SAFE HANDLING OF HAZARDOUS DRUGS

Updated 3/5/2025

CONTENTS

INTRODUCTION

PURPOSE:

This policy has been developed to promote safe work practices for all employees who prepare or administer hazardous drugs or clean up spills of these drugs. It is important to minimize occupational exposure to these drugs because of the risk of adverse health effects.

This policy was originally based on the Occupational Safety and Health Administration's Technical Manual Section on Hazardous Drugs, which has now been replaced by OSHA's Safety and Health Topics Page on Hazardous Drugs. Further information on specific drugs can be found on the Pharmacy-sponsored Micromedex web page or on the Safety Data Sheet (SDS), which can be obtained by calling the Pharmacy that supplied the drug or using the OESO SDS Resources web page.

DEFINITION:

Hazardous Drug: Defined by the American Society of Health System Pharmacists in 1990 as being a drug which displays one or more of the following characteristics: genotoxicity, carcinogenicity, teratogenicity or fertility impairment, or serious organ or other toxic manifestation at low doses in experimental animals or treated patients. The National Institute of Occupational Safety and Health (NIOSH) revised the definition in 2004 to include drugs that exhibit one or more of the following six characteristics in humans or animals: carcinogenicity, teratogenicity or other developmental toxicity, reproductive toxicity, genotoxicity, organ toxicity at low doses, or structure and toxicity profiles of new drugs that mimic existing drugs determined hazardous by the other criteria. Appendix A of this policy lists drugs that are considered hazardous by NIOSH as well as any additional drugs that have been determined to be hazardous by Duke. Additionally, all investigational drugs will be handled as hazardous drugs unless there is adequate information available about potential toxicity and exposure risks to patients and employees to exclude them.

RESPONSIBILITIES:

Departments with employees who handle hazardous drugs on a regular basis must:

- Ensure that employees follow the procedures outlined in this policy.
- Develop additional written procedures as appropriate and ensure that employees follow these procedures.
- Comply with the Hazard Communication Policy (Section V, Chapter II), as it applies to hazardous drugs. This means ensuring that hazardous drugs are labeled appropriately and that SDSs are available for all drugs in liquid, powdered, and gaseous form. (Departments

may use the OESO SDS Resources web page or contact the Pharmacy or manufacturer for SDSs for hazardous drugs.)

- Develop a plan for cleaning up spills of hazardous drugs and provide spill kits to all areas where hazardous drugs are administered. (Hazardous drug spill kits are available through Pharmacy and from Materials Management.) Whenever possible, spills of LIQUID hazardous drugs will be handled by employees in the area of the spill.

- Ensure that appropriate personal protective equipment (PPE) is available and worn by employees.

- Ensure that tasks involving hazardous drugs in powdered form are performed in a controlled area inside a chemical fume hood, biological safety cabinet (BSC, vertical flow hood), or other containment primary engineering control (C-PEC) as defined in USP 800 whenever feasible. Such tasks would include reconstitution of powders or crushing of tablets. For hazardous drugs used in the healthcare setting, these tasks will be performed in the appropriate Pharmacy.

Employees who handle hazardous drugs will:

- Comply with the procedures outlined below and with department- or site-specific procedures related to handling hazardous drugs.

- Report any exposures (skin or eye contact or inhalation of an aerosol or dust) to their supervisors and Employee Occupational Health and Wellness.

- Report spills to Pharmacy Medication Safety and, if patient or visitor exposure is involved, to Hospital Risk Management. (This step is necessary only if Pharmacy dispensed the drug and if patient treatment is involved. It does not apply to research laboratories.)

Employee Occupational Health and Wellness will provide medical care/consultation to employees who have been exposed to hazardous drugs (Reporting of Work-Related Injuries and Illnesses Policy, Section I, Chapter 3) or who have questions about Reproductive Health (Section I, Chapter 7).

The Occupational and Environmental Safety Office (OESO) will:

- Respond to spills of hazardous drugs in areas where appropriate PPE is not available.

- Respond to large spills that are beyond the capacity of employees in the vicinity of the spill.

- Respond to all releases of hazardous gases.

- Provide telephone advice/assistance to any employee who will be cleaning up any spill of hazardous drugs.

- Provide hazardous waste pick up services for spills involving the drugs regulated by the EPA.

The Pharmacy will:

- Provide access to SDSs for hazardous drugs that it distributes. These SDSs are available by calling the pharmacy that distributed the drug or by visiting the OESO SDS Resources web page.

- Provide a warning on the label of hazardous drugs that it distributes, indicating that special handling precautions are necessary.

- Ensure that hazardous drugs that will be used for patient treatment are handled in the Pharmacy during all processes involving drugs in powdered or granular form. (Such processes would include reconstitution of powders and crushing of tablets where feasible.)

Respiratory Therapy will:

- Ensure that gaseous or aerosolized hazardous drugs are safely contained during administration and will communicate necessary precautions to other healthcare providers.

PROCEDURES

HANDLING OF LIQUID HAZARDOUS DRUGS:

Equipment Needed:
Employees should wear gloves that are protective against the hazardous drug they are using.

- For chemotherapy and other hazardous drugs, employees must wear gloves tested for use with chemotherapy drugs in the appropriate size.

- Gloves are required during handling of hazardous drugs (e.g., drug preparation, initial administration, changing of IV bags, and discontinuation of chemotherapy and other hazardous drugs). If there is a potential for leaking or splashing, such as during compounding and administration, double gloves are required.

- If there is a potential for splashing, employees must also wear a cuffed gown that is resistant to permeability by hazardous drugs and a face shield and/or splash goggles. (Splash goggles are required when eye protection is needed.) The employee's department must provide these items.

Work Practices:
General:

- Employees must wash their hands before donning and after removing gloves. Gloves or clothing that become contaminated must be changed as soon as possible. Employees will be trained in proper methods to remove contaminated gloves and gowns.
- IV tubing connection sites must be taped unless they have Luer-lock fittings or equivalent.
- If IV sets are primed at the administration site, they will be primed with compatible IV fluid before the IV bag is spiked. IV containers with venting tubes should not be used. Alternately, IV sets can be primed in a C-PEC at the Pharmacy.
- Air will be expelled from syringes by the Pharmacy in their C-PEC.

Administration:

- A closed-system drug-transfer device (CSTD) will be used when the dosage form allows unless an Assessment of Risk (AoR) has been conducted and approved allowing for alternative containment strategies and/or work practices.
- If a CSTD cannot be used, a plastic-backed absorbent pad will be placed under the tubing during IV push administration to catch any leakage. Sterile gauze will be placed around any push sites for absorbing leakage.
- If syringes, IV bottles and bags, or pumps become contaminated with drug solution, they must be wiped clean with sterile gauze as soon as possible without interfering with the administration.
- Infusion sets and pumps, which should have Luer-lock or CSTD fittings, should be watched for signs of leakage during use.

Disposal:

- Used and empty bottles, syringes, IV bags, and tubing will be placed in a biohazard box (red bags).
- Bottles, syringes without needles, IV bags and tubing containing unused or partially used hazardous drugs labeled for disposal into the blue bins should be placed into Duke pharmaceutical blue bins (white container, blue lid) for proper disposal. All other hazardous drugs not labeled or listed for disposal in the pharmaceutical blue bin should be placed in an appropriate bin per the entity's guidelines for non-hazardous waste disposal.
- Contaminated gloves and other disposable PPE will be placed in a biohazard box. Protective goggles (if worn) will be cleaned with detergent and properly rinsed before reuse.
- Gloves and other disposable PPE that are not contaminated may be placed in the trash.
- Needles and syringes must not be crushed, clipped, or capped, but will be placed directly in a sharps box.

REPORTING INCIDENTS OR SPILLS INVOLVING HAZARDOUS DRUGS

Incidents or spills involving hazardous drugs must be reported to the appropriate departments as indicated below.

Patient, Visitor or Personnel Exposure:

Overt contamination of gloves, clothing, skin or eyes will be treated as follows:

a) Remove contaminated gloves or clothing (if applicable).

b) Wash the affected skin area with soap (not germicidal cleaner) and lukewarm water. (Hot water will open pores and increase skin absorption.) For eye exposure, immediately flush the affected eye with water or isotonic eyewash designated for that purpose for at least 15 minutes.

c) For direct skin or eye contact,

- Obtain medical attention as soon as possible. Employees should go to Employee Occupational Health and Wellness or the Emergency Department.
- Fill out the appropriate incident report form and submit as appropriate.

- Employees who are exposed must fill out an A-016 injury report at https://forms.hr.duke.edu/workcomp/. If patient injury occurs, notify Pharmacy Medication Safety (**pager 919-970-2494**) and Risk Management (**pager 919-970-2404**) immediately and complete a report in the Safety Reporting System at https://rlapp.dhe.duke.edu/rl6_prod.
- If a family member or visitor is exposed, complete a Safety Reporting System report at https://rlapp.dhe.duke.edu/rl6_prod.
    - Inform the appropriate area manager.

Other Incidents during Patient Treatment:

Whether there is an exposure or not, any incident involving a hazardous drug should be documented in a Safety Reporting System report at https://rlapp.dhe.duke.edu/rl6_prod.

Note: **It is not necessary to report hazardous drug spills to OESO or Duke Police unless you need assistance or advice**. If the spill is beyond the capacity of employees in the area or you have questions about cleaning up the spill safely, call 911 from a campus phone or 919-684-2444 from a mobile phone. Tell the dispatcher there is a hazardous drug spill and give a number where you or someone else in your work area can be reached. Please make sure someone is available to answer the telephone and talk with the Spill Responder from OESO.

