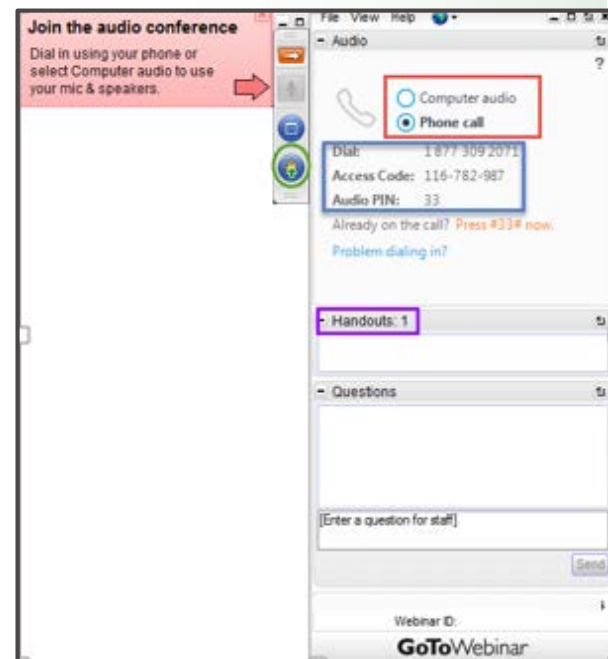


Welcome to the webinar.

The presentation will begin shortly.

- You may listen via phone or via computer audio if your computer has speakers.
- This webinar will be in a “listen only” mode with opportunity to ask questions at the end of the presentation as time allows.
- All lines have been muted. Please enter any questions via the question feature in your control panel.
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- Thank you for your participation!



USP <800>: Understanding the Organizational Impact of Safe Handling of Hazardous Drugs

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8/29/2019



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Overview

- Rationale
- USP <800> Background and Overview
- Preparation Efforts
- Definition of a Hazardous Drug
- Hazardous Drug List and Assessment of Risk
- Processes, Policies, and Procedures
- Plant Operations
- Personnel
- Personal Protective Equipment (PPE)
- Summary



Rationale: Case Studies

- A nurse on the floor is administering ganciclovir to a patient. She isn't too familiar with it so she looks it up and is nervous about the side effects and precautionary statements. She calls you and asks, "Should I be wearing gloves or something?"
- A patient is in the ER being treated for ectopic pregnancy. The physician orders MTX IV and the nurse picks it up from Pharmacy. One of the new nurses who is shadowing/being trained says, "When I worked in the chemo clinic I had to wear 2 pairs of chemo gloves and a plastic gown when I administered methotrexate. Shouldn't we wear that here?"
- The delivery driver is pushing a cart full of totes to the pharmacy. As he rolls past the cafeteria one of the totes falls off, crashes to the floor, and starts leaking a reddish liquid. You quickly grab paper towels and contain the spill so no one slips while Environmental Services is paged. Then you think, "I wonder what that liquid is?"



Published Evidence of Contamination and Risk

1. Connor TH, DeBord G, Pretty JR et al. Evaluation of antineoplastic drug exposure of health care workers at three university-based US cancer centers. *J Occup Environ Med.* 2010; 52:1019-27.
2. Connor TH, Anderson RW, Sessink PJ et al. Surface contamination with antineoplastic agents in six cancer treatment centers in Canada and the United States. *Am J Health-Syst Pharm.* 1999; 56:1427-32.
3. Fransman W, Roeleveld N, Peelen S et al. Nurses with dermal exposure to antineoplastic drugs: reproductive outcomes. *Epidemiology.* 2007; 18:112-9.
4. Hama K, Fukushima K, Hirabatake M et al. Verification of surface contamination of Japanese cyclophosphamide vials and an example of exposure by handling. *J Oncol Pharm Pract.* 2011; 18:201-6.
5. Hon CY, Teschke K, Chu W et al. Antineoplastic drug contamination of surfaces throughout the hospital medication system in Canadian hospitals. *J Occup Environ Hyg.* 2013; 10:374-83.
6. Hon CY, Teschke K, Chua P et al. Occupational exposure to antineoplastic drugs: identification of job categories potentially exposed throughout the hospital medication system. *Saf Health Work.* 2011; 2:273-81.
7. Hon CY, Teschke K, Shen H et al. Antineoplastic drug contamination in the urine of Canadian healthcare workers. *Int Arch Occup Environ Health.* 2015; 88:933-41.
8. Hon CY, Astrakianakis G, Danyluk Q et al. Pilot evaluation of dermal contamination by antineoplastic drugs among hospital pharmacy personnel. *Can J Hosp Pharm.* 2011; 64:327-32.
9. Hon CY, Teschke K, Demers PA et al. Antineoplastic drug contamination on the hands of employees working throughout the hospital medication system. *Ann Occup Hyg.* 2014; 58:761-70.



