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USP Chapter 800: Implications for Community Oncology

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Oncology Practice Education Series

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Today's agenda

- Overview of USP
- Definition of Hazardous Drugs
- Section by Section overview of USP Chapter 800
- Timeline and Next Steps

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Overview of the United States Pharmacopia

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The United States Pharmacopia Convention

Scientific non-profit organization that sets the standards for the identity, strength, quality and purity of medicines, food ingredients, and dietary supplements manufactured, distributed and consumed worldwide.

Founded in 1820, USP has helped secure the quality of the American drug supply. The agency works with scientists, practitioners and regulators to develop and revise the standards that help protect the public health worldwide.

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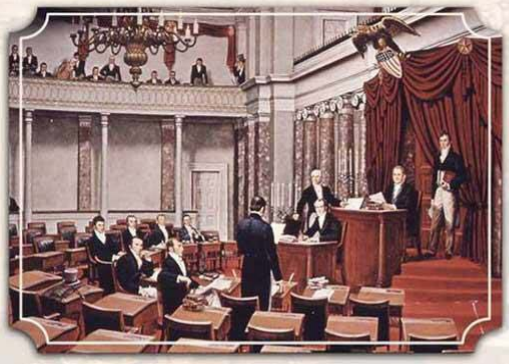
1820



Spalding

Bigelow

Mitchill

USP was founded in 1820 by 11 physicians, in Washington, D.C.

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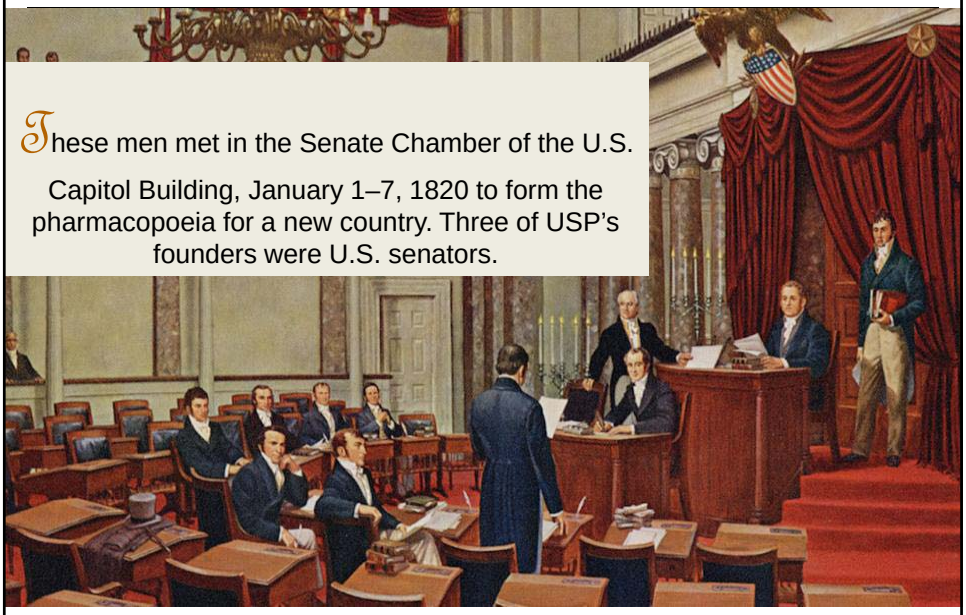
These men met in the Senate Chamber of the U.S. Capitol Building, January 1–7, 1820 to form the pharmacopoeia for a new country. Three of USP's founders were U.S. senators.



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The United States Pharmacopia

The United States Pharmacopeia (and The National Formulary, aka USP–NF) is a book of public pharmacopeial standards for chemical and biological drug substances, dosage forms, compounded preparations, excipients, medical devices, and dietary supplements.

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General Chapter

Authored by the Expert Committee, assigned by the USP Counsel of Experts.

Provide guidance, recommendations, regulations around drug manufacturing and manipulation.


