

Hazardous Drug Control Program



Hazardous Drug Control Program

Nursing Caregiver

Learning Objectives

1. Identify hazardous drugs on formulary
2. Identify appropriate personal protective equipment (PPE) and its function to safely handle hazardous drugs.
3. Identify safe work practices to receive, store, transport, compound, prepare, administer and dispose of hazardous drugs.
4. Know the proper procedure for safely decontaminating and cleaning a hazardous drug spill.
5. Know how to access the PSJH Hazardous Drug Control Program policy and the Hazardous Drug Assessment of Risk and Handling Instruction references.

Hazardous Drug Definition

What makes a drug "Hazardous"?

Any drug identified by at least one of the following six criteria:

- Carcinogenicity → *Can cause cancer*
- Teratogenicity or developmental toxicity → *May cause birth defects*
- Reproductive toxicity in humans → *May be expressed as decreases in fertility, or fetal loss during pregnancy*
- Organ toxicity at low doses in humans or animals (*e.g., liver damage, local necrosis of exposed tissue*)
- Genotoxicity → *Cause damage to or mutation of DNA*
- New drugs that mimic existing hazardous drugs in structure or toxicity

Hazardous drugs can:

Hazardous drugs can:

- Cause cancer
- Cause birth defects
- Decrease fertility
- Cause damage to organs
- All of the above

Exposure Routes

Hazardous drugs can enter and affect your body in any of these ways:

Dermal Absorption

- Some hazardous drugs may be absorbed through intact skin.



Ingestion

- Hazardous drugs can be accidentally ingested from contaminated surfaces, including hands.



Inhalation

- Hazardous drugs can be aerosolized in a powder or mist that may be inhaled. Some hazardous drugs are volatile if not sealed in intact containers and can generate a toxic vapor.



Injection

- Exposure to hazardous drug can occur from an accidental needle stick or puncture with sharp object.



Exposure Prevention

By preventing exposure from all four routes, you can work with hazardous drugs SAFELY.

Prevent Dermal Absorption

- Clean potentially contaminated surfaces (vials, countertops)
- Use safe practices for handling contaminated body fluids, clothing, dressings, linens
- Wear gloves designed for hazardous drug protection



Prevent Ingestion

- Wash hands with soap and water
- Clean work surfaces properly to avoid spreading contamination



Prevent Inhalation

- Compound hazardous drugs in ventilated cabinets (Pharmacy BSC)
- Use closed system transfer devices for compounding & administering HD as instructed
- Use self-contained pill-crushing devices
- Wear a respirator when working with hazardous drugs outside of containment (ex, spill clean-up)



Prevent Injection

- Use needleless IV systems, like Luer-lock connections
- Use safety needles and dispose promptly in sharps containers



1.1 What are the mechanism(s) that caregivers can be exposed to hazardous drugs?

What are the mechanism(s) that caregivers can be exposed to hazardous drugs? (Select all that apply)

- Dermal
- Inhalation
- Ingestion
- Injection

NIOSH Classification of Hazardous Drugs

Group 1 Antineoplastic

- A cytotoxic medication that is used for treating cancer, but may be used for non-oncologic conditions.

Group 2 Non-Antineoplastic

- 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).

Group 3 Reproductive Risk

- Non-antineoplastic drugs that primarily have adverse reproductive effects and may be present in breast milk.

Group 1, 2 & 3: Unopened, intact tablets and capsules may NOT pose the same degree of occupational exposure risk as injectable drugs. Cutting, crushing, or otherwise manipulating tablets and capsules will increase the risk of exposure to workers.

Examples of Hazardous Drugs

Group 1
Antineoplastic



Box of Capecitabine Tablets USP



Click on the

Group 2
Non-Antineoplastic

Group 3
Reproductive Risk Only

Examples of Hazardous Drugs

Group 1
Antineoplastic

Group 2
Non-Antineoplastic

Group 3
Reproductive Risk Only



Click on the
buttons to
learn more!