SPILLS OF LIQUID HAZARDOUS DRUGS:

- For information about the hazards of the spilled drug, contact the area pharmacy or use the Pharmacy-sponsored Micromedex web page.

- Whenever possible, spills of LIQUID hazardous drugs will be handled by employees in the area of the spill, according to Appendix D. Pregnant employees shall leave the area of a spill and not participate in the cleanup.

- Employees may call 911 from a campus phone or 919-684-2444 from a mobile phone to contact OESO for telephone advice or assistance cleaning up the spill. OESO will respond to large spills that are beyond the capacity of employees in the vicinity of the spill.

HANDLING AND SPILLS OF POWDERED OR AEROSOLIZED HAZARDOUS DRUGS:

Reconstitution and handling of powdered hazardous drugs will occur only in the pharmacy or in other areas approved by OESO. These areas must follow the safety procedures outlined in Appendices B and C of this Supplement and the spill clean-up procedures in Appendix E.

Tablets of hazardous drugs which may produce dust or potential exposure to the handler must be counted in the pharmacy in a C-PEC. (Capsules, i.e., gel-caps or coated tablets, are unlikely to produce dust unless broken in handling.) Any hazardous drug tablets that must be crushed prior to administration must be handled in the Pharmacy C-PEC.

Aerosolized hazardous drugs, including Ribavirin and Pentamidine, require special handling. Refer to Appendices F (Ribavirin) and G (Pentamidine) for specific procedures related to these drugs.

TRAINING

Supervisors of employees who handle hazardous drugs must make their employees aware of the potential health effects of these drugs, as required by the OSHA Hazard Communication Standard. The supervisor should refer to the SDS for information about the hazards. The supervisor must also communicate and enforce proper handling procedures, and must advise employees on how they are to handle emergencies, including personnel exposure and spills.

REFERENCES

- American Society of Hospital Pharmacists. ASHP technical assistance bulletin on handling cytotoxic and hazardous drugs. *Am J Hosp Pharm.* 1990; 47:1033-49.
- Hazard Communication Policy (Safety Manual Section V, Chapter 2)
- Occupational Safety and Health Administration Hazardous Drugs Safety and Health Topics
- NIOSH Alert: Preventing Occupational Exposures to Antineoplastic and other Hazardous Drugs in Healthcare Settings, DHHS (NIOSH) Publication No. 2004-165 (2004)

- NIOSH List of Hazardous Drugs in Healthcare Settings, 2024, DHHS (NIOSH) Publication No. 2025-103 (Supersedes 2016-161). Department of Health and Human Services. December 2024.
- USP. USP General Chapter <800> Hazardous Drugs—Handling in Healthcare Settings.

Appendix A:
Duke University Health System Hazardous Drug List

This list is based on the NIOSH List of Hazardous Drugs in Healthcare Settings, 2024, DHHS (NIOSH) Publication No. 2025-103 (Dec. 2024) and additional drugs deemed hazardous (generally those not yet evaluated by NIOSH) based on an internal hazard assessment utilizing DHHS (NIOSH) Publication No. 2023-129 Procedures for Developing the NIOSH List of Hazardous Drugs in Healthcare Settings as a guideline**.**

Duke University Health System Hazardous Drug List

Updated: **08/28/19, 3/20/20, 1/2025**

Approved by PMMC: 1/2017, 10/7/19, 05/04/20, 02/03/2025

Introduction

National Institute for Occupational Safety and Health (NIOSH) develops a list of hazardous drugs to assist employers in identifying FDA approved drugs that are hazardous to the health and safety of workers who handle these drugs. Definitions of Hazardous Drug categories are at the bottom of the document.

The risk to health care workers depends on factors such as dosage form, routes of exposure, work practices, and the type of engineering controls or personal protective equipment used. Dispensing a single tablet poses little to no risk, while mixing an intravenous chemotherapy poses a higher risk.

When a hazardous drug is added to formulary, it is subsequently added to the DUHS Hazardous Drug List and noted in FormWeb. The Center for Medication Policy will collaborate with the Duke Occupational and Environmental Safety Office to periodically update the DUHS hazardous drug list.

	DUHS List of Medication deemed as potentially hazardous				
Drug	**DUHS Formulary** (as of 01.30.25)	**NIOSH Table**	**Only Developmental and/or Reproductive Risk**	**Closed System Transfer Device**	**Blue Bin Disposal Required**
Abacavir tablet & oral solution	Yes	Table 2		No	No
Abacavir-lamivudine tablet	Yes	Table 2		No	No
Abacavir-lamivudine-zidovudine tablet	Yes	Table 2		No	No
Abacavir-dolutegravir-lamivudine tablet	Yes	Table 2		No	No

This list is NOT inclusive of any hazardous drug Active Pharmaceutical Ingredients (API) (such as bulk powders and liquids) utilized by the Duke Compounding Facility.

	DUHS List of Medication deemed as potentially hazardous				
Drug	**DUHS Formulary** (as of 01.30.25)	**NIOSH Table**	**Only Developmental and/or Reproductive Risk**	**Closed System Transfer Device**	**Blue Bin Disposal Required**
Abiraterone acetate tablet	No	Table 2 Antineoplastic	YES	No	No
Acitretin capsule	No	Table 2	YES	No	No
Ado-trastuzumab emtansine injection	Yes	Table 1 Antineoplastic		Yes	Yes
Afatinib tablet	No	Table 2 Antineoplastic		No	No
Alefacept injection	No	Table 2		No	No
Alitretinoin topical	No	Table 2	YES	No	Yes
Altretamine capsule	No	Table 1 Antineoplastic		No	Yes
Ambrisentan tablet	Yes	Table 2	YES	No	No
Anastrozole tablet	Yes	Table 2 Antineoplastic	YES	No	No
Apomorphine subcutaneous injection syringe	No	Table 2		No	No
Arsenic trioxide injection	Yes	Table 1 Antineoplastic		Yes	Yes
Axitinib tablet	No	Table 2 Antineoplastic		No	No
Azacitidine injection	Yes	Table 1 Antineoplastic		Yes	Yes
Azacitidine tablet	No	Table 1 Antineoplastic		No	Yes
Azathioprine injection	No	Table 1		Yes	Yes
Azathioprine tablet	Yes	Table 1		No	Yes
Bacillus-Calmette Guerin (BCG) intravesicular/dermal		Duke deemed Hazardous		Yes	Yes
Belantamab injection	Yes	Table 1 Antineoplastic		Yes	Yes

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	DUHS List of Medication deemed as potentially hazardous				
Drug	**DUHS Formulary** (as of 01.30.25)	**NIOSH Table**	**Only Developmental and/or Reproductive Risk**	**Closed System Transfer Device**	**Blue Bin Disposal Required**
Belinostat injection	No	Table 1 Antineoplastic		Yes	Yes
Bendamustine injection (Bendeka)	Yes	Table 1 Antineoplastic		Yes	Yes
Bendamustine injection (Treanda)	No	Table 1 Antineoplastic		Yes	Yes
Bexarotene capsule/topical	No	Table 2 Antineoplastic	YES	No	Yes - Topical No - capsule
Bicalutamide tablet	Yes	Table 2 Antineoplastic		No	No
Bleomycin injection	Yes	Table 1 Antineoplastic		Yes	Yes
Blinatumomab injection	Yes	Table 2 Antineoplastic		No	No
Bortezomib injection	Yes	Table 1 Antineoplastic		Yes	Yes
Bosentan oral suspension & tablet	Yes	Table 2	YES	No	No
Bosutinib tablet	No	Table 2 Antineoplastic	YES	No	No
Brentuximab vedotin injection	Yes	Table 1 Antineoplastic		Yes	Yes
Busulfan injection	Yes	Table 1 Antineoplastic		Yes	Yes
Busulfan tablet	Yes	Table 1 Antineoplastic		No	Yes
Cabazitaxel injection	Yes	Table 1 Antineoplastic		Yes	Yes
Cabergoline tablet	Yes	Table 2	YES	No	No
Cabozantinib capsule	No	Table 2	YES	No	No

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	DUHS List of Medication deemed as potentially hazardous				
Drug	**DUHS Formulary** (as of 01.30.25)	**NIOSH Table**	**Only Developmental and/or Reproductive Risk**	**Closed System Transfer Device**	**Blue Bin Disposal Required**
		Antineoplastic			
Capecitabine tablet	Yes	Table 1 Antineoplastic		No	Yes
Capivasertib tablet*	No	Table 2 Antineoplastic		No	No
Carbamazepine capsule, tablet, & oral suspension	Yes	Table 2		No	No
Carboplatin injection	Yes	Table 1 Antineoplastic		Yes	Yes
Carfilzomib injection	Yes	Table 2 Antineoplastic	YES	No	No
Carmustine injection	Yes	Table 1 Antineoplastic		Yes	Yes
Carmustine topical	No	Table 1 Antineoplastic		No	Yes
Carmustine wafer implant	Yes	Table 1 Antineoplastic		No	Yes
Ceritinib tablets	No	Table 2 Antineoplastic	YES	No	No
Cetrorelix injection kit	No	Table 2	YES	No	No
Chlorambucil tablet	Yes	Table 1 Antineoplastic		No	Yes
Chloramphenicol injection	No	Table 1		Yes	Yes
Choriogonadotropin alpha injection	No	Table 2	YES	No	No
Cidofovir oral solution & topical	No	Table 1		No	No
Cidofovir injection	Yes	Table 1		Yes	No
Cisplatin injection	Yes	Table 1 Antineoplastic		Yes	Yes
Cladribine injection	Yes	Table 1		Yes	Yes

