

Managing Hazardous Drugs with One KP Vision

Announcements

Hazardous Drug Spill Response (Updated) Guidelines

Please share the following announcement from the National Hazardous Drug Workgroup (NHDW) with your pharmacy, nursing, EH&S, EVS, WPS and other appropriate partners who handle hazardous drugs.

In collaboration with pharmacy, nursing and safety, the *Hazardous Drug Spill Response Guidelines* have been updated (previous guidelines issued December 2013) to clarify the following:

1. Spill response categories, trigger thresholds, response protocol and respiratory protection.
2. Management of spills inside and outside of hoods.
3. Spill kit supplies and training.
4. Inclusion of hyper-links embedded throughout the document to access additional resources (e.g., click these links to be directed to additional resources).

Operational Impact

Although most locations have existing spill response programs, this is a good opportunity to review local spill response policies and programs and update as appropriate. The NHDW recommends the following action:

1. Work in collaborate with the local Environmental, Health & Safety (EH&S) Department.
2. Identify departments and staff that handle hazardous drugs.
3. Ensure departments have appropriate spill kits and/or supplies readily accessible.
4. Train staff on use of spill kits and incidental spill response

Additional information can be found on the [National HD Workgroup SharePoint Site](#) such as:

- Overview hazardous drug evaluation methodology.
- Access completed drug evaluations for newly approved FDA drugs.
- Request new drug evaluations.
- Obtain reference materials (e.g., guidelines, communications, etc.).

Please feel free to contact us for any questions.

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Hazardous Drug Spill Response Guidelines

1. What is a Hazardous Drug?

The National Institute for Occupational Safety and Health (NIOSH) considers a drug hazardous when it exhibits the ability to cause health effects such as cancer, fertility problems, birth defects, organ toxicity, and genetic damage.

All drugs listed on the [NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2016](#) are considered hazardous. New drugs entering the market are evaluated against the NIOSH hazardous drug criteria and can be found on the [National Hazardous Drug Workgroup SharePoint Site](#). Requests to evaluate drugs can also be submitted through the SharePoint Site.

Additional Resources

Ctrl + Click on embedded hyper-links throughout the document to access additional resources.

2. Categories of Spills

Spills of hazardous drugs involve volatile and non-volatile agents and can occur within or outside of a Biological Safety Cabinet (BSC)/Closed Aseptic Containment Isolator (CACI). These spills are categorized into two different groups: Incidental and Emergency Response (Table 1: Spill Response Categories) and entail different levels of respiratory protection and response protocol (Table 2: High Level Overview Respiratory Protection and Spill Response Protocol).

Types of Volatile Agents

Volatile^{1,2,3,4} agents include the following hazardous drugs:

1. carmustine (BiCNU)
2. cyclophosphamide (Cytoxan, Neosar)
3. fluorouracil (5-FU)
4. ifosfamide (Ifex)
5. nitrogen mustard (Mustargen)

Agents not listed are considered non-volatile.

¹ Connor TH, Shults M, Fraser MP (2000). [Determination of the vaporization of solutions of mutagenic antineoplastic agents at 23 °C and 37 °C using a desiccator technique](#). Mutat Res.,470:85-92.

² Kiffmeyer TH, Kube C, Opiolka S, Schmidt KG, Schöppe G, Vokswirt D, Sessink PJM (2002). [Vapour pressures, evaporation behavior and airborne concentrations of hazardous drugs: implications for occupational safety](#). The Pharmaceutical Journal, 268:331-337.

