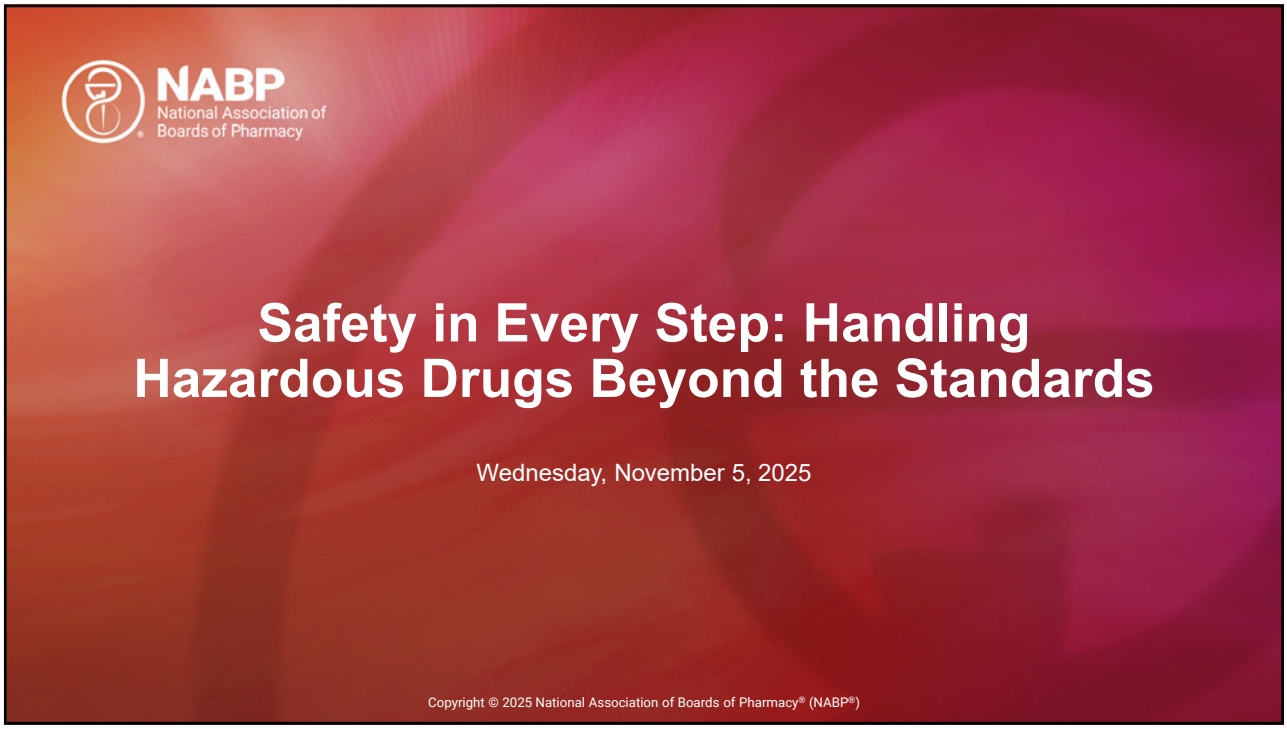


1

The handout for today's presentation can be found at:

www.nabp.pharmacy/webinar

NABP

2

Financial Disclosures

Our speaker Fred Massoomi declares that he has a current affiliation or financial arrangement as a speaker for Pharmacy Purchasing and Products and as an owner of Albarello, LLC. He also had an affiliation or financial arrangement as a speaker for Equashield and as an employee of PharmacyStars within the past 24 months.

Additionally, NABP staff involved in the planning of this activity do not have a current affiliation or financial arrangement with any ineligible companies that may have a direct interest in the subject matter of NABP's CPE Program within the past 24 months.

All relevant financial relationships have been mitigated.

NABP

3

NABP National Association of Boards of Pharmacy

Safety in Every Step: Handling Hazardous Drugs Beyond the Standards

Fred Massoomi, PharmD, BCSCP, FASHP
Compounding Consultant Pharmacist
Albarello, LLC

4

5

Disclosures

Our speaker Fred Massoomi declares that he has a current affiliation or financial arrangement as a speaker for Pharmacy Purchasing and Products and as an owner of Albarello, LLC. He also had an affiliation or financial arrangement as a speaker for Equashield and as an employee of PharmacyStars within the past 24 months.

Additionally, NABP staff involved in the planning of this activity do not have a current affiliation or financial arrangement with any ineligible companies that may have a direct interest in the subject matter of NABP's CPE Program within the past 24 months.

All relevant financial relationships have been mitigated.

HD = Hazardous Drug

6

Learning Objectives

Define a Hazardous Drug.

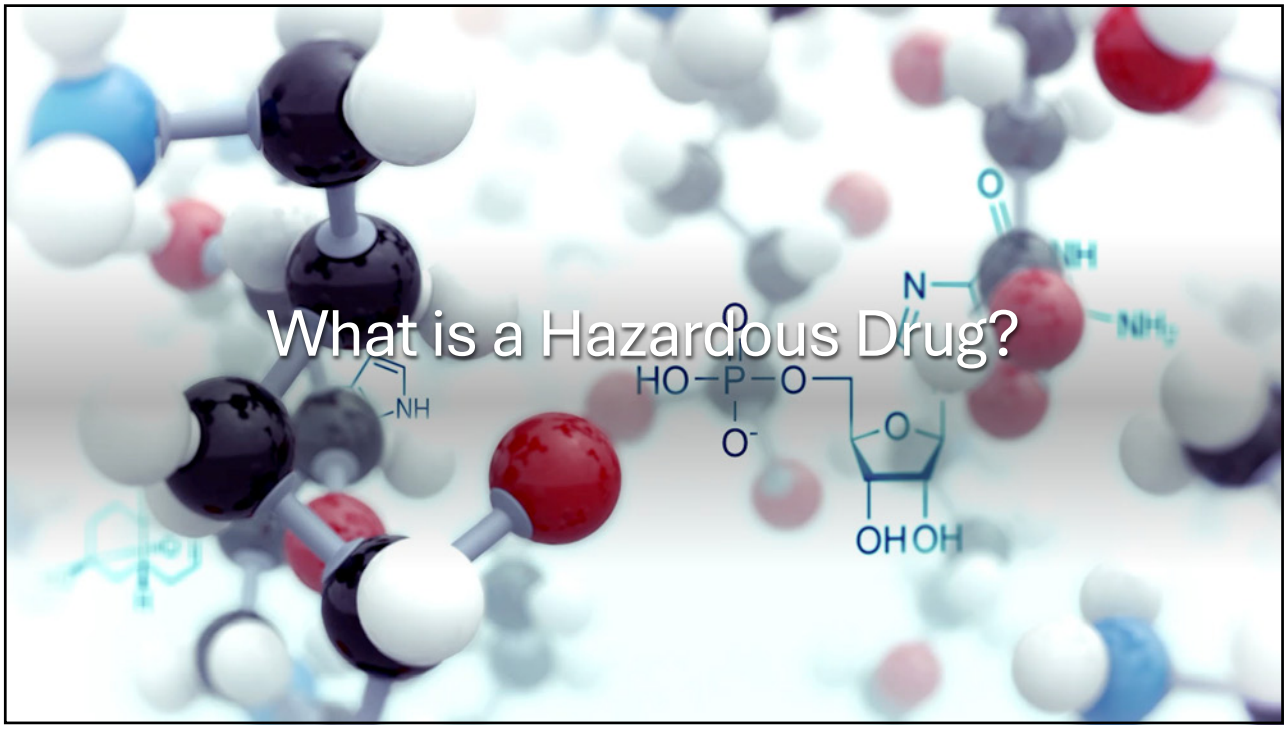
Describe an effective site-specific Hazardous Drug list.

Identify main gaps and challenges in maintaining ongoing compliance with USP <800>.

Outline strategies for complying with USP <800> elements.

List best practices for the safe handling of Hazardous Drugs beyond USP <800>.

7



8

First Published Study of Cytotoxic Drug Risks

1979

MUTAGENICITY IN URINE OF NURSES HANDLING CYTOSTATIC DRUGS

SIR,—Anti-cancer drugs are known to be cancer-causing agents also, but we know of no studies of the possible occupational hazards in handling such drugs in oncological units. We have used a very sensitive screening procedure to look for mutagenic activity in the urine of patients on chemotherapy and of nurses administering these drugs.

Source: Falck K, et. Al. Lancet June 9, 1979: 1250-1251

9

The Origination of 'Hazardous Drugs' Terminology

ASHP Technical Assistance Bulletin on Handling Cytotoxic and Hazardous Drugs

ASHP's Clinical Affairs Department in collaboration with Luci A. Power, MS, Senior Consultant, Power Enterprises, San Francisco, CA.

American Journal of Hospital Pharmacy, **1990** ;47:1033-49

"*The remainder of the document, however, will refer exclusively to "hazardous" drugs or agents*"

"*The safe handling of* ***hazardous drugs*** *is an issue that must be addressed in health-care settings, and one that may even affect, in a home care environment, persons other than the patient.*"

"*Inasmuch as possible, the pharmacist should take the lead in establishing policies and procedures to ensure the proper handling of* ***all hazardous drugs*** *in any health-care setting.*"

10

Occupational Safety and Health

US Department of Labor

- Occupational Safety and Health Act (OSHA) of 1970
  - Safety and health standards for US workers
  - Employers must provide work and a workplace free from recognized and serious hazards

OSHA standards for Hazardous Drugs

- Hazard Communication Standard
  - Standard (29 CFR part 1910 – 1200)
- Controlling Occupational Exposure to Hazardous Drugs
  - In: *OSHA Technical Manual*, TED 1–0.15A, Sec VI, Chap II: 1995, 1999, 2016 https://www.osha.gov/hazardous-drugs
- Hazardous Waste Operations and Emergency Response (HAZWOPER)
  - Standard (29 CFR 1910.120)

11

Who the Heck is NIOSH?