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	DUHS List of Medication deemed as potentially hazardous				
Drug	**DUHS Formulary** (as of 01.30.25)	**NIOSH Table**	**Only Developmental and/or Reproductive Risk**	**Closed System Transfer Device**	**Blue Bin Disposal Required**
		Antineoplastic			
Cladribine tablet	No	Table 1 Antineoplastic		No	Yes
Clobazam film, suspension, & tablet	Yes	Table 2	YES	No	No
Clofarabine injection	Yes	Table 1 Antineoplastic		Yes	Yes
Clomiphene tablet	Yes	Table 2	YES	No	No
Clonazepam oral solution	Yes	Table 2	YES	No	No
Clonazepam tablet	Yes	Table 2	YES	No	No
Cobimetinib tablet	No	Table 2 Antineoplastic	YES	No	No
Colchicine capsule/tablet	Yes	Table 2	YES	No	No
Colchicine – probenecid tablet	No	Table 2	YES	No	No
Crizotinib capsule	No	Table 2 Antineoplastic		No	No
Cyclophosphamide injection	Yes	Table 1 Antineoplastic		Yes	Yes
Cyclophosphamide capsule/ solution/tablet	Yes	Table 1 Antineoplastic		No	Yes
Cyclosporine capsule/drops	Yes	Table 1		No	Yes
Cyclosporine oral solution	Yes	Table 1		No	Yes
Cyclosporine injection	Yes	Table 1		Yes	Yes
Cytarabine injection (also liposomal injection)	Yes	Table 1 Antineoplastic		Yes	Yes
Cytarabine intrathecal (also liposomal injection)	Yes	Table 1 Antineoplastic		No	Yes
Dabrafenib capsule	No	Table 2 Antineoplastic		No	No
Dabrafenib tablet for oral	No	Table 2		No	No

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	DUHS List of Medication deemed as potentially hazardous				
Drug	**DUHS Formulary** (as of 01.30.25)	**NIOSH Table**	**Only Developmental and/or Reproductive Risk**	**Closed System Transfer Device**	**Blue Bin Disposal Required**
suspension					
Dacarbazine injection	Yes	Table 1 Antineoplastic		Yes	Yes
Dactinomycin injection	Yes	Table 1 Antineoplastic		Yes	Yes
Dasatinib tablet	No	Table 1 Antineoplastic		No	Yes
Daunorubicin injection	Yes	Table 1 Antineoplastic		Yes	Yes
Daunorubicin – Cytarabine injection	Yes	Table 1 Antineoplastic		Yes	Yes
Decitabine injection	Yes	Table 1 Antineoplastic		Yes	Yes
Decitabine-cedazuridine tablets*	No	Table 1 Antineoplastic		No	Yes
Deferiprone tablets & oral solution	No	Table 2		No	No
Degarelix injection	Yes	Table 2 Antineoplastic	YES	No	No
Dexrazoxane injection	Yes	Table 1		Yes	No
Diethylstilbestrol tablets and injection	No	Table 1		Yes	Yes
Dihydroergotamine injection	Yes	Table 2	YES	No	No
Dihydroergotamine nasal spray	No	Table 2	YES	No	No
Dinoprostone suppository/gel	Yes	Table 2	YES	No	No
Divalproex tablet & capsule	Yes	Table 2	Yes	No	No
Docetaxel injection	Yes	Table 1 Antineoplastic		Yes	Yes
Doxorubicin injection (also liposomal injection)	Yes	Table 1 Antineoplastic		Yes	Yes

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Drug	**DUHS Formulary** (as of 01.30.25)	**NIOSH Table**	**Only Developmental and/or Reproductive Risk**	**Closed System Transfer Device**	**Blue Bin Disposal Required**
Dronedarone tablet	Yes	Table 2	YES	No	No
Dutasteride capsule	Yes	Table 2	YES	No	No
Elacestrant tablets*	No	Table 2 Antineoplastic		No	No
Enfortumab vedotin injection	Yes	Table 1 Antineoplastic		Yes	Yes
Entecavir tablet & oral solution	Yes	Table 2		No	No
Enzalutamide capsule	No	Table 2 Antineoplastic	Yes	No	No
Epirubicin injection	Yes	Table 1 Antineoplastic		Yes	Yes
Eribulin mesylate injection	Yes	Table 1 Antineoplastic		Yes	Yes
Erlotinib tablet	No	Table 2 Antineoplastic	YES	No	No
Eslicarbazepine tablet	Yes	Table 2	YES	No	No
Estradiol tablet/topical/intravaginal	Yes	Table 2		No	No
Estradiol injection	Yes	Table 2		No	No
Estradiol transdermal	Yes	Table 2		No	No
Estramustine capsule/oral solution	Yes	Table 1 Antineoplastic		No	Yes
Estrogen/Progestin combinations tablet	Yes	Table 1		No	No
Estrogens, conjugated injection	Yes	Table 1		No	No
Estrogens, conjugated tablet & topical	Yes	Table 1		No	No
Estropipate tablet	No	Table 2		No	No
Etonogestrel implant*	Yes	Table 2	YES	No	No
Etoposide capsule	Yes	Table 1		No	Yes

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Drug	**DUHS Formulary** (as of 01.30.25)	**NIOSH Table**	**Only Developmental and/or Reproductive Risk**	**Closed System Transfer Device**	**Blue Bin Disposal Required**
		Antineoplastic			
Etoposide injection	Yes	Table 1 Antineoplastic		Yes	Yes
Everolimus tablet/oral solution (Afinitor)	Yes (soluble tablet)	Table 1 Antineoplastic		No	Yes
Everolimus tablet (Zortress)	Yes	Table 1 Antineoplastic		No	Yes
Exemestane tablet	Yes	Table 2	YES	No	No
Exenatide injection & pen device	No	Table 2		No	Yes
Fam-Trastuzumab deruxtecan injection	Yes	Table 1 Antineoplastic		Yes	Yes
Finasteride tablet	Yes	Table 2	YES	No	No
Fingolimod capsule	Yes	Table 2		No	No
Floxuridine injection	Yes	Table 1 Antineoplastic		Yes	Yes
Fluconazole tablet, suspension & injection	Yes	Table 2	YES	No	No
Fludarabine injection	Yes	Table 1 Antineoplastic		Yes	Yes
Fluorouracil injection	Yes	Table 1 Antineoplastic		Yes	Yes
Fluorouracil topical	Yes	Table 1 Antineoplastic		No	Yes
Fluoxymesterone tablet	Yes	Table 2		No	No
Flutamide capsule	No	Table 2 Antineoplastic		No	No
Fosphenytoin injection	Yes	Table 2		No	No
Fruquintinib capsules*	No	Table 2 Antineoplastic		No	No

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Drug	**DUHS Formulary** (as of 01.30.25)	**NIOSH Table**	**Only Developmental and/or Reproductive Risk**	**Closed System Transfer Device**	**Blue Bin Disposal Required**
Fulvestrant injection	Yes	Table 2 Antineoplastic	YES	No	Yes
Futibatinib tablets*	No	Table 2 Antineoplastic		No	No
Ganirelix injection pre-filled syringe	No	Table 2	YES	No	No
Ganciclovir injection	Yes	Table 1		Yes	No
Ganciclovir capsule/oral suspension/topical	No	Table 1		No	No
Gemcitabine injection	Yes	Table 1 Antineoplastic		Yes	Yes
Gemtuzumab injection	Yes	Table 1 Antineoplastic		Yes	Yes
Gonadotropin, chorionic injection	Yes	Table 2	YES	No	No
Goserelin implant	Yes	Table 2 Antineoplastic	YES	No	No
Histrelin implant	Yes	Table 2 Antineoplastic	YES	No	No
Hydroxyurea capsule & oral solution	Yes	Table 1 Antineoplastic		No	Yes
Hydroxyurea tablets	No	Table 1 Antineoplastic		No	Yes
Ibrutinib capsule*	No	Table 2 Antineoplastic		No	No
Icatibant injection syringe	Yes	Table 2	YES	No	No
Idarubicin injection	Yes	Table 1 Antineoplastic		Yes	Yes
Ifosfamide injection	Yes	Table 1 Antineoplastic		Yes	Yes

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Drug	**DUHS Formulary** (as of 01.30.25)	**NIOSH Table**	**Only Developmental and/or Reproductive Risk**	**Closed System Transfer Device**	**Blue Bin Disposal Required**
Imatinib mesylate tablet & oral suspension	Yes	Table 1 Antineoplastic		No	Yes
Inotuzumab ozogamicin injection	Yes	Table 1 Antineoplastic		Yes	Yes
Irinotecan injection (also liposomal injection)	Yes	Table 1 Antineoplastic		Yes	Yes
Isotretinoin capsule	Yes	Table 2	YES	No	No
Ivabradine tablets	Yes	Table 2	YES	No	No
Ixabepilone injection	Yes	Table 1 Antineoplastic		Yes	Yes
Ixazomib capsule	No	Table 1 Antineoplastic		No	Yes
Lazertinib tablets*	No	Table 2 Antineoplastic		No	No
Leflunomide tablet	Yes	Table 2		No	No
Lenalidomide capsule	No	Table 1 Antineoplastic		No	Yes
Lenvatinib capsule	No	Table 2 Antineoplastic	YES	No	No
Letrozole tablet	Yes	Table 2 Antineoplastic	YES	No	No
Leuprolide acetate injection	Yes	Table 2 Antineoplastic	YES	No	No
Leuprolide acetate injection kits	Yes	Table 2 Antineoplastic	YES	No	No
Leuprolide acetate subcutaneous injection	No	Table 2 Antineoplastic	YES	No	No
Levonorgestrel intrauterine device*	Yes	Table 2	YES	No	No
Lomitapide capsule	No	Table 2	YES	No	No