Examples of Hazardous Drugs

Group 1
Antineoplastic

Group 2
Non-Antineoplastic

Group 3
Reproductive Risk Only



Which of the following are considered hazardous based on NIOSH criteria? (Select all that apply)

Azathioprine

Capecitabine

Oxytocin

Valganciclovir

Warfarin

Principles of Exposure Prevention



The U.S. National Institute for Occupational Safety and Health (NIOSH) describes the following exposure controls:

- **Engineering or environmental controls, such as:**
 - **Closed-system drug transfer devices [CSTDs] in pharmacy & nursing**
 - **Ventilated biological safety cabinets [BSCs] in pharmacy**
- **Administrative or work practice controls, such as:**
 - **Labeling hazardous drugs and storing them separately**
 - **Cleaning/decontaminating work surfaces**
 - **Proper waste disposal**
- **Use of personal protective equipment (PPE), such as:**
 - **Gloves, gowns, respirators, booties.**

The USP 800 chapter becomes official on December 1, 2019. Regulatory agencies encourage utilization of 800 in the interest of advancing public health.

How Do I Know What Drugs are Hazardous?

Your ministry may use one of the methods to alert that the drug is "hazardous"

Medication label banner or auxiliary label



Epic will identify each HD in eMAR

ganciclovir (CYTOVENE) 90 mg in sodium chloride 0.9% 100 mL IVPB : Dose 1.25 mg/kg = 71.2 kg :



Admin Instructions:
Hazardous: Use appropriate handling precautions.
Product Instructions:
Hazardous agent: Use appropriate precautions for handling and disposal.

Ordered Admin Amount:	90 mg
Frequency:	ONCE
Route:	Intravenous
Order Dose:	1.25 mg/kg = 71.2 kg
Ordered Infusion Rate:	101.5 mL/hr
Infused Over:	60 Minutes