³ U.S. Department of Health and Human Services, National Institutes of Health, Pub Chem, [Open Chemistry database](#)

⁴ Kaiser Permanente SBAR: Volatile Hazardous Drugs dated December 01, 2016

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Table 1: Spill Response Categories

Type of Spill <u>Outside of</u> BSC/CACI	Incidental Response	Emergency Response
Volatile: Undiluted liquid or Reconstituted powder	Less than (<) 5 mL	Greater than or equal to (\geq) 5 mL
Volatile: Diluted liquid	Less than (<) 1 Liter	Greater than or equal to (\geq) 1 Liter
Non-volatile: Undiluted liquid or Reconstituted powder	Less than (<) 1 Liter	Greater than or equal to (\geq) 1 Liter
Non-volatile: Diluted liquid	Less than (<) 1 Liter	Greater than or equal to (\geq) 1 Liter
Powder in solid form	Any amount	N/A

Table 2: High Level Overview Respiratory Protection and Spill Response Protocol

	Incidental Response	Emergency Response
Respiratory Protection	Fit-tested, surgical N95 or P100 respirator or Powered Air Purifying Respirator (PAPR) with High Efficiency Particulate Air (HEPA) filter (see Section 5, Table 3)	Full-facepiece respirator or hooded PAPR with combination HEPA filter, Organic Vapor (OV) and Acid Gas (AG) cartridges (see Section 5, Table 3)
Protocol	Trained KP staff respond using incidental spill protocol (see section 3)	Emergency Responders respond using HAZWOPER protocol (see section 4)

Manage all spills⁵ **within** a BSC/CACI without lifting the sash and/or breaking the plane of the BSC/CACI using extender arms and wipes. Upon completion of initial spill containment, don a fit-tested, surgical N95 or P100 respirator or PAPR with HEPA filter, lift the sash and/or break the plane of the BSC/CACI to decontaminate/clean/disinfect the hood per pharmacy policy.

⁵ Once the spill has been cleaned-up within the BSC/CACI, the remaining residue is in a particulate form. Residue from a volatile hazardous drug no longer emits vapors and reactivation of a volatile drug when mixed with a cleaning, disinfection or deactivation agent is unlikely due to dilution and/or inactivation of the drug. Due to the numerous air changes per hour within the BSC/CACI, staff may immediately lift the sash and/or break the plane of the BSC/CACI with a fit-tested, surgical N95 or P100 respirator or PAPR with HEPA filter to commence decontamination.

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3. Incidental Spill Response Protocol

In the event of an incidental spill, KP trained staff should:

1. Establish a wide perimeter to prevent people from tracking through the spill. Evacuation is not required. Width of perimeter will vary depending upon size of area.
2. Obtain chemotherapy spill kit (see Section 5).
3. Don personal protective equipment (PPE) identified in Section 5 in the following order: don shoe covers, inner gloves, gown with cuff over inner gloves, outer gloves and respiratory protection (e.g., fit-tested, surgical N95 or P100 respirator or PAPR with HEPA filter), goggles and face shield (only required for use with N95 or P100). Note: if spill occurs within the Pharmacy USP 797/800 space, wear additional PPE required to enter the area (e.g., double shoe covers, head and hair covers and sterile outer gloves).
4. Absorb the spill with absorbent pads.
5. Deactivate the residual drug with appropriate agent to prevent spread of surface contamination (See Section 5).
6. Clean the area with germicidal detergent and water. (Pharmacy USP 797/800 areas only: Disinfect area with sterile 70% isopropyl alcohol per pharmacy policy).
7. Doff PPE in the following order: outer gloves, face shield and goggles (if applicable), gown, shoe covers, respiratory protection (e.g., fit-tested, surgical N95 or P100 respirator or PAPR with HEPA filter) and inner gloves.
8. Contain and dispose of all materials utilized to clean spill as bulk hazardous waste (See Section 6).

4. Hazardous Waste Operations and Emergency Response (HAZWOPER) Protocol

In the event of an emergency spill follow local emergency spill response procedures outlined in the Hazardous Materials Business Management Plan (HMBP) and/or Emergency Management Plan (e.g., code designated for spills). These plans typically activate one of the two options below:

Option 1 (Preferred): Contact outside emergency responders such as the fire department or an authorized Hazardous Materials (HAZMAT) contractor (e.g., Clean Harbors or other locally contracted vendor) to conduct spill clean-up.

