).
- **Buffer Room:** "An ISO Class 7 or cleaner room with fixed walls and doors where PEC(s) that generate and maintain an ISO Class 5 environment are physically located. The buffer room may only be accessed through the anti-room" (USP).
  - **Ante-Room:** "An ISO Class 8 or cleaner room with fixed walls and doors where personnel hand hygiene, garbing procedures, and other activities that generate high particulate levels may be performed. The ante-room is the transition room between the unclassified area of the facility and the buffer room" (USP).





Determining SEC Room Type

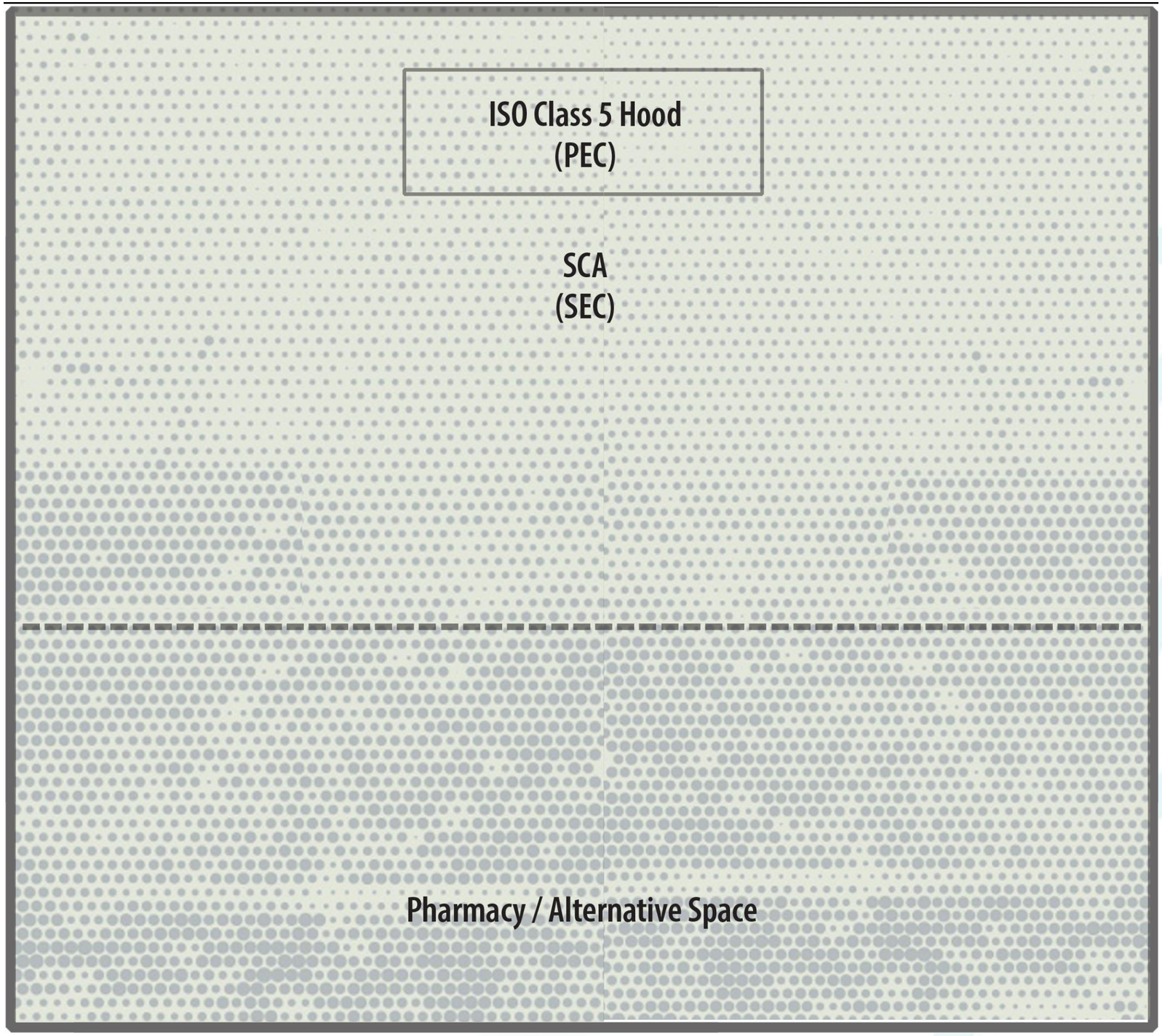




SEC Comparison Chart

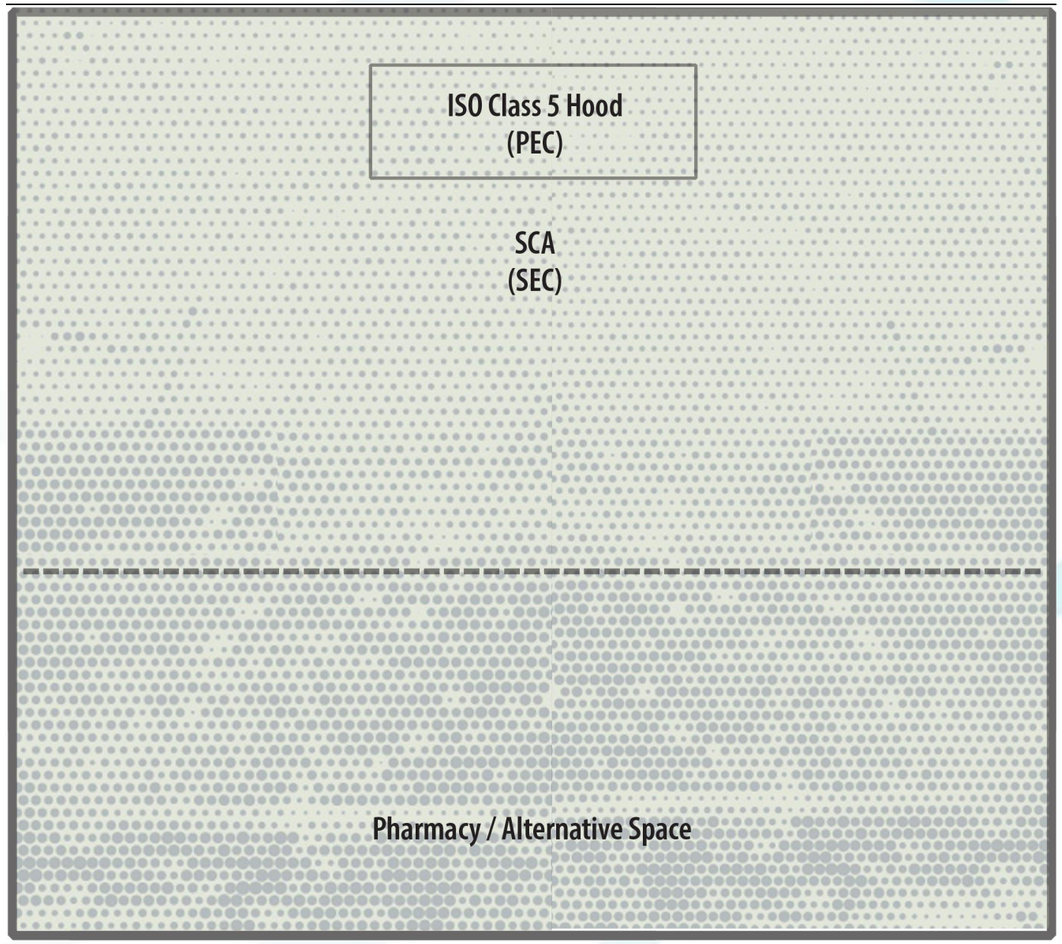
SEC COMPARISON CHART	SCA FOR STERILE COMPOUNDING	BUFFER ROOM FOR STERILE COMPOUNDING
Sterile environment?	NO	YES
ISO Classified?	NO	ISO CLASS 7
Requires anteroom?	NO	YES
Secure-access?	YES	YES
Can have a pass-through?	YES	YES
Positively pressured?	NO	YES
Air changes per hour (ACPH)?	N/A	30

SCA:



SCA (Segregated Compounding Area)

- ISO unclassified space
- Only Category 1 Sterile Preparations
- Away from unsealed windows, doors to the outdoors, and traffic flow
  - Away from "environmental control challenges (e.g. restrooms, warehouses, or food preparation areas" (USP)
- Boundaries marked with visible perimeter
- "Must be clean, uncluttered and dedicated to compounding" (USP)
  - "Surfaces… must be smooth, impervious, free from cracks and crevices, and non-shedding so they can be easily cleaned" (USP)
- Water Source: "Sink must be accessible but located at least 1 meter away from the PEC" (USP)
  - CANNOT be inside perimeter of SCA



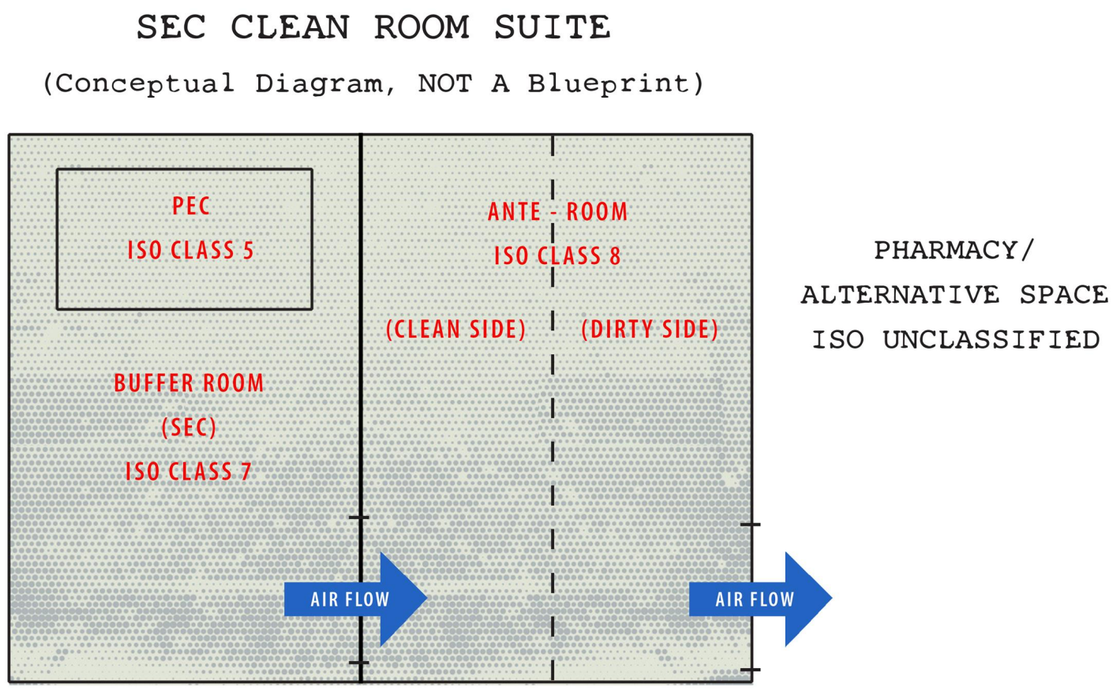
SEC CLEAN ROOM SUITE

(Conceptual Diagram, NOT A Blueprint)

