

STANDARD OPERATING PROCEDURE OVERVIEW	
<b>SOP TITLE:</b>	USP 800: Hazardous Drug (HazD) Spill Management in Pharmacy
<b>ISSUANCE DATE:</b>	December 1, 2019
<b>REVISION DATE:</b>	DECEMBER 10, 2021
<b>PROCESS OWNER:</b>	System Pharmacy Operations
<b>SOP NUMBER:</b>	OHS.PHARM.SOP.051

**BACKGROUND:**

The purpose of this SOP is to define the activities necessary for spill management of a hazardous drug (HazD) within the department of pharmacy.

**NOTES (ASSUMPTIONS, EXCEPTIONS, ETC.):**

- Safety Data Sheets (SDS) for all NIOSH HazDs are available on the Ochweb by clicking on Resources, then Safety Data Sheets.
- Spills must be contained and cleaned immediately.
- Laminate spill cleanup instruction sheet and keep with spill kit.
- Documented observational competency in spill management must be completed at hire and annually thereafter.
- All sites that handle HazDs should perform at least one HazD spill drill annually.

USP 800 SOPs:

- OHS.PHARM.SOP.038 – USP 800: Hazardous Drug (HazD) Receiving
- OHS.PHARM.SOP.050 – USP 800: Garbing for Hazardous Drug (HazD) Compounding and Manipulation
- OHS.PHARM.SOP.051 – USP 800: Hazardous Drug (HazD) Spill Management in Pharmacy
- OHS.PHARM.SOP.052 – USP 800: Hazardous Drug (HazD) Waste Management in Pharmacy
- OHS.PHARM.SOP.053 – USP 800: Hazardous Drug (HazD) Formulary Review and Assessment of Risk
- OHS.PHARM.SOP.054 – USP 800: Hazardous Drug (HazD) Transport
- OHS.PHARM.SOP.055 – USP 800: Hazardous Drug (HazD) Storage
- OHS.PHARM.SOP.056 – USP 800: Hazardous Drug (HazD) Compounding, Manipulation, and Dispensing
- OHS.PHARM.SOP.057 – USP 800: Hazardous Drug (HazD) Surface Wipe Analysis in Pharmacy
- OHS.PHARM.SOP.058 – USP 800: Designated Person
- OHS.PHARM.SOP.059 – USP 800: Supply List
- OHS.PHARM.SOP.060 – USP 800: Hazardous Drug (HazD) Crushing and Splitting
- OHS.PHARM.SOP.061 – USP 800: 3M Rugged Comfort-Quick Latch Half Facepiece Reusable Respirator 6500 QL Series
- OHS.PHARM.SOP.062 – USP 800: 3M Particulate Respirator R95
- OHS.PHARM.SOP.063 – USP 800: 3M Versaflo TR-600 Series Powered Air Purifying Respirators (PAPR)
- OHS.PHARM.SOP.014 – USP 795/797/800: Labeling of Compounded Sterile and Nonsterile Preparations
- OHS.PHARM.SOP.114 – USP 800: Cleaning and Disinfecting in the Hazardous Drug (HazD) Compounding Area
- OHS.PHARM.SOP.115 – USP 800: OnGuard™ Closed Medication System with TEVADAPTOR®

PROCESS STEP:	DESCRIPTION:
<p>1. SPILL KIT &amp; SUPPLIES</p>	<p>Store two <u>Chemo Spill Kits</u> <i>plus</i> <u>additional supplies</u></p> <p>Each Chemo Spill Kit contains:</p> <ul style="list-style-type: none"> <li>• gloves</li> <li>• caution sign</li> <li>• pair goggle</li> <li>• yellow hazardous waste disposal bags and ties</li> <li>• pair shoe covers</li> <li>• gown</li> <li>• scoop with detachable scraper</li> <li>• N95 mask</li> <li>• absorbent pads (gel forming pads)</li> <li>• absorbent towels</li> </ul> <p>Additional supplies:</p> <ul style="list-style-type: none"> <li>• ASTM D6978 gloves various sizes</li> <li>• HazD (chemo) gowns various sizes</li> <li>• Shoe covers</li> <li>• Yellow (trace) RCRA waste container</li> <li>• 1 pack low-linting wipes</li> <li>• 70% isopropyl alcohol</li> <li>• Peridox RTU®</li> <li>• 3M™ Rugged Comfort-Quick Latch Half Facepiece with P100 filters</li> <li>• 3M™ Full-Face-Piece Respirator with P100 Filter</li> <li>• Powered air-purifying respirator (PAPR)</li> <li>• Bottle of Sterile Water.</li> </ul>
<p>2. PRE-CLEANUP SPILL ASSESSMENT</p>	<ul style="list-style-type: none"> <li>• If personnel have come into contact HazD, locate the SDS sheet for the HazD agent and seek immediate first aid per SDS. Employee Health must be contacted.</li> <li>• If SDS suggests a risk to vapor or spill involves powder, wear one of options below: <ul style="list-style-type: none"> <li>○ Goggles with 3M™ Rugged Comfort-Quick Latch Half Facepiece with P100 Filter (refer to USP 800: 3M™ Rugged Comfort-Quick Latch Half Facepiece Reusable Respirator 6500 QL Series – Handling Chemotherapy and HazDs ).</li> <li>○ The 3M™ Full-Face-Piece Respirator with P100 Filter</li> <li>○ Powered air-purifying respirator (PAPR)</li> </ul> </li> <li>• Isolate spill and restrict access to the area by posting the caution sign.</li> <li>• Assess the size and scope of spill and any danger to people in the vicinity.</li> <li>• Assess clothing contamination. Contaminated clothing or shoes must be removed. Items must be discarded or decontaminated before leaving the facility.</li> </ul>
<p>3. SPILL CLEANUP WITHIN CONTAINMENT PRIMARY ENGINEERING CONTROL (C-PEC)</p>	<p><i>Note: Any personnel in Negative Buffer Room must be appropriately garbed. (refer to OHS.PHARM.SOP.050 – USP 800: Garbing for Hazardous Drug (HazD) Compounding and Manipulation)</i></p> <ul style="list-style-type: none"> <li>• C-PEC should remain on during spill cleanup unless the HEPA filter is affected by the spill. If the HEPA filter of a C-PEC is affected by the spill, the device must be turned off and placed out of service until the filter can be changed.</li> <li>• If the C-PEC must be turned off, don safety goggles and a 3M™ Rugged Comfort-Quick Latch Half Facepiece with P100 Filter (refer to USP 800: 3M™ Rugged Comfort-Quick</li> </ul>