Published Evidence of Contamination and Risk

10. Lawson CC, Rocheleau CM, Whelan EA et al. Occupational exposures among nurses and risk of spontaneous abortions. *Am J Obstet Gynecol.* 2012; 206:327.e1-8.
11. Martin S. Chemotherapy handling and effects among nurses and their offspring. *Oncol Nurs Forum.* 2005; 32:425.
12. Mason HJ, Blair S, Sams C et al. Exposure to antineoplastic drugs in two UK hospital pharmacy units. *Ann Occup Hyg.* 2005; 49:603-10.
13. Pethran A, Schierl R, Hauff K et al. Uptake of antineoplastic agents in pharmacy and hospital personnel. Part I: monitoring of urinary concentrations. *Int Arch Occup Environ Health.* 2003; 76:5-10.
14. Ratner PA, Spinelli JJ, Beking K et al. Cancer incidence and adverse pregnancy outcome in registered nurses potentially exposed to antineoplastic drugs. *BMC Nurs.* 2010; 9:15.
15. Sottani C, Porro B, Cornelli M et al. An analysis to study trends in occupational exposure to antineoplastic drugs among health care workers. *J Chromatog B.* 2010; 878:2593-605.
16. Yuki M, Sekine S, Takase K et al. Exposure of family members to antineoplastic drugs via excreta of treated cancer patients. *J Oncol Pharm Pract.* 2013; 19:208-17.
17. Yuki M, Takase K, Sekine S et al. Evaluation of surface contamination with cyclophosphamide in the home setting of outpatients on cancer chemotherapy. *J Nurs Educ Pract.* 2014; 4:16-23.
18. Yuki M, Ishida T, Sekine S. Secondary exposure of family members to cyclophosphamide after chemotherapy of outpatients with cancer: a pilot study. *Oncol Nurs Forum.* 2015; 42:665-71.



Rationale: Vital Improvements

- Healthcare can be hazardous
- Identifying and containing the risk is a leader's primary job
- Invisible, but real
 - Trace chemo on packaging
 - Accidental exposure
- Chemotherapy is not the only dangerous type of drug
- Consistency and standardization leads to greater safety



USP Background

- USP is an organization that provides safety standards for medication and food
- USP 797 published- Protecting the drug from us (2004)
 - Focus on conditions and practices to prepare compounded sterile product (CSP) to prevent patient harm
 - Pharmacy compounding
 - Occasional non-pharmacy sterile compounding
- Revised to the current official chapter (2008)