1970 US Occupational Safety and Health Act

OSHA

Occupational Safety and Health Administration (OSHA)

Regulatory
Enforcing workplace safety and health standards

CDC Workplace Safety and Health NIOSH National Institute for Occupational Safety and Health

Non-Regulatory
Research to prevent work related injury, illness, death

12

The Original US Hazardous Drugs List

1986

Antineoplastic Agents In Use

Alkylating Agents
Cisplatin
Cyclophosphamide
Mechlorethamine HCl
Thiotepa
Carmustine
Streptozocin
Busulfan
Chlorambucil
Lomustine
Melphalan
Teosulfan
Uracil Mustard
Chlormaphazine
Dacarbazine

Investigational Drugs
Azacitidine
Amsacrine
Teniposide
Ifoshfamide
Mitoxantrone HCl
Vindesine

Antimetabolites
Cytarabine
Fluorouracil
Methotrexate
Mercaptopurine
Azathioprine
Procarbazine

Antibiotics
Doxorubicin HCl
Dactinomycin
Daunorubicin HCl
Mithramycin
Mitomycin

Miotic Inhibitors
Vincristine Sulfate
Vinblastine Sulfate
Etoposide

Miscellaneous
Asparaginase

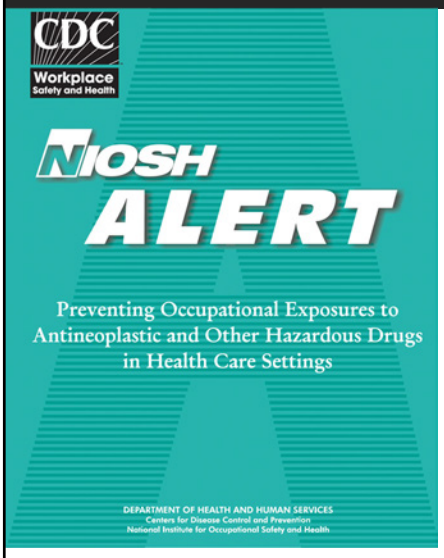
36
1-list

Primary Focus: Oncology Drugs

Source: **OSHA** Work-practice guidelines for personnel dealing with cytotoxic (antineoplastic) drugs. Am j of Hosp Pharm 1986;43:1193-1204

13

NIOSH Definition of a Hazardous Drug

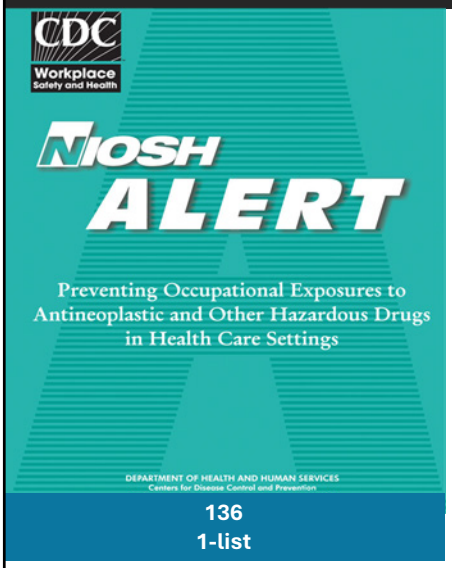


1. Carcinogenic
2. Teratogenicity or Developmental Toxicity
3. Reproductive Toxicity
4. Organ Toxicity at Low Doses
5. Genotoxicity
6. Structure & Toxicity Mimicity*

Source: *https://www.cdc.gov/niosh/docs/2004-165/default.html*

14

The First US All Hazardous Drugs List

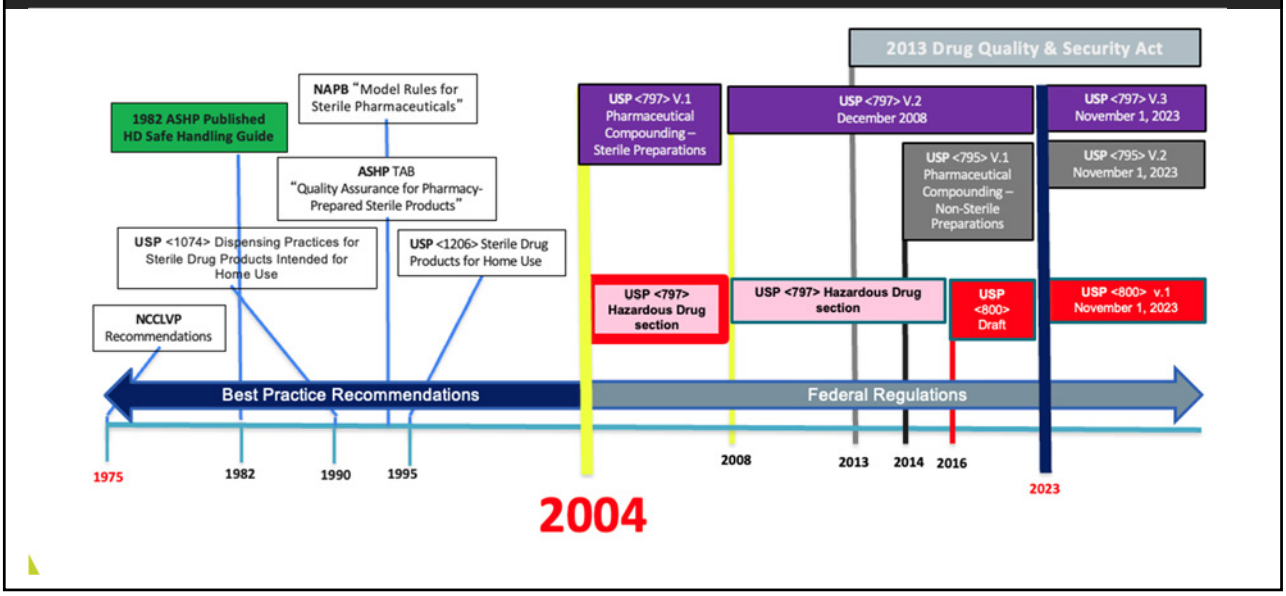


• **Antineoplastic**	75
• Androgens	3
• Antibiotic	1
• Anti-infectives (misc.)	2
• Antiretroviral Agent	1
• Antiviral	7
• Cell Stimulants/Proliferants	1
• Contraceptives	2
• Estrogens	7
• Estrogen agonist/antagonists	1
• Gonadotropin	4
• Immunosuppressive	2
• Oxytocics	4
• Progestins	1
• Skin Mucous Membrane	3
• Vaccine	1
• Other*	22

Source: *https://www.cdc.gov/niosh/docs/2004-165/default.html*

15

Hazardous Drug Handling Regulations Timeline



16

"This chapter describes practice and quality standards for handling hazardous drugs (HDs) to promote patient safety, worker safety, and environmental protection."

17

USP <800> Is Compendial ONLY if States Accepted

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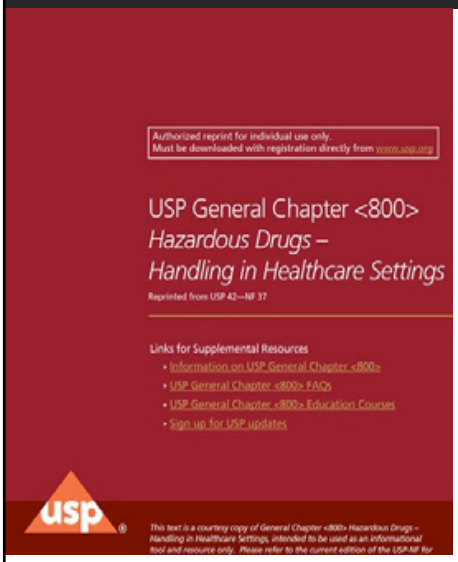
Hazardous Drug Safety Program



Hazardous Drug Safety Program

1. Introduction and Scope
2. List of Hazardous Drugs
3. Types of Exposures
4. Responsibilities of Personnel Handling HDs
5. Facilities and Engineering Controls
6. Environmental Quality and Control
7. Personnel Protective Equipment
8. Hazard Communication Program
9. Personnel Training
10. Receiving
11. Labeling, Packaging, Transport, and Disposal
12. Dispensing Final Dosage Forms
13. Compounding: Sterile and Non-sterile
14. Administering
15. Deactivating, Decontamination, Cleaning and Disinfecting
16. Spill Control
17. Medical Surveillance

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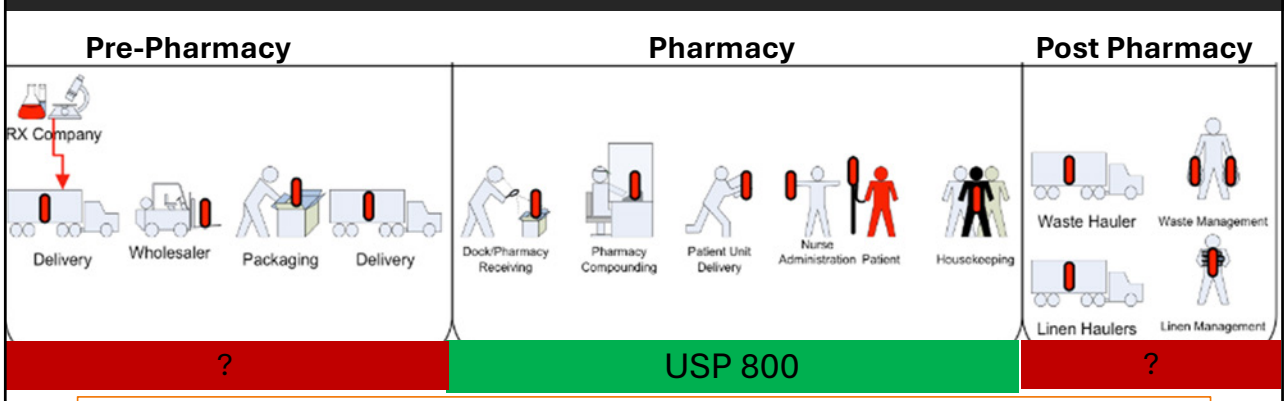
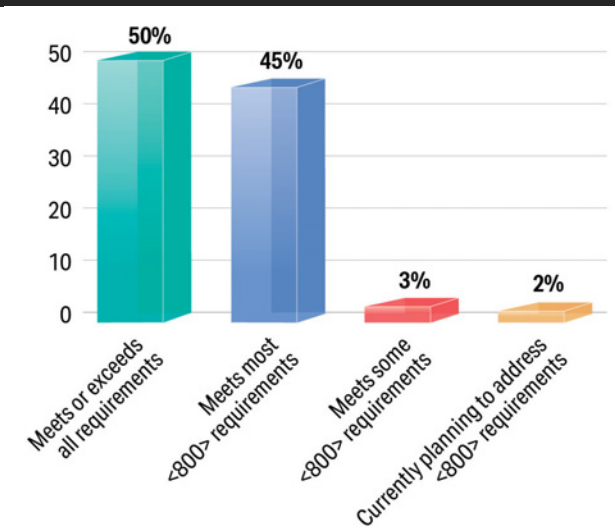
Scope of USP <800>



- Pharmacists, pharmacy technicians, nurses, physicians, physician assistants, housekeeping, waste haulers, linen processing, home health care workers, veterinarians, and veterinarian technicians
- Not listed: manufacturers; wholesale personnel; researchers; family
- **Must** incorporate into Hazard Communication Plan

20

Current Trend In Reported USP <800> Compliance



95% Meets Most

N= 334

Used with permission: Source: USP <800> Compliance. Pharmacy Purchasing & Products 2025;7:S1-S9

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Top Areas of Compliance Observation Gaps

USP <800>

Board Inspections

1. Assessment of Risk Documentation
2. Hazardous Drug List annual review
3. Respiratory equipment assessment
4. Hazardous drugs are stored in an externally exhausted room
5. Hazardous Drug labeling for defined products

Accreditation Inspections

1. Receiving & Storage Practices
2. Standard Operating Procedures gaps
3. Training and Competency Documentation
4. Hazardous Drug Disposal
5. Hazardous Drug Spills training

Source: National Association of Boards of Pharmacy; 2025 Inspection Observations
Source: Halvorsen D. Hazardous drug handling: 6th annual USP <800> survey results. *Pharm Purch Prod.* July 2024: 21(7)suppl.