Latch Half Facepiece Reusable Respirator 6500 QL Series – Handling Chemotherapy and HazDs).

**For pills less than 30 mL:**

- If the spill is a solid, wet absorbent towels with sterile water and place on top of the spill.
- Place sterile absorbent wipe over the spill.
- Wipe any spill residual and discard the saturated wipe in a black RCRA waste container.
- Doff outer glove and discard in a yellow trace RCRA waste container
- Prior to donning second pair of gloves, sanitize gloved hands by applying sIPA, rub gloved hands together, and allow to dry. Then sanitized outer glove prior to re-entering the PEC.
  
- Clean the deck and any other affected area in the C-PEC by wiping with Peridox<sup>®</sup>RTU, followed by a second wipe with Peridox<sup>®</sup>RTU and allow to dwell for 3 minutes, then wipe with Sterile 70% Isopropyl Alcohol (sIPA).
- Discard all pads, sponges, and wipes in yellow trace RCRA waste containers.
- Doff contaminated outer glove inside of the C-PEC and place into a receptacle or resealable clear plastic bag with yellow HazD label or sticker located inside of the C-PEC.
- Don a new pair of sterile ASTM D6978 gloves prior to further compounding. (refer to: OHS.PHARM.SOP.050 – USP 800: Garbing for Hazardous Drug (HazD) Compounding and Manipulation)

**For spill greater than 30 mL:**

- Notify pharmacy leadership for assistance. Pharmacy leadership will determine if additional resources are necessary to contain and clean the spill.
- Take all contents out of spill kit and place on a work surface.
- Don safety goggles.
- Replace mask with a 3M<sup>™</sup> Rugged Comfort-Quick Latch Half Facepiece with P100 Filter (refer to USP 800: 3M<sup>™</sup> Rugged Comfort-Quick Latch Half Facepiece Reusable Respirator 6500 QL Series – Handling Chemotherapy and HazDs)
- If the spill is a solid, wet sterile absorbent towels with sterile water and place on top of the spill.
- Place absorbent pads over the spill.
- The pads will absorb the liquid and transform it into a gel to assist in disposal.
- Detach scoop from scraper and use both to pick up the formed gel. Spill cleanup should proceed progressively from areas of lesser to greater contamination. Completely remove and place all contaminated gel, towels and, materials in yellow hazardous waste disposal bags.
- When finished using scoop, place the scoop in yellow hazardous waste disposal bag.
- Clean the deck and other areas in the C-PEC, affected by the spill, by wiping with Peridox<sup>®</sup>RTU, followed by a second wipe with Peridox<sup>®</sup>RTU and allow to dwell for 3 minutes, then wipe with Sterile 70% Isopropyl Alcohol (sIPA).
- Discard cleaning towels in a yellow hazardous waste disposal bag.
- Doff contaminated outer glove inside of the C-PEC and place into a receptacle or resealable clear plastic bag with yellow HazD label or sticker located inside of the C-PEC.
- Seal yellow hazardous waste disposal bags using tie wrap.
- Discard sealed yellow hazardous waste disposal bags in black RCRA waste container.
- Don a new pair of sterile ASTM D6978 gloves. (refer to: OHS.PHARM.SOP.050 – USP 800: Garbing for Hazardous Drug (HazD) Compounding and Manipulation)

