SAFE HANDLING OF HAZARDOUS DRUGS

Updated 04/27/2018

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based on the Occupational Safety and Health Administration's Technical Manual Section on Hazardous Drugs, which has now been replaced by OSHA's updated Controlling Occupational Exposure to Hazardous Drugs.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, organ toxicity at low doses, genotoxicity, 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 the Pharmacy and from various manufacturers). 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. 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 Quality Improvement 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.)

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.

- 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 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 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 blue bins for proper disposal. All other hazardous drugs not labeled or listed for disposal in the 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 the needle 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 Room.
- 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 Quality Improvement (**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 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 Technical Manual, Section VI: Chapter 2, "Controlling Occupational Exposure to Hazardous Drugs"
- Occupational Safety and Health Administration guidelines "Controlling Occupational Exposure to Hazardous Drugs"
- NIOSH Alert: Preventing Occupational Exposures to Antineoplastic and other Hazardous Drugs in Healthcare Settings, DHHS (NIOSH) Publication No. 2004-165 (2004)
- NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2016, DHHS (NIOSH) Publication No. 2016-161. Department of Health and Human Services. September 2016.
- USP [2016]. 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 Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2016, DHHS (NIOSH) Publication No. 2016-161 (Sept. 2016) as well as additional drugs deemed hazardous based on an internal hazard assessment**.**

Periodic updates to the NIOSH list can be found at: http://www.cdc.gov/niosh/topics/hazdrug/.

Duke University Health System Hazardous Drug List

Updated: 1/20/2017

Approved by PMMC: March 2, 2017

Introduction

A hazardous drug is any drug 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] The actual risk to health care workers depends on what is done with the drug (manipulation, handling, etc) and the type of hood or personal protective equipment is used. Dispensing a single tablet poses little to no risk, while preparing an intravenous chemotherapy poses a higher risk.

For drugs which are hazardous if the dosage form is altered: crushing, breaking, splitting, or otherwise modifying the drug from its intended, stable dosage form, requires the individual preparing or administering the drug to wear gloves and a protective gown. Additional protective equipment (biosafety cabinet, face and eye shield, respiratory protection) may be required if altering the dosage form of these drugs constitutes a splash or aerosol risk. See Table 2 for more information.

Drugs undergoing review for addition to the Duke University Health (DUHS) System Formulary are formally evaluated according to the NIOSH hazardous drug criteria. This information is presented to the appropriate Formulary Evaluation Team and subsequently the DUHS Pharmacy Medication Management Committee. When a hazardous drug is added to formulary, it is subsequently added to the DUHS Hazardous Drug List. The Center for Medication Policy will collaborate with the Duke Occupational and Environmental Safety Office to periodically update the DUHS hazardous drug list.

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.

Table 1: DUHS List of Medication deemed as potentially hazardous

Hazardous Drug	DUHS Formulary? (as of 11.8.16)
Abacavir tablet & oral solution	Yes
Abiraterone acetate tablet	No
Acitretin capsule	No
Ado-trastuzumab emtansine injection	Yes
Afatinib tablet	No
Alitretinoin topical	No
Altretamine capsule	No
Ambrisentan tablet	Yes
Anastrozole tablet	Yes
Apomorphine subcutaneous injection	No
Arsenic trioxide injection	Yes
Asparaginase injection	Yes
Axitinib tablet	No
Azacitidine injection	Yes
Azathioprine injection	No
Azathioprine tablet	Yes
Bacillus-Calmette Guerin (BCG) intravesicular/dermal	Yes
Belinostat injection	No
Bendamustine injection	Yes
Bexarotene topical	No
Bicalutamide tablet	Yes
Bleomycin injection	Yes
Bortezomib injection	Yes
Bosentan tablet	Yes
Bosutinib tablet	No
Brentuximab vedotin injection	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.

Busulfan injection	Yes
Busulfan tablet	Yes
Cabazitaxel injection	Yes
Cabergoline tablet	No
Cabozantinib capsule	No
Capecitabine tablet	Yes
Carbamazepine capsule, tablet, & oral suspension	Yes
Carboplatin injection	Yes
Carfilzomib injection	Yes
Carmustine injection	Yes
Carmustine wafer implant	Yes
Cetrorelix injection	No
Chlorambucil tablet	Yes
Chloramphenicol injection	Yes
Choriogonadotropin alpha injection	No
Cidofovir injection	Yes
Cisplatin injection	Yes
Cladribine injection	Yes
Clofarabine injection	Yes
Clomiphene tablet	Yes
Clonazepam tablet	Yes
Colchicine tablet	Yes
Crizotinib capsule	No
Cyclophosphamide injection	Yes
Cyclophosphamide tablet	Yes
Cyclosporine capsules and solution	Yes
Cyclosporine injection	Yes
Cytarabine injection (also liposomal injection)	Yes
Dabrafenib capsule	No
Dacarbazine injection	Yes
Dactinomycin injection	Yes
Dasatinib tablet	No

