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WELCOME

USP <800> and Proposed <795>/<797> Compliance

ACHC

PCAB PHARMACY COMPOUNDING ACCREDITATION BOARD

WELCOME

- Housekeeping Items

Restrooms

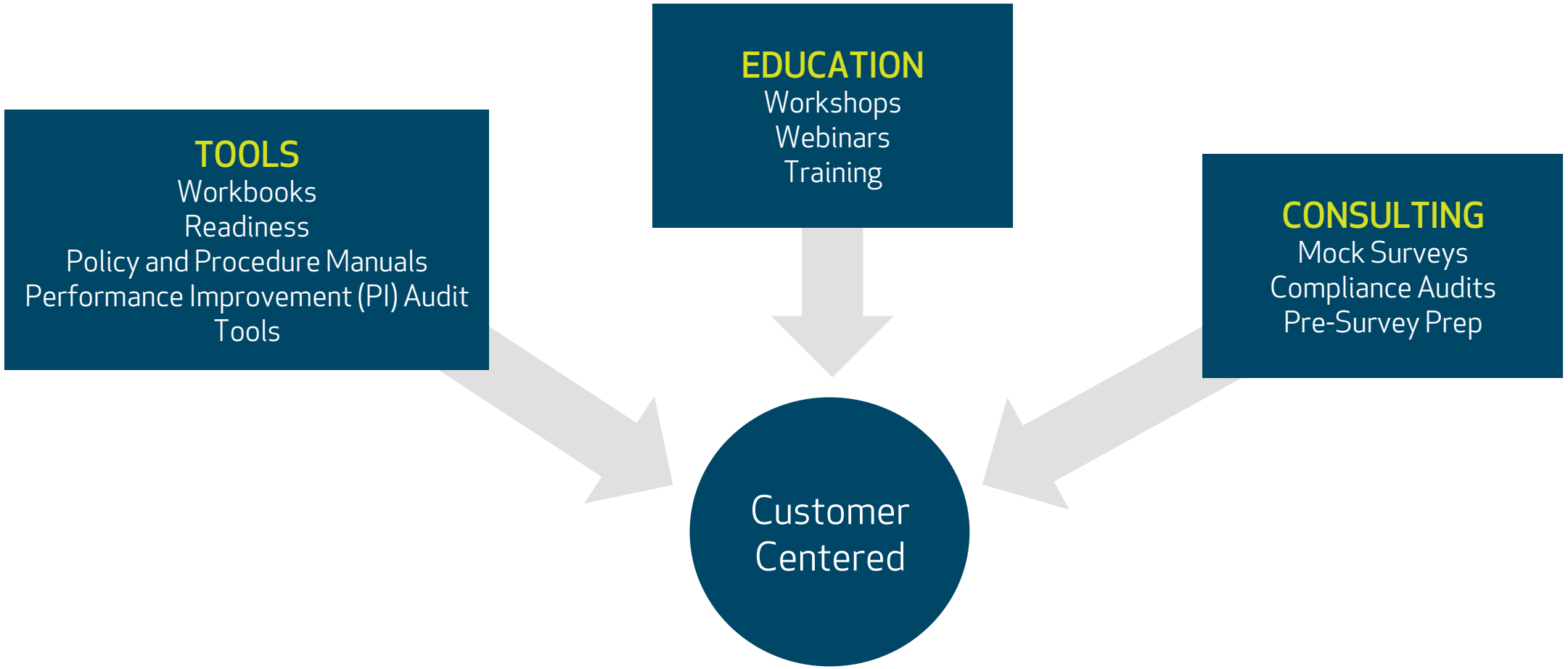
No Smoking

Breaks

Lunch

Evaluations

ACCREDITATION UNIVERSITY



GREG STOWELL

Education and Consulting Manager

JON PRITCHETT, PHARM D, RPH

Associate Director, Pharmacy

OUR PROGRAM

- Introduction and implementation of USP <800>
- What's new in the proposed USP <795> and <797>?
- Today is your opportunity to ask questions about how these changes will impact your pharmacy
- *Network with your colleagues!*

ACHC PHARMACY ACCREDITATION

- Hazardous Drug standards are currently incorporated into PCAB and IRX standards
- The *Distinction in Hazardous Drug Handling* provides standards built from USP <800>

Pharmacy Services:

AIC – Ambulatory Infusion Center

IRN – Infusion Nursing

IRX – Infusion Pharmacy

SRX – Specialty Pharmacy

SRX Only – SRX without DMEPOS

LTC - Long Term Care Pharmacy

PCAB Accreditation

CFNS – Non-Sterile Compounding (Ref. USP <795>)

CFST – Sterile Compounding (Ref. USP <797>)

AIS – ACHC Inspection Services

Distinctions*

ONC – Distinction in Oncology

HDH – Distinction in Hazardous Drug Handling (Ref. USP <800>)

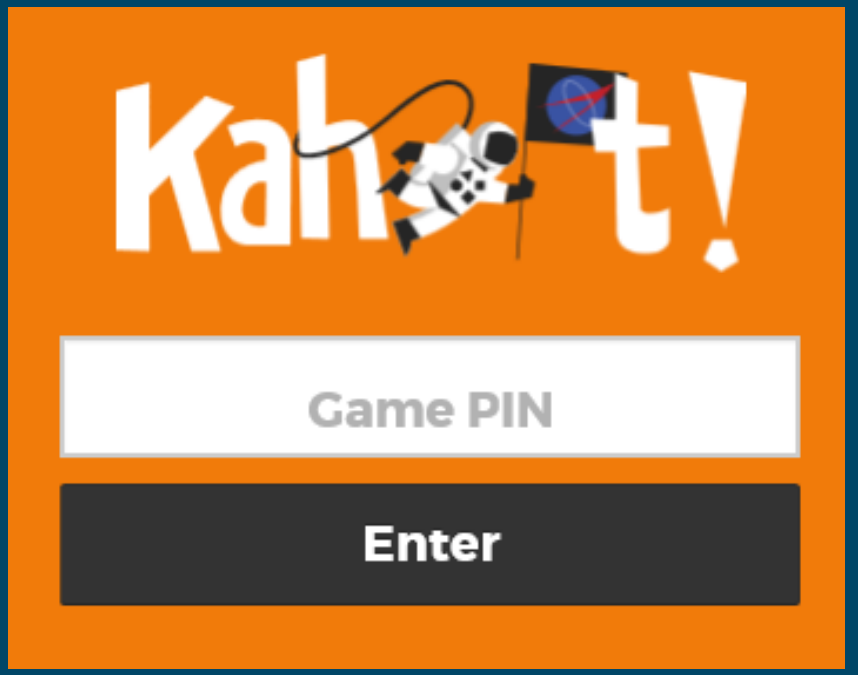
HIV – Distinction in Infectious Disease Specific to HIV

NTS – Distinction in Nutrition Support

*The provider must be accredited with ACHC to be eligible for a distinction service.

TEACHING TOOL: Kahoot!

- Cell phone or laptop
- Go to Kahoot.it
- Enter game PIN
- Enter your nickname
- See “You’re in”
- You’re ready!



Exposure to Hazardous Drugs:

Why Should I Care?

WHY SHOULD I CARE? – INDUSTRY EVIDENCE

- 1999: Pharmacists, techs, and nurses handling HDs
  - 40% higher risk of stillbirths and spontaneous abortions
- 2010: Healthcare Worker Study (including pharmacy)
  - Chromosome 5 and 7 abnormalities
  - Breast and prostate cancer both linked to C-5
- 2014: Pharmacy student dies of fentanyl overdose at a compounding pharmacy
  - After only four days on the job
- 2014: Evaluation of manufacturing practices finds drug residue on external packaging of containers of 5-FU and cisplatin

WHY SHOULD I CARE? – EXTERNAL FACTORS

- HD protection is growing as a regulatory requirement
  - State Boards of Pharmacy
  - FDA
  - OSHA – *Controlling Occupational Exposure to Hazardous Drugs*

- Growing interest in waste-streams
- Liability?

WHY SHOULD I CARE? – EXTERNAL FACTORS

Hartford News

OSHA cites New Haven pharmacy for multiple violations

Posted: 10/23/2014, 03:00pm | WTNH

New Haven, Conn. (WTNH) — The Occupational Safety and Health Administration (OSHA) has cited a New Haven pharmacy for multiple violations during their most recent inspections following a July chemical spill that sent four employees to the hospital.

In all, OSHA's proposed fines total $77,220.

HISTORY

- Concern about exposure to hazardous drugs (HDs) is not new!
  - 1986 – first OSHA guidelines for cytotoxic drugs
  - 1990 – ASHP technical assistance bulletin on handling cytotoxic and hazardous drugs
  - 2004 – NIOSH Alert - Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings
  - 2008 – USP Chapter <797> included sterile hazardous drug guidance
  - March 2014 – USP Chapter <800> draft released
  - February 2016 – final version of Chapter <800> released
  - December 1, 2019 – "Effective Date" for <800> *Hazardous Drugs – Handling in Healthcare Settings*

INTRO TO USP <800>

- How to read a Safety Data Sheet (SDS)
- The HD list
- The compounding environment
- Primary Engineering Controls (PECs)
- Deactivation and decontamination
- Personal protective equipment (PPE)
- Personnel
- Receiving, shipping, and storage
- Occupational Safety and Health Administration (OSHA) Hazard Communication program
- Disposal

USP <800>

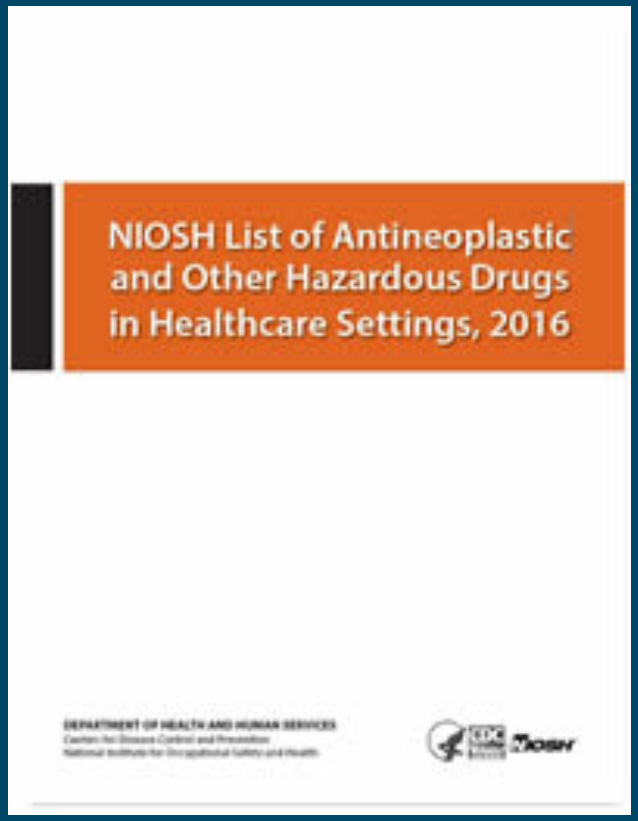
- Establishes quality and practice standards for handling HDs
- Promotes worker and patient safety
- Defines processes to minimize exposure to HDs
- Eliminates previous exemptions for handling HDs

- Applies to all healthcare personnel who handle HDs:
  - Pharmacists
  - Techs
  - Delivery personnel

WHAT IS A "HAZARDOUS" DRUG???

- NIOSH HDs are:
  - Carcinogenic
  - Teratogenic
  - Reproductive toxicity

- NIOSH Classification:
  - Group 1 (Table 1) - Antineoplastics
  - Group 2 (Table 2) - Other drugs that nonetheless meet NIOSH criteria
  - Group 3 (Table 3) - Substances mainly posing reproductive risk



THE NIOSH LIST CATEGORIES

- Antineoplastic drugs:
  - Tamoxifen
  - Fluorouracil
  - Cyclophosphamide
- Non-Antineoplastic Drugs:
  - Estradiol
  - Progesterone
  - Testosterone
  - Apomorphine
  - Cyclosporine
- Reproductive Hazards:
  - Misoprostol
  - Spironolactone
  - Human chorionic gonadotropin (HCG)

SAFETY DATA SHEETS

HOW TO READ AN SDS

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-212-573-2222

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161
Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

Material Name: Cyclophosphamide Powder for Injection

Trade Name:	SYKLOFOSFAMID, CYCLOBLASTIN, CYCLOPHOSPHAMIDE, CYCLOPHOSPHAMID, CYCLOSTIN, NEOSAR
Chemical Family:	Alkylating Agent
Intended Use:	Pharmaceutical product used as Antineoplastic

2. HAZARDS IDENTIFICATION

Appearance: White crystalline powder
Signal Word: DANGER

Statement of Hazard:
Toxic if swallowed.
May cause cancer.
May damage fertility or the unborn child.
May cause genetic defects.

Additional Hazard Information:
Long Term: The use of this drug during pregnancy has resulted in birth defects. Animal studies have shown a potential to cause adverse effects on the fetus. Repeat-dose studies in animals have shown a potential to cause adverse effects on reproductive system.

Known Clinical Effects: Effects on blood and blood-forming organs have also occurred.