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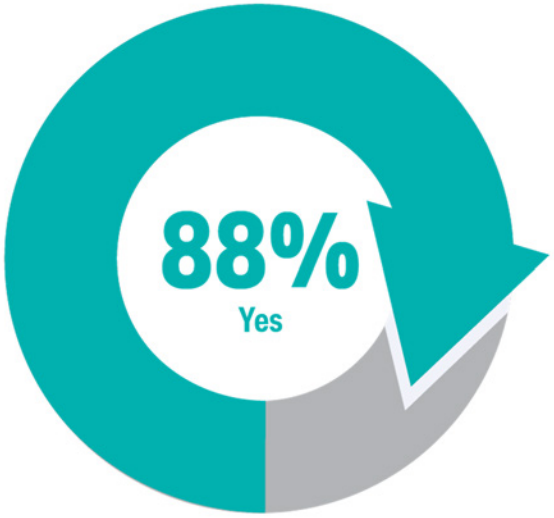
Assigned Designated Person



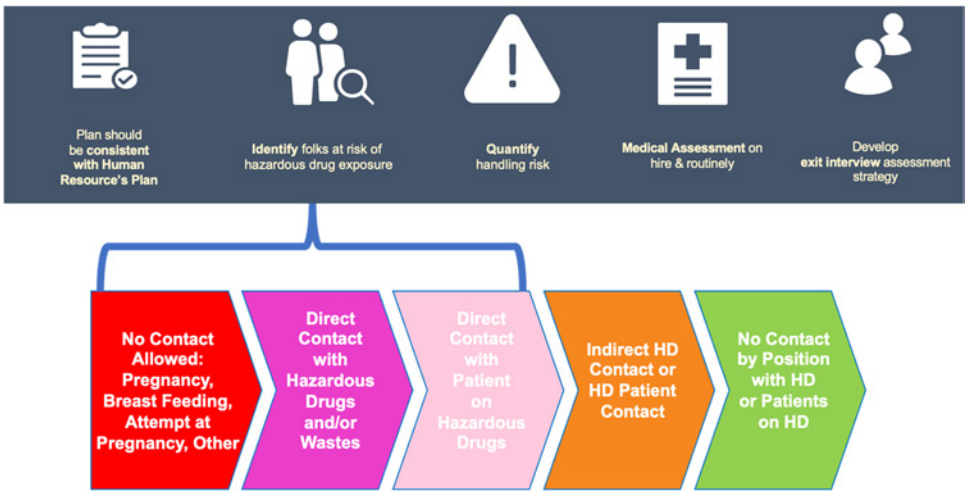
Role of the Expert

1) Write and Implement SOPs
2) Review SOPs every 12 months
   - Communicate changes to staff
3) Ensure that formal, written quality assurance and quality control programs are established
4) Corrective action capacity
5) Oversee personnel training program
6) Oversee compliance
7) Oversee monitoring of the facility
8) Review all certification records
9) Must be able to recognize problems, deviations, failures, errors
10) Confirm the appropriateness of sterilizing filters

Used with permission: Source: USP <800> Compliance. Pharmacy Purchasing & Products 2025;7:S1-S9

23

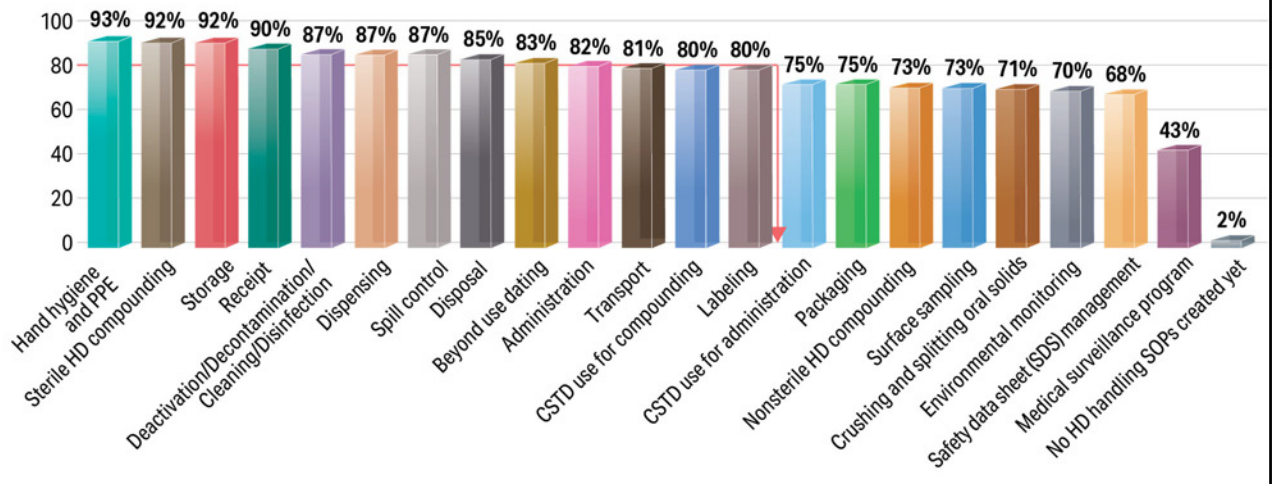
Define Who Can Handle Hazardous Drugs



Audit Point Site has defined all personnel who handle hazardous drugs

24

Standard Operation Procedures



Used with permission: Source: USP <800> Compliance. Pharmacy Purchasing & Products 2025;7:S1-S9

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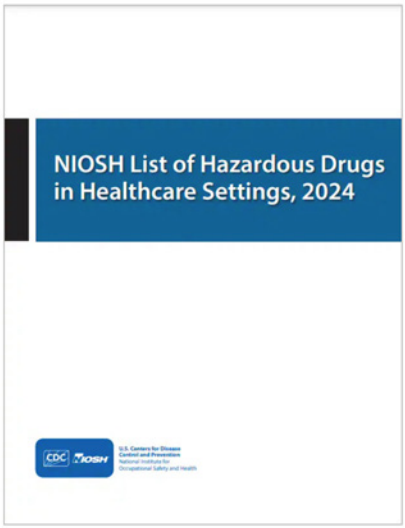
Site Specific Hazardous Drug List

- Current Hazardous Drugs list (dated)
- Include drugs from the current NIOSH list
- Update the list at least every 12 months
- Use NIOSH criteria to identify Hazardous Drugs
- Dosage forms of drugs may pose less risk
- Sites can conduct an “assessment of risk”
- If no assessment of risk is performed, all drugs listed are hazardous and must follow all containment requirements

Generic name	Brand Name/ (Formulation)	NIOSH Category	Personal Protection Equipment (PPE) Required			Additional Information
			Pharmacy Handling Preparing Compounding[1]	Nursing or Pharmacy Cutting-Crushing-Splitting[1]	Administering	
Cyclophosphamide	Cytoxan (injection)	Antineoplastic	High[1,2]	N/A	Moderate[1,2,3]	IARC Group 1 carcinogen; FDA Pregnancy Category D. ***Note: Cyclophosphamide is volatile. *Wear PPE when handling patient urine and feces for 5 days days after administration.
Cyclosporine	Neoral, Gengraf, SandIMMUNE (capsule)	Non-antineoplastic	Minimum	Not recommended to open capsule.	Low[1,2] If capsule opened.	IARC Group 1 carcinogen; FDA Pregnancy Category C.
				High[1,2]	Minimum if unaltered capsule.	
Cyclosporine	Neoral, Gengraf, SandIMMUNE (injection)	Non-antineoplastic	High[1,2]	N/A	Moderate[1,2,3]	IARC Group 1 carcinogen; FDA Pregnancy Category C.
Cyclosporine	Restasis (ophthalmic)	Non-antineoplastic	Minimum	N/A	Low[1,2]	IARC Group 1 carcinogen; FDA Pregnancy Category C.
Cyclosporine	Neoral, Gengraf (oral solution)	Non-antineoplastic	Moderate[1,2,3]	N/A	Low[1,2]	

26

NIOSH Definition of a Hazardous Drug



1. Carcinogenic
2. Teratogenicity or Developmental Toxicity
3. Reproductive Toxicity
4. Organ Toxicity at Low Doses
5. Genotoxicity
6. Structure & Toxicity Mimicity*

Source: *https://www.cdc.gov/niosh/docs/2004-165/default.html*

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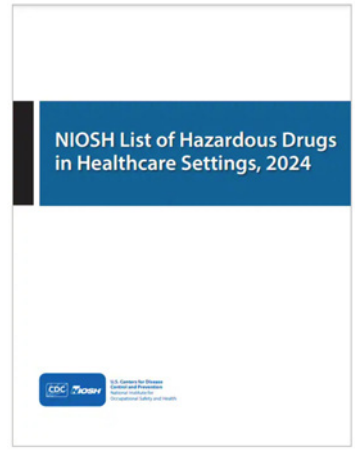
2024 NIOSH Hazardous Drug List



236
Table 1 - 106
Table 2 - 130

Table 1 NIOSH Hazardous Drug
1. NIOSH Defined Hazard of Carcinogen*
2. Manufacturer Special Handling Instructions
3. NOTE: Now includes non-antineoplastic drugs

*IARC and/or National Toxicology Program

Table 2 NIOSH Hazardous Drug
1. NIOSH Defined Hazard
2. Non-carcinogen
3. No Manufacturer Special Handling Instructions
4. NOTE: Now includes antineoplastic drugs

CAUTION: Drugs purchased and used by a facility may have entered the marketplace after the list below was assembled. This list is not all inclusive. Drugs reviewed for this update were new drug approvals or received safety-related new warnings from FDA during the period from January 2014 through December 2015.

Source: *https://www.cdc.gov/niosh/docs/2025-103/pdfs/2025-103.pdf?id=10.26616/NIOSHPUB2025103*

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Gaps to the 2024 NIOSH List

Drugs Excluded from the 2024 NIOSH Hazardous Drug List

The agents listed herein will not be reviewed or included in the NIOSH HD list.