PHARMACY/
ALTERNATIVE SPACE
ISO UNCLASSIFIED

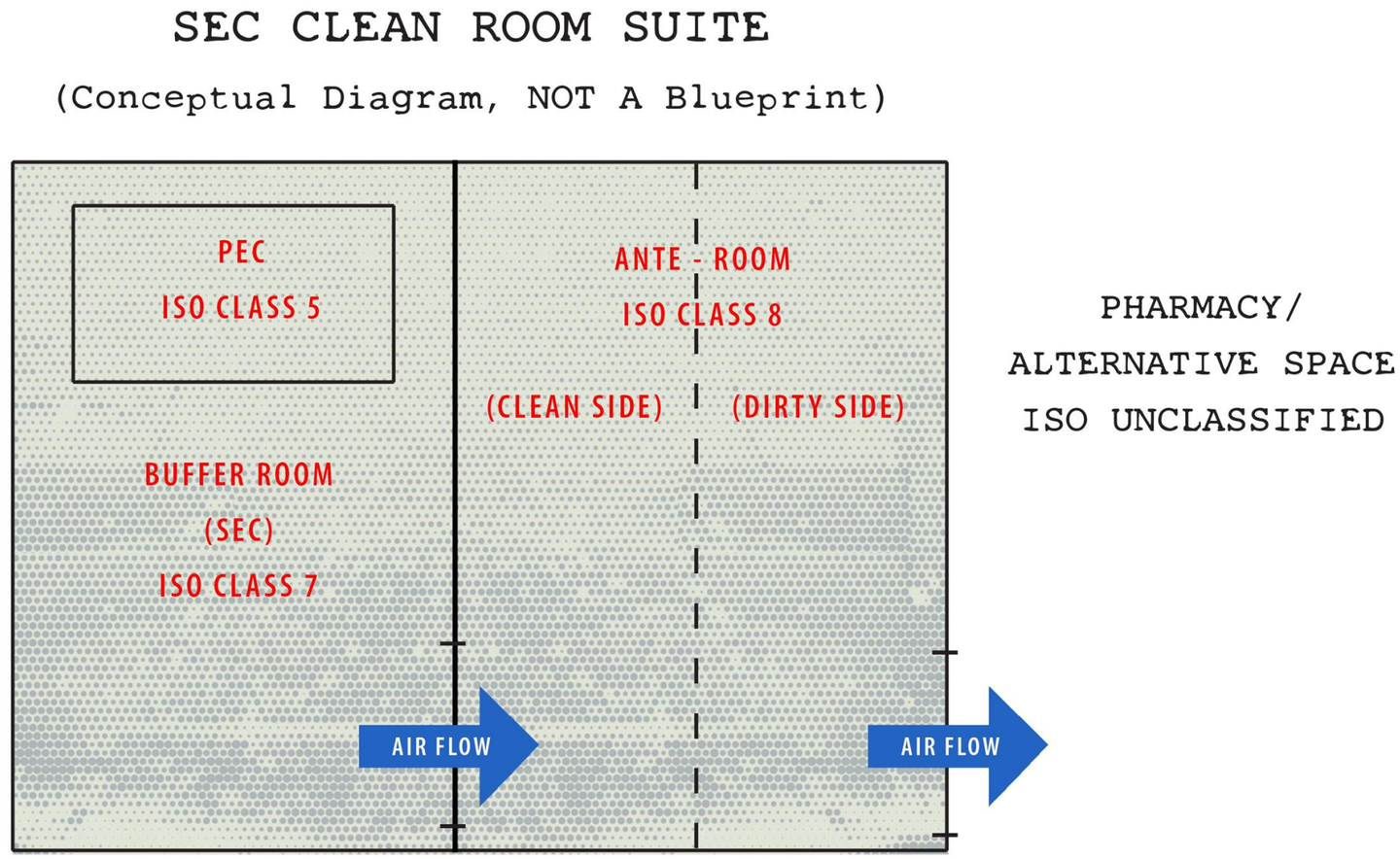
Clean Room Suite (Buffer Room and Ante-Room)

- Separated from ISO unclassified spaces by fixed walls and door
- "Surfaces of ceilings, walls, floors, doors, door frames, fixtures, shelving, work surfaces, counters, and cabinets… must be smooth, impervious, free from cracks and crevices, and non-shedding so they can be cleaned…" (USP).
- Air supplied through HEPA filters in the ceilings. Air returns low on the wall.
- Pressure-differential monitoring system: continuous monitoring with results checked and documented daily on days when compounding takes place
  - At least 0.020-inch water column positive pressure differential required between Buffer Room (higher pressure) and Ante-Room (lower pressure)
  - At least 0.020-inch water column positive pressure differential also required between Ante-Room (higher pressure) and surrounding unclassified area (lower pressure)



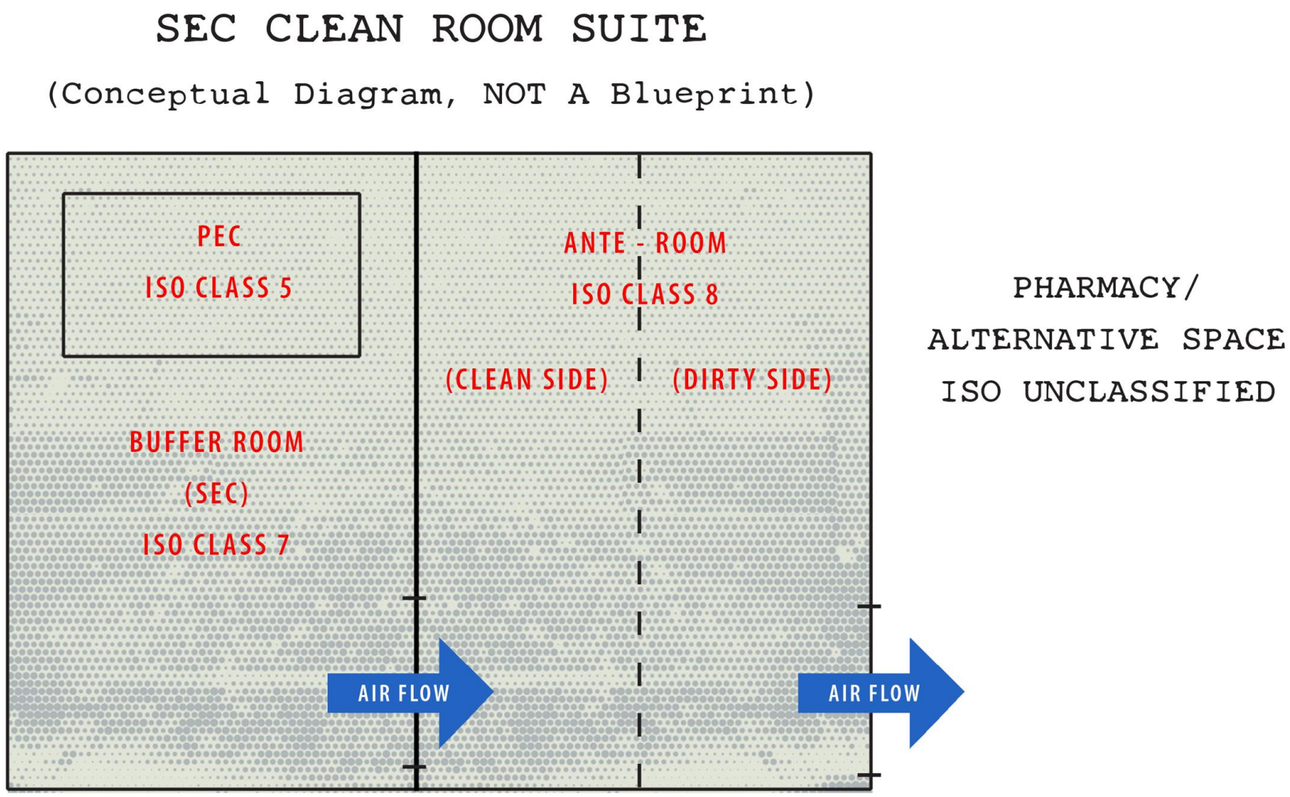
Buffer Room

- ISO Class 7
  - Greater than or equal to 30 total ACPH
  - At least 15 ACPH supplied by HEPA-filtered HVAC (in which case, the PEC must provide the rest))
- Both Category 1 and 2 Sterile Preparations
- If passthrough used, must have interlocking doors
- Hands-free door access
- Recommendation: Interlocking Doors

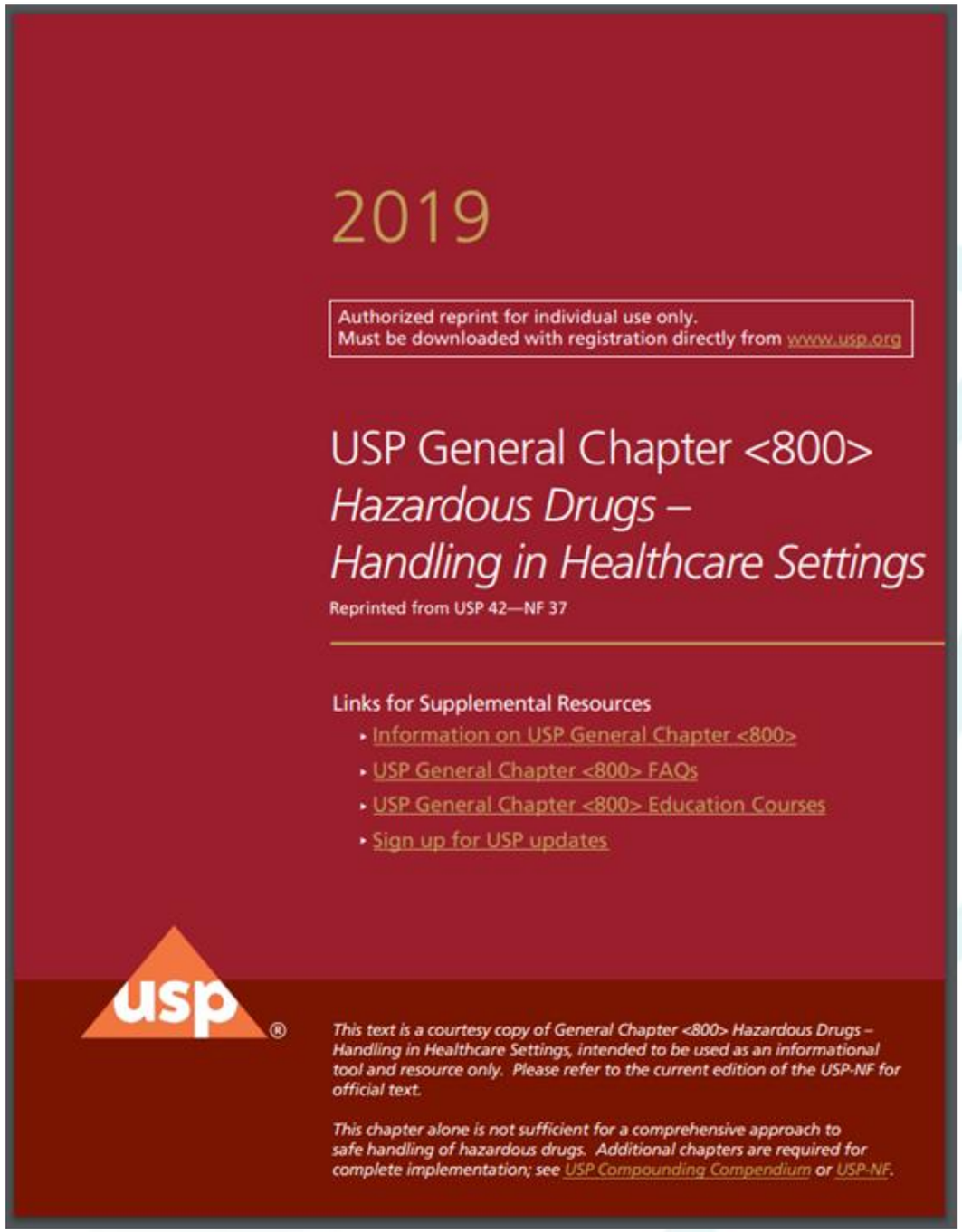


Ante-Room

- ISO Class 8
  - Greater than or equal to 20 ACPH
- Line of Demarcation separates clean and dirty sides (otherwise, two Ante-Rooms necessary)
- Sink Placement
  - NO sink or plumbed water source in Buffer Room
  - If sink outside Ante-Room, must be in “a clean space”
  - If sink in Ante-Room, can be on either clean or dirty side
    - Ante-Room must NOT have floor drains



USP General Chapter <800> *Hazardous Drugs – Handling in Healthcare Settings*



Only 19 pages!