EU Classification
EU Indication of danger:
Toxic
Toxic to reproduction: Category 1
Carcinogenic: Category 1
Mutagenic: Category 1

EU Hazard Symbols:

T

EU Risk Phrases:
R25 - Toxic if swallowed.
R45 - May cause cancer.
R46 - May cause heritable genetic damage.
R60 - May impair fertility.
R61 - May cause harm to the unborn child.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Cyclophosphamide	50-18-0	200-015-4	T;R25 Repr.Cat.1;R60-61 Carc. Cat.1;R45 Mut. Cat.1;R46	100

4. FIRST AID MEASURES

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

5. FIRE FIGHTING MEASURES

Extinguishing Media:	Use carbon dioxide, dry chemical, or water spray.
Hazardous Combustion Products:	Carbon dioxide, carbon monoxide, and oxides of nitrogen phosphorous
Fire Fighting Procedures:	During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
Fire / Explosion Hazards:	Fine particles (such as dust and mists) may fuel fires/explosions.

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions:	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
Measures for Cleaning / Collecting:	Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.
Measures for Environmental Protections:	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
Additional Consideration for Large Spills:	Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

General Handling: Restrict access to work area. Designate a change area to facilitate 'good manufacturing' decontamination practices. Ground and bond all bulk transfer equipment. No open handling permitted. All operations should be fully enclosed. Avoid inhalation and contact with skin, eye, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Storage Conditions: Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

No Occupational Exposure Limit (OEL) or Short Term Exposure Limit (STEL) has been identified.

Engineering Controls: Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. All operations should be fully enclosed. No air recirculation permitted.

Environmental Exposure Controls: Refer to specific Member State legislation for requirements under Community environmental legislation.

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands: Wear impervious, disposable gloves as minimum protection (double recommended).

Eyes: Wear safety glasses as minimum protection.

Skin: Wear impervious disposable protective clothing when handling this compound.

Respiratory protection: Whenever excessive air contamination (dust, mist, vapor) is generated, respiratory protection, with appropriate protection factors, should be used to minimize exposure.

9. PHYSICAL AND CHEMICAL PROPERTIES

Melting/Freezing Point (°C): 41

10. STABILITY AND REACTIVITY

Chemical Stability: Stable under normal conditions of use.
Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

11. TOXICOLOGICAL INFORMATION

Carcinogen Status: See below

Cyclophosphamide

IARC: Group 1 (Carcinogenic to Humans)
NTP: Known Human Carcinogen
OSHA: Listed

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

This material is regulated for transportation as a hazardous material/dangerous good.

UN number:	UN 2811
UN proper shipping name:	Toxic solid, organic, n.o.s. (cyclophosphamide)
Transport hazard class(es):	6.1
Packing group:	III

15. REGULATORY INFORMATION

OSHA Label:
DANGER
Toxic if swallowed.
May cause cancer.
May damage fertility or the unborn child.
May cause genetic defects.

Cyclophosphamide

CERCLA/SARA Hazardous Substances and their Reportable Quantities:	10 lb 4.54 kg
California Proposition 65	carcinogen initial date 2/27/87 developmental toxicity initial date 1/1/89 female reproductive toxicity 1/1/89 male reproductive toxicity initial date 1/1/89

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

R25 - Toxic if swallowed.
R45 - May cause cancer.
R46 - May cause heritable genetic damage.
R60 - May impair fertility.
R61 - May cause harm to the unborn child.

Data Sources: Pfizer proprietary drug development information. Publicly available toxicity information.

Reasons for Revision: Updated Section 3 - Composition / Information on Ingredients.

Prepared by: Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet

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THE HAZARDOUS DRUG LIST

THE HAZARDOUS DRUG LIST

ACHC CUSTOMER CENTRAL™

- OSHA requirement (29 CFR 1910.1200)
- Guides all activities for handling and disposal of HDs
- Must be used to train employees
- An ongoing reference for employees

- Must include all NIOSH-listed drugs
- Must be reviewed at least annually
- Must be updated with new HDs
- Recommendation: Keep an electronic version

RESOURCES TO CREATE YOUR LIST

- NIOSH List
- SDS:
  - **Create an SDS file for all HDs stocked!**
  - Risks
  - Transport requirements
- Package inserts:
  - Special handling requirements

WHAT SHOULD BE ON THE LIST?

Drug	Form	CAS#	Category	Hazard	Location
Estradiol	API	50-28-2	Non-Antineoplastic	May cause cancer. May damage fertility or the unborn child.	HD Storage HD NS Compounding
	Capsules	50-28-2		May cause cancer. May damage fertility or the unborn child.	HD Storage HD NS Compounding Pick Up
Cyclophosphamide	Vials	50-18-0	Antineoplastic	Toxic if swallowed. May cause cancer. May damage fertility or the unborn child. May cause genetic defects.	HD ST Buffer Pick Up

WHAT SHOULD BE ON THE LIST?

Drug	Form	Location	Receiving	Compounding	Counting FD	Transport
Estradiol	API	HD Storage HD NS Compounding	Full Precautions per SOP XXX	Full Precautions	N/A	N/A
	Capsules	Storage Pick up HD NS Compounding	N/A	Full Precautions	Dedicated Utensils Std HD precautions per SOP XXXX	HD Precautions per SOP XXXX
Cyclophosphamide	Vials	HD ST Buffer Pick Up	Full Precautions per SOP XXX	Full Precautions	Gown/Double gloves	HD Precautions per SOP XXXX

WHAT SHOULD BE ON THE LIST?

Drug	Shipping	Disposal	Pregnant	Alternative Containment Strategy
Estradiol	Not Dangerous Goods	HD Waste	PR Protocol	N/A
	Not Dangerous Goods	HD Waste	PR Protocol	N/A
Cyclophosphamide	UN2811 Toxic solid, organic, n.o.s. (cyclophosphamide) Hazard Class: 6.1 Packing Group 3 Air Cargo: 30 ml or less per inner container Upto 1 liter total in box "E" Label Ground 4 liters per inner container 5 kg if solid	HD Waste	PR Protocol	N/A

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CONTAINMENT REQUIREMENTS

CONTAINMENT REQUIREMENTS

- What qualifies?
- What are environmental requirements?
- Engineering controls?
- Additional equipment?

WHAT REQUIRES CONTAINMENT?

- NIOSH-list drugs that must follow <800>'s containment requirements:
  - HD API
  - Antineoplastics requiring *further manipulation*

- NIOSH-list drugs that do not have to follow containment requirements *if an assessment of risk is performed and implemented:*
  - Final dosage forms of compounded HD preparations
  - Conventionally manufactured HD products that require no further manipulation than counting or repackaging
  - Non-antineoplastic HD dosage forms on the NIOSH list

ALTERNATIVE/NO CONTAINMENT

- Final dosage forms that only require counting/repackaging:
  - Avoid automated counting or packaging machines
  - Consider manufacturer exceptions

To minimize the risk of dermal exposure, always wear impervious gloves when handling vials containing CYTOXAN sterile powder for injection, or bottles containing CYTOXAN tablets. This includes all handling activities in clinical settings, pharmacies, storerooms, and home healthcare settings, including during unpacking and inspection, transport within a facility, and dose preparation and administration.

- Assessment of Risk must include the following:
  - Type of HD
  - Dosage form
  - Risk of exposure
  - Packaging
  - Manipulation

ALTERNATIVE/NO CONTAINMENT

- Assessment of Risk (cont.)
  - Must list each drug and dosage form individually:
    - May have same information for multiple drugs or dosage forms
  - Must document **what** alternative containment strategies or work practices are being employed
  - Must be reviewed every 12 months:
    - Review must be **documented**!

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THE COMPOUNDING ENVIRONMENT

NON-STERILE HD COMPOUNDING

Containment Secondary Engineering Control (C-SEC):

- Dedicated room for HD compounding
- Negative pressure -0.01 to 0.03 inches water
- 12 ACPH
- Unclassified air
- Externally vented

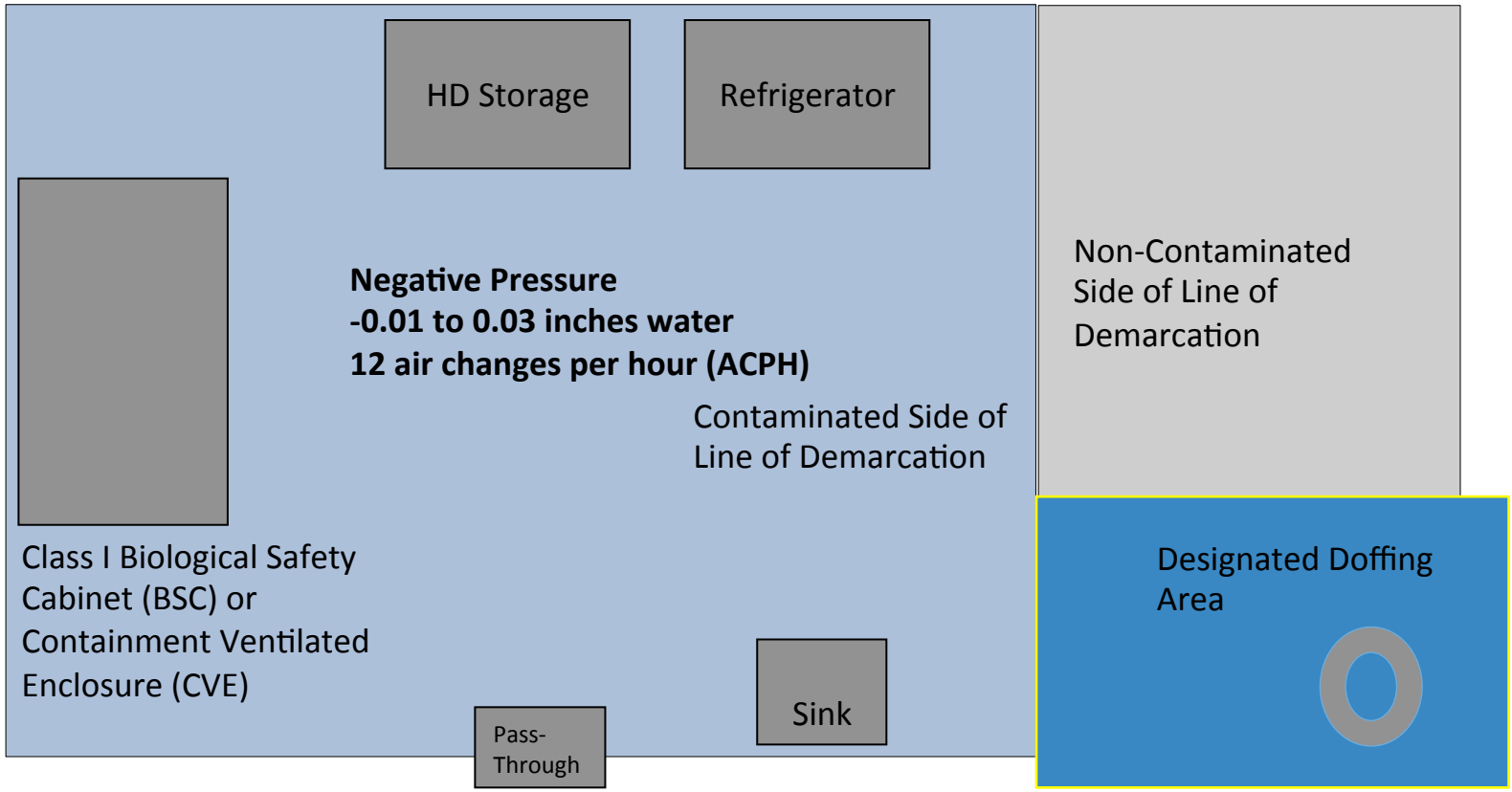
NON-STERILE HD COMPOUNDING

Smooth, seamless, and impervious surfaces:

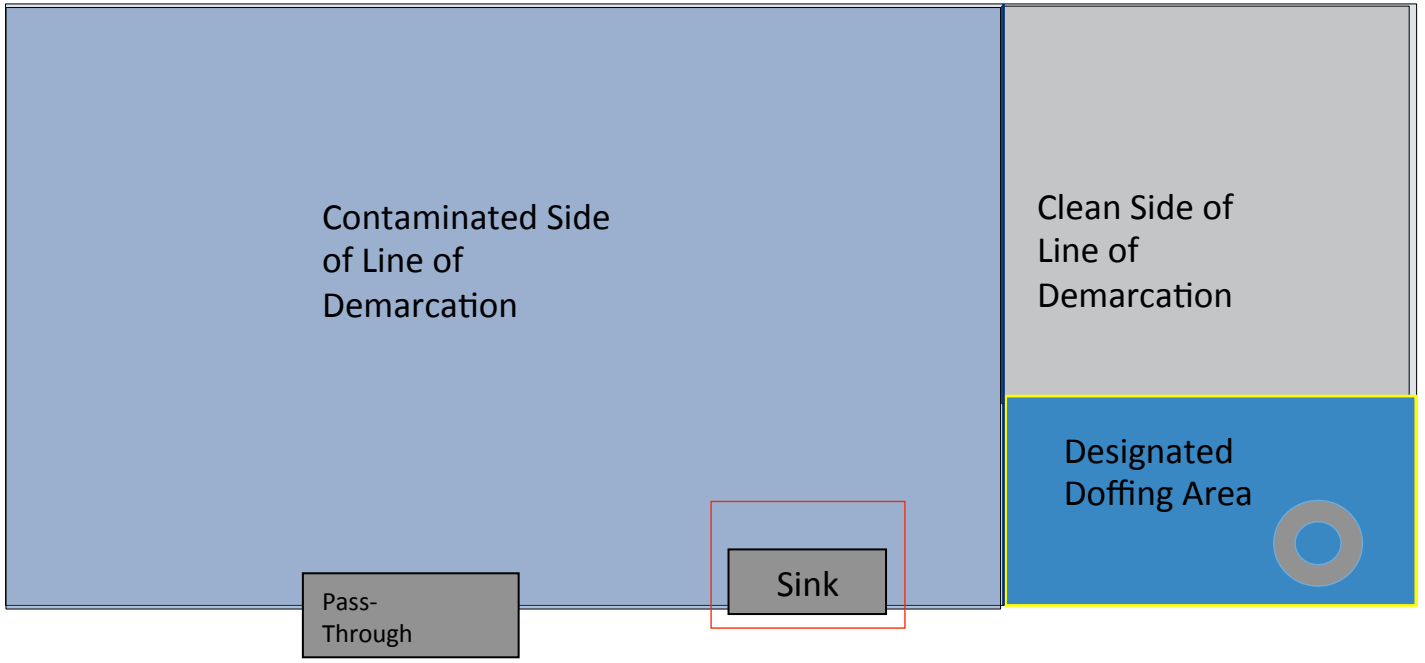
- Avoid particle board
- Floor laid seamlessly
- Epoxy drywall or other wall material
- Coved moldings
- Impervious ceiling tiles and lighting fixtures