Drugs Approved by FDA's CBER
- Vaccines, including BCG*
- Blood and blood components
- Somatic cells
- Gene therapy
- Tissues
- Recombinant therapeutic proteins
- Viral and bacterial vector-based therapies

Drugs Regulated by the Nuclear Regulatory Commission

Drugs Specific to Veterinary Medicine

Investigational Drugs

Drugs Not Approved in the United States
- FDA emergent use of foreign approved drug formulations

Chemicals (unless approved by FDA's CDER)**
- Active pharmaceutical ingredients (excluding those listed in NIOSH)
- Compounding components

Emerging Technologies
- Nanoparticle based therapies not approved by CDER
- Microrobotic based therapies not approved by CDER

*BCG package inserts have important MSHIs regarding special handling
**Chemicals are regulated under OSHA and follow the Global Harmonization System for hazard classification

Used with Permission: Source: Massoomi F. Implications of the NIOSH 2024 HD List Update. Pharm Purch Products. 2025 April; 7-10

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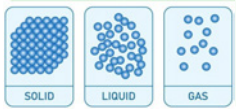
Pharmacy Assessment of Risk

Type of Hazard

Dosage Form

Risk of Exposure



Packaging

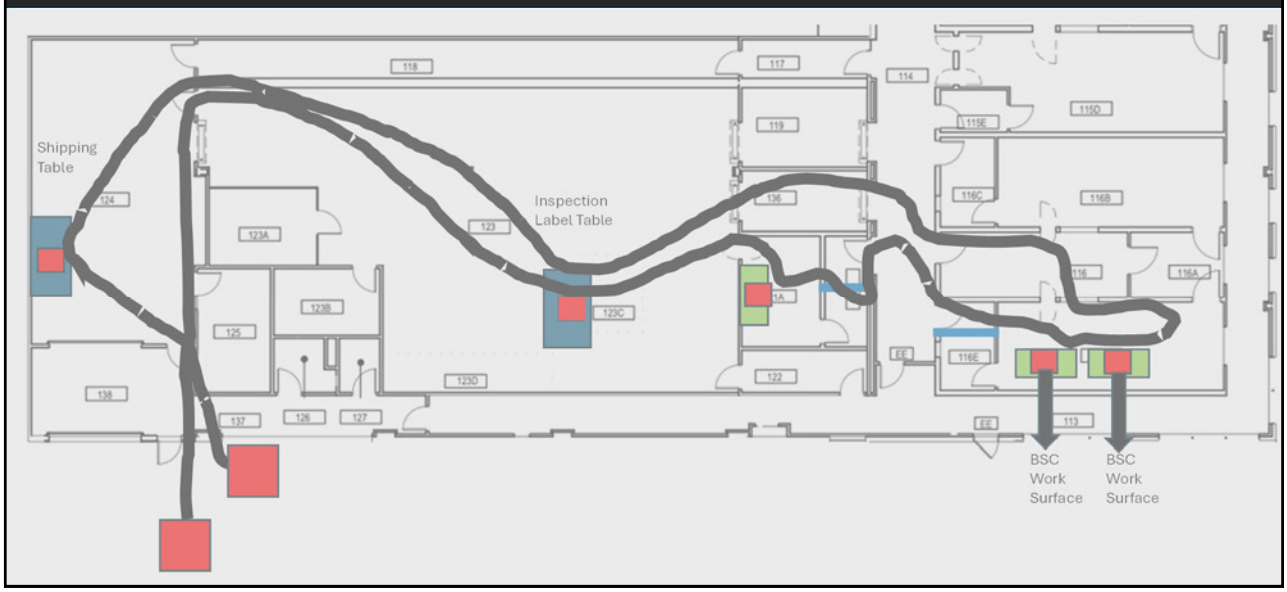
Manipulation

Who Handles the HD

Source: European Association of Hospital Pharmacists. Special Interest Group on Hazardous Medicinal Products: Final Report.
Source: USP (2024). General Chapter, ⟨800⟩ Hazardous Drugs-Handling in Healthcare Settings. USP-NF. Rockville, MD: United States Pharmacopeia..

30

Hazardous Drug Mapping



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Pharmacy Assessment of Risk (AOR)

McKnight HE, Kienle P. Updating the HD Assessment of Risk Pharmacy Purchasing & Products; October 2025 Supplement

USP <800> Hazardous Drugs Assessment of Risk

Per Policy, these drugs are exempt from USP<800> handling requirements - see other documentation for full USB<800> handling details.)

	generic (Brand) Route [Packaging: Manufacturer ⇒ Dispense]	NIOSH Group
Drug and Dosage Forms	**abacavir (Ziagen) PO [UD ⇒ UD]**	Non - Antineoplastic
Pharmacy Handling	**Pharmacy: Receiving / Storage / Preparation** *Exposure Risk: minimal*	• Handling/preparation PPE Requirements: n/a • Receiving from Distributor: Standard • Pharmacy Storage Area: Carousel • Packaging/Reconstitution Location: n/a • Compounding (Non-Sterile/Sterile) Location: n/a • Omnicell load: No
Transport	**Transport**	• Transport (dose is placed inside a plastic sealable bag): Standard
Nurse Handling	**Nursing: Storage / Admin.** *Exposure Risk: low*	• Handling/administration PPE Requirements: Single CX gloves, wash hands after handling • Storage of Finished dose in Nursing Area/Procedural Area: Patient Med Drawer • Signage on Patient Door Required: No • Closed System Storage Device: No • Manipulation of Dosage Form: Standard • Special Manipulation for Administration: do not crush tablet
Disposal	**Disposal / Spills**	• Disposal of Drug Waste: Full- purple bin, trace/packaging- trash • Disposol of Used PPE: trash bin (inside plastic bag) • Spill management: n/a
Additional Information	**NIOSH Supplemental Information:** *malignant tumors observed in male/female mice/rats; genotoxic in in vivo micronucleus tests*	
FINAL ASSESMENT	**Reason for exemption of USP<800> Containment Requirements:** *Purchased in final dosage form; packaged as unit dose. Does not require additional manipulation for dispensing.*	

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AOR Reference #1: Package Inserts

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed.

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AOR Reference #2: Safety Data Sheets

CYCLOPHOSPHAMIDE (ANHYDROUS) ICSC: 0489 (April 2017)
2-Bis(2-chloroethyl)amino)tetrahydro-2H-1,3,2-oxazaphosphorin-2-amine 2-oxide
N,N-Bis(2-chloroethyl)tetrahydro-2H-1,3,2-oxazaphosphorin-2-amine 2-oxide
2-H-1,3,2-Oxazaphosphorinane

CAS #: 50-18-0
UN #: 3464
EC Number: 200-015-4

	ACUTE HAZARDS	PREVENTION	FIRE FIGHTING
FIRE & EXPLOSION	Combustible. Gives off irritating or toxic fumes (or gases) in a fire.	NO open flames.	Use water spray, powder, foam, carbon dioxide.

AVOID ALL CONTACT! AVOID EXPOSURE OF BREASTFEEDING WOMEN!

	SYMPTOMS	PREVENTION	FIRST AID
Inhalation		Use closed system and ventilation.	Fresh air, rest.
Skin		Protective gloves. Protective clothing.	Remove contaminated clothes. Rinse skin with plenty of water or shower.
Eyes		Wear face shield or eye protection in combination with breathing protection.	Rinse with plenty of water for several minutes (remove contact lenses if easily possible).
Ingestion	Diarrhoea. Dizziness. Nausea. Vomiting. Abdominal pain.	Do not eat, drink, or smoke during work. Wash hands before eating.	Rinse mouth. Refer for medical attention .

SPILLAGE DISPOSAL

Personal protection: particulate filter respirator adapted to the airborne concentration of the substance. Sweep spilled substance into covered sealable containers. If appropriate, moisten first to prevent dusting. Carefully collect remainder. Then store and dispose of according to local regulations.

STORAGE

Separated from food and feedstuffs. Dry. Keep in the dark. Well closed. See Chemical Dangers.

PACKAGING

CLASSIFICATION & LABELLING

According to UN GHS Criteria

DANGER

Toxic if swallowed
May cause genetic defects
May cause cancer
May damage fertility or the unborn child
May cause harm to breast-fed children
May cause damage to blood, bone marrow and lungs through prolonged or repeated exposure

Transportation
UN Classification
UN Hazard Class: 6.1; UN Pack Group: III

Prepared by an international group of experts on behalf of ILO and WHO, with the financial assistance of the European Commission.
© ILO and WHO 2021

CYCLOPHOSPHAMIDE (ANHYDROUS) ICSC: 0489

Source: *https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1200*

1. Product Identifier/Contact Info
2. **Hazards Identification**
3. Composition/Ingredients
4. **First-Aid Measures**
5. Fire-Fighting Measures
6. Accidental Release Measures
7. **Handling and Storage**
8. **Exposure Controls/Personal Protection**
9. Physical and Chemical Properties
10. Stability & Reactivity
11. Toxicological Information
12. Ecological Information
13. **Disposal Considerations**
14. **Transportation Information**
15. Regulatory Information
16. **Other Information**

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AOR Reference #3: Chemical Hazards

EPA flags cancer risks tied to formaldehyde: 5 notes

Mackenzie Bean (Twitter) - an hour ago

SAFETY DATA SHEET
FORMALDEHYDE

Source: https://www.beckershospitalreview.com/public-health/epa-flags-cancer-risks-tied-to-formaldehyde-5-notes.html?origin=BHRE&utm_source=BHRE&utm_medium=email&utm_content=newsletter&oly_enc_id=4234C7600690I

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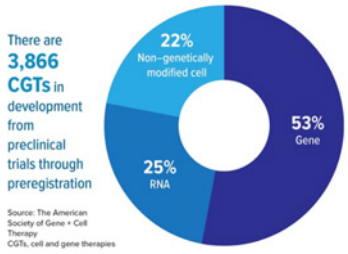
AOR Reference #4: Cell & Gene Based Therapies

A Call To Action: Health-System Pharmacists Must Stand Up to Meet the Growing Demand for Cellular Based Therapies

Jill E Blind, PharmD, CCRP, Diana N Nowicki, PharmD, BCPS, BCACP, AAHIVP, Kimberly McConnell, PharmD, BCPS, CCRP, Adam J Motsney, PharmD, Ada Kong, PharmD

American Journal of Health-System Pharmacy, Volume 80, Issue 14, 15 July 2023, Pages 944–947



https://www.pharmacypracticenews.com/Policy/Article/03-24/The-Time-Is-Now-to-Ensure-Safe-Handling-of-Cell-amp-Gene-Therapy/73051