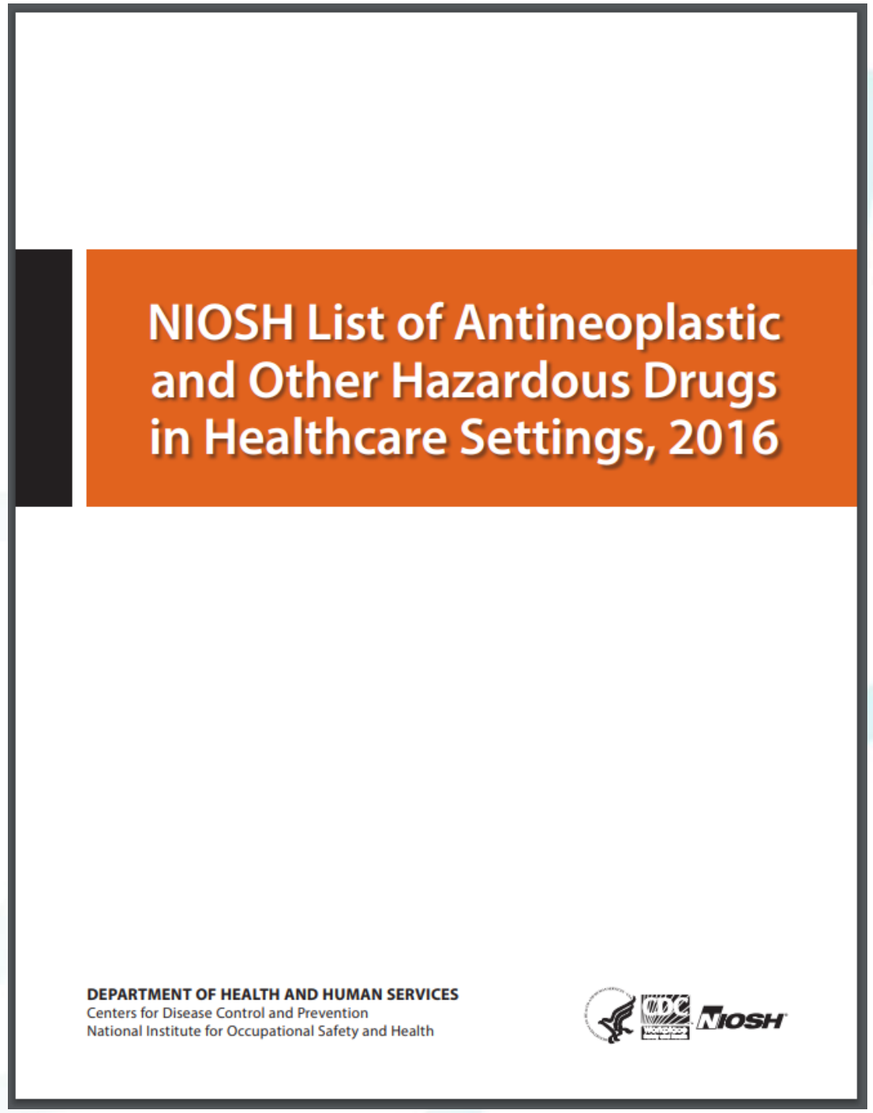
Why has USP <800> been created?

- USP formerly addressed **Hazardous Drugs (HDs)** only briefly within <797>.
- In general, previous approaches to HDs prioritized the safety of patients while doing little to address worker protection.
  - Trace amounts of HDs are sometimes found throughout hospitals and in the urine of employees, regardless of association with HD handling.

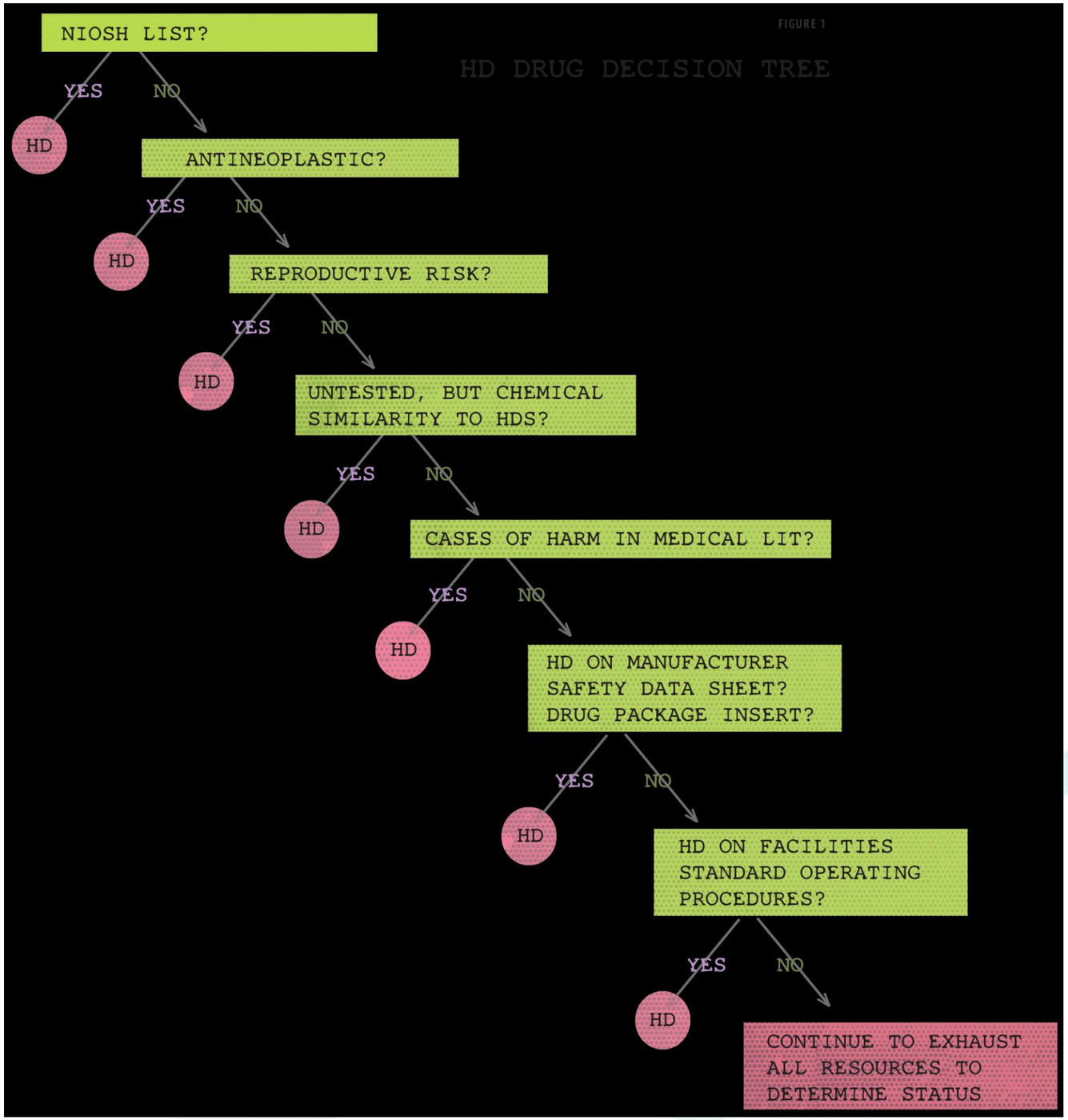
Hon CY, Teschke K, Shen H, et al. Antineoplastic drug contamination in the urine of Canadian health-care workers. *Int Arch Occup Environ Health.* 2015; 88:933–41.

What qualifies as a Hazardous Drug (HD)?

- "The NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings"
  - NIOSH = 'The National Institute for Occupational Safety and Health' within the Centers for Disease Control and Prevention' (CDC)
- Three HD Categories
  - Antineoplastic
  - Non-Antineoplastic
  - Reproductive Risk Only

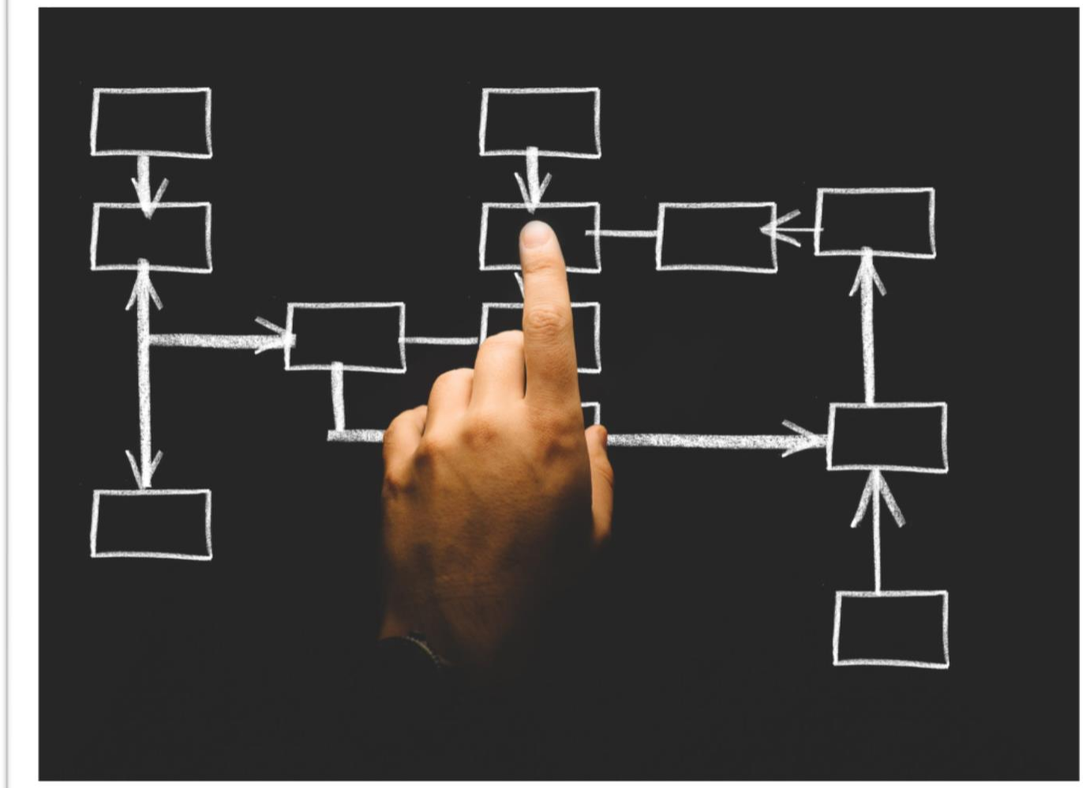


HD Drug Decision Tree:



HD Compounding Categories

- <800> references <797> because HD drugs can also be sterile.
  - <800> also references <795> because HD drugs can be non-sterile.
- Three categories of HD compounding:
  - Nonsterile, HD Preparations
  - Category 1 Sterile, HD Preparations with 12-hour or less BUD (24-hour if refrigerated)
  - Category 2 Sterile, HD Preparations with more than 12-hour BUD (24-hour if refrigerated)



Sterile or Non-Sterile?

