

Taming the Jungle: Completing an Assessment of Risk in a Community Pharmacy to Comply with USP <800>

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Disclosure

- ▶ Patricia Kienle is an employee of Cardinal Health
- ▶ She is a member of the USP Compounding Expert Committee, but this presentation is not endorsed by or affiliated with USP
- ▶ She is an author of several ASHP publications

Objectives

- ▶ Cite the document that defines drugs that are hazardous to personnel
- ▶ Identify the drugs and dosage forms eligible for an Assessment of Risk
- ▶ Describe elements of an Assessment of Risk
- ▶ List examples of alternative containment strategies and work practices that could be incorporated into an Assessment of Risk

Why USP <800>?

- ▶ <800> Hazardous Drugs – Handling in Healthcare settings protects
 - ▶ Patients
 - ▶ Personnel
 - ▶ Environment
- ▶ It supplements but does not replace <795> on Nonsterile Compounding
- ▶ First enforceable standard that protects healthcare personnel from risk of hazardous drugs

Scope of <800>

- ▶ Healthcare settings
- ▶ NOT suppliers
- ▶ NOT patients' homes



Enforceability of USP Standards

- ▶ <800> will become federally enforceable on December 1, 2019
- ▶ States may place <800> into state regulations
 - ▶ State Board of Pharmacy
 - ▶ Other state agencies

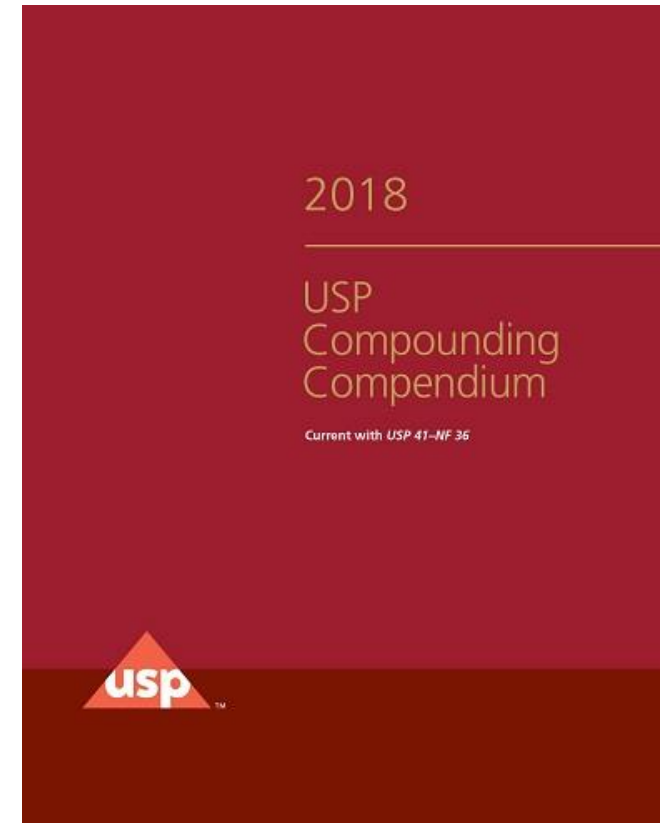
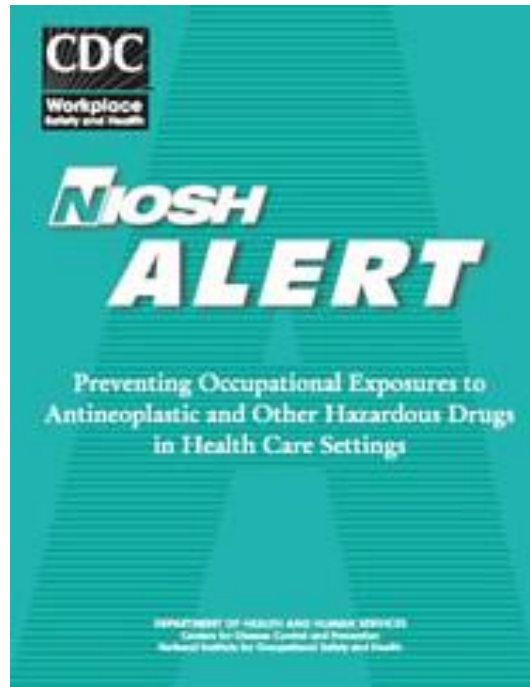


Photo courtesy of USP

Genesis of USP <800>



www.cdc.gov/niosh/docs/2004-165/pdfs/2004-165.pdf
www.ashp.org/DocLibrary/BestPractices/PrepGdlHazDrugs.aspx

NIOSH Hazardous Drug Information

The National Institute for Occupational Safety and Health (NIOSH)

Workplace Safety and Health Topics


Hazards & Exposures

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Hazardous Drug Exposures in Health Care



Health care workers who prepare or administer hazardous drugs (e.g., those used for cancer therapy, and some antiviral drugs, hormone agents, and bioengineered drugs) or who work in areas where these drugs are used may be exposed to these agents in the workplace. About 8 million U.S. healthcare workers are potentially exposed to hazardous drugs, including pharmacy and nursing personnel, physicians, operating room personnel, environmental services workers, workers in research laboratories, veterinary care workers, and shipping and receiving personnel.