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Drug	**DUHS Formulary** (as of 01.30.25)	**NIOSH Table**	**Only Developmental and/or Reproductive Risk**	**Closed System Transfer Device**	**Blue Bin Disposal Required**
Lomustine capsule	Yes	Table 1 Antineoplastic		No	Yes
Loncastuximab injection	Yes	Table 1 Antineoplastic		Yes	Yes
Lovotibeglogene autotemcel infusion*	Yes	Duke deemed hazardous		No	Yes
Lurbinectedin injection	Yes	Table 1 Antineoplastic		Yes	Yes
Macitentan tablet	Yes	Table 2	YES	No	No
Mechlorethamine injection	Yes	Table 1 Antineoplastic		Yes	Yes
Mechlorethamine topical	No	Table 1 Antineoplastic		No	Yes
Medroxyprogesterone acetate injection	Yes	Table 2	YES	No	No
Medroxyprogesterone ophthalmic solution (compounded)	Yes	Table 2	YES	No	No
Medroxyprogesterone tablet	Yes	Table 2	YES	No	No
Megestrol tablet & oral suspension	Yes	Table 2		No	Yes
Melphalan tablet	Yes	Table 1 Antineoplastic		No	Yes
Melphalan injection	Yes	Table 1 Antineoplastic		Yes	Yes
Melphalan flufenamide injection	No	Table 1 Antineoplastic		Yes	Yes
Menotropins injection kit	No	Table 2	YES	No	No
Mercaptopurine tablet & oral suspension	Yes	Table 1 Antineoplastic		No	Yes

This list is NOT inclusive of any hazardous drug Active Pharmaceutical Ingredients (API) (such as bulk powders and liquids) utilized by the Duke Compounding Facility.

	DUHS List of Medication deemed as potentially hazardous				
Drug	**DUHS Formulary** (as of 01.30.25)	**NIOSH Table**	**Only Developmental and/or Reproductive Risk**	**Closed System Transfer Device**	**Blue Bin Disposal Required**
Methimazole oral solution & tablet	Yes	Table 2		No	No
Methotrexate oral solution/ tablet	Yes	Table 1 Antineoplastic		No	Yes
Methotrexate auto-injection	No	Table 1 Antineoplastic		No	Yes
Methotrexate intrathecal injection	Yes	Table 1 Antineoplastic		No	Yes
Methotrexate injection	Yes	Table 1 Antineoplastic		Yes	Yes
Methylergonovine/ergonovine tablet & injection	Yes	Table 2	YES	No	No
Methyltestosterone tablet & capsule	No	Table 2	YES	No	No
Mifepristone tablet	Yes	Table 2	YES	No	No
Miltefosine capsule	No	Table 2	YES	No	No
Mipomersen subcutaneous injection syringe	No	Table 2		No	No
Mirvetuximab soravtansine injection	Yes	Table 1 Antineoplastic		Yes	Yes
Misoprostol tablet	Yes	Table 2	YES	No	No
Misoprostol-diclofenac tablet	No	Table 2	YES	No	No
Mitomycin bladder irrigation	Yes	Table 1 Antineoplastic		No	Yes
Mitomycin ophthalmic injection kit	Yes	Table 1 Antineoplastic		No	Yes
Mitomycin injection	Yes	Table 1 Antineoplastic		Yes	Yes
Mitotane tablet	Yes	Table 1 Antineoplastic		No	Yes

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	DUHS List of Medication deemed as potentially hazardous				
Drug	**DUHS Formulary** (as of 01.30.25)	**NIOSH Table**	**Only Developmental and/or Reproductive Risk**	**Closed System Transfer Device**	**Blue Bin Disposal Required**
Mitoxantrone injection	Yes	Table 1 Antineoplastic		Yes	Yes
Mycophenolate mofetil (tablet/capsule/oral solution)	Yes	Table 1		No	No
Mycophenolate mofetil injection	Yes	Table 1		Yes	No
Mycophenolate sodium tablet	Yes	Table 2		No	No
Nafarelin intranasal	No	Table 2	YES	No	No
Nelarabine injection	Yes	Table 1 Antineoplastic		Yes	Yes
Nevirapine tablet & oral suspension	Yes	Table 2		No	No
Nilotinib capsule	No	Table 2 Antineoplastic	YES	No	No
Olaparib capsule	No	Table 2 Antineoplastic		No	No
Omacetaxine injection	No	Table 1 Antineoplastic		Yes	Yes
Ospemifene tablet	No	Table 2		No	No
Oxaliplatin injection	Yes	Table 1 Antineoplastic		Yes	Yes
Oxcarbazepine tablet & oral suspension	Yes	Table 2		No	No
Oxytocin injection	Yes	Table 2	YES	No	No
Paclitaxel injection	Yes	Table 1 Antineoplastic		Yes	Yes
Palifermin injection	Yes	Table 2		No	No
Pamidronate injection	Yes	Table 2	YES	No	No
Panobinostat capsule	No	Table 1 Antineoplastic		No	Yes

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	DUHS List of Medication deemed as potentially hazardous				
Drug	**DUHS Formulary** (as of 01.30.25)	**NIOSH Table**	**Only Developmental and/or Reproductive Risk**	**Closed System Transfer Device**	**Blue Bin Disposal Required**
Paroxetine tablet & oral suspension	Yes	Table 2	YES	No	No
Pasireotide injection	No	Table 2	YES	No	No
Pasireotide long-acting injection	Yes	Table 2	YES	No	No
Pazopanib tablet	No	Table 2 Antineoplastic	YES	No	No
Peginesatide injection	No	Table 2	YES	No	No
Pemetrexed injection	Yes	Table 1 Antineoplastic		Yes	Yes
Pentamidine inhalation*	Yes	Duke deems Hazardous		No	No
Pentetate calcium trisodium injection	No	Table 2	YES	No	No
Pentostatin injection	Yes	Table 1 Antineoplastic		Yes	Yes
Phenoxybenzamine capsule	Yes	Table 2		No	No
Phenytoin tablet, capsule & oral suspension	Yes	Table 2		No	No
Phenytoin injection	No	Table 2		No	No
Plerixafor injection	Yes	Table 2	YES	No	No
Polatuzumab vedotin injection	Yes	Table 1 Antineoplastic		Yes	Yes
Pomalidomide capsule	No	Table 1 Antineoplastic		No	Yes
Ponatinib tablet	No	Table 2 Antineoplastic		No	No
Pralatrexate injection	No	Table 1 Antineoplastic		Yes	Yes
Procarbazine capsule	Yes	Table 1		No	Yes

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	DUHS List of Medication deemed as potentially hazardous				
Drug	**DUHS Formulary** (as of 01.30.25)	**NIOSH Table**	**Only Developmental and/or Reproductive Risk**	**Closed System Transfer Device**	**Blue Bin Disposal Required**
		Antineoplastic			
Progesterone capsule	No	Table 2		No	No
Progesterone injection	Yes	Table 2		No	No
Progesterone topical	No	Table 2		No	No
Progestins	Yes	Table 2		No	No
Propylthiouracil tablet	Yes	Table 2		No	No
Quizartinib tablets*	Yes	Table 1 Antineoplastic		No	No
Raloxifene tablet	Yes	Table 2		No	No
Rasagiline tablet	No	Table 2		No	No
Regorafenib tablet	No	Table 2 Antineoplastic	YES	No	No
Relugolix tablet*	No	Table 2 Antineoplastic		No	No
Ribavirin capsules/tablets	Capsules-Yes	Table 2	YES	No	No
Ribavirin inhalation	Yes	Table 2	YES	No	No
Riociguat tablet	Yes	Table 2	YES	No	No
Ripretinib tablet*	No	Table 1 Antineoplastic		No	No
Romidepsin injection	Yes	Table 1 Antineoplastic		Yes	Yes
Sacituzumab govitecan injection	Yes	Table 1 Antineoplastic		Yes	Yes
Selpercatinib capsule & tablet*	No	Table 2	YES	No	No
Sirolimus injection (protein-bound)	Yes	Table 2		No	Yes
Sirolimus oral solution	Yes	Table 2		No	No
Sirolimus tablet	No	Table 2		No	No
Sonidegib capsule	No	Table 2 Antineoplastic	YES	No	No