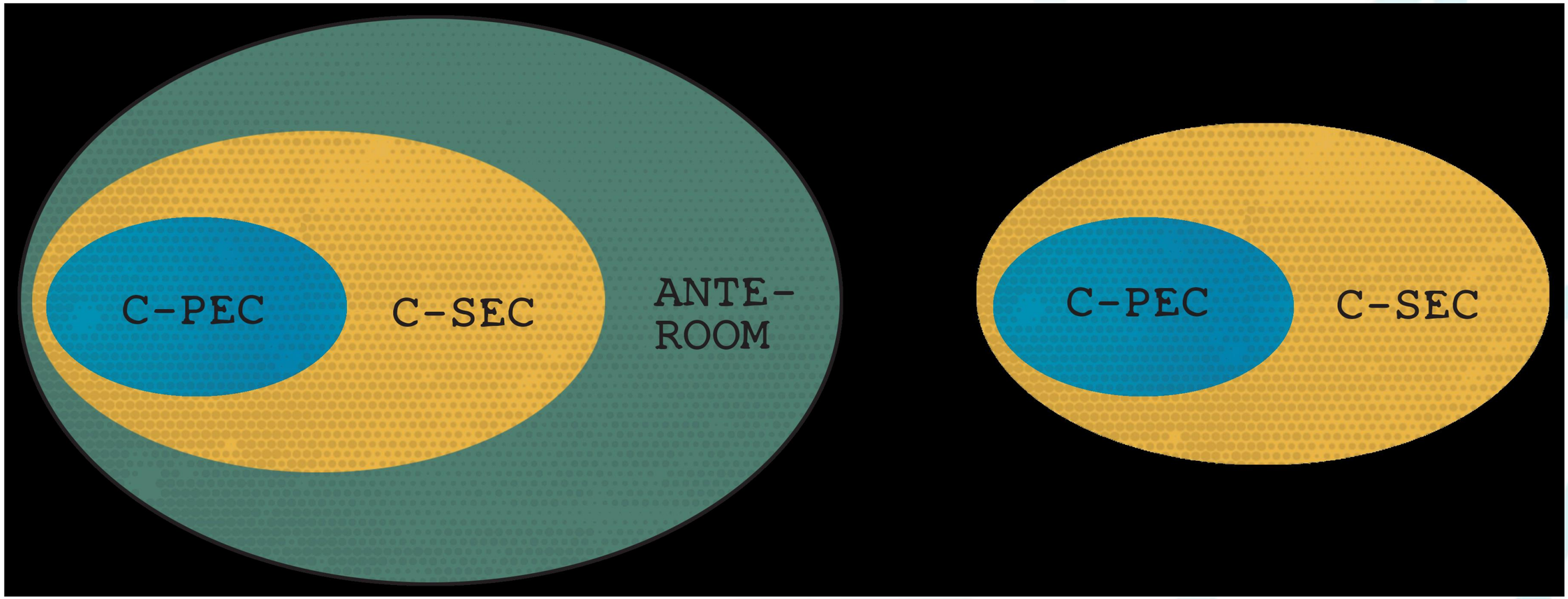
Compound Non-Sterile Preparation (CNSP)	Compound Sterile Preparation (CSP)
• Solid/ Liquid Oral Preparation • Rectal/ Vaginal/ Topical • Nasal/ Sinus Preps of local applications • Otic preparation (applied to or in ear) • USP <795>	• Injections/ Infusions • Irrigations for internal body cavities (does not include those listen in CNSP) • Ophthalmic Dosage forms (Eye drops/ gels/ lotion) • USP <797>

Designing a USP <800> Compliant Pharmacy

Isolation and Containment Concepts

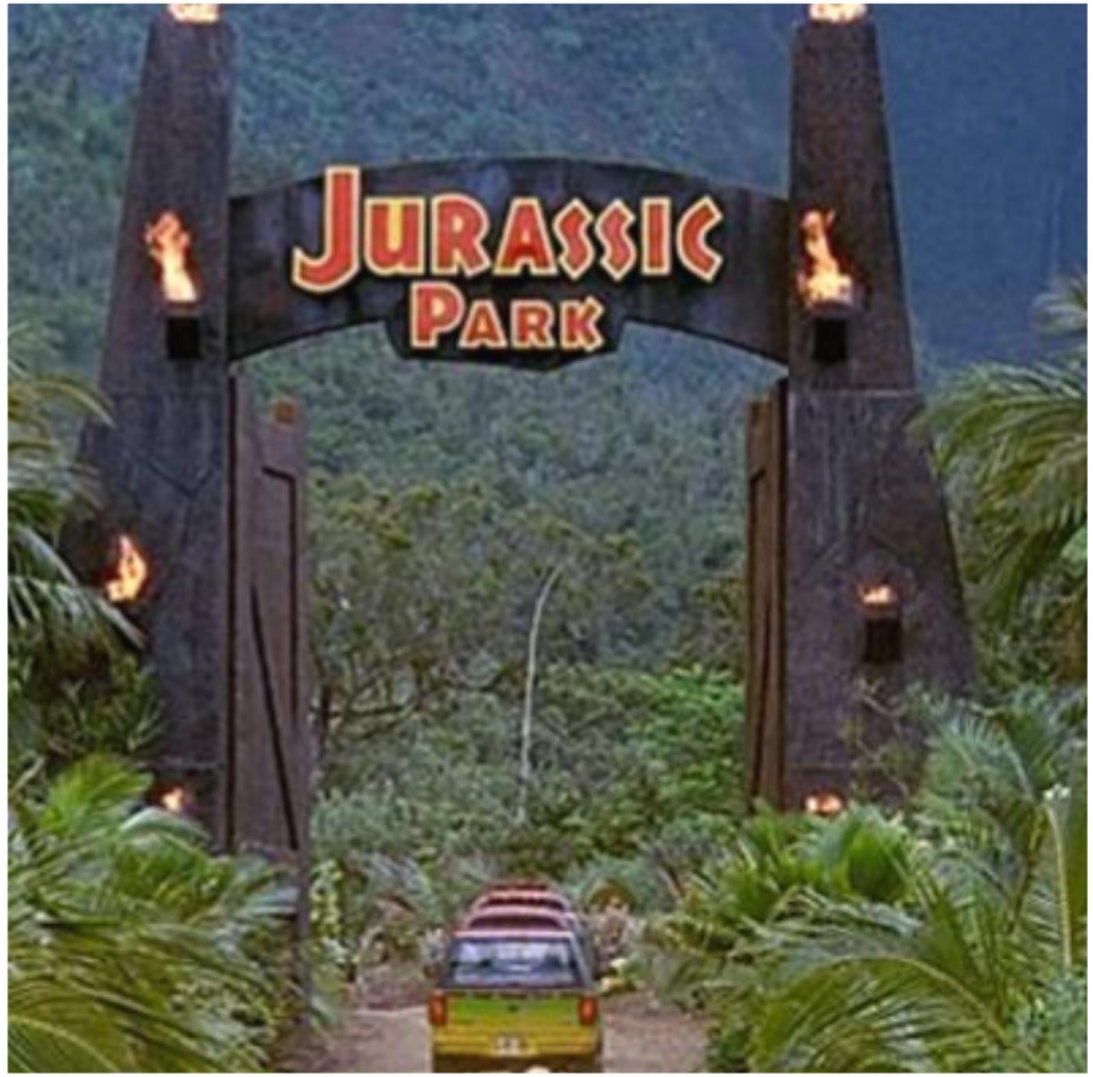
HD Clean Room Suite (HD Buffer Room + Ante-room) = Category 2

C-SCA = Category 1



C-PEC (Containment Primary Engineering Control)

- C-PEC (Containment Primary Engineering Control): "A ventilated device designed and operated to minimize worker and environmental exposures to HDs by controlling emissions of airborne contaminants through the following:"
  - "The full or partial enclosure of a potential contaminant source"
  - "The use of airflow capture velocities to trap and remove airborne contaminants near their point of generation"
  - "The use of air pressure relationships that define the direction of airflow into the cabinet"
  - "The use of HEPA filtration on all potentially contaminated exhaust streams" (USP)
  - Externally ventilated



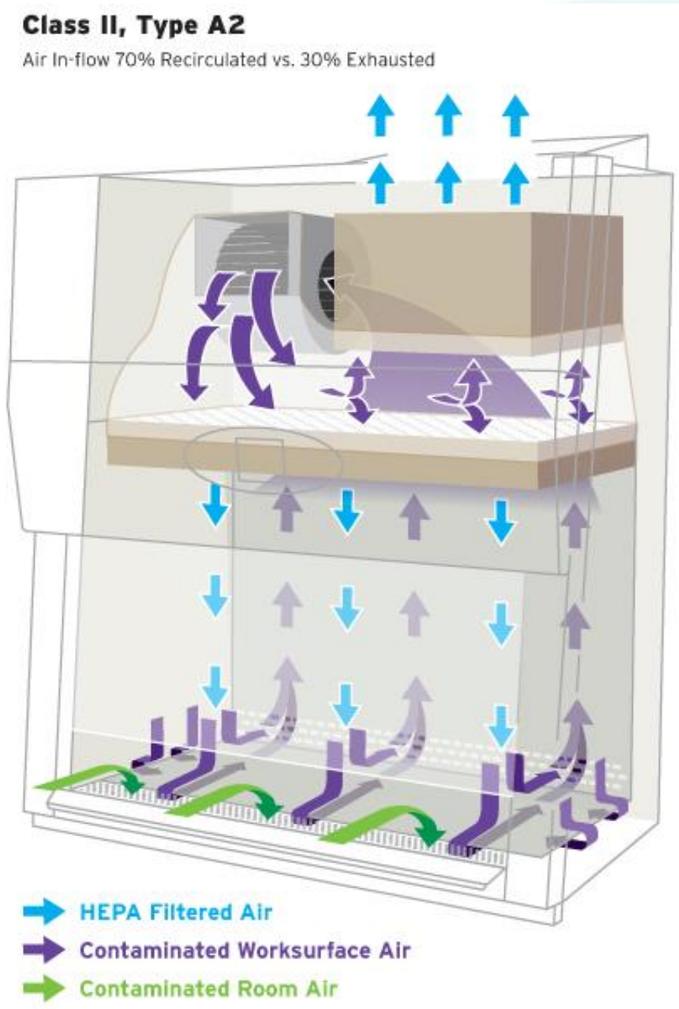
What are we trying to contain exactly?