Details on how to contact Clean Harbors can be found on the SafetyNet: [Clean Harbors Emergency Response Standard Operating Procedure](#).

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Option 2: Notify your in-house HAZMAT emergency response team, if applicable. Very few facilities maintain HAZMAT emergency response teams due to onerous HAZWOPER requirements. **HAZMAT emergency response teams that clean-up emergency spills are required to comply with the [Hazardous Waste Operations and Emergency Response \(HAZWOPER\) Standard, 29 CFR 1910.120](#)**, which requires:

- Designated response team (minimum 6 people).
- 40 hours of initial training.
- 8 to 16 hours of annual training.
- Development of a written health and safety plan and an emergency response plan.
- Medical surveillance.
- Procurement, maintenance, and donning a full-facepiece respirator or hooded PAPR with a P100/HEPA, OV, and AG combination cartridge, in addition to other personal protective equipment.

5. Spill Kits

Ensure available spill kit contains sufficient supplies to absorb a liquid spill of at least 1 liter (about 1-2 spill kits depending upon type of spill kit and quantity of absorbent material) and appropriate PPE to protect the employee during response and clean-up. The majority of spill kits contain the **Required Items**^{6,7,8,9} listed below, however sizes and quantities vary by manufacturer. Medtronic ChemoPlus™ (formally known as Kendall and Covidien ChemoBloc™) Spill Kits are the most commonly used spill kits in Kaiser Permanente, although other spill kits are available from other manufacturers. Augment spill kits and/or ensure additional items are readily accessible per Table 3: Spill Kit Requirements.

⁶ [ASHP Guidelines on Handling Hazardous Drugs](#). Am J Health-Syst Pharm. 2006; 63:1190, Appendix H.

⁷ [NIOSH Personal Protective Equipment for Health Care Workers Who Work with Hazardous Drugs](#). DHHS (NIOSH) Publication Number 2009-105, October 2008 (Cincinnati, OH).

⁸ [NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Setting, 2016](#). DHHS (NIOSH) Publication Number 2016-161, September 2016 (Cincinnati, OH).

⁹ Occupational Safety & Health Administration (OSHA) Technical Manual, Section VI: [Chapter 2: Hazardous Drugs: Controlling Occupational Exposure to Hazardous Drugs \(2016\)](#).

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Table 3: Spill Kit Requirements

Quantity	Required Item	Medtronic ChemoPlus™ Chemo Spill Kit		
		#DP5016K (Preferred Kit)	#DP5108K	#CT4004
2 pairs	Disposable ASTM D6978-05 chemotherapy tested gloves	M and L	M	LATEX: L and XL. Replace with nitrile gloves.
1 each	Protective disposable gown (lint-free, coated, low-permeability fabric with a closed front and long sleeves with tight fitting cuffs)	XL	XXL	L
1 set	Impervious shoe covers	Included	Not in spill kit. Make available.	Included
Absorbent Material	Enough absorbent, plastic-backed sheets or spill pads, disposable toweling to absorb at least 1 Liter of a liquid spill	3 absorbent towels measuring 12"x12" 2 spill control pillows	Chemo Bio-Wipe Bag	2 ChemoSorb pads 3 spill towels
1 set	Disposable scoop and brush for collecting glass fragments	Included	Not in spill kit. Make available.	Included
1 each	Waste collection bag (typically yellow)	2 gallon and 15 gallon	15 gallon	Two, 20 gallon
1 each	Face shield and safety goggles	Safety glasses included, although they do not meet safety goggle specifications. Replace safety glasses with a separate face shield and separate safety goggles (seal to the face).		
1	Respirator	N95 respirator included (most likely not a surgical N95 respirator) in spill kits. To maintain regulatory compliance, utilize the respirator that staff were trained and fit tested to use instead of using the respirator included in the spill kit.		