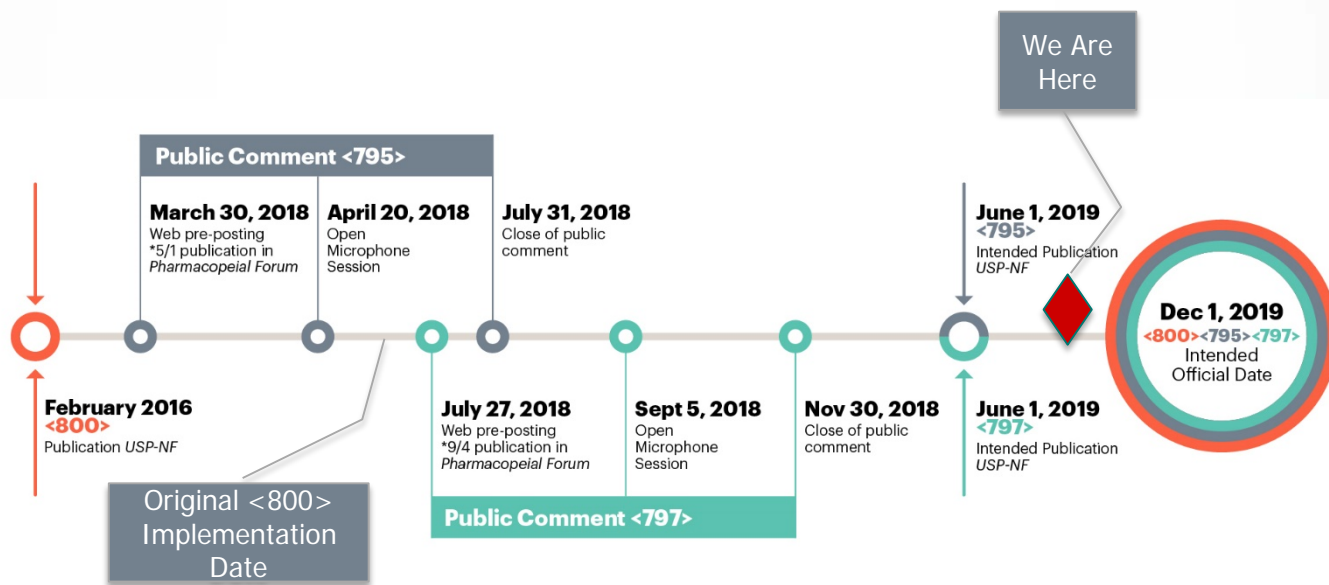


USP Background

- USP 800 final version published – Protecting us from the drug (2016)
- Guides the handling of hazardous drugs (HDs) in healthcare settings
- Applies to all personnel who handle HD preparations
- Includes, but not limited to, receipt, storage, mixing, preparing, compounding, dispensing, administering, disposing, and otherwise altering, counting, crushing, or pouring HDs
- Applies to all locations where HDs are stored, transported, and administered
- Both sterile and nonsterile products



USP Timeline



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

<https://www.usp.org/compounding>



History of Sterile Compounding Focus

- 1995 – MO Department of Health Sterile Compounding rules
- 2004 – USP Chapter <797> published
- 2012 - New England Compounding Center (NECC) tragedy
- 2013 – Federal law creates 503B Registered Outsourcing Facilities
- 2015 – CMS added USP <797> to the State Operations Manual
- 2018 – The Joint Commission announces it is focusing on sterile compounding
- 12/1/2019 – Effective date of revised USP <795> and USP <797>, and new USP <800>



Enforcement and Scope

Who Could Regulate?

- CMS
- DHSS
- Joint Commission
- OSHA

Who is Affected?

- Anyone who could handle a newly defined hazardous drug, from delivery dock to patient dose or disposal
- Key Points
 - USP 800 is not an "Oncology Thing"
 - USP 800 is not a "Pharmacy Thing"



How Do You Prepare?

- Gap analysis assessment
- Operational Improvements
 - Assessments of risk
 - Policy changes
 - Training
 - PPE
- Construction



USP 800 Sections

1. Introduction and Scope
2. List of Hazardous Drugs
3. Types of Exposure
4. Responsibilities of Personnel Handling Hazardous Drugs
5. Facilities and Engineering Controls
6. Environmental Quality and Control
7. Personal Protective Equipment
8. Hazard Communication Program
9. Personnel Training
10. Receiving
11. Labeling, Packaging, Transport, and Disposal
12. Dispensing Final Dosage Forms
13. Compounding
14. Administering
15. Deactivating, Decontaminating, Cleaning, and Disinfecting
16. Spill Control
17. Documentation and Standard Operating Procedures
18. Medical Surveillance



