



# Society of Air Force Pharmacy



---

## **USP 797 & 800: Lessons Learned**

**Lt Col Tara Stogdill**

**Maj Tiffany Gooding**

---



# Attendance Code

---

To obtain CPE credit for this activity, you are required to actively participate in this session. You will need this attendance code in order to access the evaluation and CPE form for this activity. Your CPE must be filed by **September 30, 2020, at 1700 EST** in order to receive credit.



# CPE Information and Disclosures

---

Lt Col Tara Stogdill and Maj Tiffany Gooding: “declare(s) no conflicts of interest, real or apparent, and no financial interests in any company, product, or service mentioned in this program, including grants, employment, gifts, stock holdings, and honoraria.” or declare disclosures.



The Tennessee Pharmacy Association is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.



# CPE Information

---

Target Audience: Pharmacists and Pharmacy Technicians

ACPE#: 0575-0000-20-089-L07-P

0575-0000-20-089-L07-T

Activity Type: Knowledge



# Learning Objectives:

---

1. Identify key aspects of USP 797/800 updates
2. Describe initial lessons learned from USP 797/800 implementation at Wave Travis sites
3. State the challenges of implementing USP 797/800 at small, medium, and large MTFs
4. Discuss options for training and maintenance of compliance records



# USP General Chapters

---

United States Pharmacopeia (USP) is a standard-setting organization

- USP 795- Pharmaceutical compounding- Nonsterile Preparations
- USP 797- Pharmaceutical compounding- Sterile Preparations
- USP 800- Hazardous Drugs- Handling in Healthcare Settings
- USP 825- Radiopharmaceuticals

Important for protecting healthcare workers and their patients

Information may be used or incorporated into regulations

Often added by accrediting bodies as best practices or requirements

Be AWARE: USP 795 and USP 825 also had updates/revisions!



# USP Updates: It's Here...*Or is it?*

---

Published 1 June 2019

Appeals include:

- Beyond-Use Date provisions in <795> and <797>
- Removal of Alternative Technology provision from <797>
- Applicability of <795> and <797> to veterinary practitioners

USP says that they consider Chapter <800> to be informational only and not compendially applicable until the revisions to <797> are resolved, BUT *federal and state regulators will make their own decisions regarding enforcement*



# USP Overview

---

## ■ Guidelines

- Recommended Practice
- Based on evidence
- From a reliable source
- What “Should” be
- Example: ASHP Guidelines

## ■ Standards

- Expectations for practice
- Based on strong evidence
- From a reliable source or regulatory agency
- What “Must” be
- Example: JC Standards





# Key Aspects of USP Updates

---

It is a set of guidelines that is enforced by:

- State regulatory agencies (Board of Pharmacy, State Dept of Environmental Protection) and
- Federal agencies (FDA, EPA, OSHA) as well as
- Accrediting bodies (TJC)

Be aware of verbiage: *must vs. should*



---

# USP <797> Pharmaceutical Compounding – Sterile Preparations

---



# USP <797> *Sterile Preparations* Revisions

---

Revision June 2019-

- Implementation as official standards on 1 Dec 19; *postponed by USP Sept 19*

Added specific standards for repackaging

Moved standards regarding radiopharmaceuticals to USP 825

Extended BUD “Immediate Use” compounded sterile preparations (CSPs)\*

Better defined requirements for primary engineering controls (PECs)



# USP <797> Facilities and Engineering

---

Primary Engineering Controls (PEC) = Hood

- Laminar Air Flow Systems (LAFS)
  - Laminar Airflow Workstation (LAFW)
  - Integrated Vertical Laminar Flow Zone (IVFLZ)
  - Biological Safety Cabinet (BSC)
- Restricted Access Barrier Systems (RABS)
  - Compounding Aseptic Isolator (CAI)
  - Compounding Aseptic Containment Isolator (CACI)



# USP <797> Facilities and Engineering

---

## Secondary Engineering Controls (SEC) = Room

- Unclassified Segregated Compounding Area (SCA)
- ISO 7 buffer room
  - At least 30 Air Changes Per Hour (ACPH)
  - Positive Pressure with pressure differential  $\geq 0.02$
- ISO 7 anteroom
  - At least 30 ACPH
  - Positive Pressure with pressure differential  $\geq 0.02$
- ISO 8 anteroom
  - At least 20 ACPH
  - Positive Pressure with pressure differential  $\geq 0.02$



# USP <797> Updates: BUDs\*

Past	New
Beyond Use Date (BUD) mainly driven by components and: <ul style="list-style-type: none"><li>sterile vs. non-sterile</li><li>for one patient or many</li><li>Complexity of the process</li></ul>	BUD driven by environment of preparation, probability of microbial growth, components, sterility and storage conditions.
“Risk Levels” (low, medium, high) determined BUD	Created 2 categories plus “immediate-use provision” to determine BUD <ul style="list-style-type: none"><li>NO provisions to extend BUDs</li></ul>
“One-Hour Rule” for immediate use compounds	BUD is 4 hours (from start of preparation of CSP) for immediate-use compounds
	Multi-Stock/Dilution bags must be made as Category 2 CSP and pass antimicrobial effectiveness test