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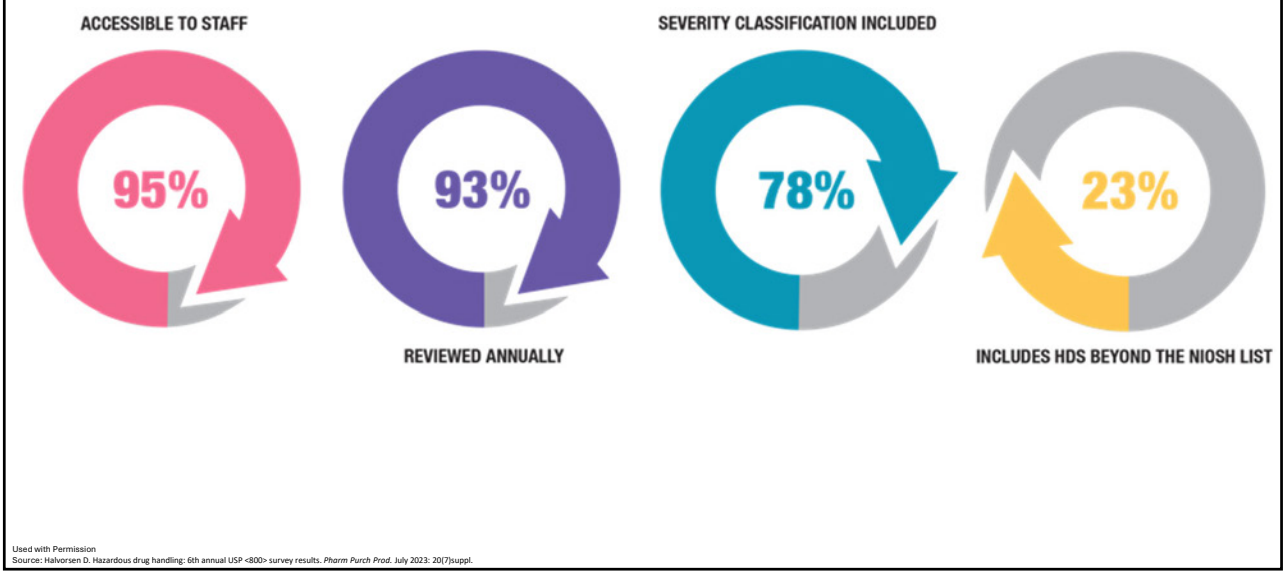
Hazardous Drug List Compliance Points



Used with Permission
Source: Halvorsen D. Hazardous drug handling: 6th annual USP <800> survey results. *Pharm Purch Prod.* July 2023: 20(7)suppl.

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Hazardous Drug Safety Training

1. All personnel who handle Hazardous Drugs **must** be trained
2. **Must** be assessed every 12 months
3. **Must** be trained on new Hazardous Drugs
4. Non-Sterile: USP <795> competencies & frequencies
5. Sterile: USP <797> competencies & frequencies
6. Entity's list of Hazardous Drugs and risks
7. SOPs related to the handling of Hazardous Drugs
8. Use of personal protective equipment
9. Use of equipment and devices (eg, CSTDs)
10. Response to Hazardous Drug exposure
11. Spill management
12. Disposal of Hazardous Drug materials

Picture Credit: Fred Massoomi

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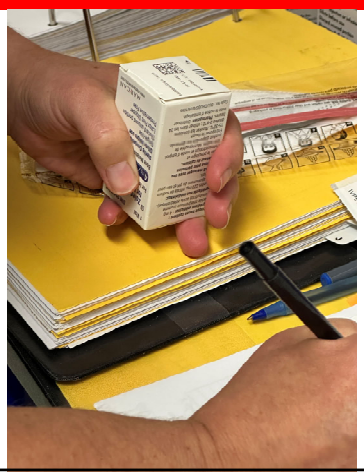
Primary Source of Exposure

Warning

NEVER handle vials or packaging with bare hands



Picture Credit: Fred Massoomi

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Hazardous Risk Acknowledgement

Hazardous Drug (HD) Acknowledgement of Reproductive Risk

I, _____, understand that working with or near hazardous drugs (HDs) in ophthalmic procedures may cause health issues such as rashes, infertility, miscarriage, birth defects, and possibly leukemia or other cancers.

I understand that the accidental exposure to some of these drugs might additionally cause irritation or damage to eyes, skin or other exposed body parts.

I understand that the facility maintains policies and procedures on proper storage, handling, transport and disposal of HDs in order to minimize my exposure to these drugs. I understand that these policies and procedures with be reviewed and revised as needed and reviewed at least annually.

I have been provided with training prior to working with hazardous drugs and have passed a written test verifying my knowledge of key information regarding them. I understand that a review of HD information and competency evaluation will occur at least every 12 months.

_____ _____
Employee Signature Date

Source: Fred Massoomi

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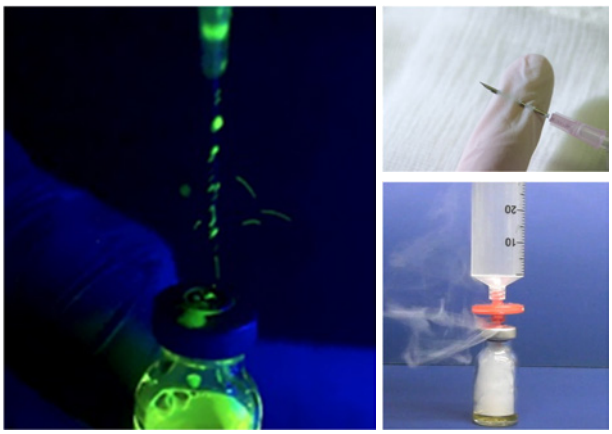
Routes of Exposure

Routes of unintentional entry

- Dermal
- Mucosal absorption
- Inhalation
- Injection
- Ingestion??



Picture Credit: Fred Massoomi

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Hazardous Drug Safety Training Competency

– Hand Hygiene Fluorescein

– Technique and handling
– Nursing certification program

– Free videos and training
– Aseptic technique and handling

43

Virtual Hazardous Drug Safety Training

Picture Credit: Fred Massoomi

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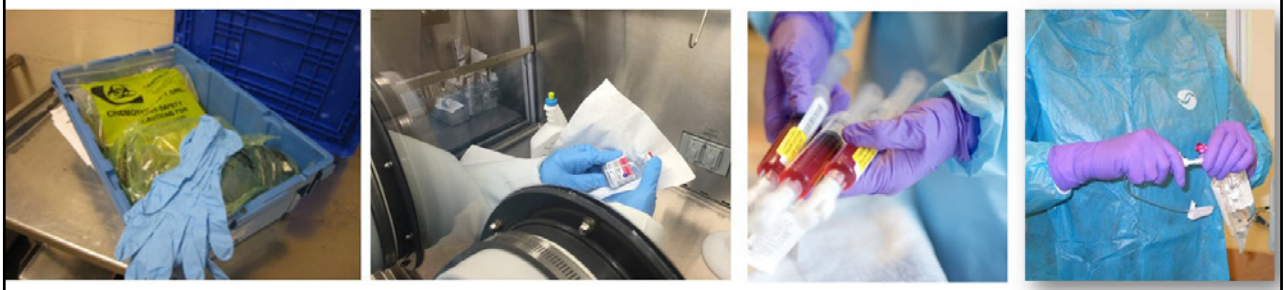
Always Handle Hazardous Drugs with Equipment

Receiving | Compounding | Delivery | Administration



Picture Credit: Fred Massoomi

Source: NIOSH [2023]. Managing hazardous drug exposures: information for healthcare settings. By Hodson L, Ovesen J, Couch J, Hirst D, Lawson C, Lentz TJ, MacKenzie B, Mead K. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 2023-130, https://doi.org/10.26616/NIOSHPUB2023130

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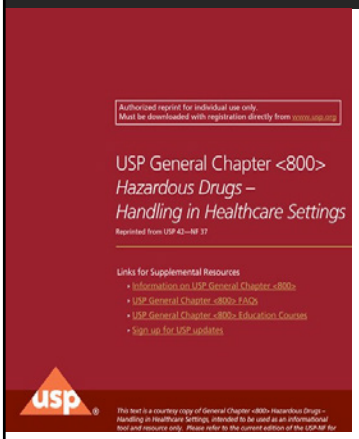
USP & NIOSH Safe Handling by Activity



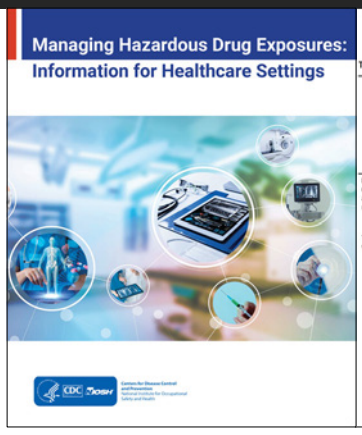


Table of Control Approaches for Safer Handling of Hazardous Drugs, by Activity and Formulation

		Control Approaches						
		Engineering Controls			Personal Protective Equipment			
Activity	Formulation	Ventilated engineering control (BSC or CACI)[1]	Closed system drug transfer device	Other	Double chemo-therapy gloves (ASTM rated)	Pro-tective gown (imper-vious, single use)	Eye, face, hair, sleeve, and shoe protection	Respiratory protection[2]
Receiving, unpacking, and placing in storage	All types of hazardous drugs	No, unless a leak is observed or suspected	NA*	NA*	No (Single pair of gloves)	No, unless a leak is observed or sus-pected	Consider protective sleeves; add addi-tional protection if a leak is observed or suspected	No, unless a leak is observed or suspected
Transportation within facility	Intact tablets or capsules, manufactur-ers' prefilled syringes	No	NA*	Transport in containers that minimize the risk of break-age or leakage; Double-bag or place in a sealed con-tainer	No (Single pair of gloves)	No	No	No
	Cut or crushed tablets or cap-sules (in con-tainers); pow-ders, liquids, or creams; in-house filled syringes	No	NA*	Transport in containers that minimize the risk of break-age or leakage; Double-bag or place in a sealed con-tainer	Yes	No	No	No

Source: NIOSH [2023]. Managing hazardous drug exposures: information for healthcare settings. By Hodson L, Ovesen J, Couch J, Hirst D, Lawson C, Lentz TJ, MacKenzie B, Mead K. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 2023-130, https://doi.org/10.26616/NIOSHPUB2023130