Must be able to withstand decontamination with sodium hypochlorite solution

NON-STERILE HD COMPOUNDING

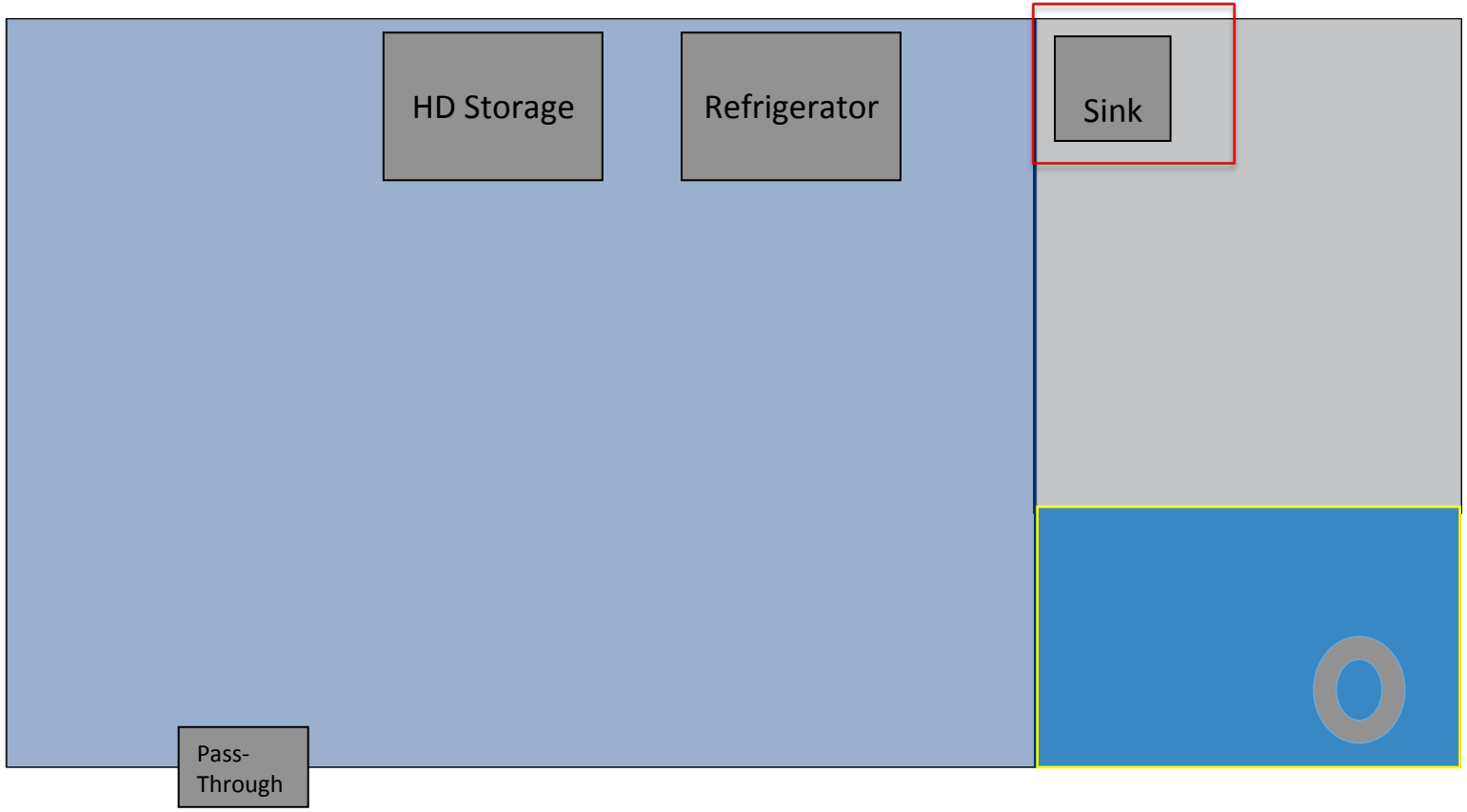


NON-STERILE HD COMPOUNDING



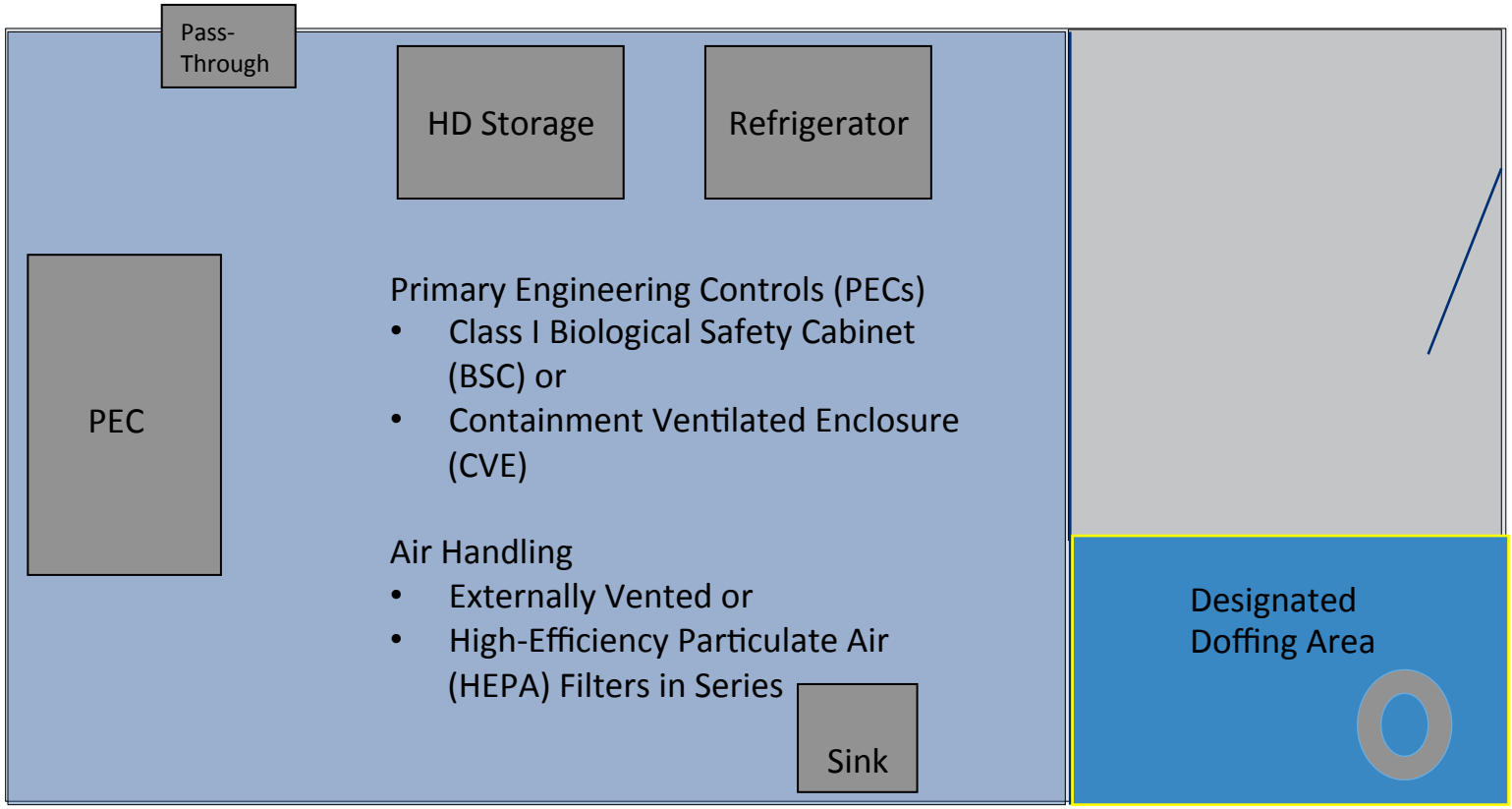
- Water must be accessible; does not specify must be in C-SEC
- USP <800> not specific about sink location
- Option: Sink in C-SEC for equipment-washing

NON-STERILE HD COMPOUNDING



- Option: Sink for hand-washing in C-SEC

NON-STERILE HD COMPOUNDING



CLASS I BSCS FOR NON-STERILE COMPOUNDING

- Protect the operator from exposure to HDs
- Do not protect HDs from exposure to the compounder