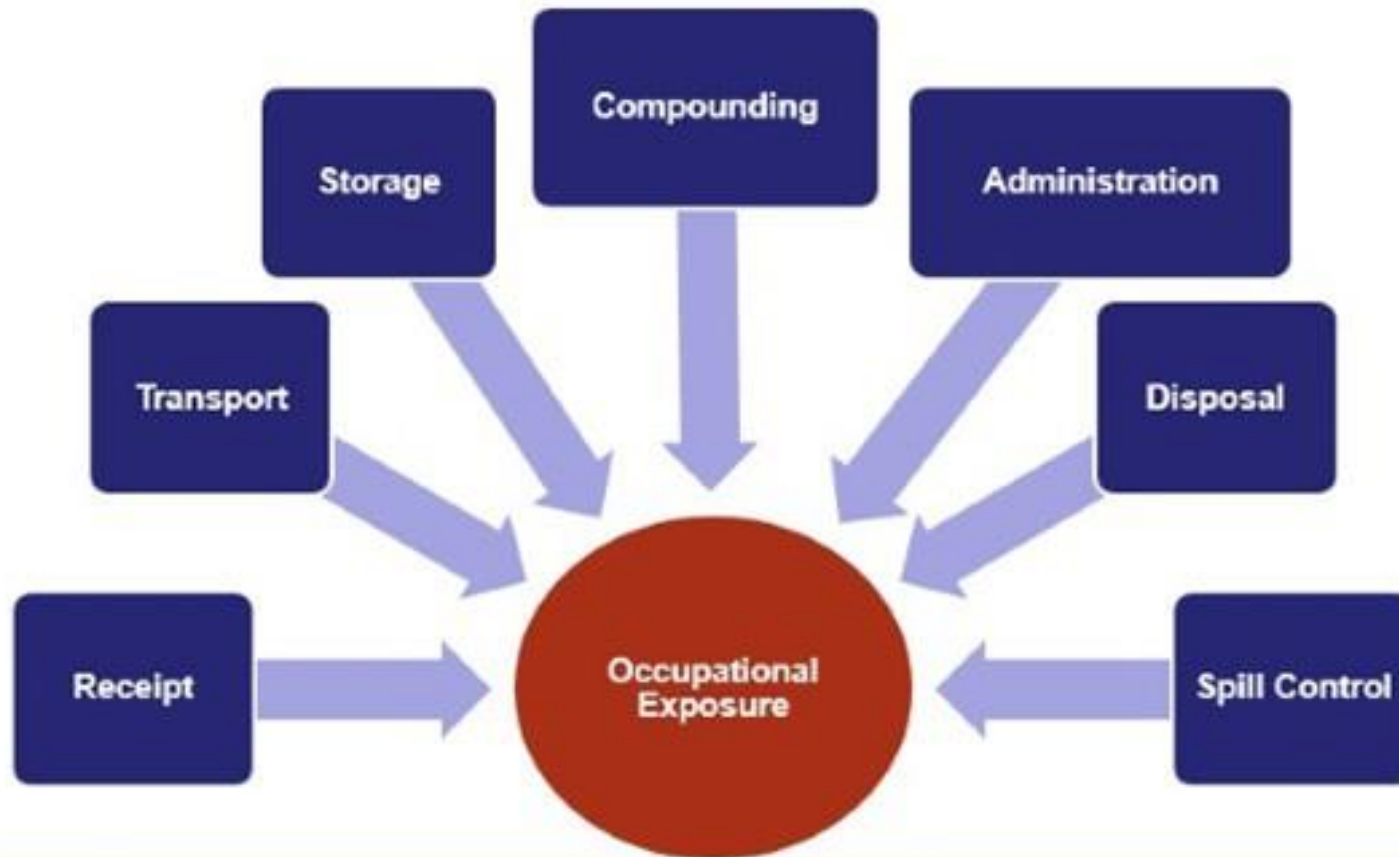


For non-EPIC ministries, refer to external link, auxiliary label or reference list at local facilities.

How will you determine whether the medication you are about to administer to your patient is hazardous?

- Medication label
- eMAR instructions
- Look up facility on-line reference (Micromedix, Lexicorp) or package insert
- All are correct

There is potential for exposure to hazardous drug throughout its lifecycle:



The following slides describe how to prevent exposure at every step, from all potential exposure routes

Use of Personal Protective Equipment (PPE)

Gloves

- Must meet American Society for Testing and Materials (ASTM) standard D6978 or Chemo-Tested and powder-free (See glove package labeling).
- Gloves are required for receiving, packaging, preparation & compounding, administering, cleaning and disposal of HD.
- Hands must be washed with soap and water after removing gloves.

REMINDER: Caregiver MUST perform hand-hygiene with soap and water AFTER removing PPE & gloves.

NOTE: Hand sanitizer is designed to kill pathogens. Soap and water remove chemicals, including hazardous drugs, from your skin.

A nursing caregiver is going to don gloves to administer a dose of Dilantin suspension. Which type of gloves is appropriate for this hazardous drug?

- Any exam gloves
- Gloves that are powder-free and chemo-tested that meet American Society for Testing and Materials standard ASTM D6978
- Must be labeled as "chemotherapy" gloves
- Must be sterile gloves

Use of PPE

Gown

- Disposable gowns made of polyethylene-coated polypropylene to resist permeability by HDs. Do NOT re-use gown.
- Gowns must close in the back (i.e., no open front), be long sleeved, and have closed cuffs that are elastic or knit.
- Gowns worn in HD handling areas must not be worn to other areas in order to avoid spreading HD contamination



Use of PPE

Eye and Face Protection (goggles, face shield)

- When there is a potential for splashing of liquid, spit up/vomit.
- When compounding/preparation not done in a ventilated control device.



Source: CriticalPoint, LLC. Used with permission.



Head & Shoe Covers

- Required for HD compounding and during spill clean-up to contain HD residue to specific area.
- A second pair of shoe covers must be donned before entering the pharmacy HD Buffer room and doffed when exiting the HD Buffer Room.