# Summary of BUD changes\*

Official <797> (last revised in 2008)	Revised <797> (published June 1, 2019)
<ul style="list-style-type: none"><li>▶ Low-risk in segregated compounding area<ul style="list-style-type: none"><li>• 12 hours at CRT*</li></ul></li><li>▶ Low-risk<ul style="list-style-type: none"><li>• 48 hours at CRT</li><li>• 14 days in a refrigerator</li><li>• 45 days in a freezer</li></ul></li><li>▶ Medium-risk<ul style="list-style-type: none"><li>• 30 hours at CRT</li><li>• 9 days in a refrigerator</li><li>• 45 days in a freezer</li></ul></li><li>▶ High-risk<ul style="list-style-type: none"><li>• 24 hours CRT</li><li>• 3 days refrigerator</li><li>• 45 days frozen</li></ul></li></ul>	<ul style="list-style-type: none"><li>▶ Category 1<ul style="list-style-type: none"><li>• ≤ 12 hours at CRT</li><li>• ≤ 24 hours in a refrigerator</li></ul></li><li>▶ Category 2<ul style="list-style-type: none"><li>• Aseptically processed, no sterility, only sterile starting components<ul style="list-style-type: none"><li>• 4 days at CRT</li><li>• 10 days in a refrigerator</li><li>• 45 days in a freezer</li></ul></li><li>• Aseptically processed, no sterility, one or more nonsterile starting component(s)<ul style="list-style-type: none"><li>• 1 day at CRT</li><li>• 4 days in a refrigerator</li><li>• 45 days in a freezer</li></ul></li></ul></li></ul>



# USP <797> Updates (Cont.)

Past	New
Compounding Aseptic Isolators (CAI) and Compounding Aseptic Containment Isolators (CACI) could be used outside cleanroom suites	Compounding Aseptic Isolators (CAI) and Compounding Aseptic Containment Isolators (CACI) must be in a cleanroom suite to prepare category 2 CSPs.
Surface sampling was required “periodically”	Monthly surface sampling required
Extend BUDs under certain conditions	Cannot extend BUDs outside those specific ones outlined in Chapter
	Requires Master Formulation Records (for CSPs for more than one patient and CSPs prepared from non-sterile ingredients) and Compounding Records (for all CSPs)





# USP 797 Challenges

---

CSP BUD changes may drive changes in:

- CSP batch/cart-fill frequency
- Staffing patterns for preparation and delivery
- Types of vial sizes and concentrations purchased

Potential facility design changes/Construction

- Time
- Cost
- Workflow changes



# Lessons Learned

USP 797 Topic	Issues	Areas to Focus On/ Ways to Resolve
Competencies	<p>More frequent competency documentation</p> <ul style="list-style-type: none"><li>• Every 6 months</li><li>• Gloved fingertip testing (GFT) and hand hygiene and garbing (HHG) testing now must be performed <u>3 times initially</u></li></ul> <p>Written competency requirements more defined in new 797 - Relias Training Available online</p>	<p>Detailed documentation of HHG, GFT, and Media-Fill competency evaluation required</p> <ul style="list-style-type: none"><li>• Consider revising/creating HHG, GFT, and Media-Fill Competency Eval forms<ul style="list-style-type: none"><li>• Specific to order outlined in SOP</li><li>• Include all required documentation elements</li></ul></li><li>• Results &amp; corrective action must be documented and maintained</li></ul>
	<p>GFT plates and Media-Fill bag must be incubated at two temperature ranges:</p> <ul style="list-style-type: none"><li>• GFT: 30°C to 35°C (48 hrs) then 20°C to 25°C (5 days)</li><li>• MF: 20°C to 25°C (7 days) then 30°C to 35°C (7 days)</li></ul>	<p>Recommend requesting lab/micro incubate and monitor samples</p>



# Lessons Learned

USP 797 Topic	Issues	Areas to Focus On/ Ways to Resolve
Engineering & Environment	More parameters to monitor: <ul style="list-style-type: none"><li>• Humidity (&lt; 60%)</li><li>• Temperature (&lt; 20°C)</li><li>• Air pressure (0.02" differential)</li></ul>	<ul style="list-style-type: none"><li>• Get new monitoring probes to address humidity</li><li>• Some compliance software (Carter-Health's A.R.T.) will automatically pull all the required data from probe</li></ul>
	<ul style="list-style-type: none"><li>• Environment for Hazardous Drugs (HDs):</li><li>• Must have both ante and buffer rooms' environment no worse than ISO 7</li></ul>	<ul style="list-style-type: none"><li>• Remodeling may be required</li><li>• Consider contracting an external consultant to ensure all USP 797 &amp; 800 requirements met</li></ul>
	Monthly cleaning with sporicidal agent	<ul style="list-style-type: none"><li>• Consult with facilities to ensure an FDA-agent is available and will be used</li><li>• One-step agents are available and may be used</li><li>• <b>For remodeling consultant:</b> make sure they consider materials being used so sporicidal agents do not damage surfaces (rusting, etc.)</li></ul>