USP 800 Requirements – Summarized

- Lists
 - Types of Hazardous Drugs on NIOSH List 1, 2, and 3
 - Facility Hazardous Drug List
 - Facility Assessment of Risk
- Processes (and Policy and Procedure)
- Physical Plant
- Personal Protective Equipment (PPE)
- People
 - Competence through Education and Training
 - Safety through Occupational Health



Lists



Hazardous Drugs, Redefined

- National Institute for Occupational Safety and Health (NIOSH) maintains and updates a list of antineoplastic and other Hazardous Drugs
- More than just chemotherapy:
 - Phenytoin Spironolactone Estrogen
 - Temazepam Clonazepam Colchicine
- Drugs considered hazardous include those that exhibit one or more of the following six characteristics in humans or animals:
 - Carcinogenicity (cancer formation)
 - Teratogenicity or other developmental toxicity (embryo or fetus)
 - Reproductive toxicity (interferes with normal reproduction or fertility)
 - Organ toxicity at low doses
 - Genotoxicity (destructive effect on cell's genetic material – DNA/RNA)
 - Structure and toxicity profiles of new drugs that mimic existing drugs determined hazardous by the above criteria



NIOSH – Group 1 Antineoplastics

- Commonly called 'chemotherapy'
- USP 800 gives specific requirements for engineering controls and PPE
- Consider the form
 - IV
 - IM
 - SC
 - Topical
 - Tablet
 - Capsule

Table 1 (Continued) Group 1: Antineoplastic drugs, including those with the manufacturer's safe-handling guidance (MSHG)

Drug	AHFS classification	MSHG	Supplemental information	Links
bosutinib	10:00 antineoplastic agents		FDA Pregnancy Category D	DailyMed ; DrugBank
brentuximab vedotin	10:00 antineoplastic agents	yes	Conjugated monoclonal antibody; FDA Pregnancy Category D	DailyMed ; DrugBank
busulfan	10:00 antineoplastic agents	yes	IARC Group 1 carcinogen; FDA Pregnancy Category D	DailyMed ; DrugBank
cabazitaxel	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed ; DrugBank
cabozantinib	10:00 antineoplastic agents		Embryo-lethal in rats at exposures below the recommended human dose; FDA Pregnancy category D	DailyMed ; DrugBank
capecitabine	10:00 antineoplastic agents	yes	Metabolized to 5-fluorouracil; FDA Pregnancy Category D	DailyMed ; DrugBank
carboplatin	10:00 antineoplastic agents	yes	FDA Pregnancy Category D	DailyMed ; DrugBank

NIOSH Group 2 – Non-Antineoplastics

- Non-antineoplastic drugs that meet one or more of the 6 NIOSH criteria for HD
- USP 800 allows some flexibility for engineering controls and PPE

Table 2 (Continued). Group 2: Non-antineoplastic drugs that meet one or more of the NIOSH criteria for a hazardous drug, including those with the manufacturer's safe-handling guidance (MSHG)

Drug	AHFS classification	MSHG	Supplemental information	Links
carbamazepine	28:12:92 anticonvulsants, miscellaneous		Black Box warning for aplastic anemia; congenital malformations in offspring of mothers who took drug; rapid transplacental passage; FDA Pregnancy Category D*	DailyMed ; DrugBank
chloramphenicol	8:12:08 chloramphenicols		IARC Group 2A carcinogen; NTP***; FDA Pregnancy Category C	DailyMed ; DrugBank
cidofovir	8:18:32 nucleosides and nucleotides	yes	FDA Pregnancy Category C	DailyMed ; DrugBank
cyclosporine	92:44 immunosuppressive agents		IARC Group 1 carcinogen; NTP**; FDA Pregnancy Category C	DailyMed ; DrugBank



NIOSH Group 2 – Non-Antineoplastics

Table 2 (Continued). Group 2: Non-antineoplastic drugs that meet one or more of the NIOSH criteria for a hazardous drug, including those with the manufacturer's safe-handling guidance (MSHG)