It seems counter-intuitive that the health care industry, whose mission is the care of the sick, is itself a "high-hazard" industry for the workers it employs. In fact, published studies have shown that workplace exposures to hazardous drugs can cause both acute



Hazardous Drugs

- ▶ Carcinogen
- ▶ Genotoxin
- ▶ Teratogen
- ▶ Reproductive toxin
- ▶ Organ toxicity at low dose in humans or animals
- ▶ New drugs that mimic existing HDs in structure or toxicity

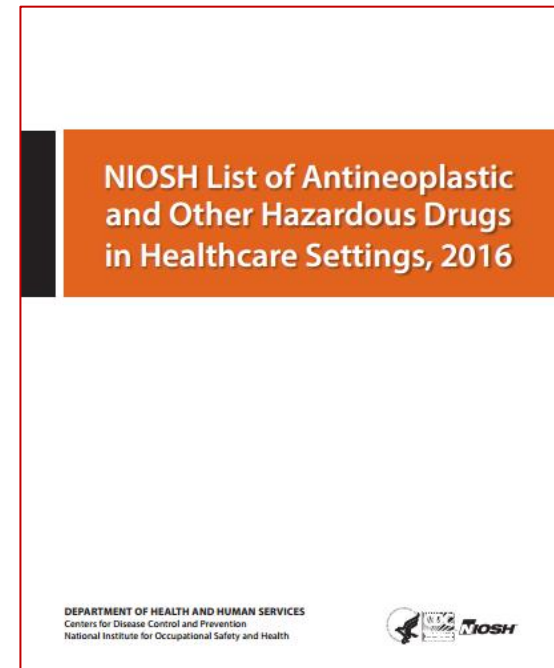
Where is the list of hazardous drugs?

- A. EPA hazardous materials
- B. OSHA web site
- C. NIOSH list of hazardous drugs
- D. PA Department of Health website



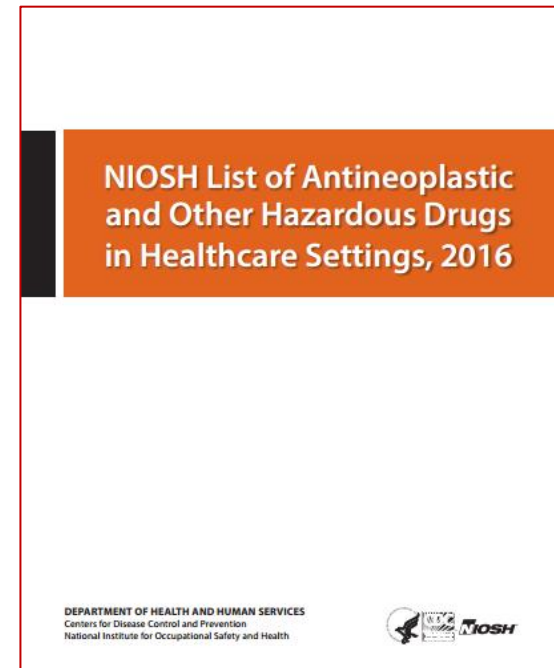
NIOSH List of Hazardous Drugs

- ▶ Antineoplastics
- ▶ Non-antineoplastics
- ▶ Reproductive only hazards



NIOSH List Tables

- ▶ Table 1 – Antineoplastics
- ▶ Table 2 – Non-antineoplastics
- ▶ Table 3 – Reproductive only hazards
- ▶ Table 4 – HDs removed from 2014 list
- ▶ Table 5 – Recommended personal protective equipment (PPE)



Ideal Situation

- ▶ Handle every drugs in every dosage form on the NIOSH list with all the containment strategies and work practices identified in <800>
- ▶ Is that possible in every case?
- ▶ Is that practical in every case?
- ▶ Is that necessary in every case?