Use of PPE

Respiratory Protection

N-95 respirator* or PAPR with particulate filter is required for:

- Cutting, crushing tablet or open capsule outside ventilated cabinet or powder containment hood.



Use of PPE

Respiratory Protection

PAPR with organic vapor filter is required for:

- Attending to hazardous drug spills
- Deactivating, decontaminating, and cleaning underneath the work surface of a ventilated engineering control in pharmacy
- Example of organic vapor filter respirator: **MaxAir CAPR with N-OV filter cartridge 2166-10.**



When managing a spill of HD OUTSIDE ventilated cabinet, caregivers should wear a PAPR with organic vapor filter.

*Caregivers wearing N-95 respirators must be fit tested and trained. Contact Caregiver Health.

PPE Quick Reference by Activity & HD Type

PSJH PPE Guide for Handling HD



Personal Protective Equipment Guide						
Work Group	Type of Hazardous Drug & Activity	Gloves	Gown	Face & Eye Shield	Mask/ Respirator	Hair & Shoe Covers
	Group 1 Antineoplastic					
Pharmacy	Receiving/Unpacking Undamaged or Opened Intact Tablet/Capsule	1 pair				
Pharmacy	Receiving/Unpacking Damaged Liquid, Injectable *Treat as HD spill	2 pairs	Yes	Yes	Respirator PAPR/CAPR with organic vapor cartridges	Yes
Pharmacy	Transport in sealed impervious, leak-proof container or bag and the HD container is decontaminated (with Perox or other oxidizing agents)	Not required				
Pharmacy	Packaging Intact dosage forms (e.g., tablets, capsules, prefilled syringes, etc.)	1 pair				
Pharmacy	Cutting, crushing or otherwise manipulating tablets or capsules • MUST be in ventilated engineering in Pharmacy only	2 pairs	Yes		Surgical mask	Yes
Pharmacy	Compounding non-sterile oral liquids, suppositories, topical preparations • MUST be in ventilated engineering in Pharmacy only	2 pairs	Yes		Surgical mask	Yes
Pharmacy	Compounding Sterile IV, SC, IM, IT, IP, injectable preparations in Pharmacy only • MUST be prepared in BSC or CACI • Use CSTD as dosage form allows Cleaning of the clean room in pharmacy and BSC	2 pairs sterile 2 pair sterile	Yes Yes		Surgical mask N-95 when cleaning under work tray	Yes *Double shoe covers in HD clean room
Nursing	Administration • Intact dosage forms – Do NOT Cut or Crush (e.g., tablets, capsules) • Oral liquid, suspension • IV, SC, IM, IT, IP, injectable **Use CSTD when dosage form allows	1 pair 2 pairs 2 pairs	 Yes Yes	 if splash potential if splash potential		
Nursing, CNA, EVS	Handling bodily fluids, blood specimen or contaminated linens within 48 hours of administration time	2 pairs	Yes	if splash potential		
Pharmacy, Nursing, EVS	Spill Management (per Ministry Policy)	2 pairs	Yes	Yes	Respirator PAPR/CAPR with organic vapor cartridges	Yes

Gloves = Chemo-Tested or ASTM D6978 rated gloves, Gown = Disposable, made of polyethylene-coated polypropylene or other laminate materials

Receiving & Transporting

RECEIVE

TRANSPORT

Click on the
buttons above
to learn more!

TRANSPORT

- Must be sealed in impervious plastic bags or leak-proof containers with a warning label, at a minimum as "Hazardous Drug" during transporting.
- **When the outer packaging is removed, gloves must be worn.**
 - Gloves are not required if the transport container or outer packaging is clean and intact.
- Pneumatic tubes must not be used to transport any liquid HDs or any antineoplastic HDs.
- Only trained personnel can transport HD.

Preparing Hazardous Drugs – Nursing

Follow instructions for PPE in [PSJH Hazardous Drug Assessment of Risk and Handling Instruction](#)

If a patient cannot swallow a HD tablet/capsule and the hazardous drug needs to be split, opened or crushed

- Follow instructions for PPE in the link above or eMAR or check with pharmacy before manipulation.