Drug	AHFS classification	MSHG	Supplemental information	Links
fluoxymesterone	68:08 androgens		Tumors in mice and rats and possibly humans; FDA Pregnancy Category X	DailyMed ; DrugBank
fosphenytoin	28:12.12 hydantoin		Metabolized to phenytoin; FDA Pregnancy Category D	DailyMed ; DrugBank
ganciclovir	8:18:32 nucleosides and nucleotides	yes	FDA Pregnancy Category C	DailyMed ; DrugBank



NIOSH Group 3 – Reproductive Risk

- Drugs primarily meet the NIOSH criteria for reproductive hazards
- These drugs may represent a potential occupational hazard to:
 - Males or females who are actively trying to conceive
 - Women who are pregnant or may become pregnant
 - Women who are breast feeding



NIOSH Group 3 – Reproductive Risk

Table 3 (Continued). Group 3: Non-antineoplastic drugs that primarily have adverse reproductive effects

Drug	AHFS classification	Supplemental information	Links
riociguat	48:48 vasodilating agents	Exclude pregnancy before the start of treatment, monthly during treatment, and 1 month after stopping treatment; FDA Pregnancy Category X	DailyMed ; DrugBank
telavancin	8:12:28 glycopeptides	Black Box warning for potential risk to fetus and adverse reproductive outcomes; reduced fetal weights and increased rates of digit and limb malformations in three species at clinical doses; FDA Pregnancy Category C	DailyMed ; DrugBank
temazepam	28:24:08 benzodiazepines	Increased risk of congenital malformations associated with treatment during the first trimester of pregnancy; FDA Pregnancy Category X	DailyMed ; DrugBank
testosterone	68:08 androgens	Children should avoid contact with unwashed or unclothed application sites on skin; FDA Pregnancy Category X	DailyMed ; DrugBank



Implications of NIOSH Tables

Must Follow All Aspects of USP 800

- Antineoplastic requiring manipulation
 - Example: compounded IV chemotherapy
- Non-Antineoplastic Hazardous Drugs on NIOSH List 2 or 3 that are in bulk formulation ("API")
 - Not used at most hospitals

May Handle Less Strictly If Assessment of Risk Is Completed

- Antineoplastic not requiring manipulation
 - Example: oral chemotherapy tablet
- Non-Antineoplastic Hazardous Drugs on NIOSH List 2 or 3
 - Examples: Many!!!!!!



Facility Implications

- The facility must create a list that includes all items on the current NIOSH list that are stocked
- May add others not on the list
- The facility list must be reviewed at least annually and whenever a new agent or dosage form is used
- The facility must perform an Assessment of Risk (AOR) that, at a minimum, considers the following:
 - Type of HD
 - Antineoplastic (Group 1)
 - Non-antineoplastic (Group 2)
 - Reproductive risk only (Group 3)
 - Dosage Form
 - Risk of Exposure
 - Packaging
 - Manipulation



Assessment of Risk steps

- How risky is the drug?
- What protections will we put into place?
- Sample format in the references



Assessment of Risk Considerations

- Consider routes of unintentional entry of HDs into the body :
 - Dermal and mucosal absorption
 - Inhalation
 - Injection
 - Ingestion
- Unopened, intact tablets/capsules may not pose the same degree of occupational exposure risk as injectable drugs, which usually require extensive preparation
- Cutting, crushing, or otherwise manipulating tablets/capsules will increase the risk of exposure to workers
- Consider activities that increase risk of exposure :
 - Generating aerosols during administration of HDs by various routes (injection, irrigation, oral, inhalation, topical, etc.)
 - Priming an IV administration set
 - Performing specialized procedures (bladder instillation)
 - Handling body fluids (urine, feces, sweat, vomit) or contaminated clothing
 - Spill generation, management, and disposal
 - Collection and disposal of HD waste and trace contaminated waste



Hazardous Drug List and Assessment of Risk

- Document what alternative containment strategies and/or work practices are being employed for specific dosage forms to minimize exposure
- AOR must be reviewed at least every 12 months and the review documented
- Multidisciplinary approach
 - Pharmacy
 - Nursing
 - Providers
 - Environmental Services
 - Safety
 - Occupational Health
 - Others