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	DUHS List of Medication deemed as potentially hazardous				
Drug	**DUHS Formulary** (as of 01.30.25)	**NIOSH Table**	**Only Developmental and/or Reproductive Risk**	**Closed System Transfer Device**	**Blue Bin Disposal Required**
Sorafenib tablet	No	Table 2 Antineoplastic	YES	No	No
Spironolactone tablet & oral suspension	Yes	Table 2		No	No
Spironolactone – hydrochlorothiazide tablet	Yes	Table 2		No	No
Streptozocin injection	Yes	Table 1 Antineoplastic		Yes	Yes
Sunitinib capsule	No	Table 2 Antineoplastic		No	No
Tacrolimus capsule & tablet	Yes	Table 2		No	No
Tacrolimus oral granules	No	Table 2		No	No
Tacrolimus suspension	Yes	Table 2		No	No
Tacrolimus injection	Yes	Table 2		No	No
Tacrolimus Ambulatory Pump Infusion	Yes	Table 2		No	No
Tacrolimus topical	Yes	Table 2		No	No
Talazoparib capsule*	No	Table 1 Antineoplastic		No	No
Tamoxifen tablet & oral solution	Yes	Table 1 Antineoplastic		No	Yes
Tazemetostat tablet*	No	Table 1 Antineoplastic		No	No
Temazepam capsule	Yes	Table 2	YES	No	No
Temozolomide capsule & oral suspension	Yes	Table 1 Antineoplastic		No	Yes
Temozolomide injection	Yes	Table 1		Yes	Yes
Temsirolimus injection	Yes	Table 1		Yes	Yes

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	DUHS List of Medication deemed as potentially hazardous				
Drug	**DUHS Formulary** (as of 01.30.25)	**NIOSH Table**	**Only Developmental and/or Reproductive Risk**	**Closed System Transfer Device**	**Blue Bin Disposal Required**
		Antineoplastic			
Teniposide injection	No	Table 1 Antineoplastic		Yes	Yes
Teprotumumab injection*	Yes	Table 2	Yes	Yes	No
Teriflunomide tablet	No	Table 2		No	No
Testosterone buccal	No	Table 2	YES	No	No
Testosterone injection	Yes	Table 2	YES	No	No
Testosterone injection kit	No	Table 2	YES	No	No
Testosterone transdermal	Yes	Table 2	YES	No	No
Thalidomide capsule	No	Table 1		No	Yes
Thioguanine tablet & oral suspension	Yes	Table 1 Antineoplastic		No	Yes
Thiotepa injection	Yes	Table 1 Antineoplastic		Yes	Yes
Tisotumab vedotin injection	Yes	Table 1 Antineoplastic		Yes	Yes
Tivozanib capsule*	No	Table 2 Antineoplastic		No	No
Tofacitinib tablet	Yes (immediate release tablet)	Table 2		No	No
Topiramate capsule & tablet	Yes	Table 2	YES	No	No
Topiramate – Phentermine capsule	No	Table 2	YES	No	No
Topotecan capsule	No	Table 1 Antineoplastic		No	Yes
Topotecan injection	Yes	Table 1 Antineoplastic		Yes	Yes
Toremifene tablet	No	Table 2	YES	No	No
Toripalimab injection*	Yes	Table 2		Yes	No

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	DUHS List of Medication deemed as potentially hazardous				
Drug	**DUHS Formulary** (as of 01.30.25)	**NIOSH Table**	**Only Developmental and/or Reproductive Risk**	**Closed System Transfer Device**	**Blue Bin Disposal Required**
		Antineoplastic			
Trabectedin injection	Yes	Table 1 Antineoplastic		Yes	Yes
Trametinib tablet	No	Table 2 Antineoplastic		No	No
Tretinoin capsule	Yes	Table 2	YES	No	No
Tretinoin topical	Yes	Table 2	YES	No	Yes
Tretinoin-clindamycin topical	No	Table 2	YES	No	No
Trifluridine ophthalmic drops	Yes	Table 1 Antineoplastic		No	Yes
Trifluridine-tipracil tablets	No	Table 1 Antineoplastic		No	Yes
Triptorelin injection	Yes	Table 2 Antineoplastic	YES	No	No
Ulipristal tablets	Yes	Table 2	YES	No	No
Upadacitinib tablets*	No	Table 2	YES	No	No
Uracil mustard capsule	No	Table 1 Antineoplastic		No	Yes
Urofollitropin injection	No	Table 2	YES	No	No
Valganciclovir tablet & oral solution	Yes	Table 1		No	No
Valproic acid capsule, injection & oral solution	Yes	Table 2	YES	No	No
Valrubicin intravesicular injection	No	Table 1 Antineoplastic		Yes	Yes
Vandetanib tablet	No	Table 1 Antineoplastic		No	Yes
Vemurafenib tablet	No	Table 2 Antineoplastic	YES	No	No
Vigabatrin tablet & oral	Yes	Table 2	YES	No	No

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	DUHS List of Medication deemed as potentially hazardous				
Drug	**DUHS Formulary** (as of 01.30.25)	**NIOSH Table**	**Only Developmental and/or Reproductive Risk**	**Closed System Transfer Device**	**Blue Bin Disposal Required**
solution					
Vinblastine sulfate injection	Yes	Table 1 Antineoplastic		Yes	Yes
Vincristine sulfate injection	Yes	Table 1 Antineoplastic		Yes	Yes
Vincristine sulfate liposomal injection kit	No	Table 1 Antineoplastic		No	Yes
Vinorelbine tartrate injection	Yes	Table 1 Antineoplastic		Yes	Yes
Vismodegib capsule	No	Table 2 Antineoplastic	YES	No	No
Voriconazole tablet, ophthalmic, oral suspension & injection	Yes	Table 2	YES	No	No
Vorinostat capsule	No	Table 1 Antineoplastic		No	Yes
Warfarin tablet	Yes	Table 2	YES	No	Yes
Zidovudine injection	Yes	Table 2		No	No
Zidovudine capsule, tablet & oral solution	Yes	Table 2		No	No
Zidovudine-lamivudine tablet	Yes	Table 2		No	No
Ziprasidone capsule	No	Table 2	YES	No	No
Ziprasidone injection	No	Table 2	YES	No	No
Ziv-aflibercept injection	No	Table 2 Antineoplastic	YES	No	No
Zoledronic acid injection	Yes	Table 2	YES	No	No
Zonisamide capsule & oral solution	Yes	Table 2	YES	No	No

* Duke designation/NIOSH Not yet reviewed

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A **hazardous drug** is any drug:

- Noted in the prescribing information/package insert that includes manufacturers special handling information (MSHI) to protect works handling the drug, or
- Identified as hazardous or potentially hazardous by the National Institute for Occupational Safety and Health (NIOSH) on the basis of at least one of the following six criteria: carcinogenicity, teratogenicity or developmental toxicity, reproductive toxicity in humans, organ toxicity at low doses in humans or animals, genotoxicity, and new drugs that mimic existing hazardous drugs in structure or toxicity.[1]

Category Classification:

- **Table 1:** Drugs that have MSHI in the prescribing information/package insert and/or meet the definition of hazardous by NIOSH and have one or more of the following:
  - National Toxicology Program (NTP) as "known to be human carcinogen"
  - International Agency for Research on Cancer (IARC)r as Group 1 "carcinogenic to humans" or Group 2 "probably carcinogenic to humans"
- **Table 2:** Drugs classified as hazardous by NIOSH and
  - Do not have MSHI
  - Are not classified by the NTP as "known to be a human carcinogen"
  - Are not classified by IARC as Group 1 "carcinogenic to humans" or Group 2A "probably carcinogen to humans"
  - Developmental/teratogenic and/or reproductive hazard

Table of NIOSH scenarios where hazardous drugs are handled and the suggested personal protective equipment and engineering controls are posted on FormWeb. The NIOSH document can be found here.

Assessment of Risk (AOR):

- USP 800 establishes containment strategies and work practices best known to control hazardous drug contamination. Examples: engineering controls, protective equipment and garb. A medication may be exempt from required containment strategies when safe alternative containment strategies and/or work practices can be identified. The exceptions can be documented in an AoR. However, if any of the following apply then an AOR cannot be documented: any hazardous drug API on the NIOSH list, any antineoplastic requiring further manipulation, and any hazardous drug that has not had an AOR performed.

This list is NOT inclusive of any hazardous drug Active Pharmaceutical Ingredients (API) (such as bulk powders and liquids) utilized by the Duke Compounding Facility.

References

1. NIOSH 2024. NIOSH List of Hazardous Drugs in Healthcare Settings, 2024 [Internet]. US Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS Publication No. 2025-103. Available from https://www.cdc.gov/niosh/docs/2025-103/pdfs/2025-103.pdf?id=10.26616/NIOSHPUB2025103
2. Duke University Health System Policy on Hazardous Drug Management Waste and Disposal
3. Hazardous Drugs – Handling in Healthcare Settings (general information chapter 800) [Internet] U.S. Pharmacopeial Convention. https://www.usp.org/compounding/general-chapter-hazardous-drugs-handling-healthcare
4. 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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Appendix B:
Safe Handling Procedures for Preparing Hazardous Drugs

Employees preparing cytotoxic or other hazardous drugs must adhere to the following safety practices. If further information is needed about the hazards of specific drugs, employees should consult the Safety Data Sheet (SDS), available from the Pharmacy or through the OESO SDS Resources web page.