Types of C-PECs (Containment Primary Engineering Control)

- Class II or III BSC or CACI
- BSC Class II: Type A2, B1, or B2
  - Type A2: "For most known HDs…. a simple and reliable integration with the ventilation and pressurization requirements of the C-SEC" (USP)
  - Type B2: "Typically reserved for use with volatile components" (USP)
- **NO** Laminar Airflow Workbenches (LAFWs) or Compounding Aseptic Isolator (CAIs) for antineoplastic HDs
- BSC or CACI used for HDs must **not** be used for non-HDs, unless "placed into a protective outer wrapper during removal from the C-PEC and is labeled to require PPE handling precautions" (USP)

Types of C-PECs (Containment Primary Engineering Control)

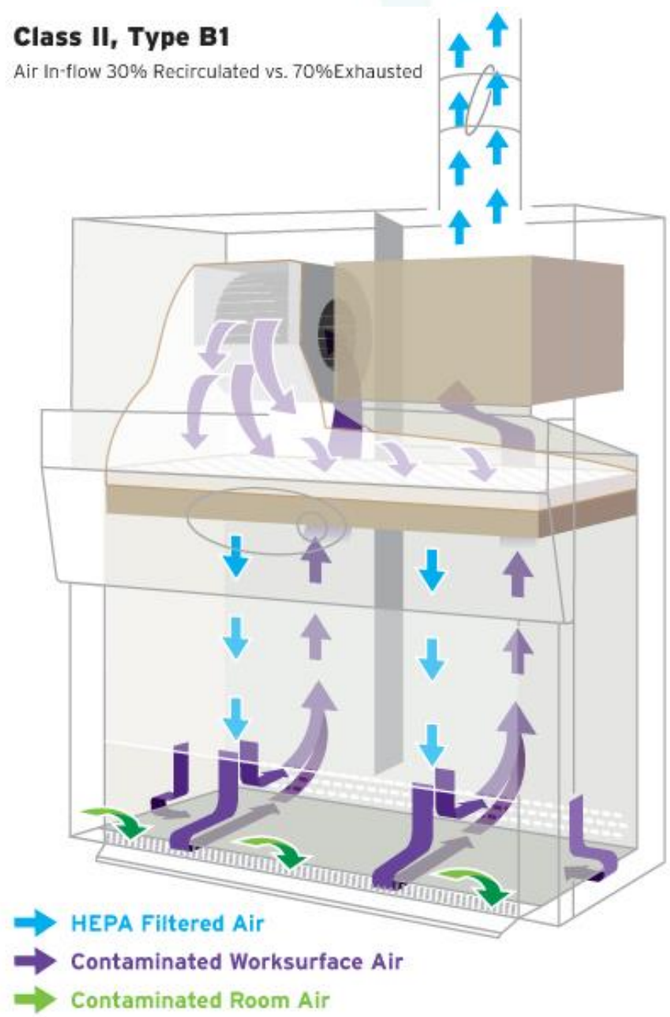
- Laminar Airflow Systems (LAFS)
  - Class II Biological Safety Cabinet: Type A2
    - Category 1: C-SCA / Category 2: HD Buffer Room



Images from NuAire

Types of C-PECs (Containment Primary Engineering Control)

- Laminar Airflow Systems (LAFS)
  - Class II Biological Safety Cabinet: Type B1
    - Category 1: C-SCA / Category 2: HD Buffer Room



Images from NuAire.

Images from NuAire

Types of C-PECs (Containment Primary Engineering Control)

- Laminar Airflow Systems (LAFS)
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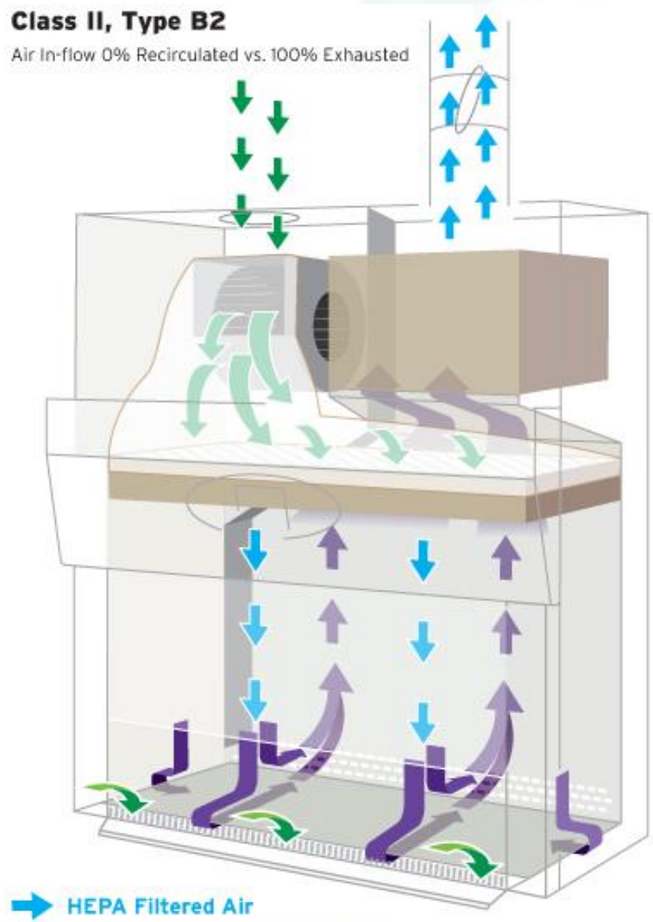
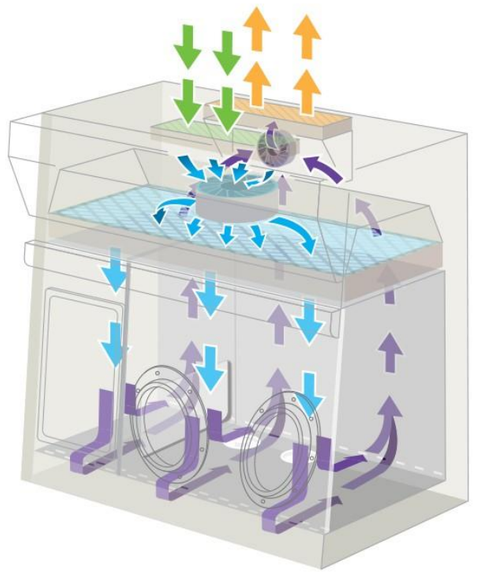


Images from NuAire.

Images from NuAire

Types of C-PECs (Containment Primary Engineering Control)

- Restricted-Access Barrier System (RABS)
  - Compounding Aseptic Containment Isolator (CACI) – Recirculation Unit
    - Category 1: C-SCA / Category 2: HD Buffer Room

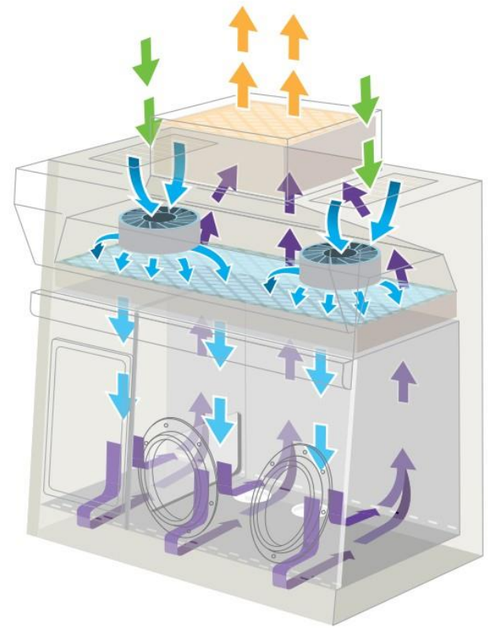


Images from NuAire.

Images from NuAire

Types of C-PECs (Containment Primary Engineering Control)

- Restricted-Access Barrier System (RABS)
  - Compounding Aseptic Containment Isolator (CACI) – Total Exhaust Unit
    - Category 1: C-SCA / Category 2: HD Buffer Room



Images from NuAire

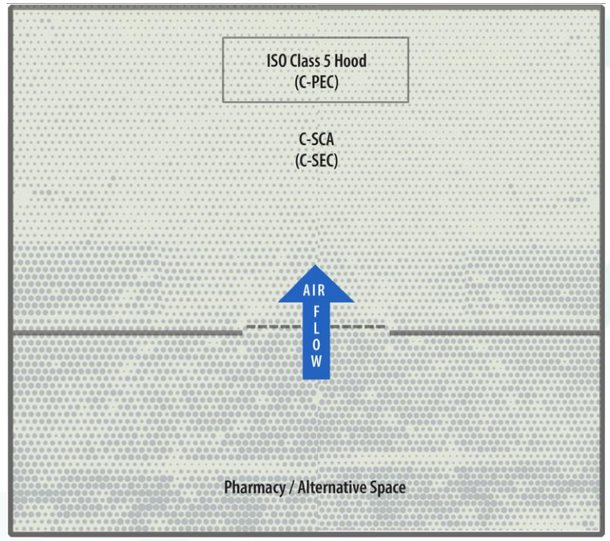
C-SEC (Containment Secondary Engineering Control)

- **C-SEC (Containment Secondary Engineering Control):** The room with fixed walls in which the C-PEC is placed. It incorporates specific design and operational parameters required to contain the potential hazard within the compounding room" (USP).
- Externally vented
- Physically separated
- Negative pressure
- Sink available for handwashing
  - "Eyewash station and/or other emergency or safety precautions" (USP)
  - Locate water/drains so as not to conflict with ISO classifications
  - Water sources and drains at least 1 meter from C-PEC

Not just any old room will do…

Types of C-SECs (Containment Secondary Engineering Control)

