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

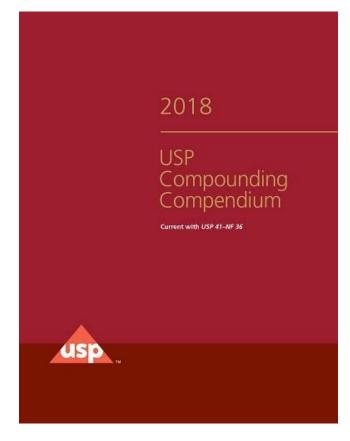
Scope of <800>

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

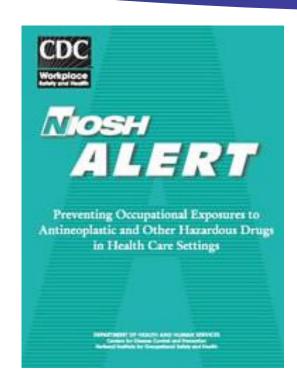


Enforceability of USP Standards

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



Genesis of USP <800>



ASHP Guidelines on Handling Hazardous Drugs

In 1994, the American Society of Health-System Pharmacies (ASISP) published in revised schools assistance behilters (TARI) on handling cytotoxic and huardass drugs. The in-ternation and recommendation contained in that document wave current to June 1985. Centeraing reports of workplace contamination and concerns for health care worker solidy prompacifies (Conquistend Solidy and Health-Administration (CSHA) to issue new guidelines on controlling occupational exposure to huardross drugs in 1995. ⁵² in 2004, the National Institute for Occupational Safety and Health (NIOSH) issued the "NIOSH Alert: Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Health Care Settings.nd The following ASHP Guidelines on Handling larardous Drugs include information from these recomlations and are current to 2004.

The purpose of those guidelines is to (1) update the reader on new and continuing concerns for health care workers handling hazardous drags and (2) provide information on recommendations, including those regarding cognipment, that have been developed since the publication of the previ-ous TAB. Hecause studies have shown that contentiation occurs in many settings, these guidelines should be imple-mented whenever hazardous drugs are received, stored, pre-pared, administered, or disposed.²⁴⁷

Comprehensive reviews of the literature covering an-

Compenhanter reviews of the literature covering accordinal and case protest of surface contensions, worker contensions, and risk assessment are available from 1000MeV of the contension of the data, professional judgment, experience, and common sense

Background

Workers may be exposed to a huxandous drug at many points during its manufacture, transport, distribution, receipt, stor-gap, propuration, and administration, as well as during stora-tured and experiment maintenance and repair, stora-tured to the second of the second of the second of the transport worked in these activities have the potential for contact with uncontained drug.

wan uncornanted drug.

Early concerns regarding the safety of workers handing potentially hazardeos drugs focused on antineoplastic drugs when reports of second cancers in patients treated with these agents were coupled with the discovery of mutagenic substances in nurses who handled these drugs and cared for reated patients. ** Exposure to those drugs in the workplace as been associated with acute and short-term reactions.

as well as long-term effects. Anecdotal and case reports in the literature range from districtated and octale effects to the like symptoms and headuck, Walth-Timo correlated starveys have reported significant increases in a marber of symptoms, including over front, chronic cough, infections, districtions, optimization, and bandachots, among manus, pharmacinis, and pharmacy technicism containly expended to hazardosa drags in the swortplace, NW Reproductive studies on band new workers have shown as persons in fall. ing from occupational exposure to these points shape, ^{20,12}
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the types of drags included on lists of Enzone or suspected
humans carcinogens by the National Entirology Programs^{20,12}
and the International Agency for Research on Cancer, ^{20,12}
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and the control of the control of the complex control
control of the contro cancer per million workers each year. This estimate, which considered workplace contamination and worker contamina-tion and excretion in combination with animal and patient studies, was based on a conservative exposure level. Conner et al. Found greater surface contamination in a study of U.S. and Canadian clinical settings than had been reported et al., "rided general statistic contentionates on a study of U.S., and Constand, clinical strings than has been represent in European analises contention by Sensia, and colleges," and Turniles et al.," reported an almost freefald greater design was reported by Sensia. These later fractings could add 12–30 haldmont Concer cases per year per military section. It Sensials's estimate, From those and other studies that have variablesen in words practice and engineering contribute to differ any be unknowned as the transition contribute to differ