Your Options

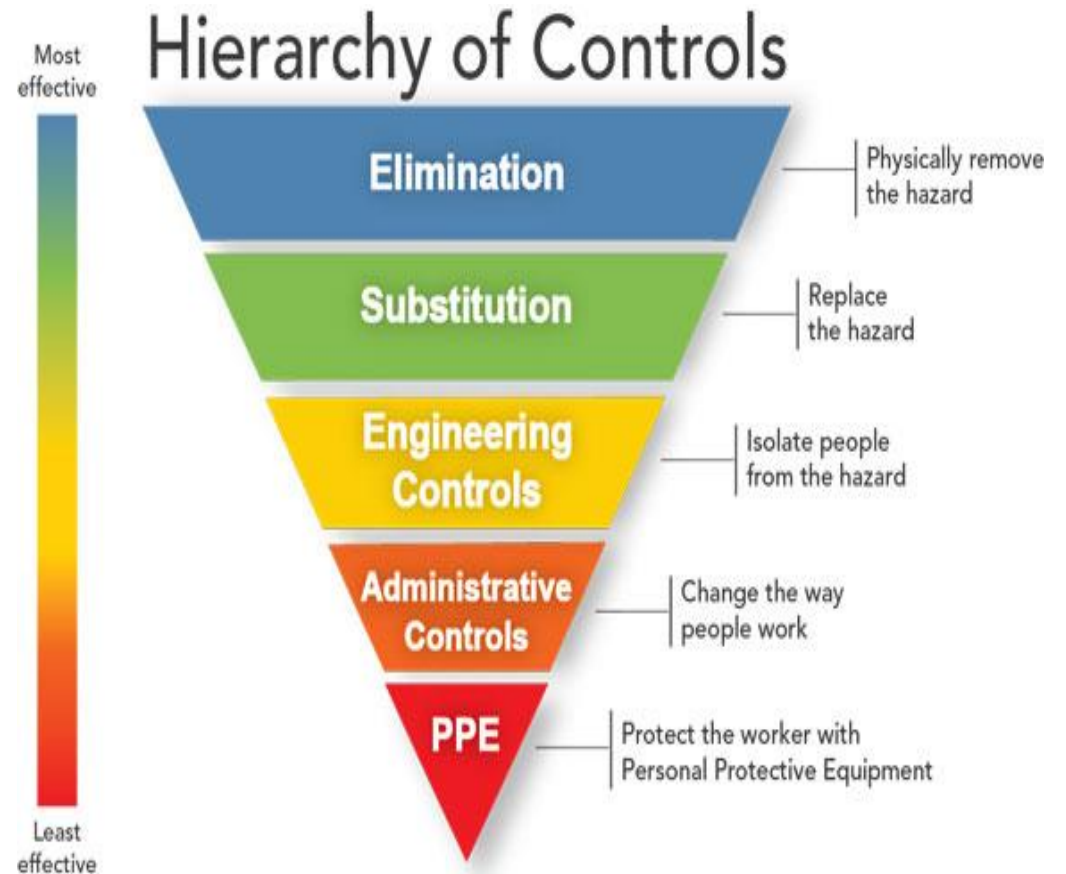
Handle all drugs and dosage forms with all containment and work practices listed in <800>

Perform an Assessment of Risk to determine alternative containment strategies and work practices

What's the Assessment of Risk All About?

- ▶ USP <800> establishes the containment strategies and work practices best known to control hazardous drug contamination
 - ▶ Engineering controls
 - ▶ Protective equipment
 - ▶ Work practices

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



HD Life Cycle in Your Pharmacy



Your Hazardous Drug List

1. Review the NIOSH list of hazardous drugs
2. Identify the drugs and dosage forms you handle
3. Perform an Assessment of Risk
4. Document review of the list annually



Required Assessment of Risk Elements

- ▶ Drug
- ▶ Dosage form
- ▶ Risk of exposure
- ▶ Packaging
- ▶ Manipulation
- ▶ Documentation of alternative containment strategies and/or work practices

Review annually and document

Which of these could be considered for an Assessment of Risk?

- A. Crushing spironolactone for a pediatric suspension
- B. Counting methotrexate tablets
- C. Pouring megestrol liquid
- D. Dispensing a vial of methotrexate



Your HD List

Require ALL containment strategies detailed in <800>	Alternative containment strategies can be considered and implemented
<ul style="list-style-type: none">• Active Pharmaceutical Ingredient (API) of any HD on the list	<ul style="list-style-type: none">• Antineoplastics you only need to count or package
<ul style="list-style-type: none">• Antineoplastics that require manipulation	<ul style="list-style-type: none">• Non-antineoplastics
<ul style="list-style-type: none">• Dosage forms that don't fit your Assessment of Risk	<ul style="list-style-type: none">• Reproductive only hazards

Active Pharmaceutical Ingredient

- ▶ Any substance or mixture of substances intended to be used in the compounding of a drug preparation, thereby becoming the active ingredient in that preparation and furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans and animals or affecting the structure and function of the body

Are These API?

- ▶ Raw chemical?
- ▶ Crushed tablet?
- ▶ Opened capsule?
- ▶ Concentrated hormone solution?

So What Happens With ...