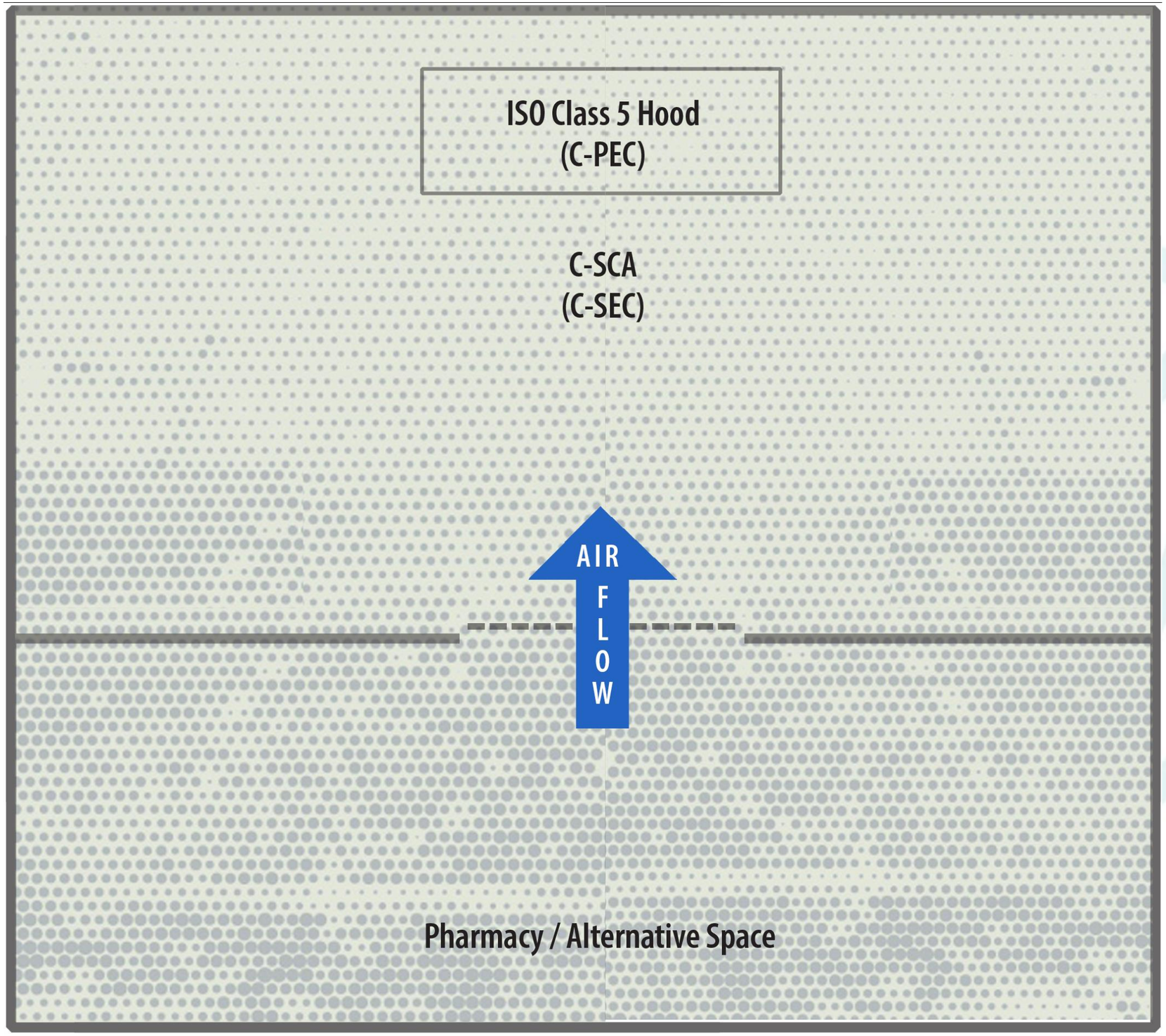
- **C-SCA (Containment Segregated Compounding Area):** "A type of C-SEC with nominal requirements for airflow and room pressurization as they pertain to HD compounding" (USP).
- **Buffer Room:** "A type of C-SEC under negative pressure that meets ISO Class 7 or better air quality where the C-PEC that generates and maintains an ISO Class 5 environment is physically located. Activities that occur in this area are limited to the preparation and staging of components and supplies used when compounding HDs" (USP).
  - **Ante-Room:** "An ISO Class 7 or cleaner room where personnel hand hygiene, garbing procedures, and other activities that generate high particulate levels are performed. The ante-room is the transition room between the unclassified area of the facility and the buffer room" (USP).



C-SEC Comparison Chart

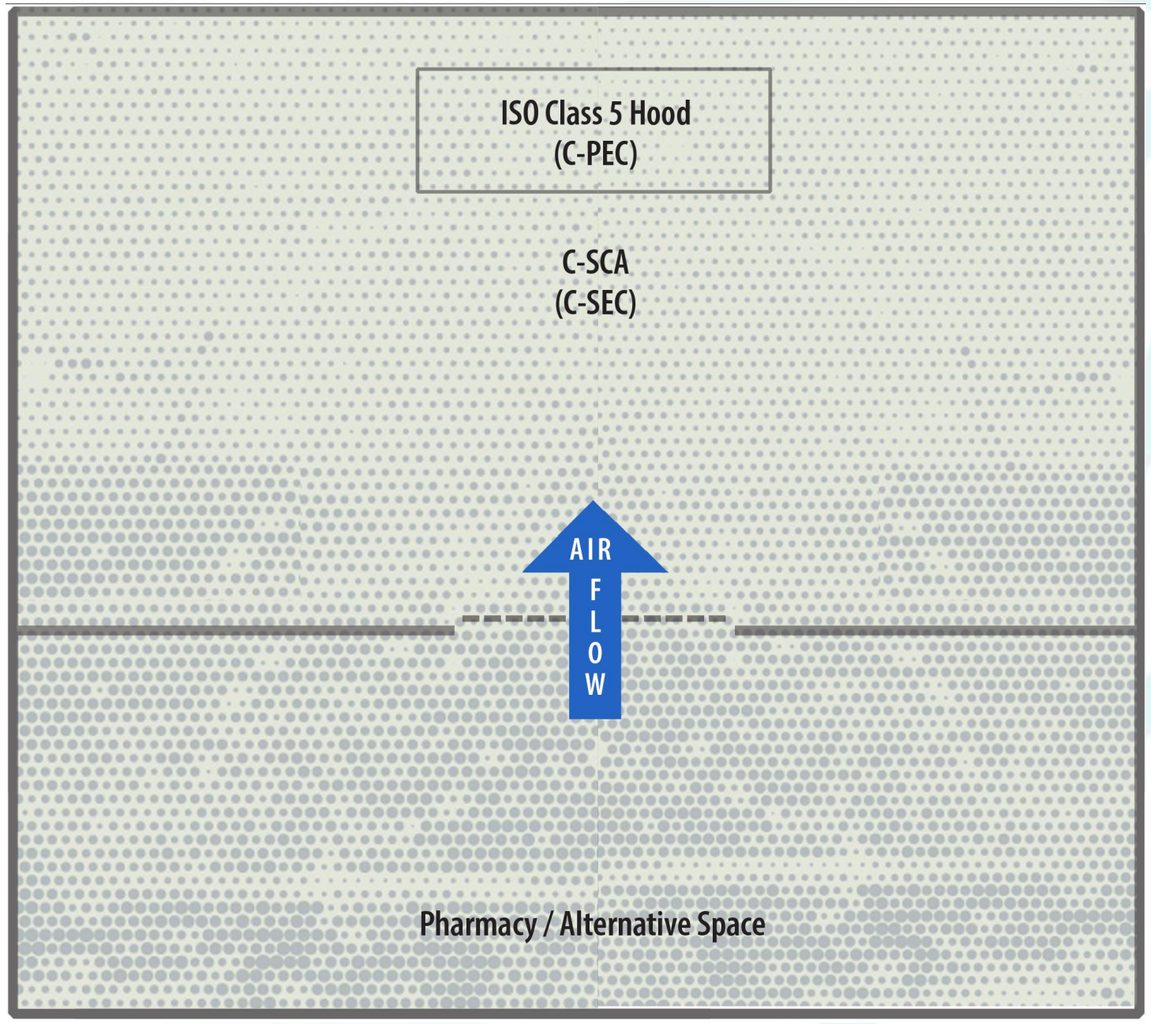
C-SEC COMPARISON CHART	C-SCA FOR STERILE COMPOUNDING	HD BUFFER ROOM FOR STERILE COMPOUNDING
Sterile environment?	NO	YES
ISO Classified?	NO	ISO CLASS 7
Requires anteroom?	NO	YES
Secure-access?	YES	YES
Can have a pass-through?	YES	YES
Negatively pressured?	YES	YES
Air changes per hour (ACPH)?	12	30

C-SCA:


ISO Class 5 Hood
(C-PEC)
C-SCA
(C-SEC)
AIR
FLOW
Pharmacy / Alternative Space

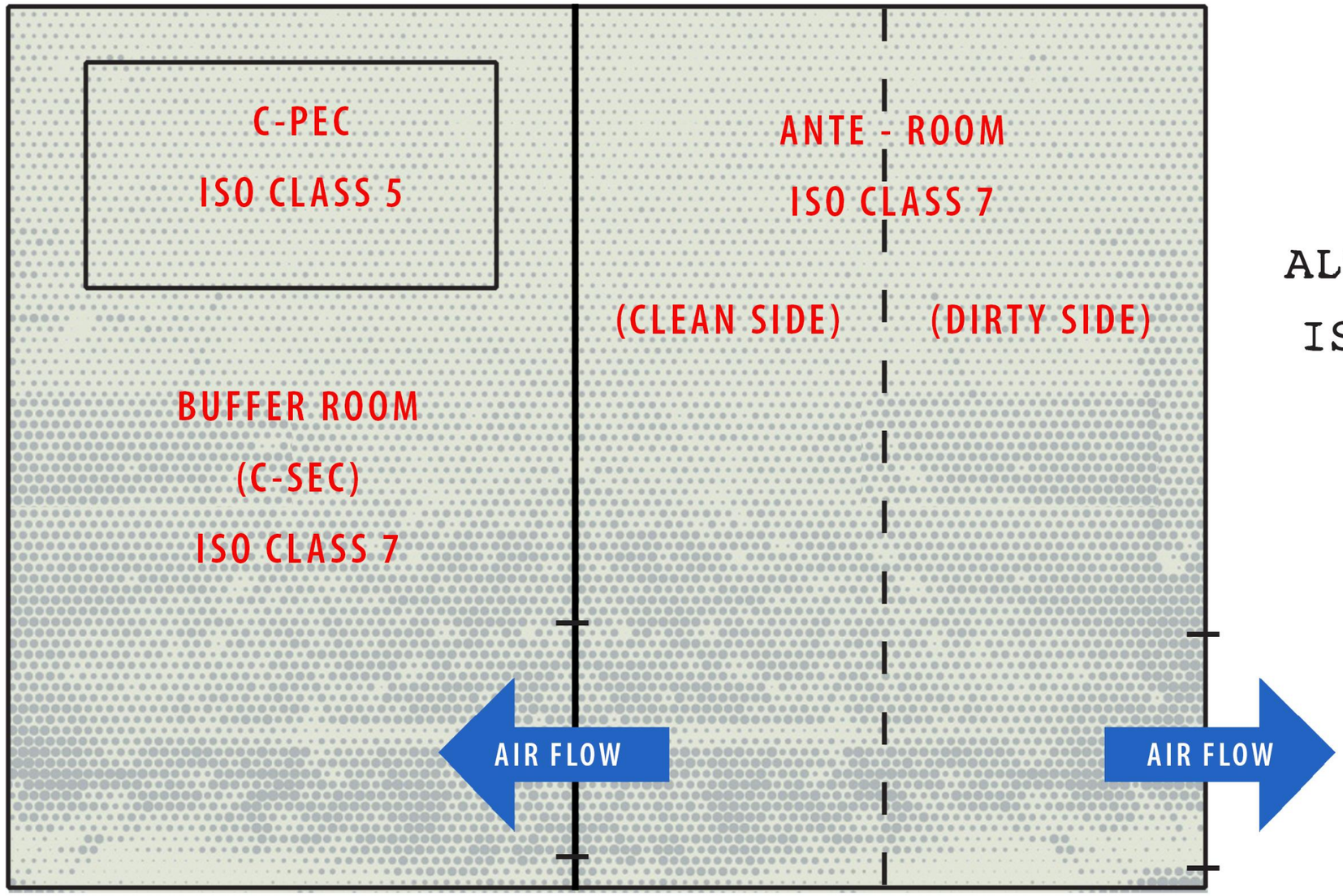
C-SCA (Containment Segregated Compounding Area)

- ISO unclassified space
- Only Category 1 Sterile, HD Preparations
- Negative pressure between 0.01 and 0.03 inches of water column relative to all adjacent areas
- Minimum of 12 Air Changes Per Hour (ACPH)
  - Externally vented
- Water Source: "hand washing sink at least 1 meter from C-PEC and may be either inside the C-SCA or directly outside the C-SCA" (USP).



