Powders, PPE, and Protection

Safeguarding staff in nonsterile HD compounding

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Learning objectives

- Summarize how USP <795> and <800> overlap in guiding nonsterile hazardous drug compounding practices.
- Assess facility and equipment design needs, including containment hoods, SCAs, and surface materials.
- Select appropriate PPE for nonsterile HD compounding based on task and exposure risk.
- Recognize cleaning and decontamination challenges and apply best practices for managing HD powder residues.

USP <795> and <800>

Examples of HDs and dosage forms used in non-sterile compounding

NIOSH Table 1

Azathioprine
Chlorambucil
Chloramphenicol
Cidofovir
Cyclosporine
Fluorouracil
Hydroxyurea
Mycophenolate mofetil

Dosage forms

Capsules
Tablet
Creams
Ointments
Liquids
Suppository
Troche
Treat

NIOSH Table 2

Anastrozole
Carbamazepine
Clonazepam
Colchicine
Dutasteride
Estradiol
Finasteride
Fluconazole
Leflunomide
Letrozole
Methimazole
Oxytocin
Paroxetine
Phenytoin
Progesterone
Spironolactone
Sirolimus
Tacrolimus
Tamoxifen
Testosterone
Topiramate
Tretinoin
Valproate sodium
Zonisamide

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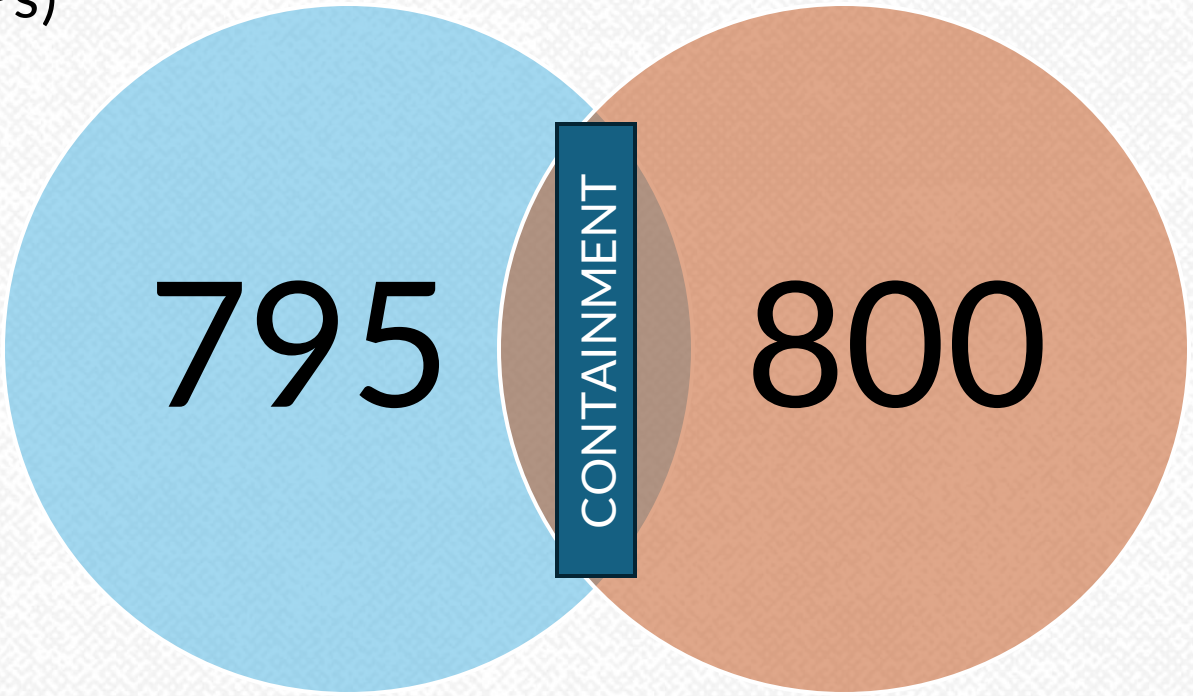
Overlap of <795> and <800>

These concepts or requirements appear in both Chapters:

- Designated Person (DP)
- Standard Operating Procedures (SOPs)
- Training and competency
- PPE requirements
- Cleaning and spill control
- Documentation



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Unique requirements of USP <795> and <800>

USP <795>

- Ingredient quality
- MFR and CR
- Release inspections and testing
- BUDs
- Labeling
- QA/QC