(797) PHARMACEUTICAL COMPOUNDING—STERILE PREPARATIONS

INTRODUCTION

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Progression to USP <800>

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Hazardous Drugs 101

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Hazardous drug characteristics

Carcinogenic

Teratogenic

Reproductive toxicity

Demonstrates organ toxicity at low doses

Genotoxic

New drug which structure/toxicity profile mimics drugs already listed

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Hazardous Drug Guidance

- American Society of Health-System Pharmacists (ASHP)
- National Institute for Occupational Safety and Health (NIOSH)
- Occupational Safety and Health Administration (OSHA)
- Oncology Nursing Society (ONS)
- US Pharmacopeia (USP)

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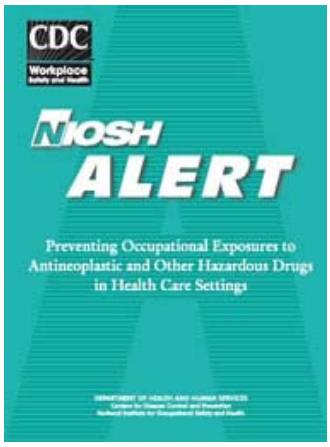
NIOSH Alert - 2004



- Made recommendations to prevent worker exposure in the health care setting that included:
- Proper use of ventilated BSCs
- Proper use of PPE
- Needleless and closed systems
- Medical surveillance

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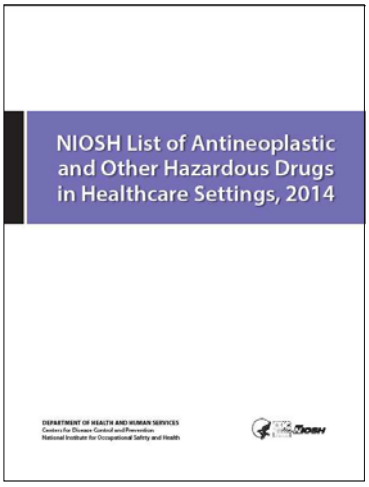
Identify the HDs Handled By Your Clinic



- The format for the 2014 list has been revised to include three groups of hazardous drugs:

1. Antineoplastic drugs
2. Non-antineoplastic hazardous drugs
3. Drugs with reproductive effects

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Available guidelines today.....

OSHA
- Technical Manual: Section VI
- "Controlling Occupational Exposure to Hazardous Drug"
- 1999
- Brief overview which address's multiple operational areas

Center for Disease Control
- "Primary Containment of Biohazards"
- 2002
- Guidance around selection/use of BSC

EPA
- "Resource Conservation and Recovery Act" (RCRA)
- 1976, 1980, 1984, 1990, 1991
- 30 drugs listed of which 9 are anti-neoplastic agents
- Focus is on disposal

National Institute for Health
- "Recommendations for Safe Handling of Cytotoxic Drugs"
- 2002
- Primary goal is preparation and administration

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Available guidelines today.....

ASHP
- "Guidelines for Handling of Hazardous Drugs"
- 1990, 2006
- Informed discussion and suggestions for all operational areas within practice

USP
- "Chapter 797"
- 2004, 2010
- Detailed guidance around compounding hazardous drugs as sterile products

ONS
- "Chemotherapy/Biotherapy Guidelines and Recommendations.."
- 2001
- Thorough overview of handling in all operational areas of practice

NSF
- ANSI 49 "Class II Biosafety Cabinetry
- 2002
- Address's classification and certification of BSC's

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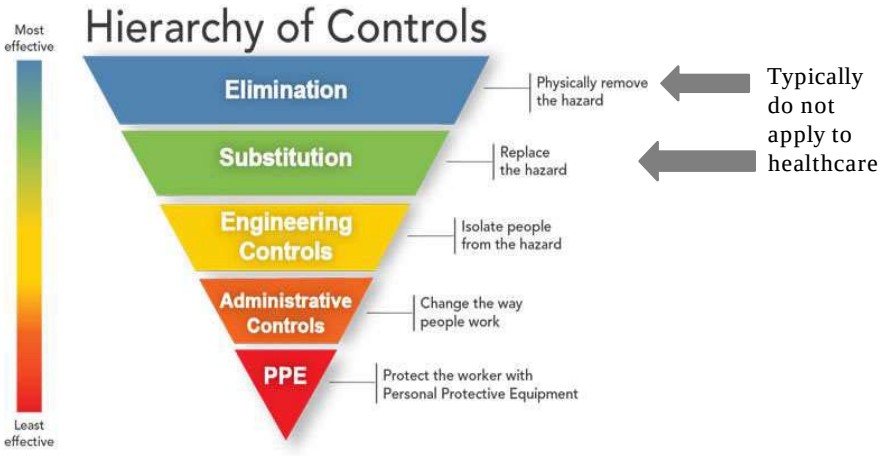
Key Component: Containment



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USP General Chapter 800

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Scope of USP <800> : Does It Apply To Me?