Reates of Exposure. Numerous studies showed the pres-ence of hazardous drugs in the urine of health care work-ers. Mark/Mail Hazardous drugs enter the body through iners. "Inzazzous stugs enter int tooly mough in-halation, accidental injection, ingestion of contaminated foodsdaffs or mouth contact with contaminated hands, and dermal absorption. While inhalation might be suspected as the primary notic of exposure, air sampling studies of pharmacy and clinic environments have often demonstrated low levels of or no althous contaminates. Nat'll Recent ion levid of or no advisors contaminate. ***MAP Basses or concerns should be filtered of the semples methods? and the possibility that at least one of the market draps may be validate.**In all them not explanted on the standard sampling filter leaves the matter of subalizonal exposure servesteed. Sufferice communication stades in the province, suggest that content and the significant states and the supplementary of the same hazerboard supplementary supplementary of the same hazerboard as tilture part should apple the same hazerboard as tilture part shower the advantages and seminative to demand subsequies in the surface contamination transferred to hashe may be imposed as the surface contamination transferred to hashe may be imposed under the proposed supplementary and the surface contamination transferred to hashe may be imposed under the proposed for resolution and the surface contamination transferred to hashe may be imposed under the proposed for resolution contamination transferred to hashe may be imposed under the proposed for resolution contamination transferred to hashe may be imposed under the proposed for resolution contamination transferred to have been contaminated to the proposed to

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

NIOSH Hazardous Drug Information



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

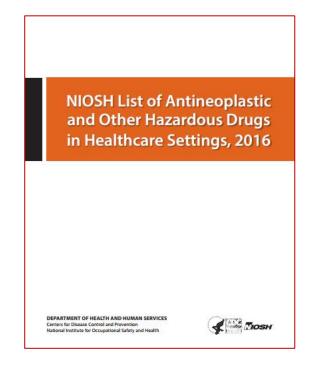
Where is the list of hazardous drugs?

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



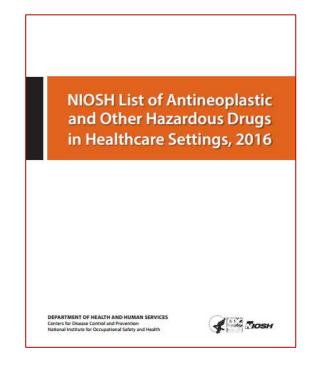
NIOSH List of Hazardous Drugs

- Antineoplastics
- Non-antineoplastics
- Reproductive only hazards



NIOSH List Tables

- ▶ Table 1 Antineoplastics
- ► Table 2 Non-antineoplastics
- ► Table3 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?

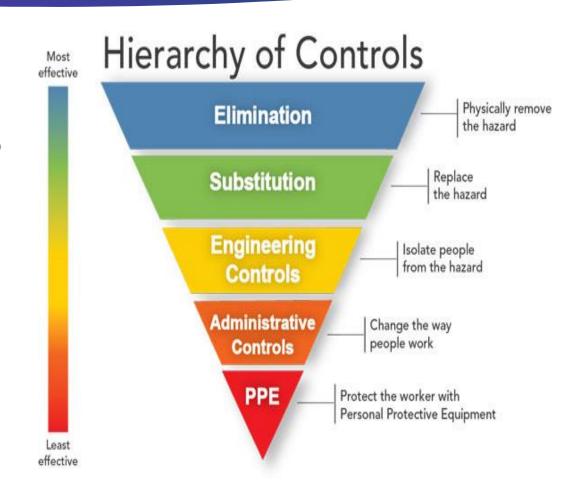
Your Options

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

- Review the NIOSH list of hazardous drugs
- 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



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
 Active Pharmaceutical Ingredient (API) of any HD on the list 	 Antineoplastics you only need to count or package
 Antineoplastics that require manipulation 	 Non-antineoplastics
 Dosage forms that don't fit your Assessment of Risk 	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 unitof-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

- Examples
- 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>

<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

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

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





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



Assessment of Risk Worksheet

Assessment of Risk Worksheet

+‡+										
	DRUG	DOSAGE FORM/ PACKAGING	RISK OF EXPOSURE	RECEIVING	TRANSPORT TO STORAGE	MANIUPLAT ION NEEDED	FINISHED DOSAGE FORM	DECONTA- MINATION	DISPOSAL	
				Integrity Decontamination	Containment	C-PEC/C-SEC/PPE	To Pt	Oxidizer	Regs	

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 <u>www.usp.org</u>
- ASHP: The Chapter <800> Answer Book (<u>www.ashp.org</u>)
- Joint Commission Resources/BD: Hazardous Drug Toolkit (www.hazmedsafety.com)
- bbraun: 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