Image used with permission of AirClean Systems

Class I BSC – Externally Vented

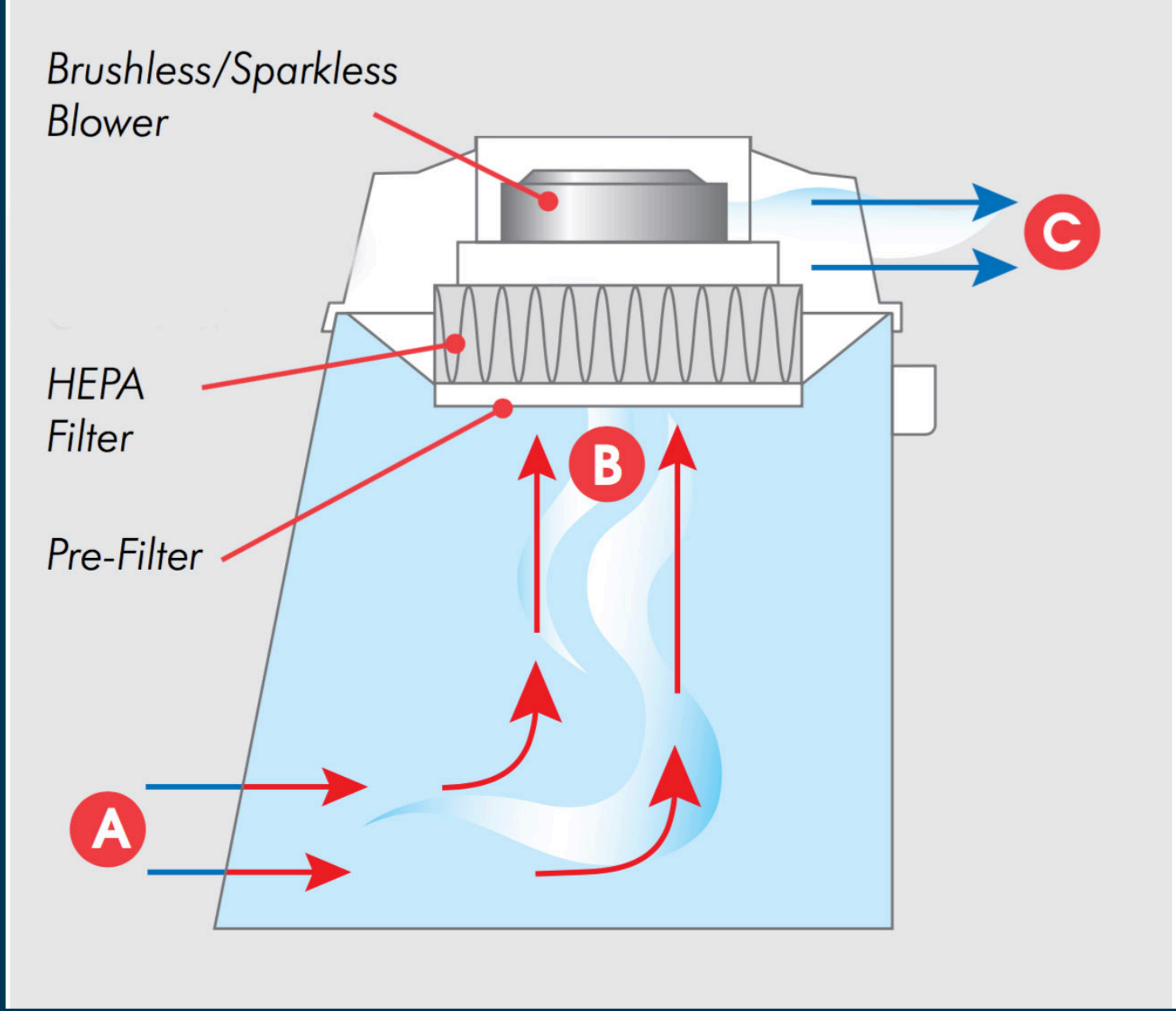


Image courtesy AirClean Systems

Class I BSC – Redundant HEPA Filter

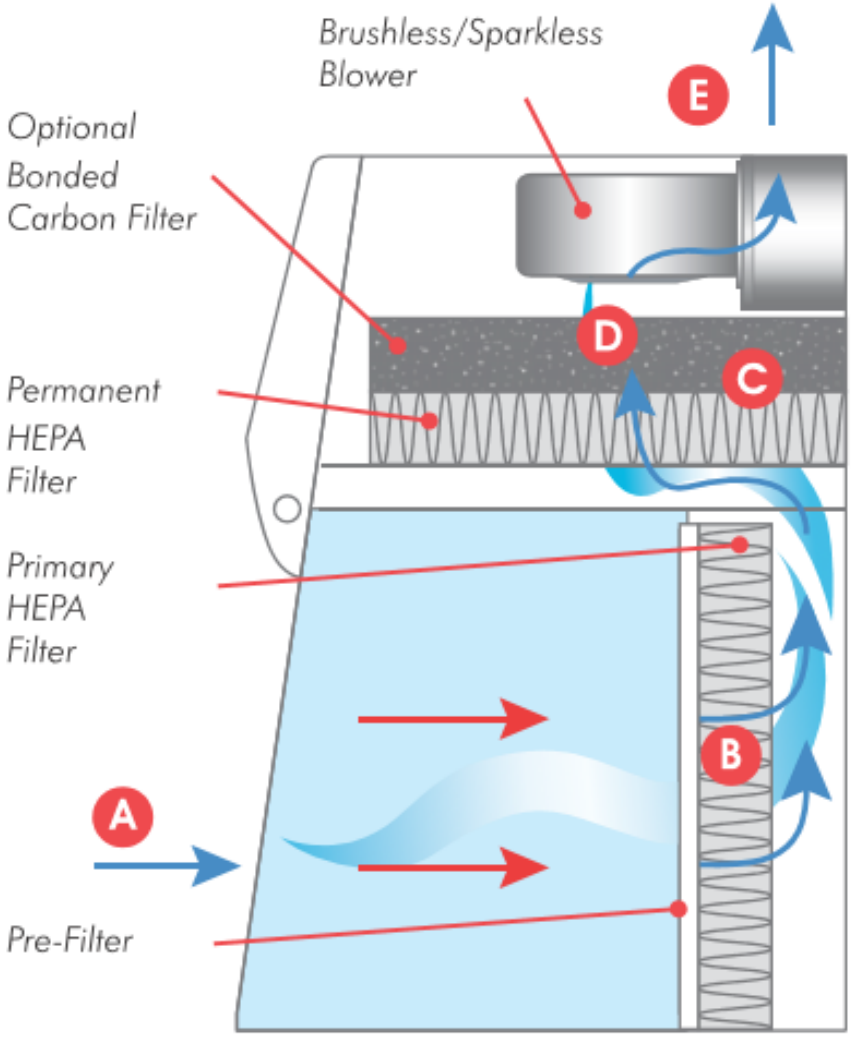


Image courtesy AirClean Systems

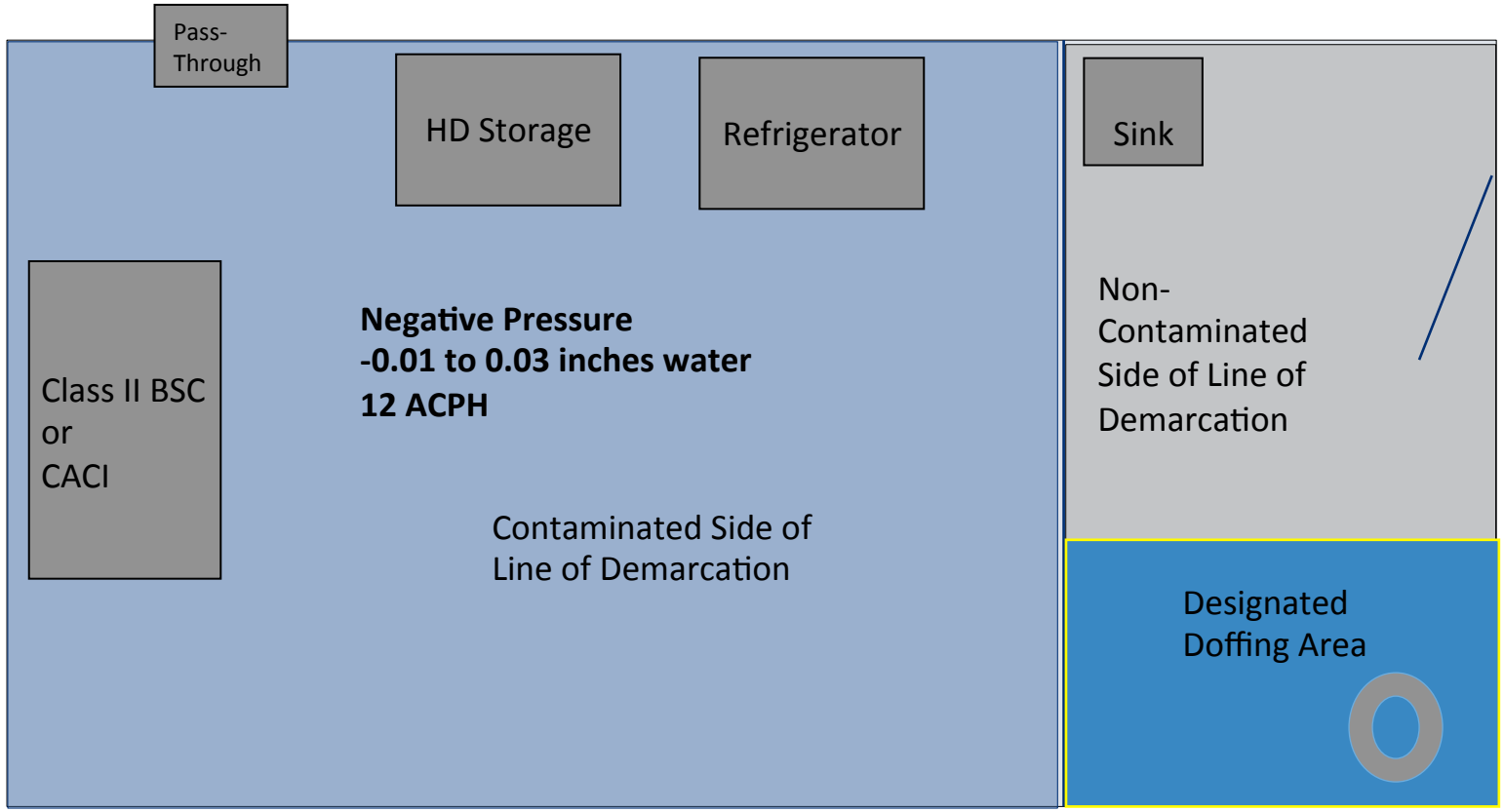
KEY POINTS ABOUT C-PECS – NS

- C-PEC can be vented externally or through redundant HEPA filters in series
- These devices can include:
  - Class I or II BSCs
  - Vented balance safety enclosures
  - Compounding Aseptic Containment Isolators (CACIs)
- The C-PEC must operate continuously if it supplies some or all of the negative pressure for the C-SEC

MORE TO THINK ABOUT

- A pass-through saves time and money
- What will you do with all that contaminated equipment?
  - Dirty side sink: Equipment never leaves the room
- Schedule your HD compounding:
  - It may not be time-saving nor PPE cost-effective to make one hormone capsule or gel Rx
- Use your old internally vented BSC to unpack
- Suggestion: Do not build in any fixtures:
  - Decontamination processes may be more difficult with drawers and cabinets
  - Use flat shelves, stainless steel tables, etc.

STERILE HD COMPOUNDING – CATEGORY 1



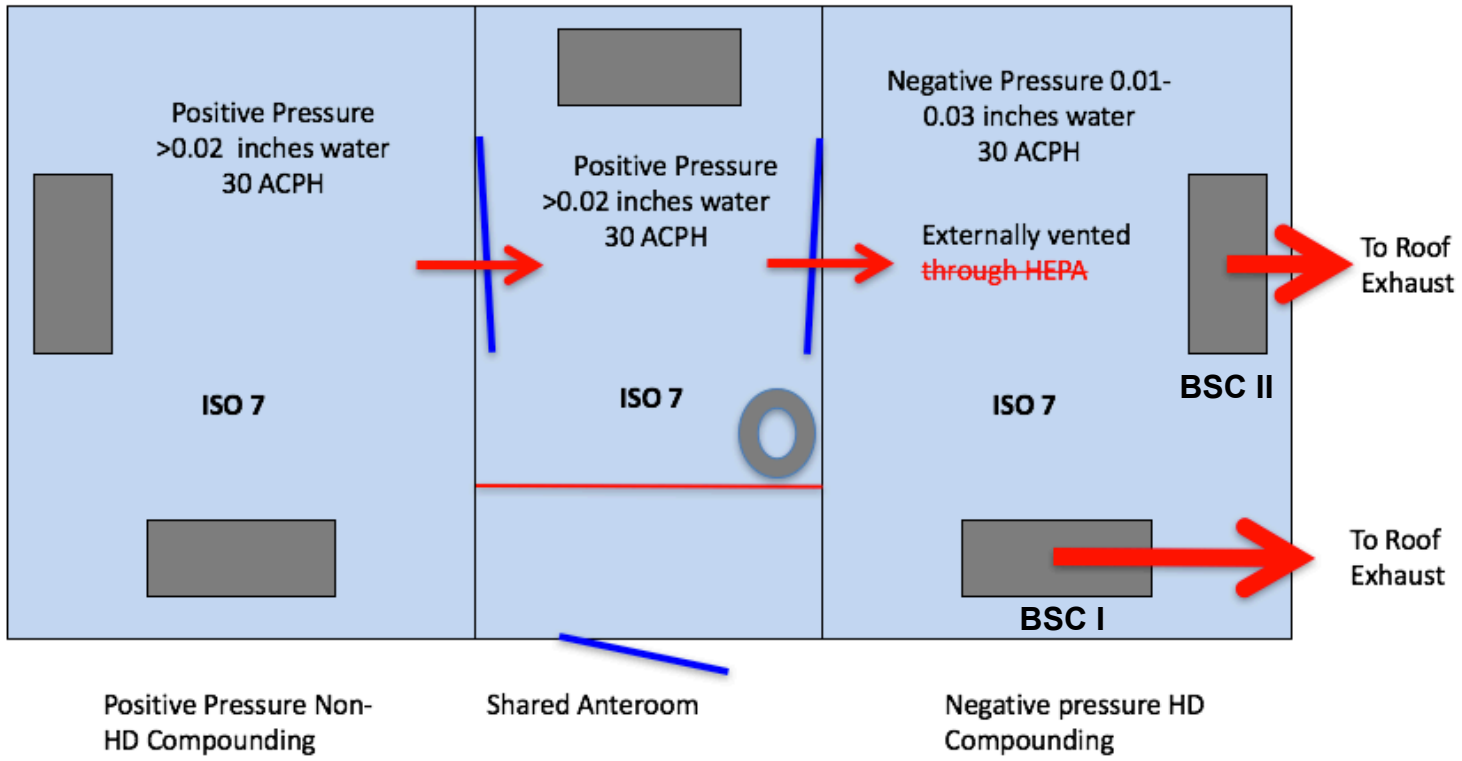
CONTAINMENT SEGREGATED COMPOUNDING AREA (C-SCA)

- Surfaces: Smooth, seamless, and impervious
- Pressure: 0.01-0.03 inches negative water column
- Air changes: 12 per hour
- Unclassified air
- May be used for storage (sterile HDs) and compounding
- **Only for Category 1 CSPs**