Daunorubicin injection (also liposomal injection)	Yes
Decitabine injection	Yes
Deferiprone tablets & oral solution	No
Degarelix injection	Yes
Dexrazoxane injection	Yes
Dinoprostone suppository/gel	Yes
Divalproex tablets & capsules	Yes
Docetaxel injection	Yes
Doxorubicin injection (also liposomal injection)	Yes
Dronedarone tablet	Yes
Dutasteride capsule	Yes
Entecavir tablet	Yes
Enzalutamide capsule	No
Epirubicin injection	Yes
Eribulin mesylate injection	Yes
Erlotinib tablet	No
Eslicarbazepine tablet	Yes
Estradiol tablet	Yes
Estradiol injection	Yes
Estradiol transdermal	Yes
Estramustine capsule	Yes
Estrogen/Progestin combinations tablet	No
Estrogens, conjugated tablet & injection	Yes
Estropipate tablet	No
Etonogestrel implant	Yes
Etoposide capsule	Yes
Etoposide injection	Yes
Everolimus tablet (Afinitor)	No
Everolimus tablet (Zortress)	Yes
Exemestane tablets	Yes
Finasteride tablet	Yes
Fingolimod capsule	Yes

Floxuridine injection	Yes
Fluconazole tablet, suspension & injection	Yes
Fludarabine inejction	Yes
Fluorouracil injection	Yes
Fluorouracil topical	Yes
Fluoxymesterone tablet	Yes
Flutamide capsule	No
Fosphenytoin injection	Yes
Fulvestrant injection	Yes
Ganirelix injection	No
Ganciclovir capsule & injection	Yes
Gemcitabine injection	Yes
Goserelin implant	Yes
Histrelin implant	Yes
Hydroxyurea capsules & oral solution	Yes
Ibrutinib capsule	No
Icatibant injection	Yes
Idarubicin injection	Yes
Ifosfamide injection	Yes
Imatinib mesylate tablet & oral suspension	Yes
Irinotecan injection (also liposomal injection)	Yes
Isotretinoin capsule	Yes
Ixazomib capsules	No
Ixabepilone injection	Yes
Leflunomide tablet	Yes
Lenalidomide capsule	No
Letrozole tablet	Yes
Leuprolide acetate injection	Yes
Liraglutide recombinant subcutaneous injection	No
Lomitapide capsule	No
Lomustine capsule	Yes
Macitentan tablet	Yes
Mechlorethamine injection	Yes

Medroxyprogesterone acetate injection	Yes
Medroxyprogesterone tablet	Yes
Megestrol tablet & oral suspension	Yes
Melphalan tablet	Yes
Melphalan injection	Yes
Mercaptopurine tablet & oral suspension	Yes
Methimazole tablet	Yes
Methotrexate tablet	Yes
Methotrexate injection	Yes
Methylergonovine tablet & injection	Yes
Methyltestosterone tablets & capsules	No
Mifepristone tablet	No
Mipomersen subcutaneous injection	No
Misoprostol tablet	Yes
Mitomycin injection	Yes
Mitotane tablet	Yes
Mitoxantrone injection	Yes
Mycophenolate mofetil (tablet/capsule/injection)	Yes
Mycophenolate sodium tablet	Yes
Nelarabine injection	Yes
Nevirapine tablet & oral suspension	Yes
Nilotinib capsule	No
Olaparib capsule	No
Omacetaxine injection	No
Osimertinib tablet	No
Ospemifene tablet	No
Oxcarbamazepine tablet & oral suspension	Yes
Oxaliplatin injection	Yes
Oxytocin injection	Yes
Paclitaxel injection	Yes
Palifermin injection	Yes
Paliperidone tablet & injection	Yes

Pamidronate injection	Yes
Panobinostat capsule	No
Paroxetine tablet & oral suspension	Yes
Pasireotide injection	No
Pazopanib tablet	No
Pegaspargase injection	Yes
Pemetrexed injection	Yes
Pentamidine inhalation	Yes
Pentetate calcium trisodium	No
Pentostatin injection	Yes
Pertuzumab injection	Yes
Phenoxybenzamine capsule	Yes
Phenytoin tablets, capsules & oral suspension	Yes
Phenytoin injection	Yes
Plerixafor injection	Yes
Podofilox topical solution/gel	No
Podophyllum topical	No
Pomalidomide capsule	No
Ponatinib tablet	No
Pralatrexate injection	No
Procarbazine capsule	Yes
Progesterone injection	Yes
Progestins (e.g., Hydroxyprogesterone injection)	Yes
Propylthiouracil tablet	Yes
Raloxifene tablet	Yes
Rasagiline tablet	No
Regorafenib tablet	No
Ribavirin inhalation	Yes
Riociguat tablet	Yes
Risperidone tablet & oral solution	Yes
Risperidione injection	Yes
Romidepsin injection	Yes