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Quantity	Required Item	Medtronic ChemoPlus™ Chemo Spill Kit		
		#DP5016K (Preferred Kit)	#DP5108K	#CT4004
		<p>Per the Respiratory Protection Standard, 29 CFR 1910.134, staff must complete a medical questionnaire or medical examination to determine an employee's ability to wear a respirator and annual training.</p> <p>Incidental spill response: At a minimum, a fit tested surgical N95 respirator must be worn during incidental spill response. A respirator such as a P100 or PAPR with HEPA filter may be used, but is not required.</p> <p>Emergency spill response: A Full-facepiece respirator or hooded PAPR with combination HEPA, OV and AG combination cartridges must be worn during emergency spill response.</p> <p>The use of a hooded PAPR eliminates the need for initial and annual fit testing. However, an initial medical evaluation and annual respiratory protection training for all users is required. A single hooded PAPR unit, properly maintained with a sufficient supply of hoods, can service an entire department.</p>		
1 each	Black RCRA container (size may vary depending upon need of department)	Not in spill kit. Make readily accessible.		
1 each	Sodium hypochlorite solution and sodium thiosulfate neutralizer	<p>Not in spill kit. Make readily accessible.</p> <p>No single deactivation agent exists to deactivate all hazardous and cytotoxic drugs. The most effective deactivation agent is a sodium hypochlorite solution followed by a sodium thiosulfate¹⁰ solution. The sodium hypochlorite solution (e.g., bleach) deactivates the drug to prevent spread of surface contamination. The sodium thiosulfate neutralizes the sodium hypochlorite to</p>		

¹⁰ Lameriie, Thomas Queruau, et. al., (May 2013). [Evaluation of Decontamination Efficacy of Cleaning Solutions on Stainless Steel and Glass Surfaces Contaminated by 10 Antineoplastic Agents](#). Ann. Occup. Hyg. 57:4:456-469.

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Quantity	Required Item	Medtronic ChemoPlus™ Chemo Spill Kit		
		#DP5016K (Preferred Kit)	#DP5108K	#CT4004
		prevent further corrosion of surfaces. The pharmacy typically uses a ready-to-use, 2-step applicator kit such as Surface Safe™, etc. Another option for departments outside of pharmacy is to use bleach wipes followed with germicidal detergent and water.		

Step-by-step instructions on how to use Medtronic ChemoPlus™ spill kits can be found on the NEH&S SafetyNet: [DP5016K](#), [DP5108K](#), and [CT4004](#).

6. Disposal

All **residue/spill cleanup material** are considered **bulk hazardous waste** (manage Arsenic trioxide as P-listed waste) and should be handled per your department or facility's hazardous waste handling procedures and disposed of in a black RCRA container or a 5-gallon screw top pail with a closeable lid.

Goggles, full-facepiece and PAPR respirators may be cleaned with mild detergent and water for reuse. All other PPE (e.g., gloves, gowns, face shields, N95 or P100 respirators, shoe covers, etc.) must be discarded after each use.

Waste disposal guidelines can be found on the NEH&S SafetyNet: [Chemotherapeutic Waste Management Guidelines](#).

7. First Aid and Reporting

In the event staff are contaminated while handling a hazardous drug:

1. Remove contamination:
 - a. Eyes: Rinse eyes for 15 minutes at nearest emergency face/eye wash.
 - b. Skin: Remove contaminated clothing and clean area with soap and water.
 - c. Needle Injection: Draw back on plunger of syringe to remove drug from tissue. Remove needle and rinse area with water.
 - d. Inhalation: Move away from the source of exposure.
2. Obtain the hazardous drug's [Safety Data Sheet \(SDS\)](#).
3. Seek medical attention.
4. Report incident to the department manager and the Safety Manager at your medical center.
5. Follow local medical center protocol to document exposure.

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NEH&S Contact for Hazardous Drug Spill Response

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