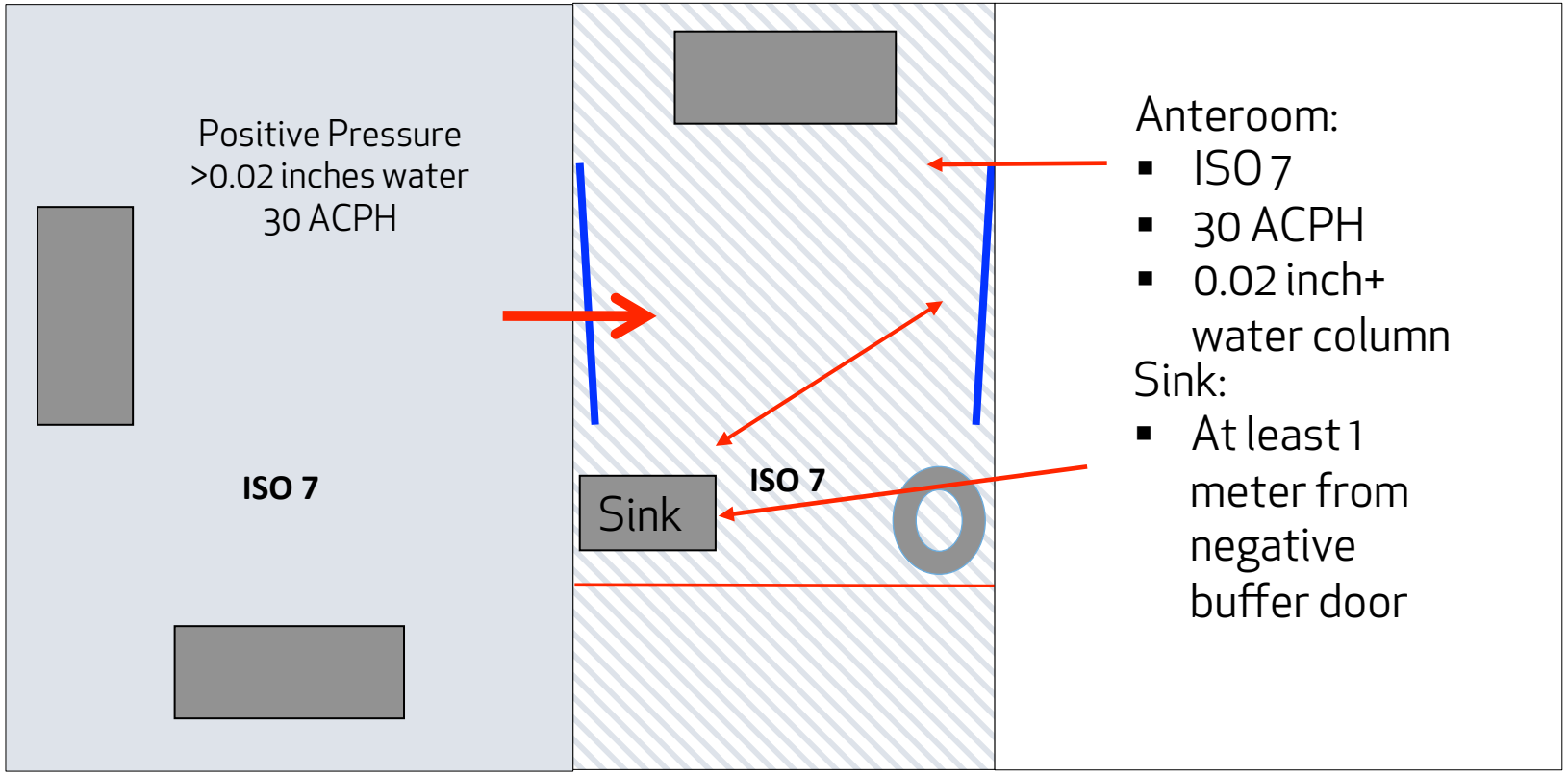
C-SCA BUDs ARE LIMITED

- Beyond-Use Date (BUD) per USP <797> for HD Compounded Sterile Preparations (CSPs) prepared in a segregated compounding area
- Current USP <797>:
  - Class II BSC/CACI: Low-risk CSPs with 12-hour BUD
  - Stand-alone CACI: Low-, medium-, maybe high-risk
- USP <797> revision:
  - Class II BSC or CACI: ≤12-hour room temperature, ≤24-hour refrigerated

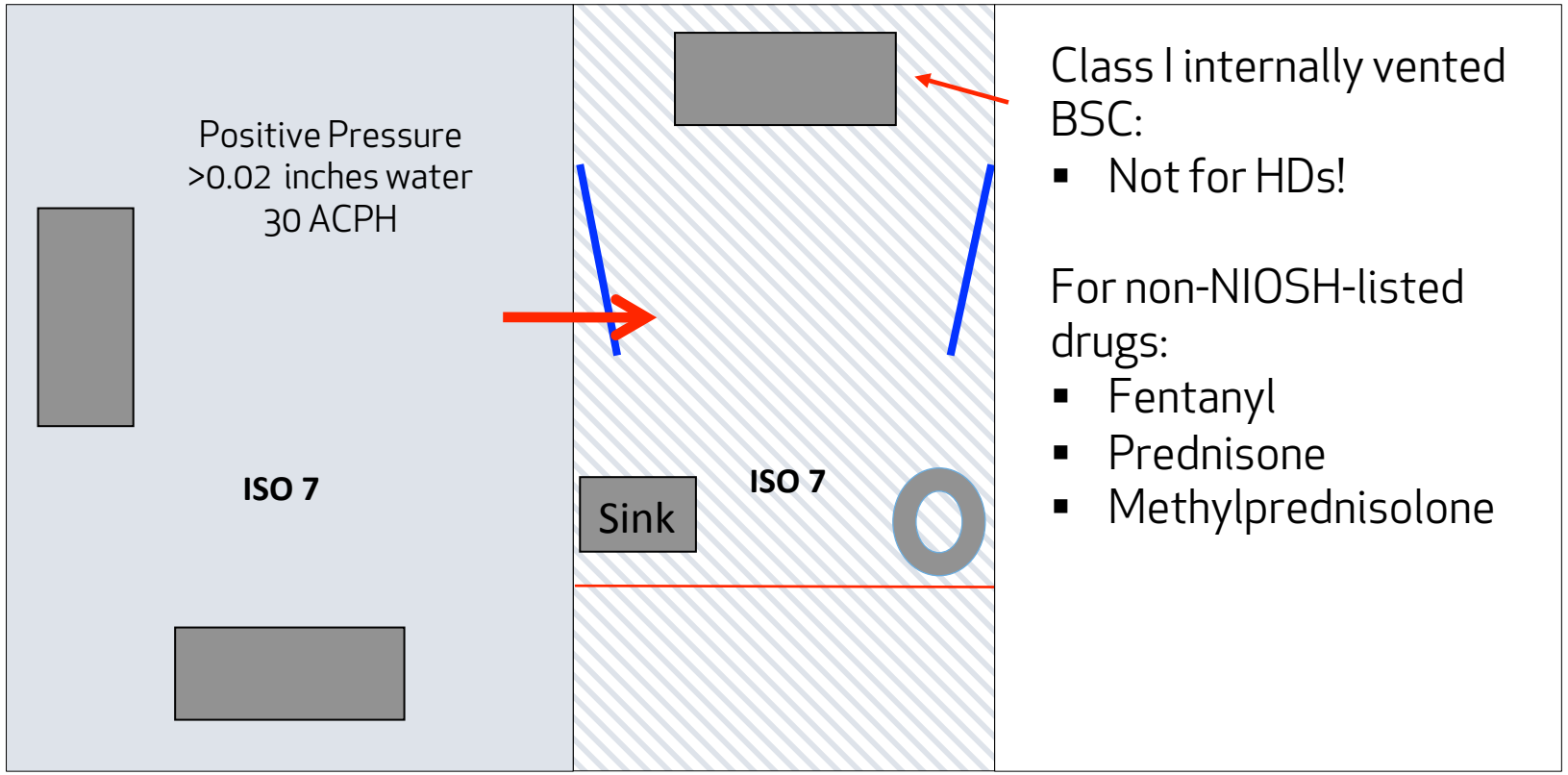
DESIGNS FOR BOTH CATEGORY 1 AND 2 COMPOUNDING



THE SHARED ANTEROOM



THE SHARED ANTEROOM



Class I internally vented BSC:

- Not for HDs!

For non-NIOSH-listed drugs:

- Fentanyl
- Prednisone
- Methylprednisolone

THE BUFFER ROOM

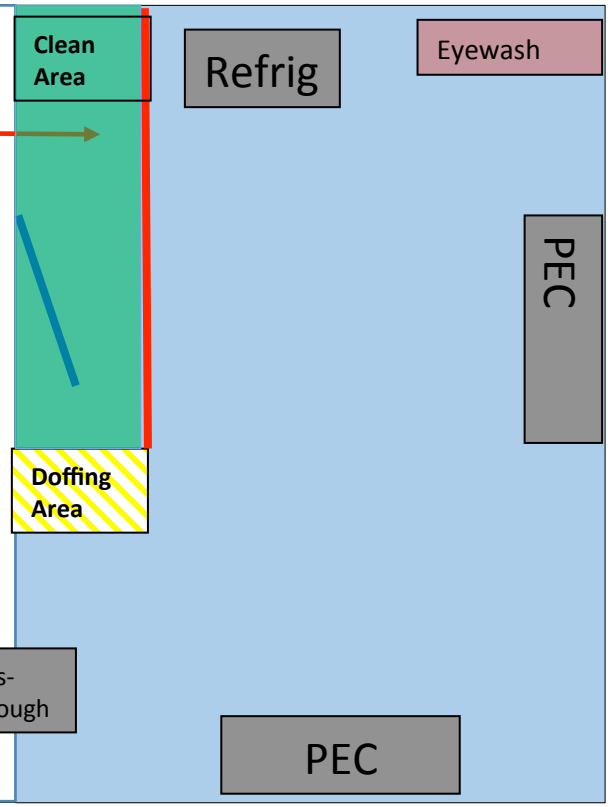
Buffer Room:

- ISO 7
- 30 ACPH
- Negative 0.01-0.03 inch-water column

Doffing Area and Line of Demarcation

Pass-through:

- Sealed doors

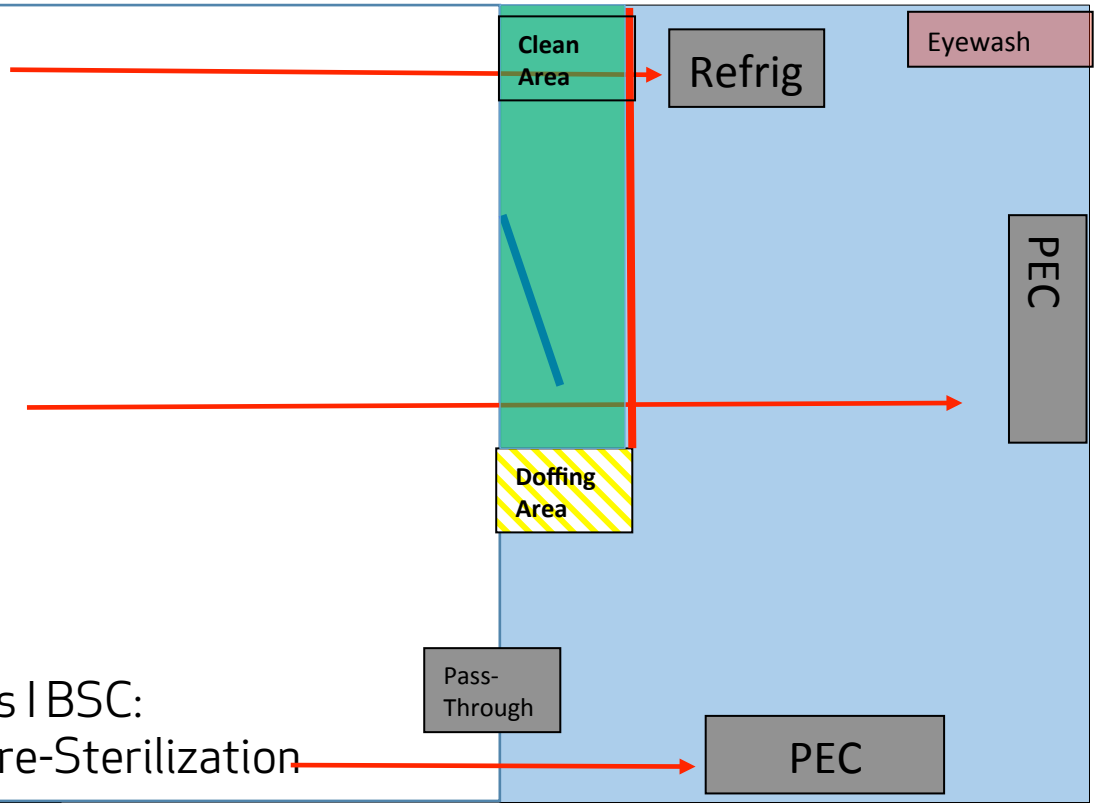


THE BUFFER ROOM

Refrigerator:
- Near exhaust plenum or
- Exhaust captured

Class II BSC:
- Aseptic manipulations
- Externally vented through a HEPA

Class I BSC:
- Pre-Sterilization



STERILE HD COMPOUNDING

- Smooth, seamless, and impervious surfaces
- Avoid particle board
- Floor laid seamlessly
- Epoxy drywall or other wall material
- Coved moldings
- Impervious ceiling tiles and lighting fixtures
- Must be able to withstand decontamination using sodium hypochlorite solution
- Can ruin stainless steel when not inactivated

BUFFER ROOM

- **Dedicated room for HD compounding:**
  - Negative pressure 0.01 to 0.03 water column
  - ISO 7
  - 30 ACPH
  - Externally vented
- **Buffer room may be used for:**
  - Compounding sterile HDs
  - May be used for storing HDs
- **ISO 7 Anteroom is required!**
  - Different than the typical ISO 8 anteroom
  - 30 ACPH for ISO 7 vs. 20 ACPH for ISO 8

CLASS II BSC TYPES

- Type A1:
  - 75 ft./min. inflow velocity
  - Exhaust into lab or canopy:
    - Into lab would be non-compliant
  - 70% of the air recirculated/30% exhausted
  - Have positive-pressure exhaust ducts - NOT SUITABLE FOR HDs
- Type A2:
  - 100 ft./min. inflow velocity
  - Exhaust into lab or through canopy:
    - Into lab would be non-compliant

CLASS II BSC TYPES

- Type B1:
  - 100 ft./min. inflow velocity
  - Exhaust to outside via direct duct connection
  - 30% of the air recirculated/70% exhausted
  - Suitable for minute quantities of volatile drugs
- Type B2:
  - 100 ft./min. inflow velocity
  - Exhaust to outside via direct duct connection
  - 100% of the air is exhausted
  - Suitable for volatile drugs