Processes, Policies, and Procedures



Policy Changes

- Pharmacy policies: receiving, storage, handling, sterile compounding, nonsterile compounding, cleaning, disposal, formulary changes
- Nursing policies: storage and administration
- Environment of Care: physical changes, spills, contamination
- Human Resources: attestation of understanding of risk, medical surveillance decision, training
- Procedural Areas: medication administration



Example Issues

- Cutting a tablet for administration (Group 1 vs Group 2 or 3)
- Crushing a tablet or opening a capsule for administration via tube
- Compounding an IV at the bedside in an emergency
- Mitomycin in the OR (eye surgery or bladder irrigation)
- Methotrexate in the ER for ectopic pregnancy



Cleaning and Spills

- Clean up - the most important step?
- Four activities:
 - Deactivation: rendering the drug inert or inactive (bleach or peroxide formulations)
 - Decontamination: removing the drug residue (bleach, peroxide, water, alcohol, physical removal)
 - Cleaning: removing organic and inorganic material (detergent, EPA 1 step cleaner)
 - Disinfection: destroying microorganisms (sterile alcohol, bleach, peroxide, acetic acid)
- Some products can accomplish more than one activity simultaneously
- What do you do if there is a spill? How do you know if it is safe to clean up? Is it volatile?



Physical Plant



Implications for Plant Operations

- Designated HD handling areas separate from non-HD areas with restricted access and signage
- Negative pressure, external venting, air changes
 - HD storage
 - HD IV Room requirements
 - HD Nonsterile compounding
- Unpacking HDs from external shipping containers in neutral or negative pressure area (not in the IV room)
- Emergency power or uninterrupted power should be considered to maintain negative pressure during power loss, or downtime procedures should be developed



Physical Plant – Hazardous Drugs

Receiving Room

Neutral or Negative
Pressure

Not in IV room

Storage Room

Physically Separate
Negative Pressure

12 ACPH

Externally vented

Dedicated refrigerator in
storage room

Can also perform
nonsterile hazardous
drug compounding here

*See USP <797> webinar for more
details about sterile compounding
requirements



Physical Plant – Cleanroom Suite

- For hazardous drug sterile compounding
- Must include an ante room and a buffer room
- Allowable Beyond Use Dating: 4 days at room temperature and 9 days refrigerated
- Requirements for physical cleanability, cleaning processes, garbing, training, and product handling



Cleanroom Suite Requirements

Ante Room

Positive Pressure to
pharmacy (0.02" w.c.)

30 ACPH

ISO 7

<68 degrees and <60%
humidity
(recommendation)

Hazardous Buffer Room

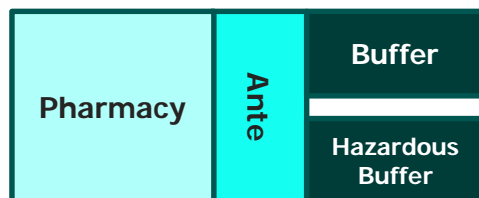
Negative Pressure to Ante
Room (-0.01 to -0.03"
w.c.)

30 ACPH

Externally Vented

ISO 7

<68 degrees and <60%
humidity
(recommendation)



Physical Plant – Containment Segregated Compounding area (C-SCA)

- For hazardous drug sterile compounding
- Must be a physical room, not an area of a larger room
- External ventilation requirements to contain hazardous drugs
- No anteroom or buffer room requirement
- Allowable Beyond Use Dating: 12 hours at room temperature and 24 hours refrigerated
- Must be located away from unsealed windows, doors that connect to the outdoors, traffic flow, restrooms, warehouses, and food preparation areas
- Requirements for physical cleanability, cleaning processes, garbing, training, and product handling



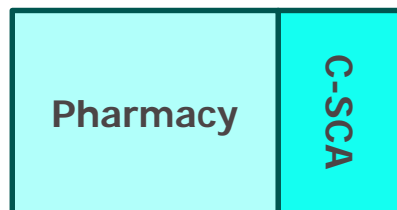
Physical Plant – Containment Segregated Compounding Area (C-SCA)

Physically separate room

Negative Pressure to pharmacy (-0.01 to -0.03" w.c.)