USP <800>

- C-PEC and C-SEC
- More PPE
- Assessment of risk
- Receiving
- Hazard identification
- Decontamination
- QA/QC recs e.g., wipe sampling

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<795> Key Principles

PATIENT FOCUS

Process of compounding
Quality and safety for the patient

<800> Key Principles

PERSONNEL FOCUS

HD identification, containment,
and protection of workers

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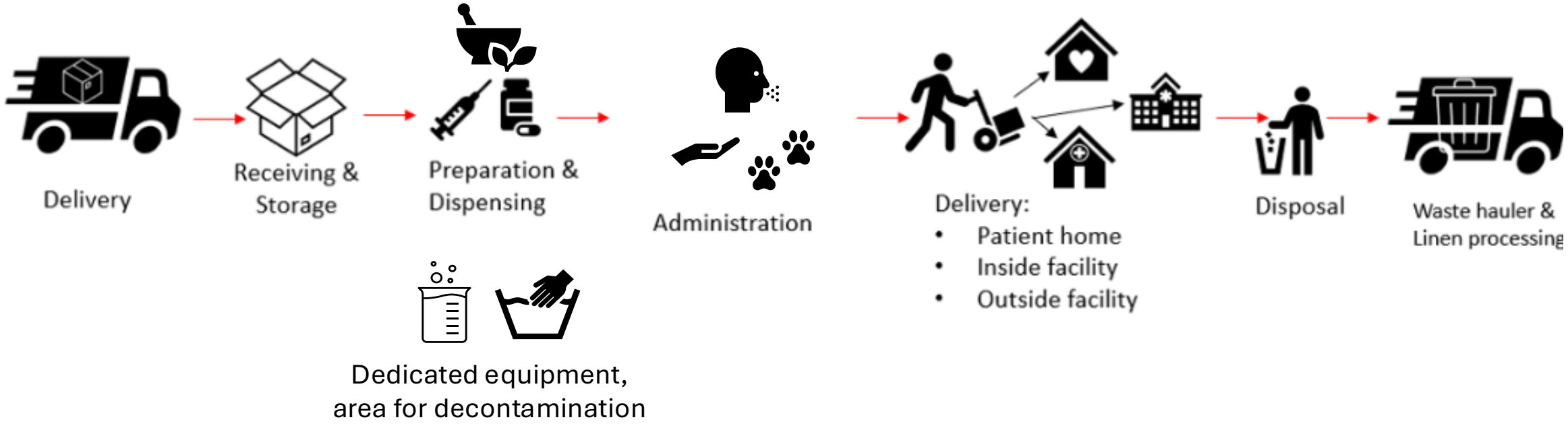
Facility Design and Equipment

HD CNSP Process

Compounding starts at the loading dock…



…and ends at disposal.

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Facility requirements of USP <795> and <800>

USP <795>

Compounding Area
- Designated area
- Monitored storage area
- Sink

PEC
- Particle generating assessment
- CVE, BSC, or glovebag
- Certification every 12 months

USP <800>

Receipt
- Neutral or negative pressure

Storage
- Negative pressure
- Externally vented
- 12 ACPH
- HD API and Table 1 antineoplastics

USP <800>

Nonsterile Compounding

C-SEC (or C-SCA)
- -0.01 to -0.03”w.c. negative pressure
- Externally vented
- 12 ACPH
- Sink and eye wash

C-PEC (CVE, BSC, or CACI)
- Externally vented or redundant HEPA filtered in series
- Not ISO classified

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Facility design workflow considerations

HD Receiving

- Proximity to storage area

HD Storage

- OK to store nonsterile and sterile items together, but not in sterile area
- OK to store in compounding area, but consider temperature

HD Compounding

- OK to do HD CNSPs in a sterile area, but C-SEC must maintain ISO 7 and C-PEC must be decontaminated, cleaned and disinfected before use for sterile compounding