Personal Protective Equipment:

- Gloves that have been tested for use with chemotherapy drugs must be worn for chemotherapy and other hazardous drugs.
    - A double layer of gloves will resist permeation considerably longer than a single layer. Double gloves shall be used for compounding hazardous drugs and administering antineoplastic hazardous drugs (unless otherwise indicated in an AoR).
    - Gloves must be changed as soon as possible if they are contaminated, torn or punctured. Otherwise they can be worn until the employee leaves the preparation area (USP 800 suggests changing every 30 minutes unless otherwise recommended by the manufacturer's documentation), at which time they will be thrown away (in the biohazard box), and replaced with new gloves when the employee returns.
    - Employees will wash their hands before putting on gloves and again after removing them.
- A protective disposable gown made of lint-free low-permeability fabric (such as Tyvek) with a closed front, long sleeves, and elastic or knit-closed cuffs must be worn, with the cuffs tucked under the outer pair of gloves. The gown will be changed as soon as possible if torn or visibly contaminated. If gowns are to be re-used, they must be stored in a manner that does not permit potential contact between outer and inner surfaces.
- Once gowns and gloves have been used in preparation, they must not be worn outside the preparation area.
- All used gowns, gloves and disposable materials used in preparation will be disposed of by placing them in red biohazard boxes.
- As long as work is performed inside a Biological Safety Cabinet (BSC) with the sash at the appropriate height, the BSC will provide essential eye, face, and respiratory protection (as will a Compounding Aseptic Containment Isolator). Work must never be performed outside a BSC or other appropriate containment primary engineering control (C-PEC) as defined in USP 800 (unless otherwise indicated in an AoR).

Preparation Area:

- Hazardous drugs will be prepared only in restricted, designated areas. (The Pharmacy will prepare all hazardous drugs that will be administered to patients when feasible.)
- Signs restricting the access of unauthorized personnel are to be prominently displayed.
- Eating, drinking, smoking, chewing gum, applying cosmetics, and storing food in the preparation area are prohibited.
- Chemotherapy/Hazardous Drug Spill Clean-up Procedures for the Pharmacy must be posted or kept in a location accessible to all staff.
- An eyewash facility should be available in the area.

Work Equipment:

- Cytotoxic drugs will only be reconstituted in an appropriate containment primary engineering control (C-PEC) such as a Class II or III BSC, also known as a Vertical Flow Hood, designated for that purpose, or in a Compounding Aseptic Containment Isolators (CACI). Each BSC will be equipped with a continuous monitoring device to allow confirmation of adequate air flow and cabinet performance. The exhaust fan or blower on the vertical airflow hood will remain on at all times, except when the hood is being mechanically repaired or moved. If the blower is turned off, the hood should be decontaminated before reuse. (See Appendix C.) The cabinet needs to be in an area with minimal air turbulence; this will reduce leakage to the environment.
- The preparation area inside the C-PEC must be covered with a disposable plastic-backed absorbent liner, which must be changed after preparation is completed for the day, or after a shift, whichever comes first. This liner will be changed immediately if there is a spill.
- Syringes and IV sets with Luer-lock fittings will always be used, and syringes must always be large enough so that they need never be more than three-quarters full.
- A covered sharps container will be available in the C-PEC.
- A biohazard box and blue bin, as appropriate, will be available nearby for disposal of used containers, gloves, gowns, paper liners, and other contaminated material.
- Reusable materials should be wiped down with damp gauze or other absorbent material, until visible drug residue has been removed. The absorbent should then be placed in the nearest biohazard box. The reusable materials should be cleaned in a designated sink with mild detergent and water, and then rinsed thoroughly with clean water for reuse.
- The cabinet will be cleaned daily with 70 percent isopropyl alcohol.
- The cabinet will be decontaminated weekly, whenever spills occur, and when the cabinet requires service or certification. The decontamination is performed according to the procedure outlined in Appendix C.
- BSCs must be certified by a qualified technician every 6 months or any time the cabinet is moved.

Work Practices in Preparation:

- All PPE must be donned before work is started in the C-PEC (e.g., BSC or CACI).
- All necessary items will be placed within the C-PEC before work is begun, and all extraneous items will be kept out of the work area in order to avoid contamination.
- Because of the pattern of airflow in Biological Safety Cabinets, the following special precautions are necessary:
    - Manipulations should not be performed close to the front grille.
    - Unsterilized items, including liners and hands, must be kept downstream from the working area.
    - Entry and exit of the cabinet should be perpendicular to the front.
    - Rapid lateral hand movements should be avoided.

  - Additional information can be found in the National Sanitation Foundation Standard 49 for Class II (Laminar Flow) Biohazard Cabinetry.

- Proper aseptic techniques are essential for worker protection, as well as patient safety.
- Labeling
  - In addition to standard pharmacy labeling practices, all syringes, IV bags and bottles containing hazardous drugs should be labeled with a distinctive warning label such as

    "SPECIAL HANDLING/DISPOSAL PRECAUTIONS".

  - All liquid and powdered drugs that pose a health hazard are covered under the Occupational Safety and Health Administration's Hazard Communication Standard. Their labels must therefore include the identity of the drug, and words, pictures, symbols, or combination thereof, which provide at least general information regarding the hazards of the drugs, and which, in conjunction with the other information immediately available to employees under the hazard communication program, will provide employees with the specific information regarding the physical and health hazards of the hazardous drug unless they are covered by the labeling requirements of the Food and Drug Administration.
- Needles
  - Syringe and needle fittings should be of the Luer-lock or equivalent variety. CSTDs should be used whenever feasible unless an AoR is in place allowing for alternative containment strategies and/or work practices.
  - The use of large-bore needles, #18 or #20, will ensure that high-pressure syringing of the solutions is avoided. However, large-bore needles may be more likely to drip. Multiuse dispensing pins or filter needles are recommended to avoid these problems.
  - Drug administration sets will be attached and primed within the hood whenever feasible, before the drug is added to the fluid, to prevent having to prime the set in a less well-controlled environment, and to ensure that any fluid that escapes during priming contains no drug. Circle priming should be considered whenever priming is necessary outside of pharmacy.
  - All syringes and needles used in the course of preparation will be placed in a sharps box for disposal without being crushed, clipped or capped.
- Vials
  - CSTDs should be used when feasible.
  - Extremes of positive and negative pressure in medication vials must be avoided, e.g., attempting to withdraw 10 cc of fluid from a 10-cc vial or placing 10 cc of a fluid into an air-filled 10-cc vial.
  - Medication vials must not be vented unless a C-PEC is used as the work area or unless a venting device is available to eliminate pressure. Venting devices such as filter needles or chemotherapy dispensing pins (with membrane filters at the vent) permit outside air to replace the withdrawn liquid. Proper worker education is essential before using these devices.
  - Although venting devices are recommended (unless a CSTD is in use), another technique is to add diluent slowly to the vial by alternately injecting small amounts, allowing displaced air to escape into the syringe. (All the diluent should not be injected at once: a large volume of displaced air will cause the syringe's plunger to back up and possibly spray the drug or cause leakage around the needles.)

When all diluent has been added, a small amount of additional air may be withdrawn to create a negative pressure in the vial, but this should not be expelled into room air because it may contain drug residue. It should either be injected into a vacuum vial or remain in the syringe to be discarded.

- A sterile gauze will be wrapped around the needles and vial top when withdrawing solution unless a CSTD is in use. (Employees should take care to avoid needle-sticks during this procedure.)
- If any negative pressure must be applied to withdraw a dosage from a stoppered vial, and handling safety is compromised, an air-filled syringe should be used to equalize pressure in the stoppered vial. The volume of drug to be withdrawn can be replaced by injecting small amounts of air into the vial and withdrawing equal amounts of liquid until the required volume is withdrawn. The drug must be cleared from the needle and hub (neck) of the syringe before separating to reduce spraying.

- Packaging hazardous drugs for transport
  - The outside of bags or bottles containing the prepared drug will be wiped with moist gauze or equivalent. Entry ports will be wiped with moist alcohol pads and capped.
  - Transport will occur in sealed plastic bags and in containers designed to avoid breakage.
  - If IV Bags are spiked at the Pharmacy in the C-PEC, they must be transported to the administration site in a secondary container, such as a sealed outer bag.
- Tablet-form hazardous drugs
  - Tablets which may produce dust or potential exposure to the handler must be counted in a C-PEC. (Capsules, i.e., gel-caps or coated tablets, are unlikely to produce dust unless broken in handling.) These are counted in a C-PEC on equipment designated for hazardous drugs only, because even manual counting devices may be covered with dust from the drugs handled. This dust constitutes a potential for employee exposure.
  - Automated counting machines must not be used unless an enclosed process isolates the hazard from the employee(s). Compressed air shall not be used to clean automated counting machines.
  - Any hazardous drug tablets which must be crushed before administration will be handled in the Pharmacy's C-PEC whenever feasible.

Appendix C:
Safety Procedures for Decontaminating and Servicing Biological Safety Cabinets Used for Hazardous Drug Preparation

Employees decontaminating or servicing biological safety cabinets (BSCs) used for reconstituting cytotoxic or other hazardous drugs must be warned about the dangers of exposure to these drugs and must adhere to the following safety practices.

If the sash must be raised, this procedure can only be performed by employees who have been medically cleared and trained to wear a respirator (and fit tested if the respirator is tight-fitting).

The cabinets must be cleaned according to the manufacturer's instructions. They will be decontaminated weekly, whenever spills occur, and when the cabinet requires moving, service or certification.