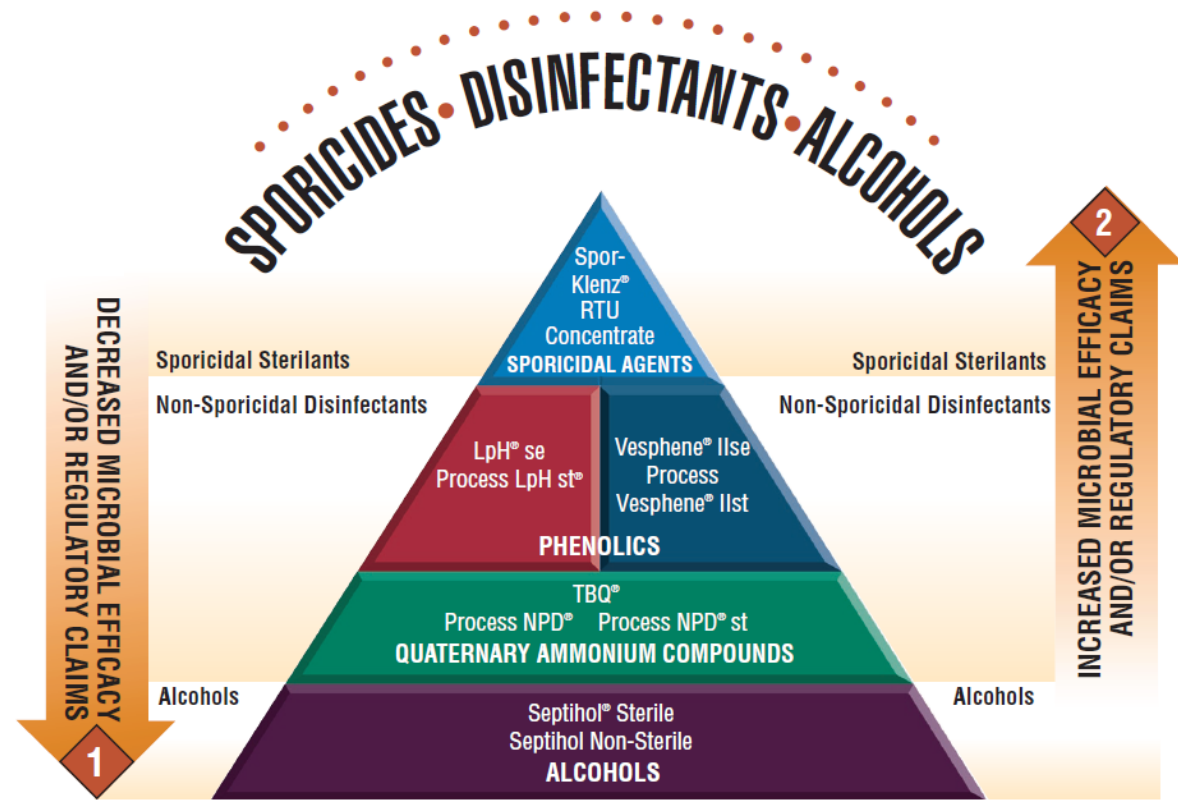


# Lessons Learned

USP 797 Topic	Issues	Areas to Focus On/ Ways to Resolve
Certifications	<p>Surface sampling:</p> <ul style="list-style-type: none"><li>• Must be done monthly</li><li>• Must have sampling locations clearly identified in SOP's</li></ul> <p>Samples need to be incubated at 2 different temperatures</p> <ul style="list-style-type: none"><li>• 30°C to 35°C (48 hrs)</li><li>• 20°C to 25°C (5 additional days)</li></ul>	<ul style="list-style-type: none"><li>• Certification contractor may not be able to sample that frequently.</li><li>• Lab/Micro will need to be involved due to incubation requirements</li><li>• Ensure locations clearly identified in OIs</li></ul>
	<p><u>OPTIONAL</u>: sampling of HD compounding area(s) for HD residues</p>	<ul style="list-style-type: none"><li>• There currently is <u>no clear guidance</u> for what is defined as “too much,” HD residue in the compounding environment: hence this is not a “must do” standard.</li></ul>



# What are you Cleaning with?



1. PRODUCTS AT THE BASE OF THE PYRAMID ARE MOST FREQUENTLY USED AND ARE GENERALLY NOT SPORICIDAL.
2. PROGRESSION UP THE PYRAMID INDICATES STRONGER PERFORMANCE OVERALL AND A BROADER SPECTRUM OF CLAIMS.

### REFERENCES



# Where do I start?

---





# Where, indeed?

---

Identify Sterile Compounding Designated Person (DP)

Perform Gap Analyses

- Identify facility issues ASAP; where air comes from & where it goes
- Assess impact due to BUD changes\* +/-modify production as needed
- Supply list –nail pics, garb, PPE, sampling plates/media, DDC(D) agents, etc.

Facility & engineering controls

- Cleaning, Monitoring
- Engage with contractors and/or certifiers EARLY

Create/revise facility policies & departmental SOPs

Train & evaluate competency of compounding personnel



# Assessment Question

---

Which of the following is evaluated and documented every 6 months?

- A. Aseptic Manipulation Competency via Media-Fill Testing
- B. Hand Hygiene & Garbing (HHG) via Gloved Fingertip & Thumb (GFT) Sampling
- C. Hand Hygiene & Garbing (HHG) via visual observation
- D. All of the above





# Assessment Question

---

How often must surface sampling be accomplished?

- A. Weekly
- B. Monthly
- C. Semi-annually
- D. None of the above



---

USP <800>

Hazardous Drugs – Handling in  
Healthcare Settings

---



# USP Chapter <800> Applies To:

**“... All healthcare personnel** who handle hazardous drug (HD) preparations and all entities which store, prepare, transport, or administer HDs.”