Equipment

- Dedicated HD equipment
- Sink placement for cleaning of dirty equipment

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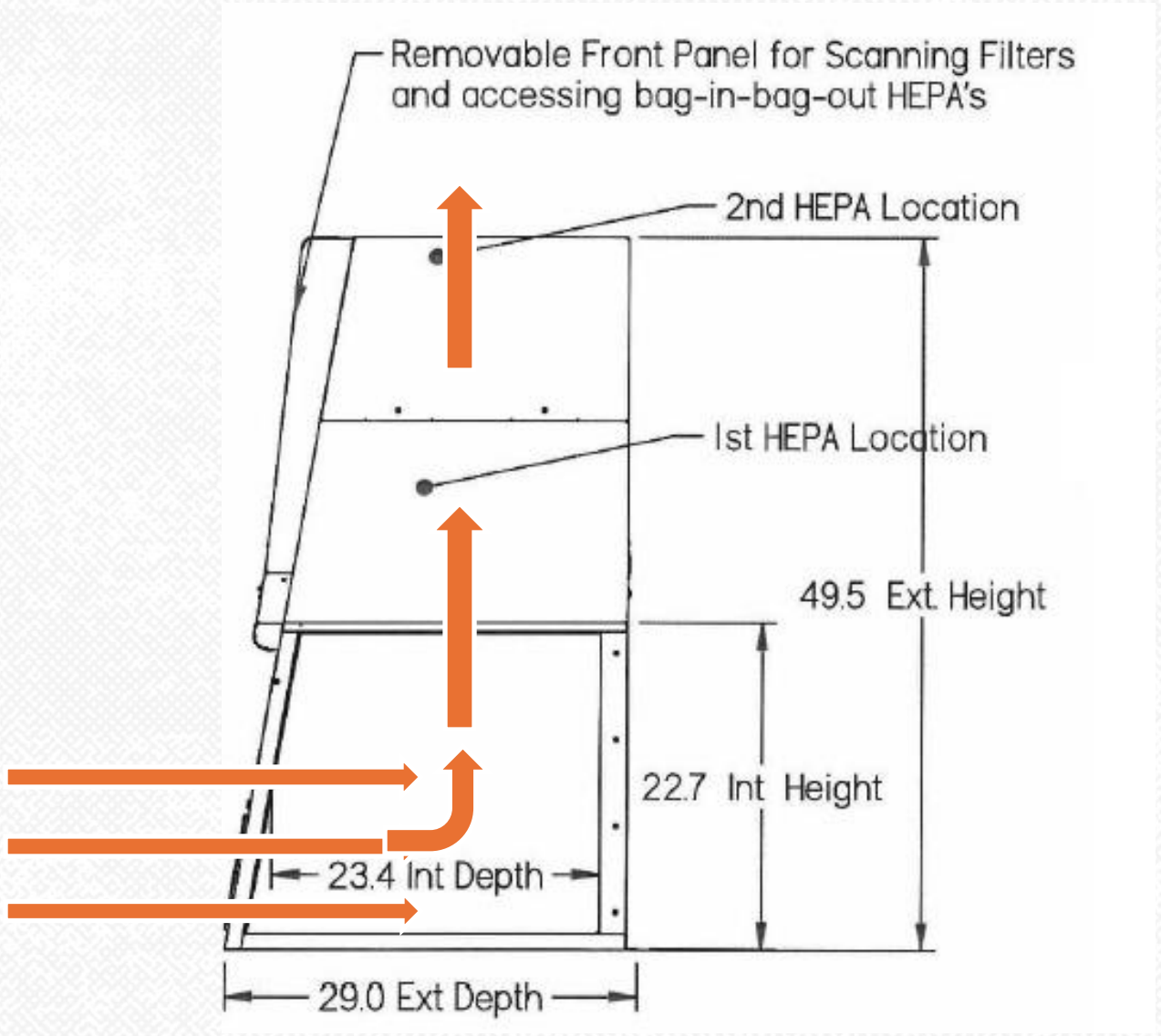
HEPA filter in series Containment ventilated enclosure (CVE)



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Workflow considerations

Assessment of Risk

Manipulation required:
Weighing or measuring
Dilution
Pouring
Repackaging

Packaging:
Ointment jar
Syringe
Tube
Pump
Wrapped unit dose
Dispensing vial

Exposure risk:
Consider based on the compounding process

Drug:	Dosage Form:
Progesterone, USP micronized	Bulk API powder
Type of review: ☐ Initial x Annual	Date of review: 10/1/2025 Reviewed by: A. Lambert, DP
Type of HD: ☐ Table 1 Antineoplastic ☐ Table 1 Non-antineoplastic X Table 2	
Additional HD Risk Information: ☐ MSHI ☐ IARC or NTP carcinogen ☐ Only developmental or reproductive risk	
Does another non-HD therapeutic alternative exist? X No ☐ Yes: _____	
Manipulation required: ☐ NONE ☐ Crushing ☐ Opening capsules X Compounding ☐ Pouring Other:_____	
Packaging: ☐ Unit dose ☐ Unit of use ☐ Bulk ☐ Other: _____	
Risk of exposure: ☐ Ingestion ☐ Inhalation ☐ Contact ☐ Vapor ☐ Other: _____	
Other applicable standards: ☐ NONE ☐ USP <797> X USP <795> ☐ Other:	