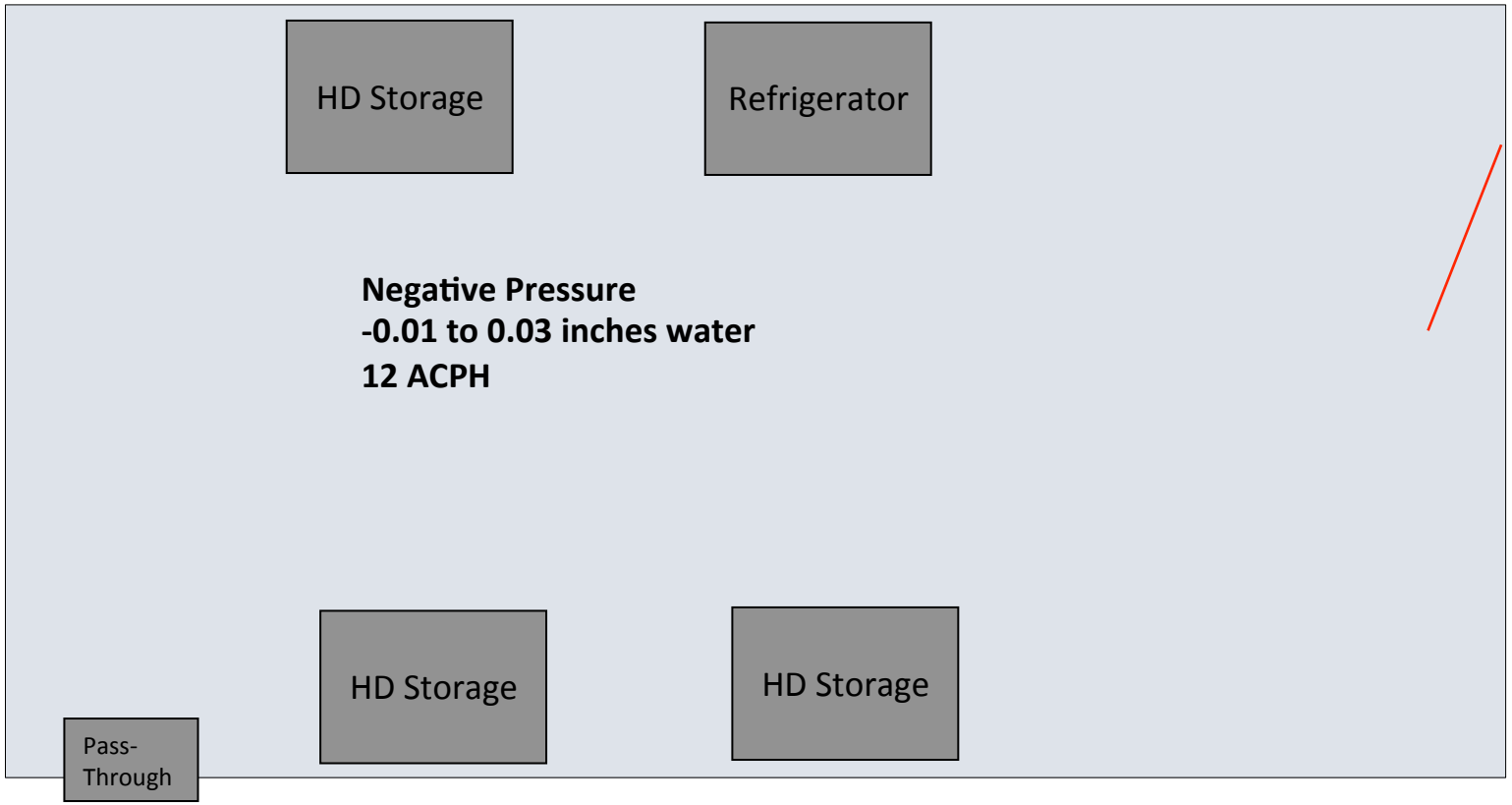
VOLATILE DRUGS

- Turns into gas at room temperature:
  - Fluorouracil (5-FU)
  - Carmustine
  - Nitrogen mustard
  - Cyclophosphamide
  - Cisplatin
  - Ifosfamide
- Class I BSCs:
  - Internally vented are unsuitable
- Class II BSCs:
  - Type A: only minute quantities
  - Type B2 – (100% vented): designed for volatile HDs

COMPOUNDING ASEPTIC CONTAINMENT ISOLATORS (CACI)

- Various flavors of ventilation:
  - Internally vented
    - Not suitable for HD compounding under USP <800>
  - Externally vented:
    - Required under USP <800>

A SEPARATE HD STOREROOM



To HD buffer room or non-sterile HD compounding

STORAGE EXEMPTIONS

- Not exempted:
  - HD active pharmaceutical ingredients (APIs)
  - Any antineoplastic requiring HD manipulation
- NIOSH-listed drugs exempted if:
  - Final dosage forms not requiring additional manipulation except counting or repackaging of
    - Compounded HDs
    - Manufactured preps
  - **… and an assessment of risk is performed**
- Other dosage forms of NIOSH-listed drugs:
  - Based on assessment of risk

OTHER EQUIPMENT

- Spill kits
- Eyewashes:
  - OSHA requirement: Handling materials that are "corrosive"
  - ANSI: Eyewash located where employees are exposed to HDs
- Closed system transfer devices should be used:
  - MUST be used for administration if the dosage form allows
- Plastic-backed prep mat on surface of PEC
- Dedicated equipment is required:
  - Mortars
  - Pestles
  - Spatulas

THINK ABOUT WORKFLOW

- Where will we deactivate/decontaminate equipment?
- Is there time to go in and out of the room all day?
- Can we deactivate/decontaminate efficiently through scheduling?
- Dosage forms:
  - Where do we transfer batched creams and ointments into dispensing containers?
  - Do our hormone capsules have powder residue on the outside?

- ✓ Deactivating 

- ✓ Decontaminating 

- ✓ Cleaning
- ✓ Disinfecting

DEACTIVATION AND DECONTAMINATION

- Deactivation:
  - Treatment of an HD contaminant on surfaces with a chemical, heat, ultraviolet light, or another agent to transform the HD into a less hazardous agent
- Decontamination:
  - Inactivation, neutralization, or removal of HD contaminants on surfaces, usually by chemical means
- Don't forget about Cleaning <795/797> and Disinfection <797>!

WHAT RECEIVES DDC?

- DDC MUST occur in all areas where HDs are handled:
  - Receiving
  - Storage
  - Compounding
- DDC MUST occur on reusable equipment:
  - PECs
  - Capsule machines
  - Balances

- Sterile compounding areas MUST also be DISINFECTED per <797>

CLEANING - SOPs AND PPE

- Written procedures for cleaning MUST include:
  - Procedures:
    - Must include training
    - PPE must be impermeable to agents and include double chemotherapy-type gloves and impermeable disposable gowns
    - If splashing likely = eye and face protection
  - Agents used
  - Dilutions
  - Frequency (see next slide)
  - DOCUMENTATION

FREQUENCY - FOLLOW <795> AND <797>

What	When
PECs	Between different HDs Daily Before/after certification After voluntary interruptions If moved
Equipment	Daily Between different HDs
Counters	Daily
Floors	Daily
Walls, ceilings, shelving, and storage	Monthly
Under BSC work trays	Monthly

WE ARE NOT QUITE DONE YET!

- Spills, splashes, and suspected contamination may require additional deactivation and decontamination
- After deactivation and decontamination:
  - Non-sterile: Cleaning per <795>
  - Sterile: Cleaning and disinfecting per <797>

HOW?

- 2% sodium hypochlorite followed by 1% sodium thiosulfate:
  - Sodium hypochlorite ruins stainless steel
  - Inactivate thoroughly with thiosulfate
  - Clean and/or disinfect surfaces thoroughly
- As recommended by manufacturer
- Commercial products:
  - Surface Safe ®
  - HD Clean®
  - PeridoxRTU® Sporicidal Disinfectant and Cleaner
- Apply to cloth and wipe; do not spray on surfaces

WHAT SHOULD I WEAR?

- PECs:
  - Routine sterile/non-sterile HD garb
- BSC trays:
  - Sterile/non-sterile garb plus full face cartridge respirator with multi-gas cartridge and P100 filter
- Floors/ceilings/equipment:
  - Sterile/non-sterile garb plus N95
  - Risk of splashing: goggles/face shield

ACCREDITATION UNIVERSITY

PPE FOR HAZARDOUS COMPOUNDING

PPE FOR HD COMPOUNDING – WHEN

- MUST be worn while handling HDs during:
  - Receipt
  - Transport
  - Storage
  - Compounding
  - Administration
  - Deactivation, decontamination, cleaning, disinfecting
  - Spill cleanup
  - Waste disposal

PPE FOR HD COMPOUNDING – WHAT

- Required for compounding:
  - Gowns
  - Gloves – two pairs
  - Hair/head covers:
    - Sterile: Facial hair cover
  - Shoe covers – two pairs
  - Eye, face, and respiratory protection
  - Sterile compounders may need two layers of PPE

- Table 5 of NIOSH 2016 can provide guidance on developing you own PPE policies

CONSIDER A TABLE FOR PPE

Activity	Where	Double Gloves	Gown	Eye Protection	Respiratory Protection
Receiving	NS HD PEC	Y	Y	N*	N*
Compounding	ST/NS PEC	Y	Y	N*	N*
Filling: Creams Ointments Liquids	NS HD PEC	Y	Y	N*	N*
Counting: Tablets Capsules	Dedicated Trays	N – use single gloves	N	N	N

- *If done in a PEC, the PEC provides respiratory and eye protection
- Counting: Capsules contaminated with HD or powdery tablets may require protection during handling

Does your PPE fit properly?

GOWNS – Non-sterile

- Disposable
- Polyethylene-coated polypropylene or laminate
- Must close in back
- Closed cuffs

GOWNS – Sterile

- Disposable
- Polyethylene-coated polypropylene or laminate
- Must close in back
- Closed cuffs
- Two layers is best practice

Changing Gowns

- Must change:
  - Every two to three hours or
  - Per manufacturer's instructions
  - If spill or splash
- Same for sterile/non-sterile

GLOVES

- Meet American Society for Testing and Materials (ASTM) standard D6978
- For sterile compounding:
  - Outer gloves must be sterile
- Outer gloves must be changed every 30 minutes unless otherwise recommended by manufacturer:
  - Applies to both sterile and non-sterile compounding
- Change if:
  - Torn
  - Punctured
  - Contaminated

RESPIRATORY PROTECTION

- **The PEC is your friend!**
- It will provide essential:
  - Eye protection
  - Face protection
  - Respiratory protection
- Doing everything in a PEC will save a lot of trouble!
  - Less strict respiratory protection requirements
  - Lower risk of contaminating facility
  - Lower risk of personnel exposure
  - Less cleanup
  - Containment of HD spills
  - Saves money

N95 MASKS

- Removes dust and small particles:
  - Does not remove vapors
  - Two types:
    - Surgical and non-surgical (surgical type is FDA-cleared for use in healthcare settings)
- Each employee must be fit tested!
  - Performed by a "qualified person"
- Single use/disposable
- Wear when there is a risk of exposure:
  - Small-spill cleanup

Full Face Cartridge Respirator with Multi-Gas Cartridge and P100 Filter

- Protects against particles and vapors
- Each employee must be fit tested
- Device is reusable
- Filter cartridges are replaceable
- Wear when:
  - Unpacking HDs not enclosed in plastic
  - Cleaning up large spills (> 5 ml)
  - Deactivating/decontaminating under work surface of a C-PEC
  - Reusable PPE must be cleaned/decontaminated after use

Eye Protection

- Goggles are required:
  - Not acceptable:
    - Safety glasses
    - Prescription eyeglasses
- Wear (with resp. protection) when:
  - Risk of spills or splashes
  - Cleaning spills
- Full face respirator is an alternative
- Face shield with goggles can protect full face

Possible Gowning Process-NS

- Entering the room:
  - Hair cover
  - Eye protection (maybe)
  - Respiratory protection (maybe)
  - Shoe covers (two pairs on each foot)
  - Wash hands
  - Put on one pair of gloves
  - Put on gown
  - Put on second pair of gloves over sleeves

Possible Gowning Process-ST

- Entering the room:
  - Hair cover
  - Eye protection (maybe)
  - Mask (or respiratory protection - maybe)
  - Step over line of demarcation while donning shoe covers:
    - Two pairs on each foot
  - Wash hands
  - Disinfect with waterless surgical scrub
  - Don one pair of sterile chemo gloves
  - Don sterile compounding inner gown
  - Don chemo gown or apron with sterile sleeves
  - Disinfect gloves with sterile isopropyl alcohol (SIPA)
  - Don sterile chemo gloves over sleeves

LEAVING THE HD COMPOUNDING AREA

- Remove the outer set of gloves in the PEC:
  - Plastic bag or suitable container in PEC
- Move to doffing area
- Remove gown:
  - Sterile compounders – the outer gown only!
- Remove first layer of shoe covers while placing each foot into "clean" zone
- Step out of HD area
- Remove mask, hair cover, and shoe cover:
  - Sterile compounders remove gown – outside of anteroom or in "dirty" side

ADMINISTRATION OF HDs

- Must use protective medical devices and techniques:
  - Needleless systems
  - Closed system transfer devices
  - Pill-crushing devices with a plastic pouch