If crushing a hazardous drug tablet is permitted per handling instructions → Use a self-contained, pill-crushing device with plastic sleeve to contain any dust or particles generated.



Preparing Hazardous Drugs – Nursing

Follow instructions for PPE in [PSJH Hazardous Drug Assessment of Risk and Handling Instruction](#)

Wear gloves to remove tablet from the package. Wear gloves, gown, and N-95 mask or PAPR to crush and also when pouring crushed medication into medicine cup.

- Attach drug package barcode to take to patient room for bedside scan.

Preparation surface must be decontaminated and cleaned after each use.



1.2 Match the exposure control with the activity below:

Administering Hazardous Drugs

Appropriate **PPE** must be worn when administering specific dosage form of HDs, i.e. intact tablet vs. liquid vs. injection formulations

- Follow instruction for PPE in [PSJH Hazardous Drug Assessment of Risk and Handling Instruction](#).

Closed System Transfer Devices (CSTD*) must be used for administration of antineoplastic HDs and high-risk group 2 & 3 HDs when the dosage form allows, including all injection routes.

- Reduce risk of leaking by
 - Double-checking the connections
 - Double-checking the luer lock connections

**Closed-system drug-transfer device (CSTD): A drug-transfer device that mechanically prohibits the transfer of environmental contaminants into the system and the escape of HD or vapor concentrations outside the system.*

Match the exposure control with the activity below:

Administering IV push of an antineoplastic/chemotherapy drug

Use face shield (if potential for splash)

Administering intact Hazardous Drug in tablet form

Wear gloves when opening package and providing tablet to patient

When patient is unable to swallow a tablet or capsule of a hazardous drug

Ask for different formulation (e.g. liquid)

Caring for Patients Receiving Hazardous Drugs

(Antineoplastic and High-risk group 2 & 3 HDs)

Follow your ministry policy for handling patient's excreta & linen

Required PPE

- Wear two pairs of gloves and gown when handling excreta from patients who have received antineoplastic and high-risk group 2 & 3 HDs in the last 48 hours.
- Wear face and eye protection if splashing is possible (e.g. urine, stool, or sweat).
- PPE should be discarded after each use or immediately when knowingly contaminated. Hands should be washed with soap and water after removal of gloves.

Caring for Patients Receiving Hazardous Drugs

(Antineoplastic and High-risk group 2 & 3 HDs)

Follow your ministry policy for handling patient's excreta & linen

Linen Handling

Environmental services staff, including housekeepers and laundry personnel follow ministry procedures, at the minimum including the PPE requirements below:

- Double bag linen materials (for patients receiving Antineoplastic and high-risk group 2 & 3 HDs in last 48 hours).
- Wear double gloves when working in patient care area.
- Wear double gloves and gowns while handling pre-washed material.

Appropriate PPE to wear when handling linen from a patient receiving an antineoplastic/chemotherapy hazardous drug:

- No gloves are needed
- Wear a single pair of gloves
- Wear double gloves
- Do not touch the linens even with gloves on

Deactivating, Decontaminating & Cleaning HD

Step 1: Deactivation, decontamination

(Render compound inert, remove HD residue)

Use approved oxidizers (e.g. Peroxide formulations)

Step 2: Cleaning

(Remove organic/inorganic materials)

Use approved germicidal detergents or wipes with appropriate wet/dwell time

For sterile compounding: Follow pharmacy procedure (Decontamination, Clean, Disinfect)

Appropriate PPE:

- Must be resistant to the cleaning agents
- Two pairs of gloves, impermeable disposable gowns, eye protection and face shields if splashing is likely and respiratory protection must be used, if warranted.

All disposable materials must be discarded per EPA regulations and ministry policies.

To avoid cross-contamination and to protect personnel:

- ✓ Use dedicated equipment for hazardous cleanup
- ✓ Dispose cleaning materials in trace HD waste (yellow bin)

After a preparation of a hazardous drug, the work surface must be decontaminated by which solution below?