*No exceptions based on HD volume, category of personnel, or facility type*

Drugs on the NIOSH list that must follow the requirements:

- Any HD API (Active Pharmaceutical Ingredient)
- Any antineoplastic requiring HD manipulation

- *An Assessment of risk (AOR) may be performed and alternative containment strategies/work practices implemented for final dosage forms that do not require manipulation other than counting or repackaging.*



# USP <800> *Hazardous Drugs* Key Aspects

Published 1 February 2016

- Implementation 1 July 2018 → 1 December 2019 → ??

Focus on Hazardous Drugs (HDs) and the occupational safety surrounding the handling of these agents

USP 800 impacts **all handling** of HDs (i.e. receiving, unpacking, dispensing, administering, cleaning, spill management)

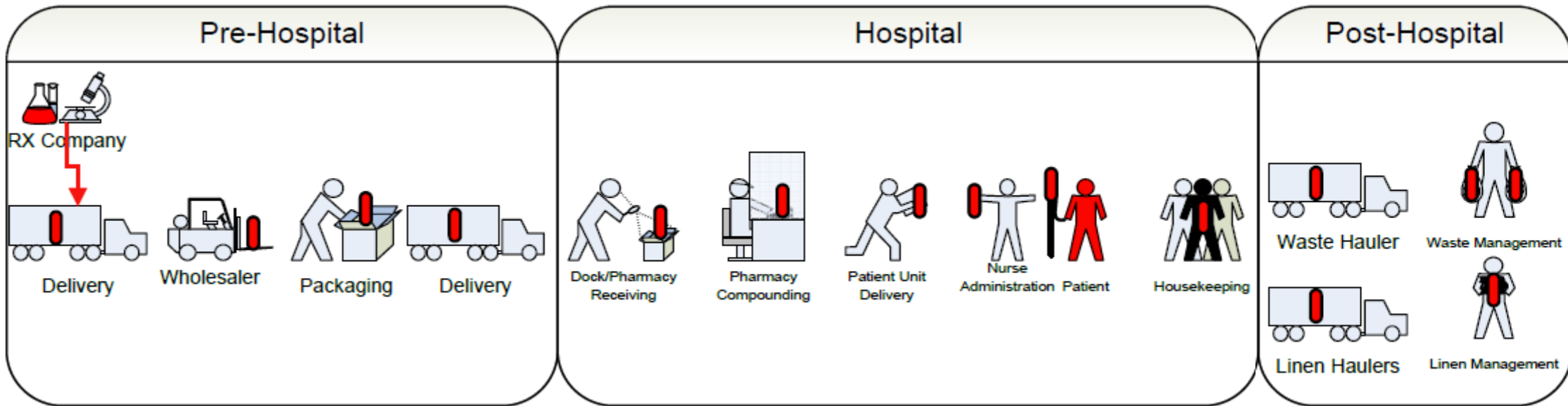
3 categories of HDs (NIOSH 2016)

- Antineoplastics
- Non-Antineoplastics
- Reproductive Risk Only

USP 800: 17 pages of fun!



# HD Process





# USP <800> Updates

Past	New
<p>“Low-Volume provision:” Could prepare HDs using the same BSCs or CACIs used for non-HDs provided the volume of HD prescriptions was not very high, and “two tiers of containment” are used</p>	<p>Provision is eliminated Class II Biological Safety Cabinets (BSCs) and CACI remain the standard PEC However, ALL manipulation of antineoplastic HDs must occur in a <u>negative-pressure environment</u></p>
<p>HD storage is preferably within a containment area such as a negative pressure room.</p>	<p>Antineoplastic HD requiring manipulation other than counting/repackaging <b>must</b> be stored and prepared separately from non-HDs</p>



# USP <800> Key Requirements

---

Facility must identify a **designated person** to oversee all requirements and compliance

Facility must **maintain a list of all HDs**

- List must be reviewed every 12 months

Establish **Assessment of Risks (AORs)** for some dosage forms of drugs defined as hazardous that may not pose a significant risk of direct occupational exposure (e.g. tablets).

- Review every 12 months

Facility must **develop Standard Operating Procedures (SOPs)**

- Minimum SOP requirements are listed in the chapter
- Establish **designated HD handling areas** and have signs before entering the area
- Facility must maintain SOPs for safe handling of HDs for all situations
- Review every 12 months

**Establish criteria** to identify HDs that enter the market after the most recent version of the NIOSH list, or that the facility handles as an investigational drug.



# USP <800> Key Requirements

---

## Personnel

- **All personnel must be trained and demonstrate competency** BEFORE they handle any HDs.
- Training must meet the minimum requirements as outlined in the chapter and be reassessed every 12 months.
- Personnel who transport, compound, or administer HDs must **document training** according to OSHA standards
- All personnel who handle hazardous drugs must adhere to facility **PPE requirements**

## Receipt:

- Facility must **develop SOPS** for receiving HDs to include PPE, what to do if shipping container or HD container is damaged
- Antineoplastics and all HD APIs must be unpacked (i.e. removal from shipping containers) in an area that is neutral/normal or negative pressure relative to the surrounding areas

## Storage:

- Stored in a manner to prevent spillage, breakage or falls but NOT on the floor
- Antineoplastic HDs requiring manipulation, other than counting or repackaging of the final dosage forms, and any HD APIs must be stored separately from non-HDs
- Sterile and nonsterile HDS may be stored together unless this will increase traffic into the sterile compounding area