- ▶ Active Pharmaceutical Ingredient (API)
- ▶ Antineoplastic dosage form dispensed in unit-of-use
- ▶ Antineoplastics that must be repackaged
- ▶ Antineoplastic oral dosage form that must be crushed
- ▶ Oral agents on Tables 2 and 3

API of Any Drug on the NIOSH List

- ▶ Active Pharmaceutical Ingredient of any antineoplastic, non-antineoplastic, or reproductive hazard
- ▶ **No option** → must treat with all the containment strategies and work practices in <800>

Antineoplastic Agents

- ▶ If any manipulation is required
 - ▶ Crushing tablets or opening capsules to make a suspension
 - ▶ Splitting tablets
- ▶ **No option** → must treat with all the containment strategies and work practices in <800>

Examples

<800> Containment

- ▶ Containment Primary Engineering Control (C-PEC)
 - ▶ Powder Hood
- ▶ Containment Secondary Engineering Control (C-PEC)
 - ▶ Room with fixed walls separate from non-hazardous compounding
 - ▶ Negative pressure
 - ▶ Vented to the outside
 - ▶ At least 12 air changes per hour



Photo courtesy of Labconco

Antineoplastic Agents

- ▶ For antineoplastic agents that only require counting or packaging
 - ▶ Methotrexate tablets
 - ▶ Conventionally-manufactured fluorouracil cream
- ▶ You can consider these dosage forms in your Assessment of Risk

Example

HDs Other Than Antineoplastics

- ▶ Non-antineoplastics
- ▶ Reproductive only hazards
- ▶ All can be considered for your Assessment of Risk
 - ▶ But some are concerning

Approach to Assessment of Risk

- ▶ The NIOSH list has links and information concerning why the drug is on the list
- ▶ Look at that information, and evaluate it based on your circumstances
- ▶ Some are situational hazards
 - ▶ Hazards in third trimester

Example

Assessment of Risk Requirements

- ▶ If you exempt specific drugs and dosage forms in your entity, you must identify the alternative containment strategies and/or work practices
- ▶ Determine how you will document this
 - ▶ Spreadsheet?
 - ▶ Separate form for each dosage form?

Receiving

- ▶ Can you tell from the outside of your packages that a hazardous drug is inside?
- ▶ Do you have any antineoplastics that must be manipulated other than counted or packaged?
- ▶ Need to identify – specific to drug and dosage form – those agents that will be handled differently from <800> and identify strategies in your Assessment of Risk



What type of gloves should be used when compounding HDs?

- A. Two pairs of any medical glove
- B. Nitrile gloves
- C. Gloves that meet ASTM D6978
- D. Gloves that meet OSHA standards



Drug Storage

- ▶ Identify as HDs
- ▶ Store in yellow, lidded bins
- ▶ Clearly note what must be done if manipulation of the dose is required

Example



Finished Dosage Forms

- ▶ Determine where they will be stored
- ▶ Waiting for patient pick-up

What level of detail has to be considered in an Assessment of Risk?

- A. Type of drug
- B. Name of drug
- C. Supplier of drug
- D. Dosage form



Examples – Table 1 Antineoplastics

- ▶ Unit-of-use
- ▶ Those that only require counting or packaging



Examples – Table 2 Non-Antineoplastics

- ▶ Azathioprine
- ▶ Carbamazepine
- ▶ Risperdone
- ▶ Spironolactone



Examples – Table 3 Reproductive Hazards

- ▶ Clonazepam
- ▶ Fluconazole
- ▶ Warfarin

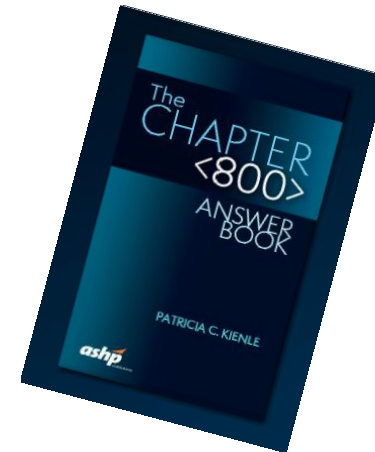


Examples of Work Practices

- ▶ Identify HDs by bins or shelf stickers
- ▶ Buy in unit-of-use when possible
- ▶ Use separate equipment for chemo
 - ▶ Designated counting tray and spatula
 - ▶ Wear chemo gloves tested to ASTM D6978
 - ▶ Decontaminate tray after use

Resources

- ▶ USP <800> FAQs at www.usp.org
- ▶ ASHP: The Chapter <800> Answer Book (www.ashp.org)
- ▶ Joint Commission Resources/BD: Hazardous Drug Toolkit (www.hazmedsafety.com)
- ▶ bb Braun: Are You Ready for 800? (www.readyfor800.com)



To-Do List

- ▶ Review the 2016 NIOSH List of Hazardous Drugs to identify the drugs and dosage forms handled at your pharmacy
- ▶ Perform an Assessment of Risk
- ▶ Review and document your Assessment of Risk at least every 12 months