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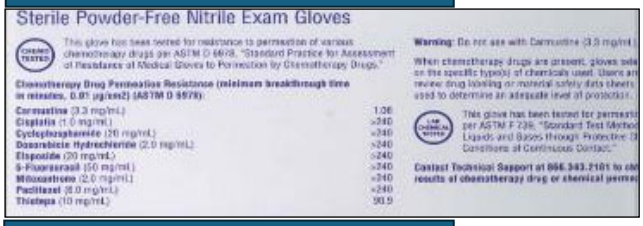
Basic Personal Protective Equipment

Head covers
Facial hair covers
Face mask or N95 mask or Respirator
Eye protection (optional)

Rated Impermeable Disposable Gowns

Gloves: x 2 pairs: **ASTM D6978**



Shoe Covers: x 2 pairs

47

Sterile Garb Components for Category 3 Hazardous Drug Personal Protective Equipment

48

Additional Personal Protective Equipment

USP <800> Section 7.5 Respiratory Protection

Keep in mind cleaning solutions refer to the SDS

N95 &
Face Sheild

Eye Protection

Respiratory
Protection

Controlled Air
Purifying
Respirator
CAPR

Powered Air
Purifying
Respirator
PAPR

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Defined Donning & Doffing Sequences

Donning

Doffing

Doffing line is not required for all negative pressure areas, but is a best practice for safety

Picture Credit: Fred Massoomi

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Safe Hazardous Drug Handling

Train on the proper handling of vials

Picture Credit: Fred Massoomi

51

Bad Garbing Practices

Missing Components

Not Using PPE Appropriately

Picture Credit: Fred Massoomi

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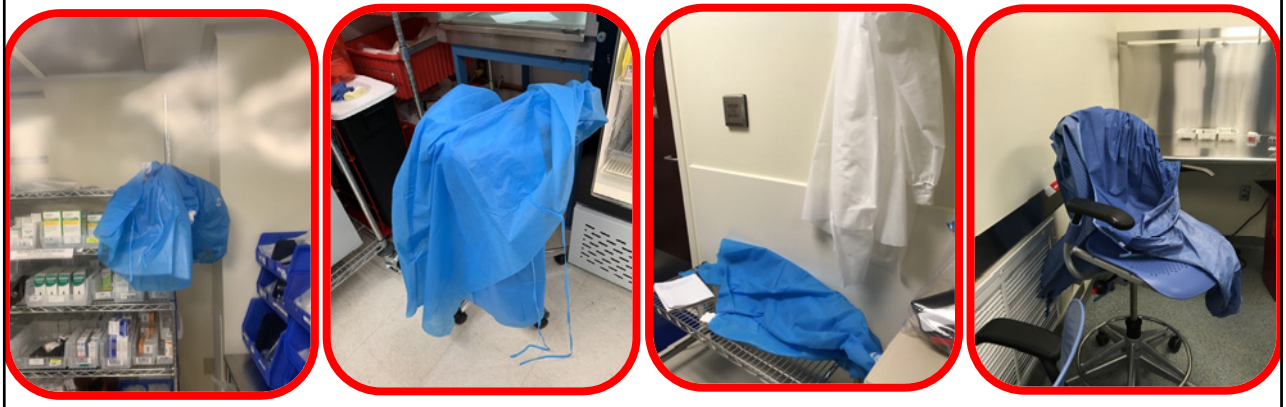
Bad Garbing Practices



Audit Point SOP on reuse of garb and PPE with allowable timeframe
Audit Point: Observe the interim storage process of reusable garb and PPE

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Must have signage in these areas

- Receiving and unpacking
- Storage
- Non-Sterile compounding
- Sterile compounding
- Drug administration
- Waste accumulation

55

Receiving Hazardous Drugs

Ideal	Not Ideal

Picture Credit: Fred Massoomi

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Receiving of Hazardous Drugs

- **Must** be unpacked in the designated area
- **Must** be neutral to negative pressure area/room
- Best practice is within a Containment Ventilated Enclosure (CVE)

Picture Credit: Fred Massoomi

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Storage of Hazardous Drugs

- **Must** store to prevent spillage/breakage
- Exhaust vent adjacent to refrigerator
- Based on the assessment of risk can be comingle with normal stock

Picture Credit: Fred Massoomi

58

Storage of Hazardous Drugs

Room Temperature

- **Antineoplastic requiring manipulation other than counting & HD active Pharmaceutical Ingredients (APIs)**
  - Separated from non-Hazardous Drugs
  - Negative pressure room
  - Externally exhausted
  - At least 12 Air Changes Per Hour (ACPH)
- **Other Hazardous Drugs**
  - Final dosage forms and packaging
  - Non-sterile HDs **should** not be stored in areas designated for sterile compounding

Refrigeration

- NIOSH Table 1 antineoplastic HDs must be stored in a dedicated (-) pressure room with 12 ACPH

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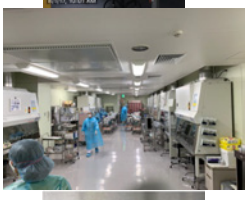
Containment Engineering Controls

Primary Engineering controls (PEC)	• **Containment** Hoods (C-PEC) • "Powder" Hoods (CVE)
Secondary Engineering Controls (SEC)	• **Containment** Rooms (C-SEC) • External Exhaust • Line of Demarcation
Supplemental Engineering Controls	• Closed System Transfer Devices (CSTDs)



Picture Credit: Fred Massoomi

60

Containment Primary Engineering Controls

Do Not use Laminar Flow Workbench

Do Not use a Compounding Aseptic Isolator (CAI) RABs unit

MUST wear PPE Garb

Sterile Compounding
Biological Safety Cabinet
Class II A2 (75% vented; 25% recirculated)
Class II B2 (100% vented)

Compounding Aseptic Containment Isolator (CACI) – RABS unit

Non-Sterile Compounding
Sterile compounding devices
Containment Ventilated

Sterile Hazardous Drug Compounding

Non-Sterile Hazardous Drug Compounding

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Containment Primary Engineering Controls

Picture Credit: Fred Massoomi

Audit Point Ceiling not sealed
Audit Point Negative pressure room brings in upper deck debris

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Robotic **Containment** Primary Engineering Controls



Audit Point Specialized Training
Audit Point Specialized Cleaning
Audit Point Maintenance and Service
Audit Point Downtime procedures

63

Robotic **Containment** Primary Engineering Controls



Audit Point Specialized Training
Audit Point Specialized Cleaning
Audit Point Maintenance and Service
Audit Point Downtime procedures

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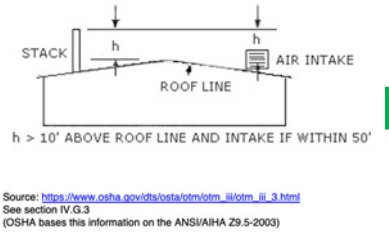
Containment Engineering Controls Exhaust



Source: https://www.osha.gov/dts/osta/otm/otm_iii/otm_iii_3.html
See section IV.G.3
(OSHA bases this information on the ANSI/AIHA Z9.5-2003)

Not to code

Audit Point Visualize the exhaust system for a 10-foot-tall stack

Picture Credit: Fred Massoomi

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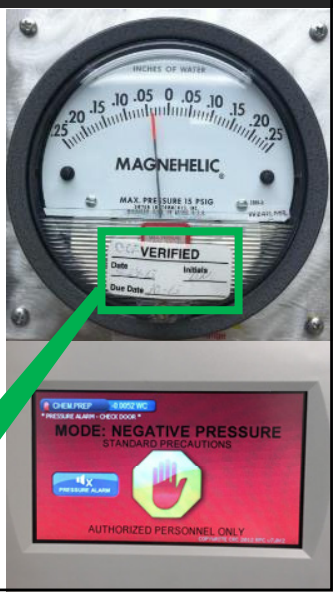
Containment Secondary Engineering Control

- Physically separated room
- Negative pressure
  - -0.01- and -0.03-inches water column
  - Continuous monitoring
- Externally exhausted
- Negative Pressure Buffer Room
  - ISO 7 Buffer Room Air Quality
  - ISO 7 Anteroom Air Quality
  - 30 ACPH
- Containment Segregated Compounding Area
  - 12 Air changes per hour

Should

- Temperature: **less** than 68ºF
- Humidity less than 60%rh



Audit Point Check devices are working
Audit Point Check for current calibration

Picture Credit: Fred Massoomi

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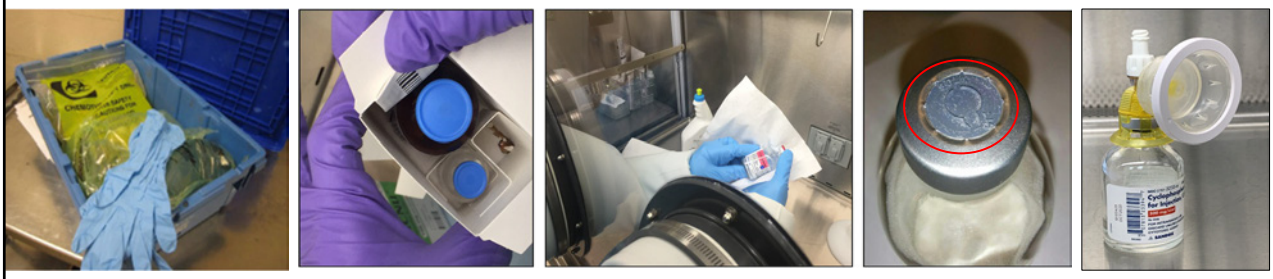
Safe Handling of Vials For Sterile Compounding
Best Practice for Compounding



Picture Credit: Fred Massoomi

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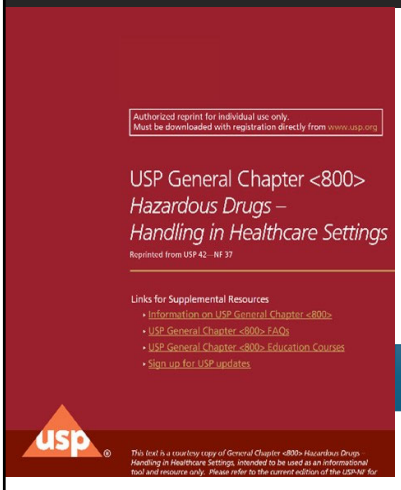
Supplemental Engineering Controls
Best Practice for Compounding



Closed System Transfer Devices (CSTD)

"A drug transfer device that mechanically prohibits the transfer of environmental contaminants into the system and the escape of Hazardous Drug or vapor outside the system."

NIOSH [2004] Alert: Preventing Occupational Exposures to Antineoplastics and Other Hazardous Drugs in Health Care Settings
NIOSH [2023]. Managing hazardous drug exposures: information for healthcare settings.