"This chapter applies to all healthcare personnel who handles HD preparations and all entities that store, prepare, transport, or administer HDs (e.g., pharmacies, hospitals and other healthcare institutions, patient treatment clinics, physicians' practice facilities, or veterinarians' offices). Personnel who may potentially be exposed to HDs include, but are not limited to: pharmacists, pharmacy technicians, nurses, physicians, physician assistants, home healthcare workers, veterinarians, and veterinary technicians."

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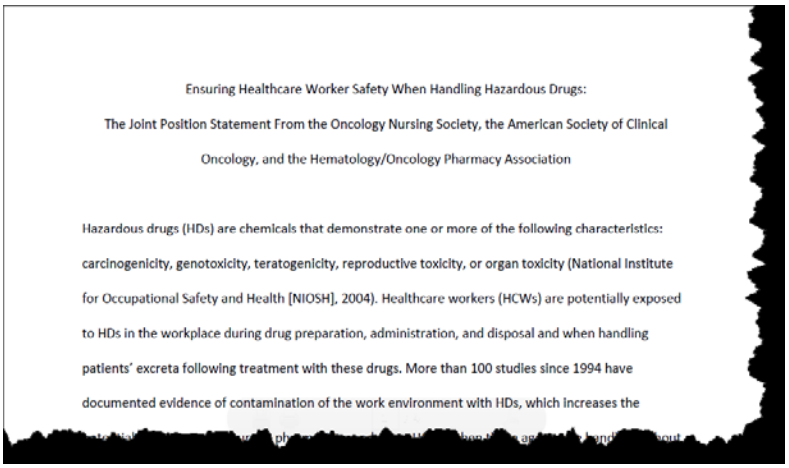
Joint Position Statement ASCO/ONS/HOPA



Ensuring Healthcare Worker Safety When Handling Hazardous Drugs:

The Joint Position Statement From the Oncology Nursing Society, the American Society of Clinical Oncology, and the Hematology/Oncology Pharmacy Association

Hazardous drugs (HDs) are chemicals that demonstrate one or more of the following characteristics: carcinogenicity, genotoxicity, teratogenicity, reproductive toxicity, or organ toxicity (National Institute for Occupational Safety and Health [NIOSH], 2004). Healthcare workers (HCWs) are potentially exposed to HDs in the workplace during drug preparation, administration, and disposal and when handling patients' excreta following treatment with these drugs. More than 100 studies since 1994 have documented evidence of contamination of the work environment with HDs, which increases the

USP 800 Objectives

Protect Personnel

Broaden standards to all aspects of handling hazardous drugs

Include non-sterile as well as sterile preparations

Ensure standards for all personnel who handles hazardous drugs and all areas of a facility where they may be found.

Composition of USP <800>

- OSHA Technical Manual
  - Controlling Occupational Exposure to Hazardous Drugs
- ASHP Guidelines
- NIOSH Alert and lists of hazardous drugs
  - Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Health Care Settings
  - 2014 List of Hazardous Drugs contains table of PPEs based on activities performed
- ONS *Safe Handling of Hazardous Drugs*
- Growing body of literature

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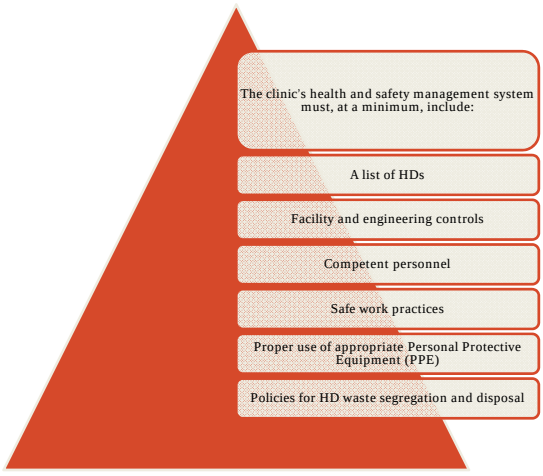
USP 800 Practice Responsibilities



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Anatomy of USP 800

Sections

- List of Hazardous Drugs
- Types of Exposure
- Responsibilities of Personnel Handling Hazardous Drugs
- Facility Design and Engineering Controls
- Personal Protective Equipment (PPE)
- Hazard Communication Program
- Training of Compounding Personnel
- Receiving
- Transport
- Dispensing HD Dose Forms Not Requiring Alteration

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Anatomy of USP 800

Sections-cont.