# USP <800> Key Requirements

---

## Labeling, Packaging, Transport and Disposal

- Facility must **develop SOPS** addressing prevention of accidental exposures or spills, personnel training on response to exposure and use of a spill kit
- HDs identified as requiring special handling must be clearly labeled during transport
- Pneumatic tubes must not be used to transport liquid HDs, APIs, or any antineoplastic HDs
- Tablet and capsule forms of antineoplastic HDs must not be placed in automated counting or packaging machines
- All personnel who perform routine custodial waste removal and cleaning activities in HD handling areas **must be trained** in appropriate procedures



# USP <800> Key Requirements

---

## Compounding

- Compounding HDs must be compliant with the appropriate USP standards 795/797
- Must be done within appropriate compounding engineering controls
- Plastic Backed preparation mat should be placed on the work surface of the containment primary engineering control (C-PEC) and changed as outlined in the chapter
- HDs must have dedicated equipment (e.g. mortars, spatulas, counting trays)
- **Sterile and Nonsterile HDs must be compounded within a C-PEC located in a containment secondary engineering control (C-SEC)!**
- Containment supplemental engineering controls (CSTDs) should be used when compounding HDs when the dosage form allows
  - CSTDs known to be physically or chemically incompatible with HDs should not be used
- CSTDs must be used administering antineoplastic HDs when the dosage form allows



# USP <800> Key Compounding Requirements

- Nonsterile HD Compounding
  - Must also follow standards in USP <795>
  - A C-PEC is not required if manipulations are limited to handling of final dosage forms (i.e. counting or repackaging of tablets and capsules) that do not produce particles, aerosols or gasses.

## Engineering Controls for Nonsterile HD Compounding

C-PEC	C-SEC Requirements
Externally vented (preferred) or redundant HEPA filtered in series Examples: Containment ventilated enclosure, (CVE), Class I or II Biological Safety Cabinet, Compounding aseptic containment isolator (CACI)	Externally vented 12 Air changes per hour (ACPH) Negative pressure between 0.01 and 0.03 inches of water column relative to adjacent areas



# USP <800> Key Compounding Requirements

## Sterile HD Compounding Engineering Controls

Configuration	C-PEC	C-SEC	Comments
ISO Class 7 buffer room with an ISO Class 7 ante-room	Externally vented	Externally vented 30 ACPH Negative pressure between 0.01 and 0.03 inches of water column relative to adjacent areas	BUD as described in <797>
Unclassified C-SCA	Externally vented	Externally vented 12 ACPH Negative pressure between 0.01 and 0.03 inches of water column relative to adjacent areas	Only Category 1 CSPs can be made in a C-SCA  BUD as described in <797> for CSPs prepared in a segregated compounding area



# USP <800> Key Requirements

---

## Environmental Quality and Control

- Environmental **wipe sampling** for HD surface residue should be performed routinely
  - Defined as initially as a benchmark and at least every 6 months or more often as needed
  - Sampling locations defined in chapter
  - Note: There are no certifying agencies for vendors of wipe sample kits and no standard for acceptable limits for HD surface contamination

## Administering

- Appropriate PPE must be worn
- Healthcare personnel should avoid manipulating HDs such as crushing tablets or opening capsules if possible
  - Liquid formulations are preferred if solid oral dosage forms are not appropriate for the patient
  - If manipulation must occur, personnel must don appropriate PPE and use a plastic pouch to contain any dust or particles
- Many healthcare facilities have operating instructions regarding medication administration

## Medical Surveillance

- Personnel who handle HDs as a part of their regular job should be enrolled in a **medical surveillance** program (elements and requirements of such program are outlined in chapter)
- Facility should have **follow-up plan** established for post-exposure requirements as outlined in chapter



# USP <800> Key PPE Requirements

---

## Personal Protective Equipment (PPE):

- Chemotherapy Gloves
  - Required for handling antineoplastic HDs; AORs and facility SOPs will guide other requirements
  - Must meet the ASTM standards D6978
  - Must be powder free
  - Two pairs of chemo gloves are required for administering antineoplastic HDs
  - Two pairs of chemo gloves are required for sterile and nonsterile HD compounding and should be changed every 30 minutes (or per manufacturer's recommendation) and when damaged.
- Gowns
  - Must be disposable
  - Must be shown to resist permeability by HDs
  - Must close in the back, be long-sleeved, and have closed elastic or knit cuffs
  - Must be changed every 2-3 hours or immediately after a spill or splash



# USP <800>

## Key PPE Requirements (cont.)

- Head, hair, Shoe and Sleeve covers
  - Continues to follow USP 797 plus...
  - When compounding HDs, a second pair of shoe covers must be donned before entering the C-SEC and doffed upon exiting C-SEC.
  - Shoe covers worn in HD handling areas must not be worn to other areas to avoid spreading residue
- Eye and face protection
  - If eye protection is required, it must be goggles
  - Must be worn when there is risk of spills, splashes or waste materials when working outside the C-PEC
- Respiratory protection
  - Risk of airborne particles (e.g. unpacking HDs not in plastic/damaged bottles or containers) : N95 or more protective respirator
  - Full-face-piece respirator (fit tested), chemical cartridge-type or powered respirator (PAPR) should be worn when:
    - Spill is larger than what can be contained by spill kit
    - Deactivating, decontaminating, and cleaning underneath the work surface of a C-PEC
    - HD is known or suspected to cause airborne exposure to powders or vapors



# USP <800> Key requirements

---

Facilities must incorporate standards into their **occupational safety plan**

Facility must **develop a Hazard Communication Program** with the minimum elements outlined in the chapter

Facility must **develop SOPs** to ensure training regarding proper labeling, transport, storage, disposal and use of Safety Data Sheets (SDS)

All personnel who may be required to clean up a spill of HDs must receive proper **training** in spill management

**Spill kits** must contain all materials needed to clean up HD spills and must be **readily available** in all areas where HDs are handled.