Section 5.4
Containment Supplemental Engineering Control

- CSTDs **should** be used during **compounding**
- CSTDs **must** be used during **administration**
  - Antineoplastic Hazardous Drugs
  - When the dosage form allows

Source: *https://www.usp.org/compounding*

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Picture Credit: Fred Massoomi

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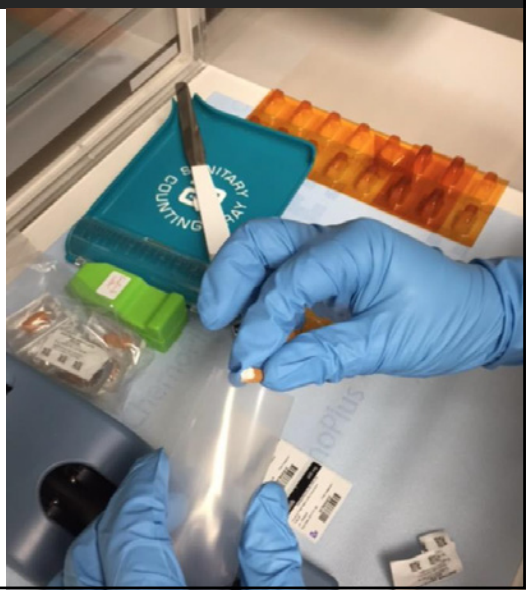
Non-Sterile Compounding

Must follow USP <795>

C-PEC required for some manipulations
- Cutting, crushing
- Containment Ventilated Enclosure
- Not required for final dosage
- Not required counting & repackaging

C-SEC
- Pressure gauge required to monitor that the C-SEC for compounding nonsterile HDs is maintained at a (-) pressure



Picture Credit: Fred Massoomi

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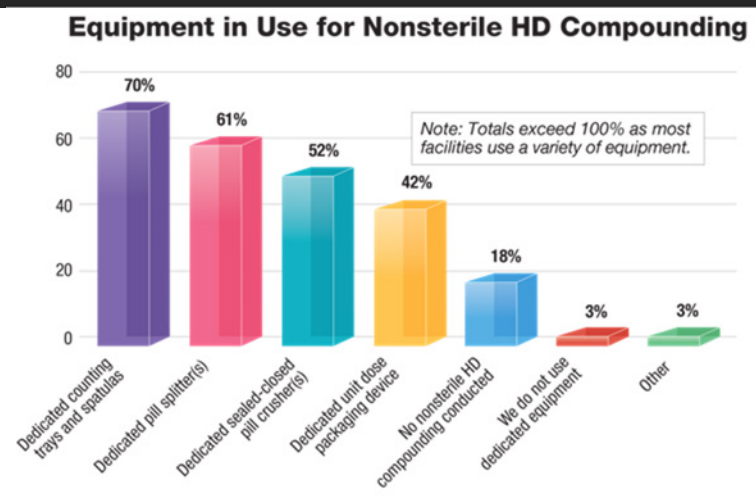
Containment of Non-Sterile Hazardous Process

71

Compounding Equipment



Used with permission: Source: USP <800> Compliance. Pharmacy Purchasing & Products 2025;7:S1-S9

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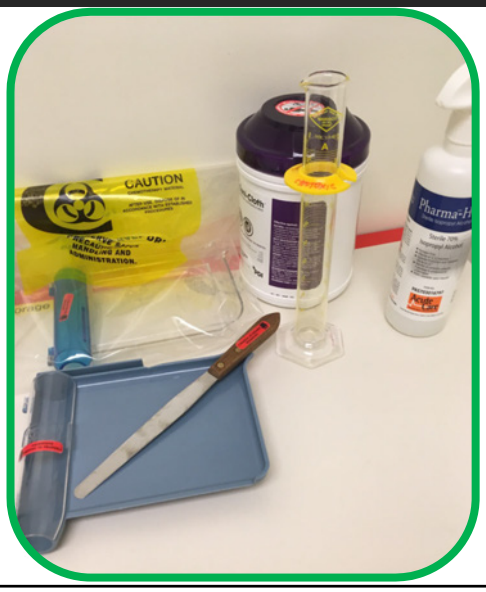
Dedicated Equipment



Picture Credit: Fred Massoomi

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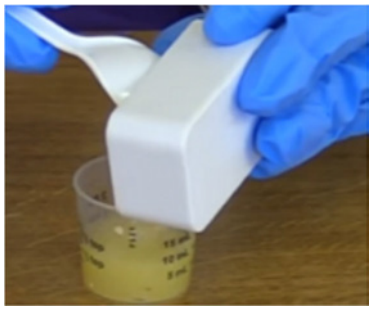
Oral Solid and Liquid Formulations



Audit Point Inquire about crushing, measuring and pouring of Hazardous Drugs for proper location
Audit Point Review required PPE for non-sterile Hazardous Drug compounding

Used with Permission: Seth Eisenberg, RN

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Non-Sterile Formulation Assessment

Audit Point Review assessment of risk for oral tablet products: specifically, methotrexate

Picture Credit: Fred Massoomi

75

Hazardous Drug Cleaning Steps

Isopropyl Alcohol is not a cleaning agent

Deactivation	Renders hazards inactive: breaks chemical bonds Example Oxidizing agents: peroxide solutions; sodium hypochlorite
Decontamination	Inactivating & neutralizing of residues from surfaces to wipes Example agents: water, alcohol, peroxide, sodium hypochlorite
Cleaning	Removal of contaminants soil; Microbes; Drug Residues Example: EPA EPA-registered germicidal detergent
Disinfecting	Disinfection ≠ Sterile Inhibiting or destroying microbes Example: 70% isopropyl alcohol

Audit Point SOP and personnel can articulate the 4-step cleaning process (note site may use 1 to 2 agents)

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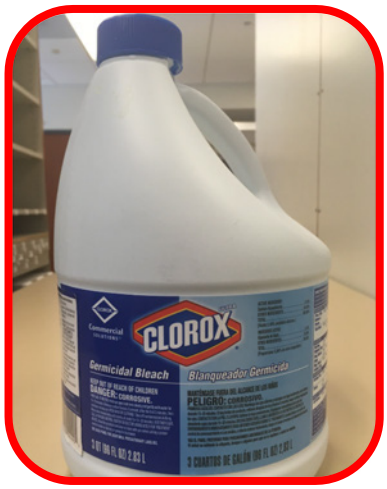
NOT Hazardous Drug Cleaning Solutions



Picture Credit: Fred Massoomi

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Cleaning The C-PEC

- Disinfecting & Cleaning of C-PEC With Sterile Supplies & Solutions
  - All interior surfaces at beginning and end of shifts
  - Horizontal work surface end of shift
  - Horizontal surface at least every 30 minutes or less
  - Spills or suspected contamination
- Sporicidal of C-PEC With Sterile Supplies & Sporicidal Solutions
  - Category 1 and Category 2: Monthly
  - **IF** Category 3: Weekly

USP <797>

- *"Work surface of the C-PEC must be decontaminated between compounding of different Hazardous Drugs."*
- *"C-PEC must be decontaminated at least daily."*
- *"C-PECs under work tray cleaned at least monthly"*

USP <800>

Audit Point Site has a cleaning plan that meets USP requirements
Audit Point Site follows cleaning plan, review of cleaning logs

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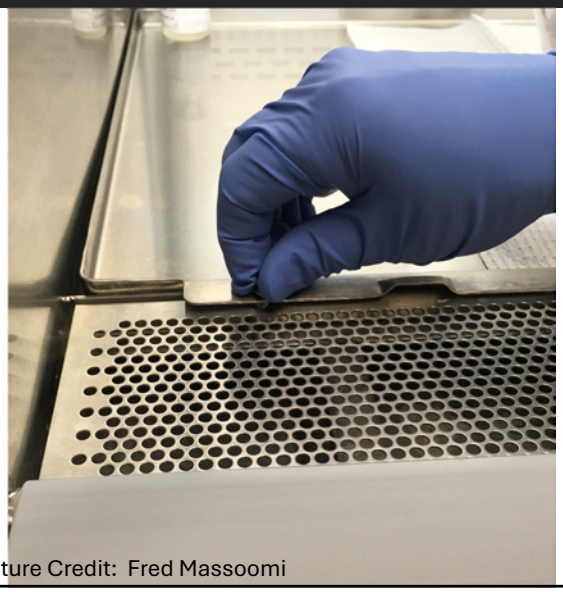
Cleaning the C-PEC



Picture Credit: Fred Massoomi

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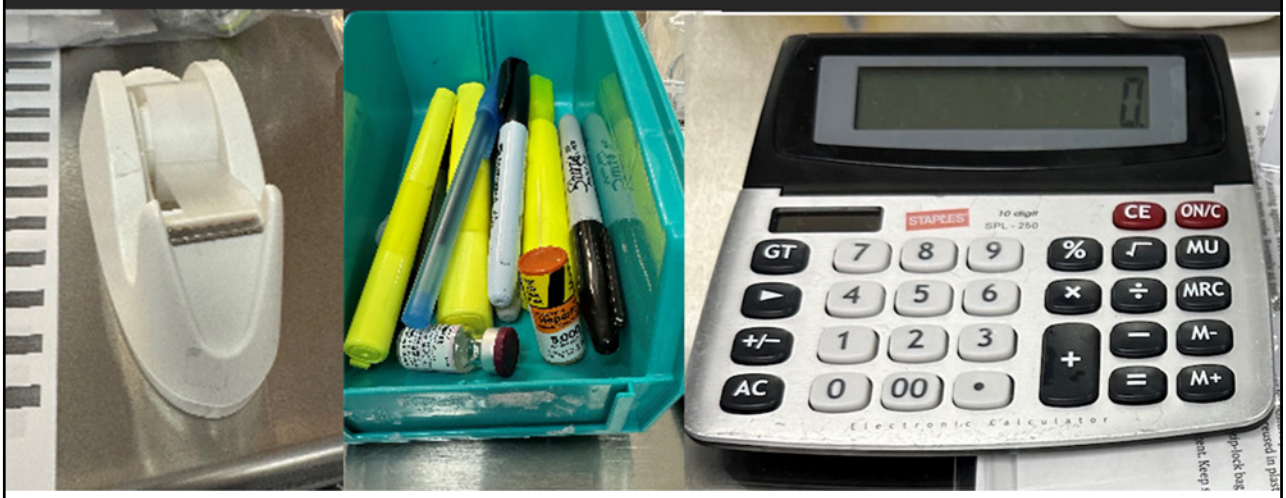
Cleanable?