- PPE must be worn and properly disposed of:
  - Two pairs of chemotherapy gloves are a MUST
  - Gowns with resistance to HD permeability are a MUST when administering injectable antineoplastics

PERSONNEL

SAFETY OFFICER (A "MUST")

- Trained and qualified for developing procedures
- Oversees compliance with USP <800>
- Ensures personnel competency
- Monitors environmental controls
- Tracks spills and personnel exposures

PERSONNEL TRAINING

- Review the list of HDs and their risks
- How to read HD labels and SDSs
- The pharmacy's Standard Operating Procedures (SOPs) related to handling of HDs
- Proper use of PPE including respiratory protection
- Techniques for compounding with HDs
- Response to known or suspected HD exposure (including use of eyewashes)

PERSONNEL TRAINING

- Deactivating and decontaminating
- Spill prevention and management (including use of spill kits)
- Proper disposal of HDs and trace-contaminated materials

PERSONNEL COMPETENCIES

- Reading an SDS – written test
- Observational:
  - PPE – observational competency
  - Location and use of spill kits and eyewashes
  - Use of closed system transfer devices
  - Signed acknowledgement of handling HDs

PROTECTING PERSONNEL

- Develop a policy for your facility
- Should address personnel that are:
  - Pregnant
  - Breastfeeding
  - Imminently conceiving

RECEIVING, SHIPPING, AND STORAGE

RECEIVING OF HDs

- Neutral or negative pressure area
- Supplier should package in impervious plastic
- If they do not:
  - Must unpack wearing full face cartridge respirator with multi-gas cartridge and P100 filter
  - Until safety is established
- If shipping container is damaged:
  - Seal container and contact supplier
  - If returning – enclose in impervious packaging and label hazardous, or discard as HD waste

RECEIVING OF HDs

- If damaged shipping container must be opened:
  - Seal in impervious container
  - Move to PEC
  - Remove undamaged items and wipe them down
  - Package the damaged goods in impervious container, mark as hazardous, and return; or
  - Dispose of them as HD waste
- PPE must be worn during unpacking:
  - Gloves
  - Gown

RECEIVING OF HDs

- Move to storage as soon as unpacked
- Damaged or leaking packages must be treated as spills:
  - Make sure you log these!
- The receiving area must be cleaned, deactivated, and decontaminated

SHIPPING OF HDs

- It is complicated:
  - Based on the specific HD
  - Based on the quantity or volume
  - Air or ground?
- It is simple:
  - A lot of HDs are exempt/partially exempt due to quantity
- How can I tell?

SDS SPECIFIES SHIPPING REQUIREMENTS

- Estradiol - not regulated for transport

14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

- Cyclophosphamide - more complicated!

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

This material is regulated for transportation as a hazardous material/dangerous good.

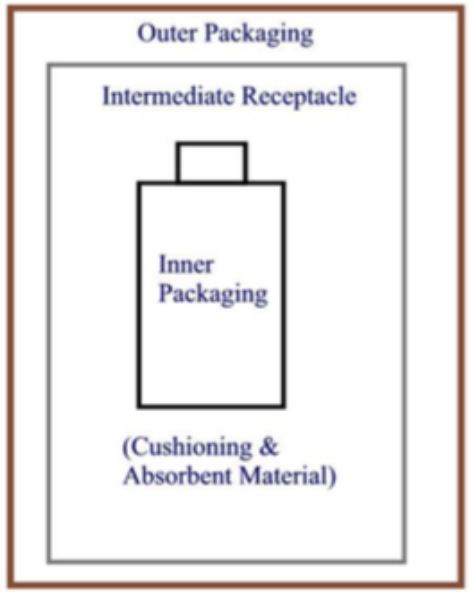
UN number:	UN 2811
UN proper shipping name:	Toxic solid, organic, n.o.s. (cyclophosphamide)
Transport hazard class(es):	6.1
Packing group:	III

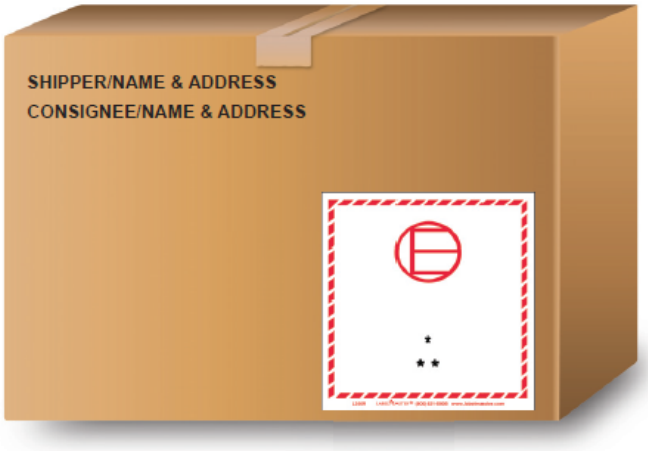
DECIPHERING CYCLOPHOSPHAMIDE

- UN number:
  - Assigned by United Nations Committee of Experts on the Transport of Dangerous Goods
  - 2811 indicates a toxic solid, organic, not otherwise specified
- Proper shipping name:
  - Required on labeling if not exempt
- Packing group – refers to level packaging required:
  - Packing Group I = great danger
  - Packing Group II = medium danger
  - Packing Group III = minor danger

SO WHAT DOES THIS ALL MEAN?

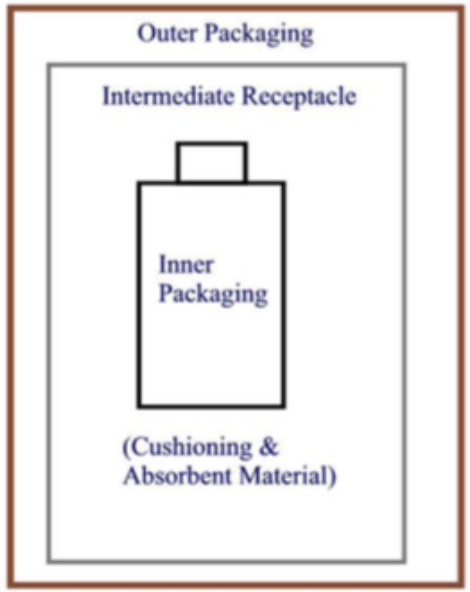
- Shipping by air:
  - 30 gm/ml or less per inner container
  - Up to 1 liter total in box
  - Triple packing:
    - Inner pack
    - Intermediate package
    - Outer package
- Exempt labeling:
  - "E" label
  - 6.1 indicates the 30 g/30 ml exemption

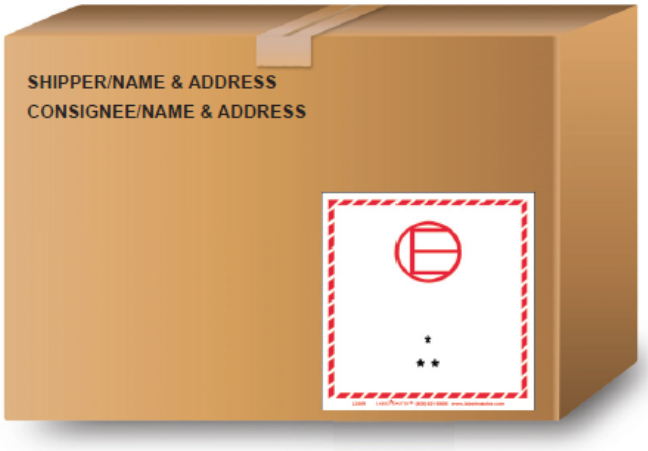




SO WHAT DOES THIS ALL MEAN?

- Shipping by ground:
  - 4 liters or 5 kg or less per inner container
  - Triple packing:
    - Inner packaging
    - Intermediate receptacle
    - Outer packaging
- Exempt labeling:
  - Limited quantity label





SHIPPING HDs

- Limited quantities:
  - Do not require dangerous goods paperwork
  - Some changes in paperwork required
  - FedEx airbills should say “Dangerous Goods in Excepted Quantities"
- FedEx/UPS have hazardous goods hotlines:
  - They are your best resource for shipping HDs
  - Have the UN number when you call!
  - Save time by recording shipping information on your HD list
- Delivery vehicle placarding:
  - May be required if exceeding certain exemptions

SOPs

Hazard Communication Program	Dispensing
Occupational Safety Program	Transport
Receipt	Environmental Monitoring
Storage	Medical Surveillance
Compounding	Medical Surveillance
Spills	HD Waste and Disposal
Disposal	
Deactivation/Decontamination	

If we discussed it today, it requires an SOP!

BEST PRACTICE – WIPE SAMPLING

- Used to detect presence of HD residues:
  - Consider all places where HDs may be present:
    - PEC
    - Pass-through
    - Staging areas
    - Storage
    - Receiving
- Limitations:
  - Cost
  - Unknown OEL – limits usefulness of data – BUT can help validate Deactivation and Decontamination

BEST PRACTICE – MEDICAL SURVEILLANCE

- Purpose – to minimize adverse health events for exposed personnel
- Looks at symptoms, complaints, labs for deviations
- Seeks to validate HD protections – PPE, engineering, practices
- Don't forget about HIPAA!
- Voluntary – employees may decide not to participate

OSHA HAZARDOUS COMMUNICATIONS PROGRAM

*This is a regulatory **requirement** today!*

STEP 1: BASICS

- Learn the requirements:
  - https://www.osha.gov/Publications/OSHA3695.pdf
- Identify who is responsible for activities:
  - Hint: the safety officer!

STEP 2: PREPARE A WRITTEN PROGRAM

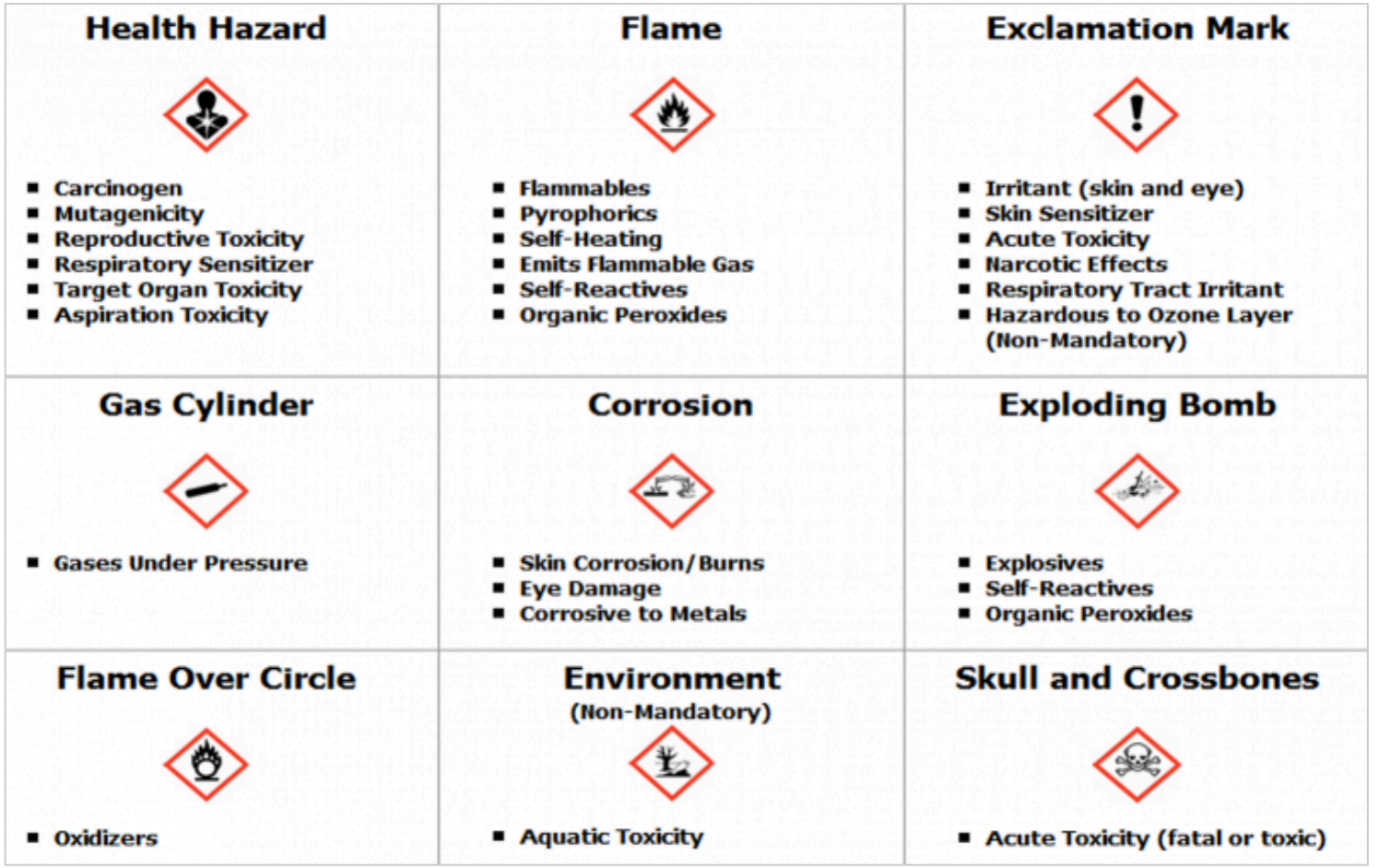
- Resources
- Requirements:
  - Written list of HDs
  - How personnel are trained and notified
  - How HDs are labeled
  - How SDSs are maintained
- Resource and template
- www.lni.wa.gov/Safety/Topics/AtoZ/HazardousDrugs/resources.asp

KEEP IN MIND…

- NIOSH and OSHA have **different definitions** of what is hazardous
- OSHA includes all NIOSH HDs and some things that are not:
  - Skin corrosion/irritation:
    - Hydrochloric acid/sodium hydroxide
  - Respiratory or skin sensitization:
    - Ketoprofen
    - Cantharidin
  - Gases under pressure

STEP 3: ENSURE PROPER LABELING

- Vendors
- Stock containers



STEP 4: MAINTAIN SDSs

- Keep SDSs on file:
  - An electronic system is acceptable to OSHA
  - *However, local fire department rules may require hard copies*
- Keep SDSs accessible to employees:
  - All employees must be able to access the electronic SDSs

STEP 5: TRAIN EMPLOYEES

- We already covered this one!