- ASHP & Oncology Nursing Society have great suggestions on what should be in an HD spill kit
- All spill materials must be disposed of as hazardous waste





# USP <800>

## Key requirements

---

### Deactivating, Decontaminating, Cleaning and Disinfecting (DDCD)

- All areas where HDs are handled and all reusable equipment must be deactivated, decontaminated, cleaned and disinfected as outlined in the chapter
- Deactivation agent (commonly bleach) may differ depending on HDs' SDS
- All personnel who perform these tasks must be properly **trained** and don appropriate PPE (minimum two pairs of chemo gloves and an impermeable gown or as outlined in chapter)
- Facility must establish **written procedures** for DDCD
- Most HDs are rendered inactive by using sodium hypochlorite (bleach); however, defer to HD SDS
- The C-PEC must be decontaminated:
  - At least daily (when used)
  - Between compounding different HDs
  - Anytime a spill occurs
  - Before and after certification
  - Any time voluntary interruption occurs
  - If the ventilation tool is moved
- The area underneath the C-PEC must be deactivated, decontaminated and cleaned at least monthly
  - Respiratory protection may be required



---

# WHERE DO I START?

---



# #1: Develop Your List of HDs

---

Additions should be based on National Institute for Occupational Safety and Health (NIOSH) hazardous drug list

Facility may include other drugs not on the NIOSH list considered hazardous

List must be reviewed at least every 12 months

Review the NIOSH website to identify HDs that enter the market after the most recent version of the NIOSH list



# #2: Develop AORs

Start with DHA templates

- Use NIOSH, SDS, other references and SME's as guidance

Must consider:

- Type of HD
- Dosage form
- Exposure risk
- Packaging
- Manipulation

Review every 12 months

Drug Name: \_\_\_\_\_ Date AOR Initially Performed: \_\_\_\_\_ Date AOR:  Reviewed or  Revised:

HD Drug Category:  Antineoplastic  Non-antineoplastic  Reproductive Risk Only

Dosage Form:  Tablet  Capsule  Topical  Liquid  Prefilled syringe  Other:

Manipulation (Select 1):  Sterile dosage form manufactured or compounded by an approved vendor and not requiring additional manipulation  
 Dosage form of conventionally manufactured *antineoplastic* product that requires only packaging or counting  
 Dosage form of conventionally manufactured *non-antineoplastic* or *reproductive hazard* product that requires only packaging/counting  
 Other (Explain): \_\_\_\_\_

Describe Packaging: (ex. Tablets are packaged in intact, sealed plastic bottles)

	*Exposure Risk	PPE	Alternative Containment Strategies/ Workflow Considerations
Receipt & Storage			
Transport & Dispensing (Counting/Repackaging/Labeling)			
Compounding & Other Manipulations			
Administration			
Deactivating and Cleaning			
Disposal/Waste			
Spills			

\*Activity Exposure Risk: 1 = Low Risk; 2 = High Risk; or N/A = Not applicable

- Do not perform an AOR for any HD API or any antineoplastic requiring HD manipulation (manipulation beyond counting or repackaging).
- An AOR is authorized for final dosage forms of HDs that do not require further manipulation in NIOSH Groups 1, 2, and 3
- Workers known to be or possibly pregnant are not allowed to handle HDs.
- Manipulation of HD occurs in designated areas of pharmacy.
- Count drugs using designated spatula and counting tray.
- Wash hands thoroughly after direct handling of HDs.

Based on Assessment of Risk will proceed as follows:  Follow alternative strategies documented above  Follow all USP <800> requirements

Assessment of Risk Reviewed by Pharmacy Chief: \_\_\_\_\_ Date: \_\_\_\_\_



# #3 Identify your HDs in workspace

---

To Segregate or not?

- Will the medication require separate counting equipment? PPE?
- Segregation only required for antineoplastic HDs requiring manipulation

What about automation equipment?

- Not for any antineoplastic HDs
- Must not stress the medication and create a powder residue when processed through the mechanism
- Eyecon pill scanner may still be used if decontaminated/cleaned after use

What about pneumatic tubes, Pyxis, or patient carts?