12 ACPH

Externally Vented



Primary Engineering Controls (PEC)

Biological Safety Cabinet or Compounding Aseptic Containment Isolator

Externally vented

ISO 5

Updated recertification standards

Gloveboxes are not eligible for the longer BUD unless they are in a cleanroom suite

Must be able to clean behind the PEC



Personal Protective Equipment (PPE)



PPE

- Appropriate PPE must be worn for all steps: Receipt, Storage, Transport, Compounding (sterile and nonsterile), Administration, Deactivation/decontamination, cleaning, and disinfecting, Spill control, Waste disposal
- Gloves – ASTM D6978 compliant, single or double depending on activity
- Gowns – impervious to liquids
- Head, hair, and shoe covers – for sterile and nonsterile compounding and as needed
- Sleeve covers – optional for sterile and nonsterile compounding
- Eye/Face protection – when needed for splash risk
- Respiratory protection - when needed for inhalation risk
- Specific PPE requirements are listed for receiving, compounding, and administration



Other Supplies

- Closed System Transfer Devices (CSTDs): Required for parenteral administration. Recommended for sterile compounding.
- Spill Kits anywhere HD's are stored, transported, or administered
- Compounding mats for sterile compounding recommended



People



Implications for Human Resources

- One person is specifically designated as the “Designated Person” or “Hazardous Drug Coordinator”
- Well trained and competent through robust initial and annual competency assessment
- Accountability to follow established practices consistently
- Signed attestation of understanding of risk of hazardous drug exposure (required for employees of childbearing potential)
- Medical Surveillance (optional)
 - Lab results and health assessment surveys to track and trend health concerns due to exposure



Common Questions/Concerns



Common Questions/Concerns

- Similar to MRI safety or cybersecurity – wouldn't every employee need to know about the risks if they work in a hospital?
- Respiratory Protection: Is a Powered Air Purifying Respirator (PAPR) or full respirator needed for any activities at your facility?
- Do the spill kits have all of the necessary components?
- Do you have goggles instead of safety glasses to protect against splashes?
- What is Environmental Services' role in cleaning?
- Do you have access to Safety Data Sheets for all drugs?
- What are the spill cleanup procedures, for small or large spills in various areas of the hospital?
- How will you handle pneumatic tube restrictions? It is not allowable to tube any antineoplastic or any liquids from Group 2 or 3.
- Will additional staff be needed due to decreased workflow efficiency and increased administrative burden?



Common Questions/Concerns

- How will your facility manage the difference between the EPA hazardous pharmaceutical waste list and the USP 800/NIOSH hazardous list?
- Are there any Group 2 or 3 drugs that need to be treated like Group 1?
- Are there any drugs that are NOT on the NIOSH lists that need to be added to your facility hazardous drug list?
- Is chemotherapy administered in any procedural area, such as the Operating Room or Interventional Radiology? Examples: intravesicular, intravitreal, intraperitoneal
- Can you purchase hazardous medications in a ready to use form?
- Will your facility utilize surface contamination sampling, as is recommended (but not required)?
- What will be the increase in expenditures on PPE, equipment, and services?



Next Steps

- Download the standards (www.usp.org/compounding)
- Meet with Pharmacy leadership to identify current state and develop gap analysis
- Determine any construction needs, equipment purchases, and other long lead time and capital intensive items
- Build USP 800 into your Environment of Care and Workplace Safety policies and meeting structures
- Include USP 800 in all future planning and building discussions
- Evaluate your area for implications of these changes
- Collaborate with Pharmacy for training, workflow and policy changes
- Education of medical staff and governing bodies/trustees



Summary

- Effective December 1, 2019
- Promotion of worker safety, patient safety, and environmental protection when handling hazardous drugs
- Addresses ALL STEPS: receipt, storage, compounding, dispensing, administration, and disposal
- Applies to ALL HEALTHCARE PERSONNEL that handle HDs
- Applies to ALL HEALTHCARE ENTITIES that store, prepare, transport, or administer HDs
- Regulatory Focus: CMS, DHSS, Joint Commission, and OSHA



Discussion and Questions

- Thank you!