Personal Protective Equipment

- Personnel must double glove with appropriate gloves for the task (i.e., chemotherapy tested gloves).
- Closed-front gowns with elastic or knit cuffs must be worn with cuffs tucked into the outer gloves.
- Face protection is required. (This can be a faceshield, mask with attached eye protection, or mask with chemical splash goggles.) If eye protection is needed, goggles must be worn.
- Ideally, the sash will remain down during cleaning. If it must be raised or if the employee's head must enter the hood, the employee must wear a particulate respirator.

Work Practices

- Decontamination will consist of surface cleaning with water and detergent followed by thorough rinsing with clean water. The use of detergent is recommended because there is no single accepted method of chemical deactivation for all hazardous drugs. Ethyl alcohol or 70% isopropyl alcohol may be used with the cleaner if the contamination is soluble only in alcohol.
- The exhaust fan/blower will be left on.
- Cleaning will proceed from least to most contaminated areas.
- Removable work trays, if present, will be removed, and the back of the work tray and the sump below will be included in the cleaning. The drain spillage area will be cleaned at least twice since it can be heavily contaminated.
- All contaminated absorbents and other materials will be disposed of by placing them in the biohazard box.

Appendix D: Liquid Hazardous Drug Spill Instructions

Equipment Needed:
Chemotherapy/hazardous drug spill kit (available from Pharmacy Store Room at 919-681-5364), including:

- Chemotherapy gown
- Shoe covers
- Splash goggles
- Face shield
- Two pairs chemotherapy tested disposable gloves
- Absorbent pads
- Scoop with detachable scraper for collecting glass fragments
- Waste disposal bags
- Hazardous Drug waste labels if bags not prelabeled

1. Alert nearby persons about the spill. Pregnant employees shall leave the area during clean up.
2. If the spilled drug got on anyone's skin, eyes, or clothing, see next page (*).
3. Prevent risk of additional skin contact with the spilled drug.
4. Obtain chemotherapy/hazardous drugs spill kit.
5. Put on safety goggles/face shield and double gloves from kit. If spill involves more than 5 mL or covers more than one square foot (or, for smaller spills, at the discretion of the person cleaning the spill), put on gown and shoe covers from kit. Tuck sleeves into the outer gloves.
6. If there are broken glass fragments, use the detachable scraper to carefully "sweep" them or other sharps into the scoop. Place these sharps in a sharps container.
7. Use the absorbent pads to cover the spilled material. **ChemoSorb pads will take a few minutes to absorb the liquid and convert it to a gel.** If additional absorbent material is needed, use plastic lined blue pads (chux) or other available materials. Place used absorbent and pads in one of the bags from the spill kit.
8. Clean the area thoroughly with water. Disposable materials used in this step should go into the open bag from the spill kit.
9. Clean the area three times using a detergent solution, then rinse. (Housekeeping can be called in for this step ONLY.)
10. Place any contaminated hospital linens in a hospital laundry bag.
11. Place other (personal) contaminated clothing in a sealed plastic bag. If it will be laundered, double bag for transport, then wash twice before combining with other laundry. If it will be discarded, place it in the open bag from the spill kit.
12. Remove the shoe covers (if used) and outer pair of gloves. Place these into the open bag from the spill kit.
13. Remove goggles and place them in the open bag from the spill kit. (Alternately, goggles may be washed and reused.)
14. Close the open waste bag (by knotting or using twist tie or tape), then place it into the second bag from the spill kit.
15. Remove the gown and inner gloves. Place these into the second bag from the spill kit. Close the outer bag.
16. Wash hands thoroughly.
17. **Read carefully for proper disposal instructions for spills of chemotherapeutic or regulated hazardous drugs:**

    If the spill involved a "blue bin" drug OR contains a constituent from the list below, the material must be disposed through the Occupational and Environmental Safety Office (OESO) and the following procedure should be followed:

    i. Determine a location where the bag can be left for a few days without being moved or thrown in the trash. Contact OESO at 919-684-2794 to arrange for waste pick-up.

    ii. Be prepared to give the name of the drug, location of the waste bag, and the name and telephone number for a responsible person who will be available during business hours.

    iii. If bag is not prelabeled, fill in the blanks on the "Hazardous Drug Waste" labels and put them on the bag, then put bag in location described to OESO.

    Drugs subject to EPA hazardous waste management requirements if discarded or unused:

Acetone	Phenacetin
Choral Hydrate	Phentermine (CIV)
Chloroform	Physostigmine
Dichlorodifluoromethane	Physotigmine Salicylate
Epinephrine (Adrenaline)	Reserpine
Formaldehyde	Resorcinol
Hexachlorophene	Selenium Sulfide
Lindane	Sodium Azide
Mercury	Streptozocin (Streptozotocin)
Nicotine	Strychnine
Nitroglycerine	Warfarin (Coumadin)
Paraldehyde	

    If the drug is not a "blue bin" drug OR on the above list, put the knotted bag of spill waste directly into a biohazard container.
18. Call the Pharmacy Store Room at 919-681-5364 to obtain a replacement spill kit.
19. Nursing staff should bag and label any contaminated pumps and send to Pharmacy.
20. Follow reporting procedures (next page **).

READ PREVIOUS PAGE FIRST!

SUPPLEMENTAL INFORMATION FOR EMPLOYEES CLEANING UP SPILLS OF HAZARDOUS DRUGS

OBVIOUS CONTAMINATION OF GLOVES, CLOTHING, SKIN OR EYES WILL BE TREATED AS FOLLOWS:

1) Remove contaminated gloves or clothing (if applicable).
2) Wash the affected skin area with soap (not germicidal cleaner) and lukewarm water. For eye exposure, immediately flush the affected eye with water or isotonic eyewash (or normal saline) for at least 15 minutes.
3) For direct skin or eye contact,
   - Obtain medical attention as soon as possible. Employees should go to Employee Occupational Health and Wellness or the Emergency Dept.
   - Fill out the appropriate incident report form and submit as follows:
     - Employees who are exposed must fill out a Report of Work-Related Injury/Illness.
     - If patient injury occurs, notify Pharmacy Medication Safety (**pager 919-970-2494**) and Risk Management (**pager 919-970-2404**) immediately.
     - If a visitor is exposed, notify Risk Management.
   - Inform the appropriate area manager.

Reporting Requirements for ALL Incidents During Patient Treatment:
Any drug spill during patient treatment should be documented in the Safety Reporting System.

About these instructions and when they should be used:

These instructions are provided with hazardous drugs spill kits so that, whenever possible, spills of LIQUID hazardous drugs can be handled by employees in the area of the spill. Hazardous drugs are those marked "Chemotherapy" or "Hazardous drug" by the pharmacy and are listed on the DUHS Hazardous Drugs List.

Additional Information:

- For information about the hazards of the spilled drug, contact the area pharmacy or use the Pharmacy-sponsored Micromedex web page. Ask for or look for a Safety Data Sheet (SDS) on the drug.
- It is not necessary to report hazardous drug spills to the Occupational and Environmental Safety Office (OESO) unless hazardous waste pickup is required. However, employees may call 911 from a campus phone or 919-684-2444 from a mobile phone to contact OESO for telephone advice or assistance cleaning up the spill. **OESO will respond to large spills that are beyond the capacity of employees in the vicinity of the spill**. Tell the dispatcher there is a hazardous drug spill and give a number where you or someone else in your work area can be reached. Please make sure someone is available to answer the telephone and talk with the Spill Responder from OESO.

Appendix E:
Spills of Powdered Hazardous Drugs

Pregnant employees will leave the area during clean-up of powdered hazardous drug spills and return once the risk of aerosolization has passed.

If you have NOT been trained to use a particulate respirator, DO NOT attempt to clean up a spill of dry chemotherapy or other powdered hazardous drugs yourself. Instead:

1.) Alert nearby persons about the spill.
2.) Clear the area.
3.) Call 911 from a campus phone or 919-684-2444 from a mobile phone to initiate OESO Chemical Spill Response.
4.) Place warning signs on the door to the room where the spill occurred.
5.) Contact maintenance to have them turn off the ventilation for the room. (This will help prevent the powder from being spread around the room or to other areas.) If the spill occurred inside a vertical flow hood/biological safety cabinet, maintenance should not turn off the exhaust fan for the hood.
6.) Re-entry to the spill area will not be permitted until the Occupational and Environmental Safety Office spill responders have cleaned the area and verified that it is safe to resume work duties.
7.) Following a spill inside a BSC, decontaminate as described in Appendix C.

If you have been

- **trained to use a HEPA-filtered Powered Air Purifying Respirator (PAPR), or**
- **trained and fit-tested to use a tight-fitting particulate respirator (e.g., N95 respirator, half- or full-face air purifying respirator with HEPA cartridges)**

AND have one available to you, you may clean up a powdered hazardous drug spill by following the procedures found below.

In addition to the respirator, you will need all of the equipment listed in Appendix D, "Liquid Hazardous Drug Spill Instructions**".**

1.) Put on N95 respirator, half- or full-face air purifying respirator with HEPA cartridges, or a Powered Air Purifying Respirator (PAPR) equipped with a HEPA filter and a hood.
2.) Put on safety goggles/face shield (unless wearing full-face respirator or PAPR), chemotherapy (or Tyvek) gown and shoe covers (or coveralls), and two pairs of chemotherapy gloves.
3.) Place warning signs around spill area if needed.
4.) Place wet absorbent material over the spill to absorb/dissolve the dry material. Once there is no visible powder, remove the absorbent material and proceed with clean-up as outlined above in the clean-up procedure for wet spills. The respirator may be removed once there is no longer a possibility for aerosolization of wet or dry hazardous drugs. N95s should be discarded. Other respirators should be put in a Ziploc bag and decontaminated before reuse. The cartridges should not be reused.