	<ul style="list-style-type: none"> <li>• Perform a monthly cleaning of the C-PEC. (refer to OHS.PHARM.SOP.114 USP 800 - Cleaning and Disinfecting of the Hazardous Drug (HazD) Compounding Area as per monthly cleaning)</li> <li>• Doff contaminated PPE in a yellow trace RCRA waste container prior to exiting the negative pressure room. (refer to USP 800: Garbing for Hazardous Drug (HazD) Compounding and Manipulation)</li> <li>• Wash hands with soap and water.</li> </ul>
<p>4. SPILL CLEANUP OUTSIDE OF THE C- PEC</p>	<p><i>Note: Any personnel in Negative Buffer Room must be appropriately garbed. (refer to OHS.PHARM.SOP.050 – USP 800: Garbing for Hazardous Drug (HazD) Compounding and Manipulation)</i></p> <p><b>For spills less than 30 mL:</b></p> <ul style="list-style-type: none"> <li>• If spill is located outside of the Negative Buffer Room, take all contents out of the spill kit and don Poly-coated gown, two pairs ASTM D6978 gloves, goggles, and shoe covers.</li> <li>• Don an N95, or 3M™ Rugged Comfort-Quick Latch Half Facepiece with P100 filter (for powder or vapor risk)</li> <li>• Place absorbent wipe over the spill.</li> <li>• If the spill is a solid, wet absorbent towels with sterile water and place on top of the spill.</li> <li>• Wipe any residual and discard the saturated wipe in yellow hazardous waste disposal bag.</li> <li>• Clean affected area by wiping with Peridox®RTU, followed by a second wipe with Peridox®RTU and allow to dwell for 3 minutes, then wipe with SIPA.</li> <li>• Discard the wipes in yellow hazardous waste disposal bag.</li> <li>• Doff contaminated outer glove and place into yellow hazardous waste disposal bag. Remove all other PPE using inner gloves and place contaminated PPE in yellow HazD disposal waste bag.</li> <li>• Seal yellow hazardous waste disposal bags using tie wrap.</li> <li>• Discard sealed yellow hazardous waste disposal bags in black RCRA waste container.</li> <li>• Remove inner gloves and place in yellow trace RCRA waste container.</li> <li>• Wash hands with soap and water.</li> </ul> <p><b>If spill is greater than 30 mL:</b></p> <ul style="list-style-type: none"> <li>• Notify pharmacy leadership for assistance. Pharmacy leader will evaluate for presence of any of the following conditions and notify the Hospital Safety Officer and Administration if any exist:             <ul style="list-style-type: none"> <li>○ Immediate danger to life and health (IDLH)</li> <li>○ Combustible or explosive hazard</li> <li>○ Threat of environment</li> <li>○ Exceeds one gallon</li> <li>○ Unable to identify chemical or cleaning process</li> </ul> </li> <li>• Facilities Department should be notified regarding any spill that cannot be contained with two spill kits.</li> <li>• Remove any unnecessary personnel from the area.</li> <li>• Take all contents out of the spill kit.</li> <li>• If spill is within the Negative Buffer Room, don safety goggles, and an N95, or a 3M™ Rugged Comfort-Quick Latch Half Facepiece with P100 filters (for powder or vapor risk). If spill is located outside of the Negative Buffer Room, don Poly-coated gown, two pairs ASTM D6978 gloves, goggles, shoe covers.</li> </ul>

**5. POST-SPILL CLEANUP**

- Don an N95, or 3M™ Rugged Comfort-Quick Latch Half Facepiece with P100 Filter (for powder or vapor risk)
  - Place caution sign in area to alert personnel.
  - If the spill is a solid, wet absorbent towels with sterile water and place on top of the spill.
  - If the spill is a liquid, lay absorbent pads over the spill.
  - The pads will absorb the liquid and transform it into a gel to assist in disposal.
  - Caution: The gel is extremely slippery when wet. Avoid skin and eye contact.
  - Detach scoop from scraper and use both to pick up the formed gel. Spill cleanup should proceed progressively from areas of lesser to greater contamination. Completely remove and place all contaminated gel, towels and, materials in yellow hazardous waste disposal bags.
  - If there is any broken glass, use scoop to place it in a hard-sided yellow trace RCRA waste container (sharps approved).
  - When finished using scoop, place the scoop in yellow hazardous waste disposal bag.
  - Once the visible spill has been removed, clean the area by wiping with Peridox®RTU, the followed by a second wipe with Peridox®RTU and allow to dwell for 3 minutes, then wipe with SIPA.
  - Discard cleaning towels in a yellow hazardous waste disposal bag.
  - Doff outer gloves and discard in yellow hazardous waste disposal bag. Remove all other PPE using inner gloves and place contaminated PPE in yellow HazD disposal waste bag.
  - Seal yellow hazardous waste disposal bags using tie wrap.
  - Discard sealed bag in black bulk chemo RCRA waste container.
  - Remove inner gloves and place in yellow trace RCRA waste container.
  - Wash hands with soap and water.
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- Employee cleaning the spill must:
    - Report spill to pharmacy leader
    - Report the spill in the Safety on Site (SOS) system within 24 hours.
    - Order/replace spill kit(s) and restock additional supplies used during spill cleanup.

Approval

*Deborah Simonson, VP Pharmacy*

*1-19-2022*

Deborah Simonson, VP Pharmacy

Date

Reviewer	Date of Review	Notes
DOP System Policy Committee	11/11/21	Approved
DOP	12/10/21	Approved