- Isopropyl alcohol
- Oxidizer
- Germicidal detergent
- Surfactant


Disposal of Hazardous Drug Waste

Dispose in containers that comply with the Pharmaceutical Waste Policy and EPA RCRA (Resource Conservation and Recovery Act) regulations and ministry pharmaceutical waste policy → See disposal instructions in [PSJH Hazardous Drug Assessment of Risk and Handling Instruction](#).

Pharmaceutical Waste (Blue Bin):

Trace Antineoplastic Waste (Yellow Bin):

Bulk/RCRA Waste (Black Bin):



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buttons to
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Continue to follow your ministry policy for disposal of other NON-HD per EPA/RCRA regulations

Immediate Treatment After Direct Skin or Eye Contact with Hazardous Drugs

1. Call for help, if needed.
2. Immediately remove contaminated clothing.
3. Flood affected eye with water or isotonic eyewash for at least 15 minutes.
4. Clean affected skin with soap and water; rinse thoroughly.
5. Obtain medical attention.
6. Contact Caregiver Health to document exposure.



NOTE: Supplies for emergency treatment (e.g., soap, eyewash, sterile saline for irrigation) should be immediately located in any area where hazardous drugs are compounded or administered.

Spill Clean-Up Procedure

Only trained personnel can handle the Hazardous Drug Spill
Follow your ministry policy & procedure

Hazardous Drug Spills
(inside a ventilated biosafety cabinet)

Hazardous Drug Spills
(all areas outside the ventilated biosafety cabinet)

MUST perform hand-hygiene with soap
and water AFTER removing PPE & gloves

Click on the
buttons to
learn more!

ned/sealed
ncluding:
ons

- Bodily fluids from patients that have received antineoplastic and high-risk group 2 & 3 HD within 48 hours.

How do I prepare for a spill?

- Have a spill kit available at all times
- Know what is in your chemo/HD Spill Kit
- Know your ministry procedure



CAUTION: An N-95 mask, normally stocked in a spill kit, is NOT a sufficient protection during a spill of ANTINEOPLASTIC hazardous drugs that may vaporize at room temperature. Use a NIOSH-approved PAPR. **Do NOT use the N-95 mask for HD spill clean up; use a NIOSH-approved PAPR.**

Spill Clean-Up Procedure

Only trained personnel can handle the Hazardous Drug Spill

****Follow your ministry policy & procedure****

Hazardous Drug Spills
(inside a ventilated biosafety cabinet)

Hazardous Drug Spills
(all areas outside the ventilated biosafety cabinet)

MUST perform hand-hygiene with soap and water **AFTER** removing PPE & gloves

Hazardous Drug Spills
(**inside** a ventilated biosafety cabinet)

1. Utilize chemo/hazardous drug spill kits, don appropriate PPE and follow pharmacy procedures.
2. Thoroughly clean and decontaminate the biosafety cabinet.
3. Dispose of spill contents into the black hazardous waste bin.

Spill Clean-Up Procedure

Only trained personnel can handle the Hazardous Drug Spill

****Follow your ministry policy & procedure****

Hazardous Drug Spills
(inside a ventilated biosafety cabinet)

Hazardous Drug Spills
(all areas outside the ventilated biosafety cabinet)

MUST perform hand-hygiene with soap and water **AFTER** removing PPE & gloves

Hazardous Drug Spills (outside a ventilated biosafety cabinet)

1. **Immediately evacuate patients and personnel from the room.**
2. Assess & treat the exposure (e.g. skin) of any individuals involved and isolate them from the spill.
3. Don PPE, including a PAPR/CAPR with organic vapor filters.
4. Post signs/barriers to limit access to spill area (signs can be found within a chemo/HD spill kit).
5. Notify your Supervisor or on-site person in-charge.
6. Notify the Safety Officer and House (Nurse) Supervisor.
7. Carefully contain and clean up spill area.
8. Dispose of contents in black hazardous waste bin

NOTE: Activate emergency response per ministry policy and for large spill that cannot be handled by one spill kit.