Picture Credit: Fred Massoomi

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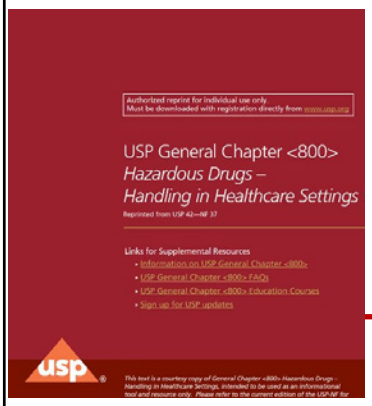
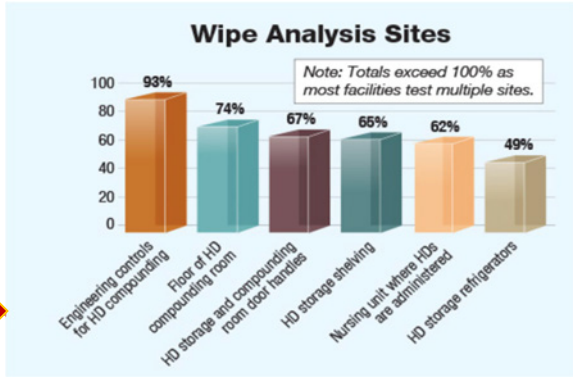
Wipe Analysis for Hazardous Drug Residues
Best Practice

Frequency **Recommendation** 'Routinely' = **Baseline** and then **every 6 months**





Audit Point This is a USP recommendation not required
Audit Point If site collects, review past data and discuss how it is used

Used with Permission
Source: Halvorsen D. Hazardous drug handling: 6th annual USP <800> survey results. *Pharm Purch Prod.* July 2023: 20(7)suppl.

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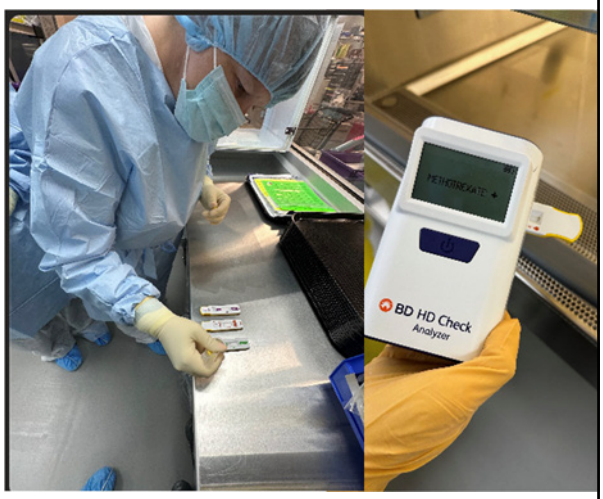
Surface Wipe Sample Tests
Best Practice

Quantitative: How Much Is There?

Qualitative: Is There Anything There?



Picture Credit: Fred Massoomi

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Surface Wipe Sample Tests
Best Practice

Top 10 most touched in the patient room

1. Patient (850 touches)
2. Computer on wheels / Medication carts (634)
3. Bedrail (375)
4. IV pump (326)
5. Bed surface (302)
6. Tray table (223)
7. Vitals machine (213)
8. Wall shelf (110)
9. Door (90)
10. In-room computer (78)

- Who cleans portable equipment?
- How is it cleaned?

Picture Credit: Fred Massoomi

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Safe Transport & Delivery of Hazardous Drugs

Audit Point No pneumatic tube delivery of liquid Hazardous Drugs
Audit Point Delivery process from pharmacy to customer: required training and PPE
Audit Point Shipping process to customers outside of the organization

Picture Credit: Fred Massoomi

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Proper Labeling

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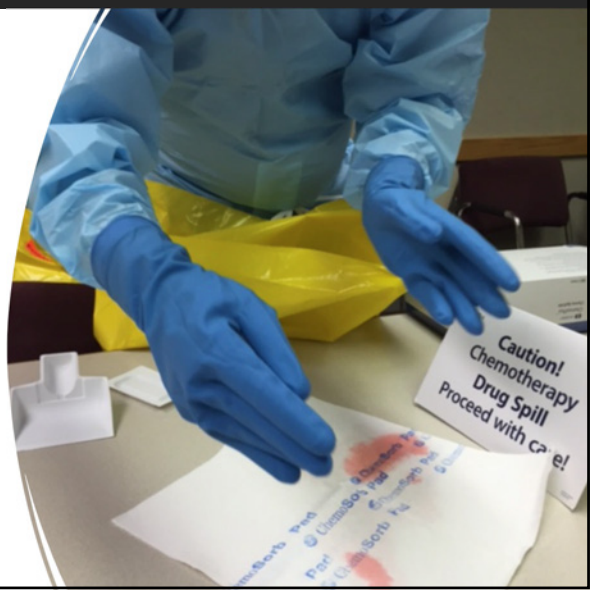
Hazardous Drug Spill Management

- **Considerations**
- Training program for Hazardous Drug spills?
- Are spill kits available?
- Do staff know where the kits are located?
- What if a spill occurs in a public area?
- Are volumes of spills addressed?



Picture Credit: Fred Massoomi

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Hazardous Drug Waste Management

Review State and Federal Environmental Regulations

*"This chapter describes practice and quality standards for handling hazardous drugs (HDs) to promote patient safety, worker safety, and **environmental protection.**"*



Brechtelsbauer E, Shah S. Update on Pharmaceutical Waste Disposal Regulations: Strategies for Success Am J Health-Syst Pharm 2020:77(7):574-82

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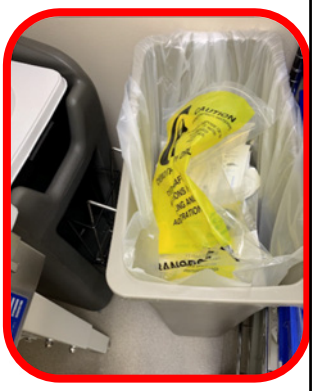
Improper Waste Management

Trace HD Waste Overflowing

RCRA Waste Overflowing

HD PPE in Biohazardous waste



HD Transfer bag in normal trash

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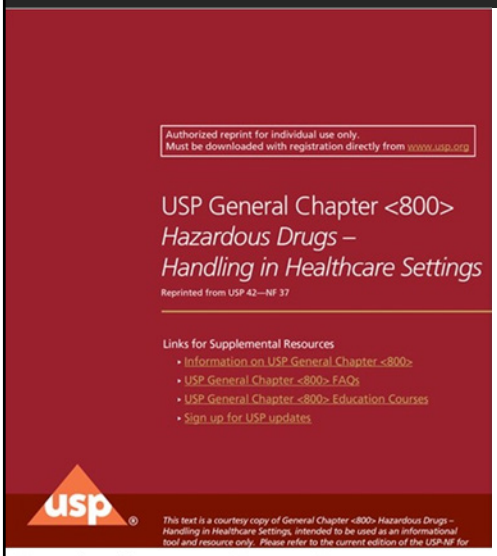
Medical Surveillance
Best Practice



"Medical surveillance is part of a comprehensive exposure control program **complementing** engineering controls, safe work processes, and use of PPE."

"Healthcare workers who handle HDs as a regular part of their job assignment **should** be enrolled in a medical surveillance program."

Source: https://www.usp.org/compounding

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Medical Surveillance
Best Practice

- Baseline HR; Risk; Employee Health
- **Tier-One** Self Surveillance
  - Education by employer of hazards
- **Tier-Two** Employer/Supervisor Surveillance
  - Annual reproductive questionnaire
  - Trending of sick calls
- **Tier-Three** Comprehensive Medical
  - Hire and annually
  - CBC, urinanalysis, LFT's
  - Urine drug testing
- **Tier-Four** Post-exposure Surveillance
  - Notation in medical record with date and drug

Source: *NIOSH:bcdc.gov/niosh/docs/wp-solutions/2013-103/pdfs/2013-103.pdf*

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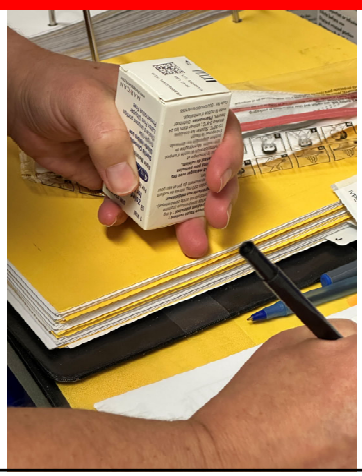
Primary Source of Exposure

Warning

NEVER handle vials or packaging with bare hands



Picture Credit: Fred Massoomi

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Key References For Emerging Hazards

- 2004 CDC NIOSH Alert: Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings: *https://www.cdc.gov/niosh/docs/2004-165/pdfs/2004-165.pdf*
- USP <800> Hazardous Drugs: Handling in Healthcare Facilities
- NIOSH List of Hazardous Drugs in Healthcare Settings, 2024 *https://www.cdc.gov/niosh/docs/2025-103/pdfs/2025-103.pdf?id=10.26616/NIOSHPUB2025103*
- McKnight HE, Kienle P. Updating the HD Assessment of Risk 2025 Pharmacy Purchasing & Products October 2025 Supplement
- Blind JE, et al. A call to action: Health-system pharmacists must stand up to meet the growing demand for cellular-based therapies. Am J Health-syst Pharm. 2023;80(14):944-947
- McLeod EN, et. al. A practical approach to assess the hazardous exposure potential of investigational drugs. Am J Health-syst Pharm. 2020;77:697-700
- NIOSH Workplace Solutions: Medical surveillance for healthcare workers exposed to hazardous drugs: *bcdc.gov/niosh/docs/wp-solutions/2013-103/pdfs/2013-103.pdf*

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Self Assessment Question

Which of the following characteristics would not solely designate a drug as hazardous to health care workers who handle it?

A. Carcinogenic
B. Teratogenic
C. Oncolytic
D. Genotoxic

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Self Assessment Question

Gloves used for handling Hazardous Drugs must have this essential element:

A. Nitrile
B. Tested to ISO9001 Standards
C. Tested to ASTM D6978 Standards
D. Tested to USP <800> Standards

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Self Assessment Question

Safe Hazardous Drug handling standards are inspected by which agencies?

A. Department of Labor: OSHA
B. Centers for Disease Control: NIOSH
C. State Boards of Health: Pharmacy
D. Food and Drug Administration

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Q&A

You may use the Q&A tool on your screen to submit questions to the presenter.

Our host will read the questions out loud in the order they are received.

NABP

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Submit Your CPE Claim

1. Claim your CPE credit by signing in to NABP's submission site: ***https://nabp.pharmacy/claimcpe*** (case-sensitive)
   If you do not have a login for NABP's CPE submission site, you will need to create an account.
2. Click on the "Live CPE" tab
3. Select the webinar from the Live Meetings and Conferences list
4. Enter the session code provided at the end of the webinar
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The handout for today's presentation can be found at:
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