STEP 6: STAY UPDATED

- Review and update annually, along with HD list
- Update when:
  - New chemicals
  - Changes in processes/procedures

HD DISPOSAL

DISPOSAL OF HDs

This is a regulatory requirement today!

SURPRISE!

- Environmental Protection Agency's (EPA) hazardous list is different than NIOSH's and OSHA's
- EPA uses several categories for hazardous materials, including:
  - P-List – acutely hazardous if >3%
  - U-List – toxic
  - D-List – products that contain residues that exceed a minimum concentration

SURPRISE! EPA'S HAZARDOUS LIST IS DIFFERENT THAN NIOSH'S AND OSHA'S

Environmental Protection Agency (EPA) Resource and Conservation and Recovery Act[11]

Regulated Pharmaceutical Wastes and Corresponding EPA Code Type[a]

P-LISTED

EPA Code	Regulated Agent
P012	Arsenic trioxide
P042	Epinephrine
P075	Nicotine
P081	Nitroglycerin
P204	Physostigmine
P188	Physostigmine salicylate
P001	Warfarin >0.3%

U-LISTED

EPA Code	Regulated Agent
U034	Chloral hydrate
U035	Chlorambucil
U044	Chloroform
U058	Cyclophosphamide
U059	Daunomycin
U075	Dichlorodifluoromethane
U089	Diethylstilbestrol
U122	Formaldehyde
U129	Lindane
U150	Melphalan
U151	Mercury
U010	Mitomycin C
U182	Paraldehyde
U188	Phenol
U200	Reserpine
U201	Resorcinol
U202	Saccharine
U205	Selenium
U206	Streptozotocin
U237	Uracil mustard
U248	Warfarin <0.3%

D-LISTED

EPA Code	Regulated Agent
D004	Arsenic (5 mg/L)
D005	Barium (100 mg/L)
D022	Chloroform (6 mg/L)
D007	Chromium (5 mg/L)
D024	M-cresol (200 mg/L)
D013	Lindane (0.4 mg/L)
D009	Mercury (0.2 mg/L)
D101	Selenium (1 mg/L)
D011	Silver (5 mg/L)

[a] This list is not all inclusive; items listed may be additives to primary formulations.

Source- Managing Pharmaceutical Waste, ASHP. http://www.ashpadvantage.com/docs/pharmawaste-discussion-guide.pdf. Accessed March 25, 2016

ANOTHER WAY TO LOOK AT IT

- More than one P- or U-listed drug
- Chemo drugs
- NIOSH or OSHA HDs
- Drugs with LD50 less than 50mg/kg
- Endocrine disrupters
- Immunosuppressants
- Vitamins and minerals with chromium, selenium, or cadmium
- Oh … and is it infectious waste?

SUMMARY OF PHARMACEUTICAL WASTE STREAMS

Compatible Hazardous Waste*

* Dual waste for sharps

- P-listed (inc. containers)
- U-listed
- D-listed toxic
- Ignitable
- Bulk chemo
- Haz/Chemo spill clean up
- PharmE Haz®

Aerosols

- Ignitable aerosols
- Pressurized aerosols

Trace Chemo (Sharps)

- Empty vials and ampules
- Empty syringes and needles
- Empty IVs

Non-Hazardous Drugs

- All non-hazardous pharmaceutical waste
- No biohazardous drugs
- No sharps

Red Sharps

- Empty syringes, needles, ampules (except chemo)
- Bio-hazardous drugs

Municipal Solid Waste

- Most packaging
- Most empty bottles and vials
- Most empty IVs
- Paper
- Plastic
- No drugs
- No P-waste containers

Trash

Sewer System

- IVs:
  - Dextrose
  - Saline
  - Sterile Water
  - Lactated Ringers
  - K salts
  - Ca salts
  - Mg salts
- Controlled substances
- No other drugs

Drain Disposal

USP <795> AND <797>: WHAT'S NEW?

HAZARDOUS DRUGS

- Both <795> and <797> revisions refer to <800> in regard to HDs
- *Do you live in, or carry a license in, a state that requires <795>/<797> compliance?*

USP <795> REVISION

- New term – **CNSP** (Compounded Non-sterile Preparation)
  - Includes nasal and sinus preparations intended for local application
- Designated Person – similar to <800> requirement
- Increased formality around hygiene and garbing
  - Hand-washing before a new CNSP – if gloves on , wash with gloves
  - Gloves required, other garb "as appropriate"

USP <795> REVISION

Table 1. Minimum Frequency for Cleaning and Sanitizing Surfaces in Nonsterile Compounding Areas

Site	Minimum Frequency
Floors	Daily, after spills, and when surface contamination (e.g., splashes) is known or suspected
Walls	Every 3 months, after spills, and when surface contamination (e.g., splashes) is known or suspected
Ceilings	Every 3 months, after spills, and when surface contamination (e.g., splashes) is known or suspected
Storage shelving	Every 3 months, after spills, and when surface contamination (e.g., splashes) is known or suspected

USP <795> REVISION

- Containment – any weighing, measuring, or other manipulation of an API must occur inside a containment device
  - **Previously only required for HDs**
- Ingredient selection – conforms more closely with DQSA language

USP <795> REVISION

- Labels to contain:
  - Assigned internal identification number (e.g., prescription or lot number)
  - Chemical and/or generic name(s), or active ingredient(s), and amounts or concentrations
  - Dosage form
  - Total amount or volume
  - Storage conditions
  - BUD
  - Indication that the preparation is compounded

USP <795> REVISION

- BUDs

Type of Preparation	BUDs (days)	Storage Temperature[a]
Solid dosage forms[b]	180	Controlled room temperature
Preserved aqueous dosage forms[c]	30	Controlled room temperature
Non-preserved aqueous dosage forms[c]	14	Refrigerator
Nonaqueous dosage forms[d]	90	Controlled room temperature

[a] See *Packaging and Storage Requirements ⟨659⟩*.

[b] Capsules, tablets, granules, powders.

[c] An aqueous preparation is one that has a water activity (Aw) of >0.6 (e.g., emulsions, gels, creams, solutions, sprays, or suspensions).

[d] Any preparation other than solid dosage forms that have a reduced Aw of ≤0.6 (e.g., suppositories, ointments, fixed oils, or waxes).

Maximum 180-day BUD!

USP <797> REVISION – ROUND 2!!!

- First draft – Sep 2015
- Second draft – July 2018
  - Second draft SIGNIFICANTLY different than first
- HDs – see USP <800>
- Radiopharmaceuticals – draft of USP <825>
- Allergenic extracts – not in first draft, exempt from requirements of the chapter if certain criteria are met

USP <797> REVISION

- Definition of CSP
  - "Sterile compounding is defined as combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug or bulk drug substance to create a sterile medication."
  - "Preparing a conventionally manufactured sterile product in accordance with the directions contained in approved labeling provided by the product's manufacturer is **not compounding** as long as the product is for an **individual patient** and follows the **provisions for administration** below."

USP <797> REVISION – ROUND 2!!!

- Risk Categories
  - Low-, medium-, high-risk … GONE!
  - New terminology based on environment
    - Category 1 – PEC in a non-ISO space
    - Category 2 – PEC in an ISO 7 or better buffer *and* ISO 8 or better anteroom
      - Note – this includes all PECs … *RABS are not exempt*

USP <797> REVISION - BUDS

- Category 1 – limited to ⩽ 12 hours room temp, ⩽ 24 hours refrigerated
- Category 2:

Table 12. BUDs for Category 2 CSPs

Preparation Characteristics		Storage Conditions		
Sterilization Method	**Sterility Testing Performed and Passed**	**Controlled Room Temperature (20°–25°)**	**Refrigerator (2°–8°)**	**Freezer (–25° to –10°)**
Aseptically prepared CSPs	No	Prepared from one or more nonsterile starting component(s): 1 day	Prepared from one or more nonsterile starting component(s): 4 days	Prepared from one or more nonsterile starting component(s): 45 days
		Prepared from only sterile starting components: 4 days	Prepared from only sterile starting components: 9 days	Prepared from only sterile starting components: 45 days
	Yes	30 days	45 days	60 days
Terminally sterilized CSPs	No	14 days	28 days	45 days
	Yes	45 days	60 days	90 days

USP <797> REVISION – TRAINING AND COMPETENCY

- Hand hygiene
- Garbing
- Cleaning and disinfection
- Calculations, measuring, and mixing
- Aseptic technique
- Achieving and/or maintaining sterility and apyrogenicity
- Use of equipment
- Documentation of compounding process
- Principles of unidirectional airflow
- Use of PECs
- Principles of movement of materials

USP <797> REVISION – TRAINING AND COMPETENCY

- Garbing and hand hygiene
  - Initial – 3x, ≥1 cfu
  - Post media-fill – every six months, >3 cfu
  - Visual observation – six months
- Media-fill – every six months (examples have been removed)
- Cleaning and disinfecting – retrain and requalify with change in procedure

USP <797> REVISION

- Hand hygiene, garbing, and gloving
  - Order to be determined by facility
  - Revision allows for sink to be inside or outside anteroom
- Presterilization
  - ISO 8 environment
  - Must be in a PEC

USP <797> REVISION

- Certification – CETA is a *must*
- Six-month cycle for viable and nonviable air sampling
- Surface sampling
  - Monthly requirement in each classified area

USP <797> REVISION

- Compounding Records
  - MFR – required if:
    - CSP prepared in a batch (if for more than one patient)
    - CSP prepared from non-sterile ingredients
  - CR – created for all CSPs
    - May be in the form of an Rx order, compounding log, or label

- Recalls, complaints, adverse event reporting – all addressed by the chapter

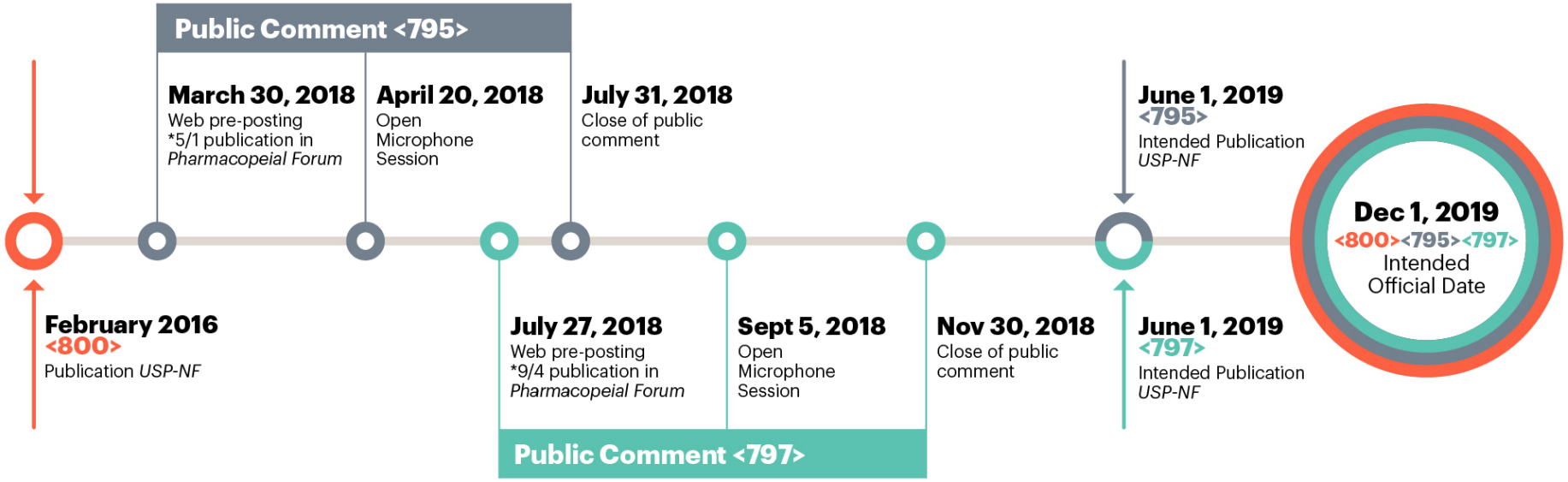
STAY UP-TO-DATE WITH USP <795> AND <797>

- Sign up for updates at www.usp.org/hqs-signup-form

- Expected date of final publication is June 1, 2019; becomes official December 1, 2019:
  - Harmonizes with USP<800> official date

USP <795> AND <797> UPDATED TIMELINE

www.usp.org/compounding/updates-on-standards, accessed 3/9/2018



Note: The current version of General Chapters <795> and <797> published in USP-NF are official.

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THANK YOU

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