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Cleaning and Decontamination

Cleaning requirements of USP <795> and <800>

USP <795>

Cleaning and sanitizing

Work surface
- Daily when compounding occurs and between diff CNSPs

CVE/BSC
- Beginning and end of shift

Floors – daily

Walls/ceilings – when visibly soiled

USP <800>

Deactivation, decontamination, and cleaning (DDC)

C-PEC Work surface
- Daily when compounding occurs and between diff HDs

Floors/walls/ceilings
- Not defined

Cleaning consistent with USP <795>
Per facility SOP

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Powders and…DDC

MAY REQUIRE MULTIPLE PRODUCTS TO GET THE JOB DONE.

Compounding components
- Creams & ointments

Agent selection
- No spray bottles!
- Frequency of use, impact to staff
- PPE

Process points
- In and out
- Between compounds
- Wet or dry

Equipment
- Tools – wet or dry wipe
- Sink location
- Compatibility
- Manufacturer's instructions

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Personal Protective Equipment

Garbing requirements of USP <795> and <800>

USP <795>

Gloves

All other garb appropriate per type of compounding performed and per facility SOPs.

USP <800>

Chemo gloves

Chemo gown

Shoe covers

Head and hair covers

Protective sleeves

Eye and face protection by task

Respiratory protection per task

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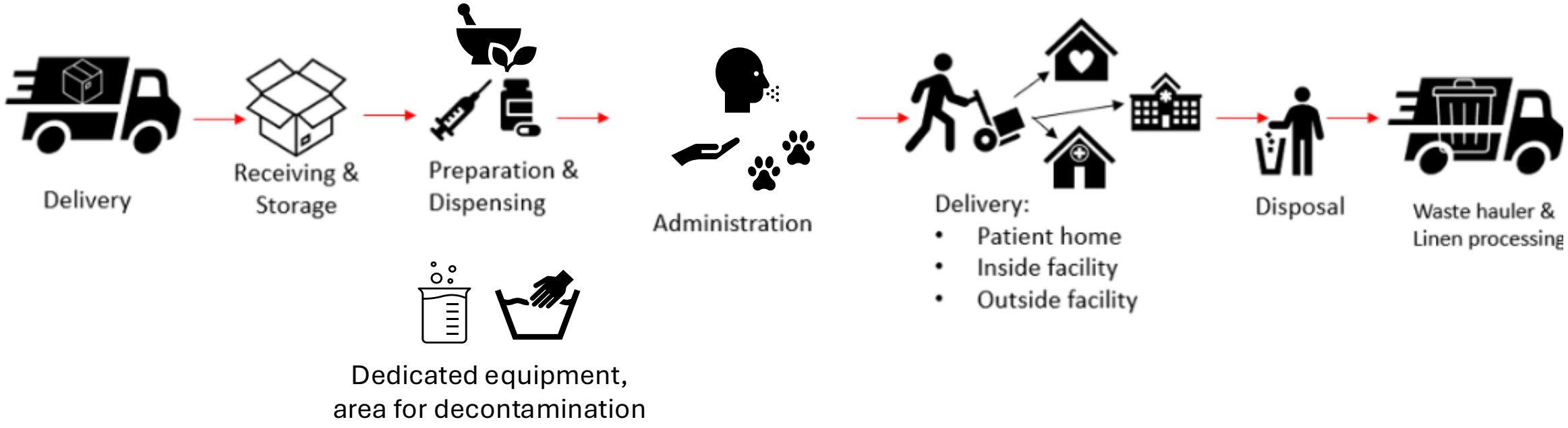
Other PPE Considerations

Protection starts at the loading dock…



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Key Takeaways

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- USP <795> and <800> align on containment to protect both patients and employees.
- Cleaning and decontamination agents should match the task. Mind compatibility with equipment and staff exposure.
- Containment and protection begin before compounding and continue beyond—from receipt and storage to compounding and decontamination.