- Pneumatic tubes must not be used to transport liquid HDs, APIs, or any antineoplastic HDs
- Non-antineoplastic, reproductive risk only, and final dosage forms of antineoplastic HDs may be stored with other inventory if permitted by entity policy.
- Use multi-disciplinary committee and develop strategies with an AOR



# #4: Write your SOP

---

## SOPs

- Safe handling of HDs based on exposure risk- all steps (e.g. receiving)
- PPE regarding HDs
- Prevention of spills and clean-up
- Training regarding proper labeling, transport, storage, disposal, SDS use

## Written procedures

- Deactivating, decontaminating, cleaning and disinfecting
- Hazard Communication plan
- **SOPs and written procedures may have minimum requirements or “must includes” as outlined in chapter**



# #5: Train your Team

---

Train staff based on their job function on the following:

- Facility HD list and their risks
- HD handling SOPs
- Proper use of PPE and equipment
- Responding to HD exposure
- Spill management
- Proper HD disposal

Personnel of reproductive capability must confirm in writing that they understand the risks of handling HDs

Requires demonstration of competency and documentation every 12 months

**Training may have minimum requirements or “must includes” as outlined in chapter**



# USP <800> Challenges

---

## Identifying the “Designated Person”

- Flight/CC? OIC? Civilian?

## Multi-disciplinary/departmental input/discussions

- Examples of areas who may be impacted by USP 800: logistics, facilities management, pharmacy, nursing, OR, etc.

## Spill Kit placement at every location HDs are handled

- All gloves for handling HDs need to be chemo (ASTM tested)





# Lessons Learned

---

## Training:

- Start within pharmacy (figure out what you're doing), then logistics, then ... nursing/providers, etc.
- Where do you keep your HDs?
- What do you do with your expired HDs?
- Do you have a quarantined area?
- Does your staff know where the AORs and SDS are maintained?
- Do you have a EPA Hazardous generator permit? (No!)

Training

Training

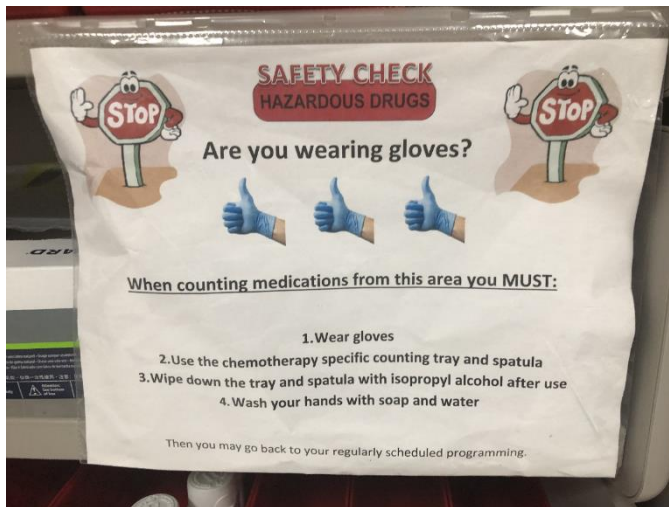
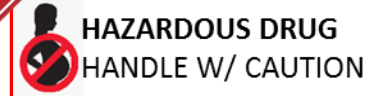
# Training



# Lessons learned

Standardize where possible across MTF pharmacies:

- HD placards/signs/alert stickers/Pyxis comments for nursing
- Segregate vs. identify
- HD handling area requirements, spill kits and filling directions



- Segregated medications

- Operationally, facilitates the use of hazardous-drug specific pharmacy tools (counting tray/spatula)
- Clear signage and instructions for staff



# Lessons learned

---

Implement as a multidisciplinary team –

- Work with other “stakeholders” to develop facility protocols/procedures: i.e. facilities, hazardous waste management, housekeeping, nursing, public health, etc.
- Other professions may have awareness/access to different resources from professional organizations (i.e. nursing, state laws for waste management)



# Lessons learned

---

## HD Spills

- Spill Kits - housekeeping may not be contracted/trained to clean HD spills
- Some kits do not come with directions on the package
- Chemo spill kits don't have detergents (to deactivate/decontaminate chemo residue)
- Make sure Kit contains chemo tested gloves (USP 800 standards)
- Know volume capacity of spill kit
- Certain chemo meds vaporize at room temp (requiring respiratory protection – get help from your chemo nurses)



# Lessons learned

---

Any patient care area can be a location for HD administration...

- Infusion center – chemotherapy treatments
- Ophthalmology (PRK) – Mitomycin
- Operating room – Mitomycin
- Oral/Plastic surgery – 5FU
- Inpatient floors – may carry oral/topical/IM/IV antineoplastic agents
- Outpatient clinics – IM/SQ (i.e. Leuprolide)



# Lessons learned

---

## Collaboration is key

- Utilize your DHA pharmacy SIGs/EPs – provides multiple perspectives (common sense tests, sustainability)
  - USP 797 working group → Inpatient Pharmacy Ops EP → Ops SIG → MTF Advisory Board
  - USP 800 group → Reports to Ops SIG → MTF Advisory Board

## Don't forget SDS sheets...

- Required by OSHA
- All manipulated HDs (liquids, powders, tablets that will be split/crushed, etc.)
- Specific to manufacturer (NDC) – may need multiple SDS for same drug/form



# Facility Modifications

\$\$ identified & contract initiated



Brief MTF Leadership



DHA Facilities Workgroup consulted/notified

Inform Consultant & DHA Inpt Workgroup



Complete Gap Analysis (include Facilities Dept)





**But wait! There's more!**

---







# NIOSH 2020 Updates

---

1 May 2020 – *DRAFT* NIOSH List of Hazardous Drugs in the Healthcare Settings

16 drugs added and 5 drugs removed

Tables categorizing HDs have been reorganized

- Groups 1, 2, and 3 eliminated and reorganized as Table 1 and Table 2

Addresses the issue that not all antineoplastics are cytotoxic or genotoxic



# NIOSH 2020 Updates

---

## Table 1

- HDs which contain Manufacturer special handling instructions (MSHI) in the PI; and/or classified by the NTP as “known to be a human carcinogen”, or classified by IARC as “carcinogenic” or “probably carcinogenic”
- Note: Not all drugs on Table 1 are antineoplastics

## Table 2

- HDs whose PI does not contain MSHI and are not classified as “carcinogenic”, “probably carcinogenic”, or “known to be a carcinogen”
- Also includes reproductive risk only HDs

USP intends to publish a revision bulletin to clarify that for the purposes of General Chapter <800>, the term “antineoplastic” is intended to refer to antineoplastic hazardous drugs (HDs) included in Table 1 of the most current NIOSH list.