Helpful Resources

- OSHA Recommended Practices for Safety and Health Programs <https://www.osha.gov/shpguidelines/> (Accessed 3/18/2019)
- FDA Good Manufacturing Guidance for Active Pharmaceutical Ingredients – Guidance For Industry: <https://www.fda.gov/downloads/Drugs/.../Guidances/ucm073497.pdf> (accessed 3/18/2019)
- FDA Definitions: <https://www.fda.gov/drugs/informationondrugs/ucm079436.htm> (Accessed 3/18/2019)
- NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2016; Dept. of Health and Human Resources, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health
- USP 797, 795, 800 Guidelines, United States Pharmacopeia, Chapter 797, Chapter 795, Chapter 800, Rockville, MD, www.nim.nih.gov
- Oncology Nursing Society (ONS) Chemotherapy Administration Safety Standards <https://www.ons.org/standards-and-reports/asco-ons-chemotherapy-administration-safety-standards> (accessed 3/18/2019)
- ONS Toolkit for Safe Handling of Hazardous Drugs for Nurses in Oncology <https://www.ons.org/toolkits/toolkit-safe-handling-hazardous-drugs-nurses-oncology> (accessed 3/18/2019)
- ONS Personal Protective Equipment for Use with Hazardous Drugs https://www.ons.org/sites/default/files/PPE_with_HDs_2016.pdf (accessed 3/18/2019)
- ONS Medical Surveillance Questionnaire <https://www.ons.org/sites/default/files/Safe%20Handling%20Medical%20Surveillance%20Questionnaire.pdf> (accessed 3/18/2019)



Helpful Resources

- Improving Safe Handling Practices for Hazardous Drugs. Joint Commission Resources.
- Power LA and Coyne JW. ASHP Guidelines on Handling Hazardous Drugs. *Am J Health-Syst Pharm.*, 2018; 75:e765-e800
- OSHA Safety and Health Topics: Respiratory Protection <https://www.osha.gov/SLTC/respiratoryprotection/> (accessed 5/7/2019)
- OSHA Respiratory Protection (3079) <https://www.osha.gov/Publications/osa3079.pdf> (accessed 5/7/2019)
- OSHA Safety and Health Topics: Hazardous Drugs <https://www.osha.gov/SLTC/hazardousdrugs/index.html> (Accessed 5/7/2019)
- NIOSH Workplace Safety and Health Topic: Hazardous Drug Exposures in Healthcare <https://www.cdc.gov/niosh/topics/hazdrug/default.html> (Accessed 5/7/2019)
- 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/pdfs/2009-106.pdf?id=10.26616/NIOSH PUB2009106> (accessed 5/7/2019)
- OSHA Safety and Health Topics: Controlling Occupational Exposure to Hazardous Drugs https://www.osha.gov/SLTC/hazardousdrugs/controlling_occx_hazardousdrugs.html#primary (accessed 5/7/2019)
- OSHA Safety and Health Topics: Pharmacy eTool <https://www.osha.gov/SLTC/etools/hospital/pharmacy/pharmacy.html> (Accessed 5/7/2019)
- [Joint Commission 4-1-1 on Sterile Compounding](#)
- [TJC Accreditation and Certification June Issue](#)
- https://www.jointcommission.org/deline_tjc/surveyors_increasing_on-site_focus_on_medication_compounding/
- https://www.jointcommission.org/at_home_with_the_joint_commission/certification_reports_of_compounding_hoods_and_rooms_affecting_accreditation_decisions/
- USP FAQs <https://www.usp.org/frequently-asked-questions/hazardous-drugs-handling-healthcare-settings>
- Example Assessment of Risk Templates
 - Kienle PC, Douglass K. Perform an Assessment of Risk to Comply with USP <800>. [Pharm Purch Prod](#) 2017;14(3):26-31.
 - Houchard G, Lewis P, et al. A Comprehensive Approach to USP <800> Compliance. [Pharm Purch Prod](#) 2017;14(11):20-30.

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