Appendix F:
Duke Safety Policy for Aerosolized Ribavirin Administration

This safety policy applies to all Duke locations where aerosolized Ribavirin is administered.

Personnel: All Ribavirin aerosol treatments will be set up by qualified respiratory therapists. Either RTs or designated nurses will turn the flow of ribavirin on at the start of the treatment. This policy applies to them as well as all other employees who must enter a room where Ribavirin is being administered. In some cases, respiratory protection will be required by this policy. In these cases, Respiratory Therapists and/or other care providers must be in compliance with the Duke University Respiratory Protection Policy, found in the Duke University Safety Manual.

Pregnant Personnel: When possible, assignments should be made so pregnant employees are not required to enter patient rooms during Ribavirin therapy. If this is not possible, respiratory protection (N95 or PAPR) should be made available to the pregnant employee(s). (Note: Call the Occupational Hygiene and Safety office at 919-684-5996 for medical clearance forms and N95 fit-testing.)

Supportive Data: Health care workers caring for patients receiving Ribavirin aerosol treatments can be exposed occupationally to this drug if proper protective measures are not taken. This drug is considered to be a "hazardous" drug by the Occupational Safety and Health Administration. Studies have shown reproductive effects in some animal species and minor pulmonary function abnormalities in human volunteers in clinical studies. These guidelines are based on a 1999 review of published literature related to Ribavirin exposure and control methods.

Equipment:
- Demistifier or other contaminant collection/HEPA filtration system
  OR (as described below)
- N95 respirators or Powered Air Purifying Respirators, in compliance with the Duke University Respiratory Protection Policy. (If you are not sure how to identify these respirators, please contact the Occupational and Environmental Safety Office at 919-684-5996. Surgical masks and isolation masks do not offer adequate employee protection.)

Safety Procedures for Administration:
<u>Administration to intubated patients</u>
If Ribavirin is administered via a mechanical ventilator to an intubated patient, the risk to staff and visitors will be minimized. No additional containment or personal protective equipment is required.

Administration to non-intubated patients

If Ribavirin is administered to a patient who is not intubated, Ribavirin can get into the room air, thereby presenting a potential for exposure to visitors and staff. In these cases, the following precautions are necessary:

- Whenever possible, these administrations will occur in negative pressure isolation rooms.
- Whenever possible, the respiratory therapist will assure that the room is under negative pressure. Negative pressure will be achieved by consultation with Engineering and Operations (by calling 919-684-3232) or other appropriate Engineering group or by use of pressure controls on the room (isolation rooms).
- The respiratory therapist will notify the nursing staff and post a 'Treatment in Progress' sign on the patient's door prior to initiating treatment. The sign can be removed 5 minutes after completion of a treatment when a demistifier is used and 30 minutes following the completion of a treatment when a demistifier is not used.
- **The respiratory therapist will administer all Ribavirin treatments inside a Demistifier,** which captures the contaminated air from around the patient and passes it through a HEPA filter. The Demistifier will continue to run throughout the Ribavirin treatment, even if the flow of Ribavirin is shut off temporarily for patient access. (Note: In some cases, a Demistifier will not be available during Ribavirin treatments. **See below**** for additional requirements for cases when a Demistifier is not available.)**
- The respiratory therapist will instruct the patient's nurse on how to turn the flow of Ribavirin off and back on in a straightforward manner so that the nurse can cut off the drug for patient care during the treatment. The RT will also instruct the nurse regarding any necessary documentation.
- For routine care, the health care provider will turn off the flow of Ribavirin and then wait at least 5 minutes before disturbing the Demistifier tent to access the patient. The provider will cut the flow of Ribavirin back on after completing tasks requiring direct patient contact.
- **For emergency care**, the provider will attend to the patient as needed but will turn off the flow of Ribavirin as soon as possible. The Ribavirin will be turned back on once direct patient contact is no longer necessary. (In these cases, employee exposure will be minimal because of the very short amount of time in the contaminated environment.)
- When the Ribavirin treatment is finished, the Demistifier will be allowed to run for at least 5 minutes (with no aerosolization of Ribavirin) before the unit is disassembled.
- Visitors to the room should be given information about the hazards associated with Ribavirin.

****In the unlikely event that the Demistifier is not used**,

- Negative pressure must be achieved in the patient room.
- All employees who enter the room during treatment must wear **N95 respirators or Powered Air Purifying Respirators (PAPRs) with HEPA filters**. All employees wearing respirators must be in compliance with the Duke University Respiratory Protection Policy. (See note below.)
- Persons with **contact lenses** should protect their eyes, either with the **Powered Air Purifying Respirator or "tight-fitting" goggles**. If eye protection is not available, people

with contact lenses should NOT enter the patient room when a treatment is in progress and for 30 minutes following its completion.
- Visitation should be discouraged during Ribavirin treatments. If visitors must enter during the treatment, they should be encouraged to wear an N95 respirator.

Post-Administration procedures

If Engineering and Operations (or other appropriate Engineering group) is involved in achieving negative pressure in the room, the Respiratory Therapist must call 919-684-3232 (or appropriate Engineering group) after the administration to have the ventilation returned to normal.

Special Note:

Any employee who will need to wear a respirator as indicated above must do the following, in accordance with the Respiratory Protection Policy found in the Duke University Safety Manual:

- Be medically cleared in compliance with the OSHA respirator standard. Medical Clearance forms are available from the Occupational Hygiene and Safety office (919-684-5996) and must be sent in to Employee Health.
- Be trained initially and annually thereafter by the Occupational and Environmental Safety Office (OESO).
- In the case of tight-fitting respirators (including N95s), be fit tested initially and annually thereafter by a competent person from OESO or EOHW.

Appendix G:
Duke Safety Policy for Aerosolized Pentamidine Administration

These procedures apply to all Duke locations where aerosolized pentamidine is administered.

This drug will only be administered by employees who have been trained by Respiratory Care Services. When a respirator is required, only employees who have been fit-tested for N95 respirators or who have been trained to use a Powered Air Purifying Respirator (PAPR) will enter the room during treatment and for 30 minutes afterward.

Safety considerations include the following:

- Patients receiving this drug are often HIV+ and therefore difficult to diagnose with *Mycobacterium tuberculosis* (TB). Whenever a patient receiving this drug has been diagnosed with pulmonary tuberculosis or cannot be ruled out for pulmonary tuberculosis, airborne isolation precautions will be implemented.
- Airborne Isolation Precautions are not required for patients who have been ruled out for pulmonary tuberculosis (i.e., three negative sputum smears collected according to current Infection Control Policy) or for patients in whom pulmonary tuberculosis is not in the differential unless the patient is HIV positive.
- The patient's care nurse should be notified that a treatment will be in progress and a 'Treatment in Progress' sign should be placed on the patient's door prior to the start of the treatment.
- Pentamidine will be administered inside a Demistifier (or other HEPA-filtered containment tent) when available. Employees and visitors can enter the room without wearing an N95 or PAPR when a Demistifier is used. However, an N95 or PAPR should be donned just prior to initiating therapy and worn when the Demistifier canopy is opened while the treatment is in progress.
- If a Demistifier is not available, pentamidine should be administered in a negative pressure isolation room with employee use of an N95 respirator or PAPR for the duration of treatment and 30 minutes thereafter.
- In the rare event that neither a Demistifier nor a negative pressure isolation room is available, occupants should wear N95 respirators or PAPRs and a portable HEPA should be used in the room and the door should be kept closed as much as possible. Portable HEPA machines are ordered from Equipment Distribution. Instructions are posted on the side of the machine or are available online at http://www.safety.duke.edu/sites/default/files/HEPA800instr.pdf.
- Aerosolized pentamidine will be administered with a nebulizer fitted with an expiratory filter meeting the industry standard of 99.9% bacterial and 99.7% viral filtering efficiency (BFE & VFE) to protect employees against secondary or exhaled aerosols.

- Patients will be instructed to pinch the tube that creates the pentamidine aerosol if they need to remove the nebulizer from their mouths during treatment. This will prevent the pentamidine from being released directly into the room.
- After setting up the administration and observing no patient side effects/complications after several minutes, the employee will leave the room.
- If the provider has to re-enter the room during treatment, he or she will minimize time in the room and will wear an N95 respirator or PAPR. (Note: If a Demistifier is used, this is not necessary.) The employee will assure that the patient is using the nebulizer correctly. If not, he or she will pinch the tube or stop the administration to prevent pentamidine particles from entering the room.
- The employee will minimize time in the room during the 30 minutes immediately following the pentamidine treatment and will wear an N95 respirator or PAPR, unless a Demistifier is used.
- To prevent other patients from being exposed to pentamidine, the treatment room will not be used for patients who are not receiving pentamidine within 30 minutes after a pentamidine treatment.

Appendix H:
Use of Hazardous Drugs in the Home Environment

The use of hazardous drugs in the home environment necessitates special precautions.

- Spill kits should be provided whenever patients are to receive hazardous drugs in liquid form outside of a Duke healthcare facility.
- Patients and family members, as well as home health care workers, should be aware of safe practices for handling hazardous drugs, as outlined above. This should include awareness of how to clean up spills and how to properly dispose of waste.
- Emergency protocols should be developed and emergency contact information should be provided to patients, family members, and home health workers.