How should you respond when there has been a hazardous medication spill? (Place the following in order)

1. Evacuate patients and activate emergency response
2. Don PPE including PAPR/CAPR
3. Clean up spill per ministry procedure
4. Properly dispose spill materials

While preparing the infusion for a Cisplatin dose, the oncology nurse noticed the leakage from the IV bag. She quickly called for help to relocate the patient and posted a sign to alert the spill. As she gathered spill supplies in the unit, she had both N-95 mask and a MaxAir CAPR. Which of the following choice provides safe protection during spill cleaning?

- PAPR/CAPR with organic vapor filter
- N-95 mask
- She can keep the surgical mask that she already donned.

Resources for Hazardous Drug Control

- PSJH policy (link)
- HD Assessment of Risk: [PSJH Hazardous Drug Assessment of Risk and Handling Instruction](#)
- PPE Guide: [PSJH PPE Guide for Handling HD](#)
- Safety Data Sheets (SDS) <https://app.maxcomsc.com/maxcomsc/maxcom.jsp>



- Product package insert
- [USP 800 Hazardous Drugs – Handling in Healthcare Settings](#), PF 40(3) [September 2017]

Regulatory Agencies and Best Practice Advisory Groups



Environmental Protection Agency (EPA) Resource Conservation and Recovery Act (RCRA) requires that hazardous waste, including pharmaceuticals and chemotherapy, be managed by following a strict set of regulatory requirements designed to protect human health and the environment.



Occupational Safety and Health Administration (OSHA) published guidelines for safe handling of antineoplastic drugs in 1986, after research revealed adverse health effects to healthcare workers. Guidelines were revised and updated in 1995 and 1999 after research continued to demonstrate occupational exposure and risk to healthcare workers. Guidelines apply to all healthcare settings where employees are occupationally exposed to HD, including hospitals, physician offices, home healthcare agencies, pharmaceutical manufacturers and veterinary clinics.



Oncology Nursing Society (ONS) publishes guidelines based on ASHP, OSHA and NIOSH recommendations and provides complete guidelines for administration and safe handling of antineoplastic and biotherapy medications. ONS also conducts continuing education courses addressing safe handling of chemotherapeutic drugs.



National Institute for Occupational Safety and Health (NIOSH) provides evidence that measurable levels of HD residue on numerous workplace surfaces continues to be common and widespread in the work place. NIOSH's 2004 Alert presented standard precautions for handling hazardous drugs safely. NIOSH classifies HD into three risk groups. The list of antineoplastic and other hazardous drugs in healthcare settings is updated regularly.



U.S. Pharmacopoeia (USP) sets standards for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements manufactured, distributed and consumed worldwide. USP's drug standards are enforceable in the United States by the Food and Drug Administration, and these standards are used in more than 140 countries.

Hazardous drug stored in dispensing cabinets (Pyxis) is flagged with a hazardous alert

View/Modify Responses.

List

Name

Hazardous Medication - ACKNOWLEDGE PRECAUTIONS TO PROCEED

Save

Responses

**I understand to don the required PPE & NO cutting/crushing

The image shows a screenshot of a software interface titled "View/Modify Responses.". It features a "List" section with a "Name" field containing the text "Hazardous Medication - ACKNOWLEDGE PRECAUTIONS TO PROCEED". To the right of this field is a "Save" button. Below the list is a "Responses" section with a single response: "**I understand to don the required PPE & NO cutting/crushing".

2. Waste bins

Pharmaceutical Waste (Blue Bin):

Non-antineoplastic, non RCRA



Trace Antineoplastic Waste (Yellow Bin):

PPE, Cleaning wipes, empty or $\leq 3\%$ remaining antineoplastic HD (IVPB/tubing), CSTD



Bulk/RCRA Waste (Black Bin):

Spill materials, > 3% remaining antineoplastic HD
(no sharps in black bins)



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