- Compounding HD Dosage Forms
- Protection When Administering HD's
- Cleaning, Deactivation, Decontamination, and Disinfection
- Spill Control
- Disposal
- Environmental Control
- Documentation
- Medical Surveillance

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Section 4: Responsibilities of Personnel Handling HD's

- Establishes requirement of compounding supervisor.
- Establishes ALL personnel handling HD's are responsible for proper compounding and handling.
- All personnel must ensure all agency standards are followed (state and federal boards, OSHA, EPA, NIOSH, accrediting organizations)

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Section 5: Facility Design and Engineering Controls

Containment-Primary Engineering Control (C-PEC)

Containment-Secondary Engineering Control (C-SEC)

Supplemental Engineering Controls

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Section 5: Facility Design and Engineering Controls

Restricted access and segregation from non-HD's

- Receiving
- Storage
  - HD's require dedicated refrigerator
    - » Should have room exhaust near compressor (discretionary)
- Compounding

New

Negative pressure gradients to adjacent areas

New

Detailed language around non-sterile HD compounding

New

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Section 5: Facility Design and Engineering Controls

C-PEC must be vented to outside environment. New

CSTD's should be used in compounding, MUST be used in administering. New

Configuration	C-PEC	C-SEC	Maximum BUD
ISO Class 7 Buffer Room	-Externally Vented -Examples: Class II BSC or CACI	-30 ACPH Externally vented -Negative pressure	As described in <797>
C-SCA	-Externally Vented -Examples: Class II BSC or CACI	-12 ACPH -Externally Vented -Negative Pressure	As described in <797> for segregated compounding area

New

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Closed System Transfer Devices

- B. Braun Medical Inc Onguard
- BD Phaseal
- CareFusion
- Equashield CSTD
- ICU Medical Inc ChemoClave

Section 6: Personal Protective Equipment

All aspects of handling.

Head/Hair and Shoe covers must be worn.

New

Eye and face protection when manipulating HD's outside a C-PEC, working at eye level or above, cleaning the C-PEC, cleaning a spill.

Respirators when appropriate.

Gloves must be tested to ASTM 6978 standard.

Gowns must be impervious and intended for use with hazardous drugs.

Section 7: Hazard Communication Program

A written program of policy and procedure.

New

Elements:

- Labeling and warnings
- Training
- MSDS are readily accessible

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Section 9: Receiving

Very detailed guidance around process of receiving.

New

Practice must establish SOPs for receiving HDs.

A spill kit must be accessible in the receiving area.

Step by step discussion with regard to handling damaged HD shipping containers.

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Section 13: Administration

CSTD's must be used when dosage form allows.

New

Appropriate PPE must be worn.

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Section 17: Documentation and SOPs

Clinics must maintain SOPs for the safe handling of HDs for all situations in which the HDs are used throughout the facility.

The SOPs must be reviewed at least every 12 months by the designated person, and the review must be documented.

There is a list of 16 categories that must be addressed with SOPs.

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Section 19: Medical Surveillance

New

-All employees should enroll

-Evaluate symptom complaints, physical findings, and lab abnormalities

-Track the employee over time

-Allows you to evaluate the effectiveness of engineering controls, PPE, safe work process, worker education program

-Confidential medical information
- Reproductive history
- Work history and exposure history – drugs, amounts, length of exposure
- Physical exam
- Lab tests

-Develop a follow up surveillance plan for abnormals


WORKPLACE SOLUTIONS
Medical Surveillance for Healthcare Workers Exposed to Hazardous Drugs

Timelines

July 2018

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
1 	2	3	4 Independence Day	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	31	1	2	3	4

HELP! Where Do We Begin?

Start Now:
- Identify HDs
- Revise Policies
- Train Personnel
- Use Correct PPE
- Monitor Environment

Plan Ahead:
- Prepare for Facility Changes
- Research CTSDs

Discussion