C-SEC CLEAN ROOM SUITE

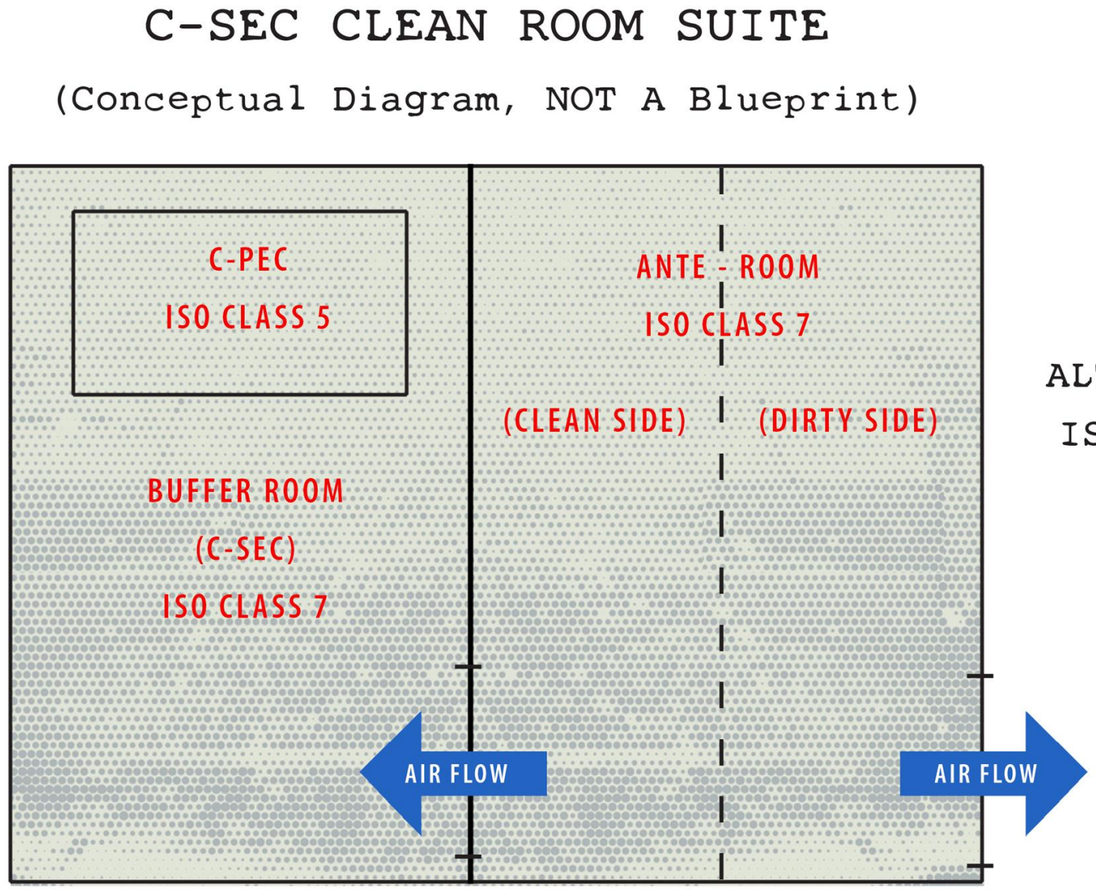
(Conceptual Diagram, NOT A Blueprint)



PHARMACY/
ALTERNATIVE SPACE
ISO UNCLASSIFIED

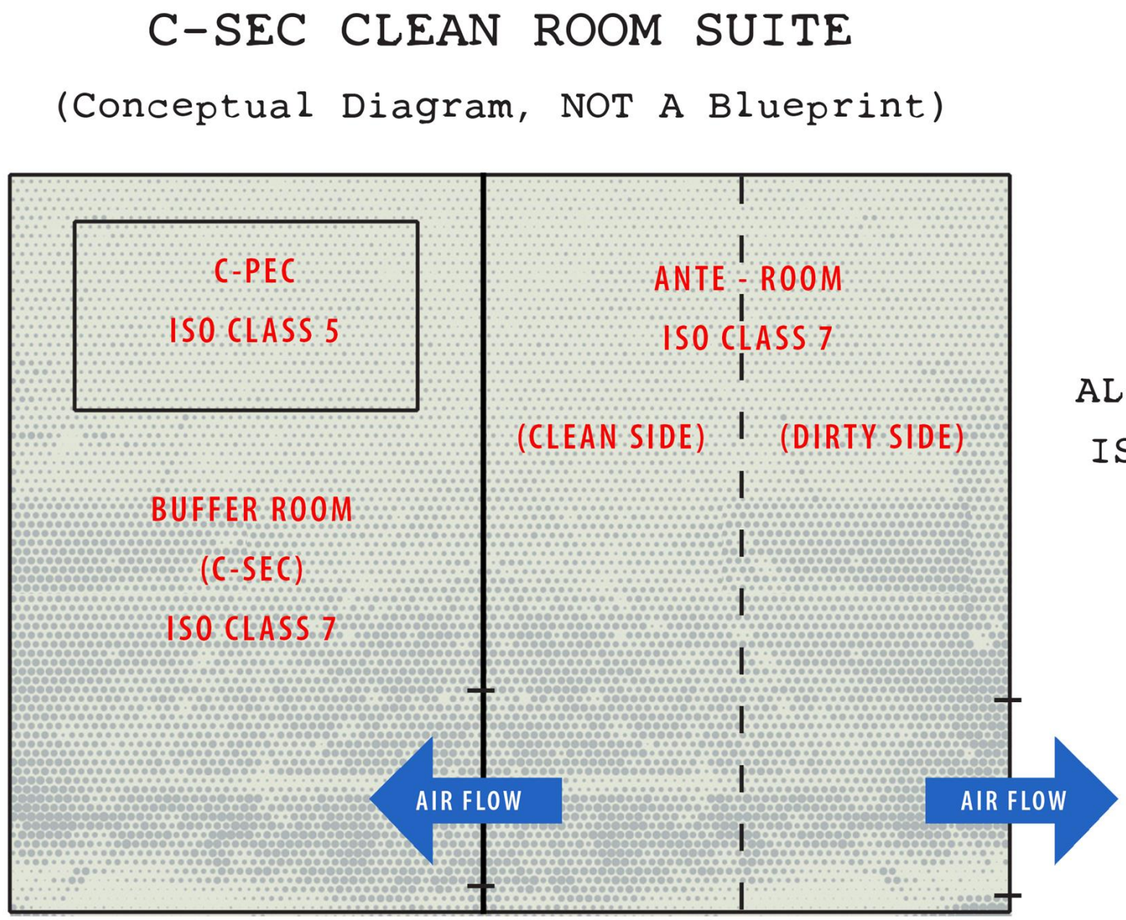
HD Buffer Room

- ISO Class 7 Air Quality or better
- Negative Pressure
- 30 Air Changes Per Hour (ACPH) of HEPA-filtered supply air



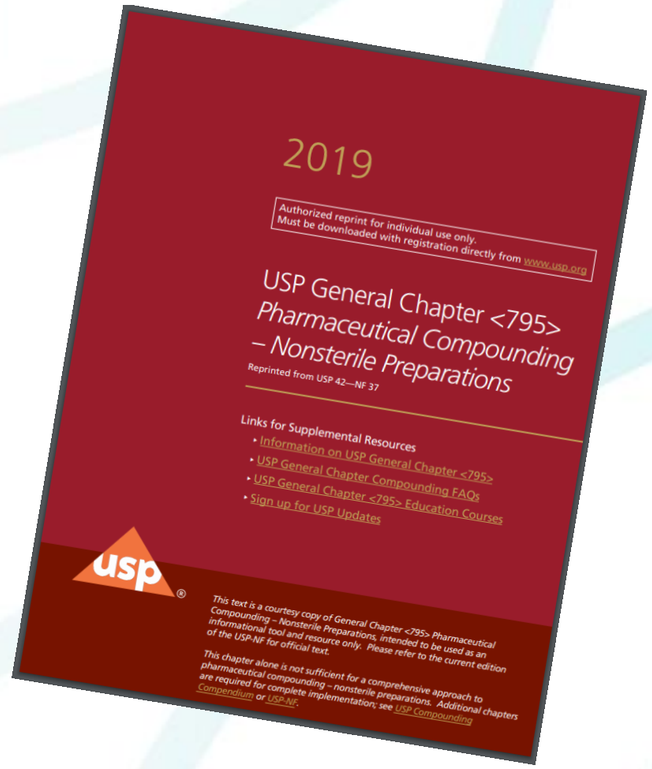
HD Ante-room

- ISO Class 7 Air Quality
- Handwashing sink MUST be placed in Ante-room
  - At least 1 meter from HD Buffer Room entrance



Nonsterile, HD Compounding

- Nonsterile C-PEC
  - C-PEC either externally vented (preferred) or have redundant-HEPA filters in series
    - Example: Class I or II Biological Safety Cabinet (BSC)
    - Example: Containment Ventilated Enclosure (CVE)
  - C-PEC used for sterile compounding may **OCCASSIONALLY** be used for nonsterile, but must be "decontaminated, cleaned, and disinfected" before resuming sterile compounding.
    - Sterile and Nonsterile C-PECs may **ONLY** be in the same room if the C-SEC maintains an ISO Class 7 environment. C-PECs must be at least 1 meter apart.
  - C-PEC exclusively used for nonsterile compounding does **NOT** require unidirectional airflow
- Nonsterile C-SEC
  - Externally vented
  - 12 ACPH
  - Negative pressure
- Reference <795>, as <797> does not apply.



HD Storage

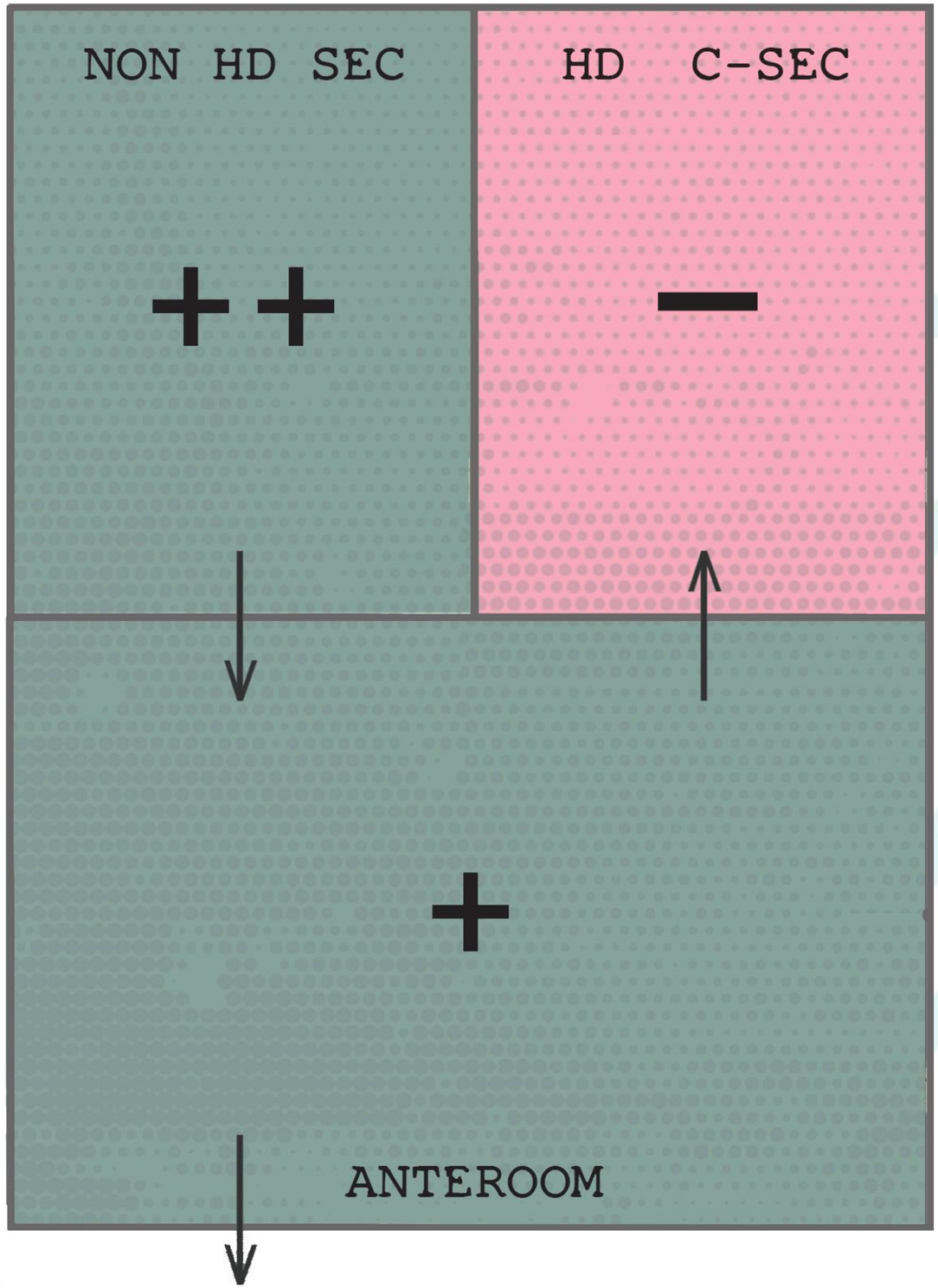
NOT a suitable storage container!