# Hazardous Waste Pharmaceuticals

---

Revised RCRA – August 21, 2019

- Ban on sewerage HWPs
- New requirements on disposal of HWPs and use of reverse distributors
- Amendment to nicotine hazardous waste listing



# Hazardous Waste Pharmaceuticals

---

Life Safety surveyor usually evaluates EC.02.02.01

- Disposal in appropriate waste containers
- Labeling: contents, hazard warnings
- Required permits, licenses, manifests, safety data sheets
- Compliance with laws/regulations



# Assessment Questions

---

How often must personnel competency on the handling of hazardous drugs be reassessed and documented for each person?

- A. Every 3 months
- B. Every 6 months
- C. Every 12 months after initial training
- D. Only once when a person starts working



# Assessment Questions

---

Which aspect of HD handling may an AOR not affect?

- A. Storage requirements
- B. PPE
- C. Containment strategies
- D. Work process



# Assessment Questions

---

Which of the following are required by USP <800>

- A. A medical surveillance program for all workers who handle HDs
- B. An environmental wipe sampling (EWS) program for HD surface residue
- C. Segregation of all HDs within the pharmacy
- D. None of the above



# Available resources

---

United States Pharmacopeia (USP)

[www.usp.org](http://www.usp.org)

The National Institute for Occupational Safety and Health (NIOSH)

<https://www.cdc.gov/niosh/topics/hazdrug/>

ASHP Guidelines

Compounding Sterile Preparations (2019)

Handling Hazardous Drugs (2018)

The Joint Commission

[www.jointcommission.org](http://www.jointcommission.org)

[www.hazmedsafety.com](http://www.hazmedsafety.com)





# Available resources

---

Local Environment of Care Plans

DHA MTF Advisory Board

[https://info.health.mil/army/pharm/DHAtemp/\\_layouts/15/start.aspx#/](https://info.health.mil/army/pharm/DHAtemp/_layouts/15/start.aspx#/)

USP<800> Gap Analysis Survey from International Journal of Pharmaceutical Compounding

<https://compoundingtoday.com/Compliance/USPGap.cfm>

Knowledge Exchange (KX)

<https://kx.health.mil/kj/kx2/Pharmacy/Pages/home.aspx>

Clean Room Design: Layout, Work Flow, Finishes (Dekker Perich Sabatini)

[https://www.youtube.com/watch?v=6\\_po9j8N4Mg](https://www.youtube.com/watch?v=6_po9j8N4Mg)



# Acknowledgments

---

Special thanks to Lt Col Julie Meek, Maj Allison Stephens, and Capt Jeremy Matsumoto for their contributions in preparing this presentation.



# References

---

ASHP Guidelines on Handling Hazardous Drugs <https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/handling-hazardous-drugs.ashx>

ASHP Guidelines on Compounding Sterile Preparations <https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/compounding-sterile-preparations.ashx>

Consensus Statement on the Handling of Hazardous Drugs Per USP Chapter <800>  
[https://compoundingtoday.com/Compliance/HDCS\\_Consensus\\_Statement.pdf](https://compoundingtoday.com/Compliance/HDCS_Consensus_Statement.pdf)

Toolkit for Safe Handling of Hazardous Drugs for Nurses in Oncology <https://www.ons.org/clinical-practice-resources/toolkit-safe-handling-hazardous-drugs-nurses-oncology>

USP Chapter 797 <https://www.usp.org/compounding/general-chapter-797>

USP Chapter 800 <https://www.usp.org/compounding/general-chapter-hazardous-drugs-handling-healthcare>

USP FAQs <https://www.usp.org/frequently-asked-questions/compounding>



# References

---

NIOSH List <https://www.cdc.gov/niosh/docs/2016-161/pdfs/2016-161.pdf>

NIOSH Workplace Solutions: Personal protective equipment for health care workers who work with hazardous drugs  
<https://www.cdc.gov/niosh/docs/wp-solutions/2009-106/>

NIOSH Alert on preventing occupational exposures to antineoplastic and other hazardous drugs  
<https://www.cdc.gov/niosh/docs/2004-165/>

OSHA: Controlling occupational exposure to hazardous drugs  
[https://www.osha.gov/SLTC/hazardousdrugs/controlling\\_occx\\_hazardousdrugs.html](https://www.osha.gov/SLTC/hazardousdrugs/controlling_occx_hazardousdrugs.html)

NIOSH Workplace Solutions: Medical surveillance for healthcare workers exposed to hazardous drugs  
<https://www.cdc.gov/niosh/docs/wp-solutions/2013-103/pdfs/2013-103.pdf>



---

QUESTIONS