- Sterile and Non-Sterile HDs may be stored together.
- No storage on the floor.
- Earthquake-proof storage, if applicable.
- "Non-antineoplastic, reproductive risk only, and final dosage forms of antineoplastic HDs may be stored with other inventory" (USP).
- Non-final dose form antineoplastic HDs and any HD Advanced Pharmaceutical Ingredient (API) CANNOT be stored with non-HDs.
  - These drugs require "an externally ventilated, negative-pressure room with at least 12 air changes per hour (ACPH)" (USP).
  - This is usually the HD Buffer Room or C-SCA.
  - HDs used for Non-Sterile compounding can be stored in an unclassified C-SCA, but they CANNOT be stored in an HD Buffer Room. Therefore, some facilities may need a Dedicated HD Storage Room.
- Refrigerated, sterile antineoplastic HDs require dedicated refrigerator in at least a 12 ACPH negative pressure space.
  - Usually the HD Buffer Room or C-SCA.
  - If placed in HD Buffer Room, "an exhaust located adjacent to the refrigerator's compressor and behind the refrigerator **should** be considered" (USP).

<797> & <800> DESIGN

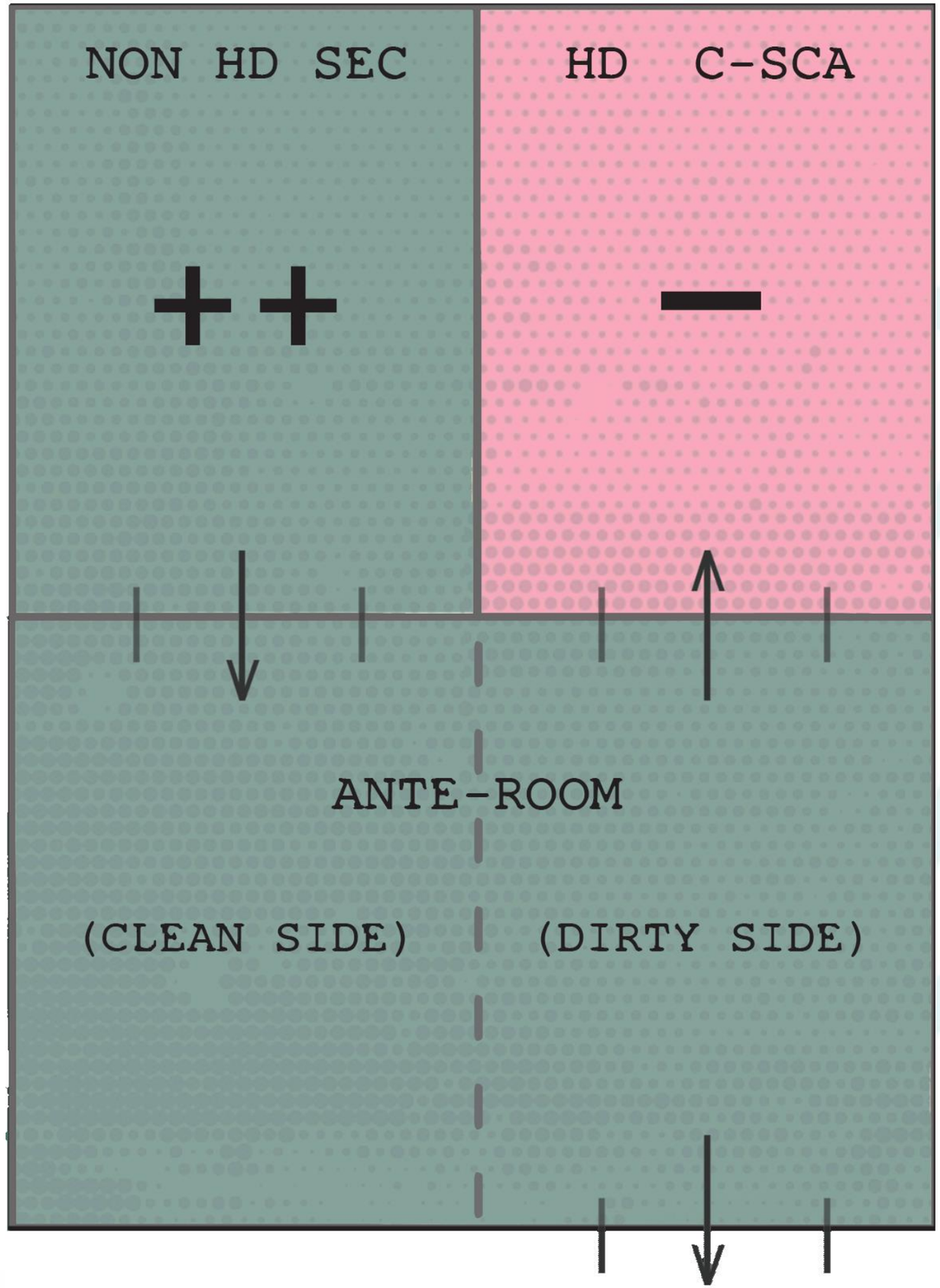
<797> and <800> Clean Room Suite:

- Non-HD and HD Buffer Rooms share a common Ante-Room.



<797> Clean Room Suite with <800> C-SCA:

- The C-SCA is entered through the dirty side of the shared Ante-room.



<797> & <800> PROCESS

The Compliance Process

- A facility must select a **Designated Person** who will be responsible for USP compliance.
- A **Gap Analysis** must detail current non-compliance and necessary next steps.
- **Standard Operating Procedures (SOPs)** must be crafted that address USP compliance.

Enforcement of USP <797> and <800>

ENFORCEMENT

?
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The Joint Commission

FDA

OSHA® Occupational Safety and Health Administration

GREAT SEAL OF THE STATE OF OKLAHOMA 1907

CMS CENTERS FOR MEDICARE & MEDICAID SERVICES

How are USP <797> & <800> enforced?

- USP itself only publishes the guidelines and has no enforcement power. However, the chapters are enforceable by several other entities.

ENFORCEMENT AND/OR	ENFORCEMENT	FORMAL ADOPTION?	INSPECTIONS?	PRIORITIES
State Boards of Pharmacy (SBoP)	YES	VARIABLE	YES	VARIABLE
Occupational Safety and Health Administration (OSHA)	YES	YES	YES	WORKER COMPLAINTS
Food and Drug Administration (FDA)	YES	YES	YES	SUSPECTED VIOLATIONS OR KNOWN HARMS
Centers for Medicare and Medical Services (CMS)	AS REQUIREMENT FOR PARTICIPATION	NO	YES	APPLICANTS FOR PARTICIPATION
The Joint Commission	NO	RECOMMENDED	NO	N/A

Oklahoma Administrative Code – Title 535: Oklahoma State Board of Pharmacy

- The revised <797> has **NOT** been considered or adopted (*SOURCE: direct from OK SBoP*).
  - The "OLD" (previously existing) <797> is referenced in the Oklahoma Administrative Code.
- The adoption of Chapter <800> is being **delayed** until July 1, 2021 (*SOURCE: direct from OK SBoP*).
  - Because <800> references the new <797>, both chapters will become unavoidable.

OSHA (Occupational Safety and Health Administration)

- OSHA investigates tips about unsafe working conditions.
- Because hazardous drugs pose a danger to compounders…
  - And because USP <800> represents the standard for worker safety with hazardous drugs…
  - OSHA could find non-compliance with USP <800> to be a violation of worker protections.
- This enforcement mechanism may only apply to <800>, but…
  - Planning and design for <797> and <800> are interlinked by shared space and resources.

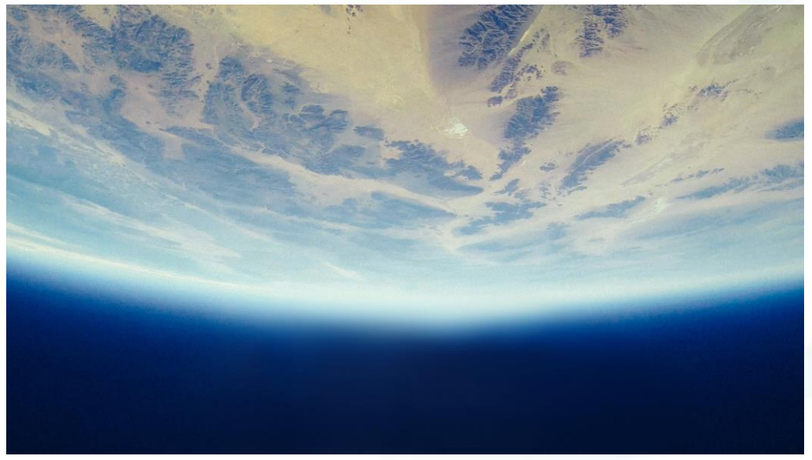
OSHA® Occupational Safety and Health Administration

Looking to the Future

- The new USP <797> and <800> may eventually become minimum standards enforceable by…
  - Professional/Trade Organizations
  - Local, State, and Federal Authorities
- Empirically, <795> and the old <797> were adopted in this way.

Summary

- The United States Pharmacopeial Convention sets best practices for compounding pharmacies via its *Compounding Compendium.*
  - The revised USP <797> pertains to sterile compounding.
    - The most substantive change is the adoption of a +/- 12-hour BUD as the threshold by which facility requirements are determined.
  - The entirely new USP <800> pertains to hazardous drugs.
    - Separate spaces for hazardous and non-hazardous drugs will be necessary in most cases.
- USP does not enforce these chapters, but other organizations either do or likely will in the future.



Session 3

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Oklahoma Association of Healthcare Engineers

2019 Summer Regional Event

HFG architecture

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