Sirolimus oral solution	Yes
Sorafenib tablet	No
Spironolactone tablet & oral suspension	Yes
Streptozocin injection	Yes
Sunitinib capsule	No
Tacrolimus capsule	Yes
Tacrolimus injection	Yes
Tacrolimus topical	Yes
Tamoxifen tablet & oral solution	Yes
Telavancin injection	No
Temazepam capsule	Yes
Temozolomide capsule & oral suspension	Yes
Temozolomide injection	Yes
Temsirolimus injection	Yes
Teniposide injection	No
Teriflunomide tablet	No
Testosterone injection	Yes
Testosterone transdermal	Yes
Thalidomide	No
Thioguanine tablet & oral suspension	Yes
Thiotepa injection	Yes
Tofacitinib tablet	No
Topiramate capsule & tablet	Yes
Topotecan injection	Yes
Toremifene tablet	No
Trametinib tablet	No
Tretinoin capsules	Yes
Tretinoin topical	Yes
Trifluridine ophthalmic drops	Yes
Trifluridine/tipracil tablets	No
Triptorelin injection	No
Ulipristal tablets	No
Uracil mustard capsules	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.

Valrubicin intravesicular injection	Yes
Valganciclovir tablet & oral solution	Yes
Valproic acid capsule, injection & oral solution	Yes
Vandetanib tablet	No
Vemurafenib tablet	No
Vigabatrin tablet & oral solution	No
Vincristine injection	Yes
Vinblastine sulfate injection (also liposomal injection)	Yes
Vinorelbine tartrate injection	Yes
Vismodegib capsule	No
Voriconazole tablet, oral suspension & injection	Yes
Vorinostat capsule	No
Warfarin tablet	Yes
Zidovudine tablet, oral solution & injection	Yes
Ziprasidone capsule & injection	No
Ziv-aflibercept injection	No
Zoledronic acid injection	Yes
Zonisamide capsule	Yes

Table 2: NIOSH list of possible scenarios where hazardous drugs are handled and the suggested personal protective equipment and engineering controls

Formulation	Activity	Double Chemotherapy Gloves	Protective Gown	Eye/face Protection	Respiratory Protection	Ventilated Engineering Controls
All types of hazardous drug	Receiving, unpacking, and placing in storage	No (single glove can be used, unless spill occurs)	Yes, when spills and leaks occur	No	Yes, when spills and leaks occur	No
Intact tablet or capsule	Administration from unit-dose package	No (single glove can be used)	No	No	No	N/A
Tablet or capsule	Cutting, crushing or otherwise manipulating tablets or capsules; handling uncoated tablets	Yes	Yes	No	Yes, if not done in a controlled device	Yes†
	Administration	No (single glove can be used)	No	Yes, if vomit or potential to spit up‡	No	N/A
Oral liquid drug or feeding tube	Compounding	Yes	Yes	Yes, if not done in a control device	Yes, if not done in a control device	Yes†
	Administration	Yes	Yes	Yes, if vomit or potential to spit up‡	No	N/A
Topical drug	Compounding	Yes	Yes	Yes, if not done in a control device	Yes, if not done in a control device	Yes†, BSC or CACI (Note: carmustine and mustargen are volatile)
	Administration	Yes	Yes	Yes, if liquid could splash‡	Yes, if inhalation potential	N/A

Subcutaneous, intramuscular injection from a vial		Preparing (withdraw from vial)	Yes	Yes	Yes, if not done in a control device	Yes, if not done in a control device	Yes, BSC or CACI
		Administration from prepared syringe	Yes	Yes	Yes, if liquid could splash‡	No	N/A
Withdrawing and/or mixing Intravenous or intramuscular solution from a vial or ampoule		Compounding	Yes§	Yes	No	No	Yes, BSC or CACI; use of CSTD recommended
		Administration of prepared solution	Yes	Yes	Yes, if liquid could splash‡	No	N/A; CTSD required per USP 800 if the dosage form allows
Solution for irrigation		Compounding	Yes	Yes	Yes, if not done in a control device	Yes, if not done in a control device	Yes, BSC or CACI; use of CSTD recommended
		Administration (bladder, HIPEC, limb perfusion, etc)	Yes	Yes	Yes	Yes	N/A
Powder/Solution for inhalation/ Aerosol treatment		Compounding	Yes	Yes	Yes, if not done in a control device	Yes, if not done in a control device	Yes, BSC or CACI;
		Aerosol administration	Yes	Yes	Yes	Yes	Yes, when applicable
		Administration	Yes	Yes	Yes, if liquid could splash‡	Yes, if inhalation potential	N/A
Drugs and metabolites in body fluids		Disposal and cleaning	Yes	Yes	Yes, if liquid could splash	Yes, if inhalation potential	N/A
Drug contaminated waste		Disposal and cleaning	Yes	Yes	Yes, if liquid could splash	Yes, if inhalation potential	N/A
Spills		Cleaning	Yes	Yes	Yes	Yes	N/A

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.

BSC=Class II Biologic Safety Cabinet; CACI=Compounding Aseptic Containment Isolator; CSTD=Closed System Drug Transfer Device; HIPEC=hyperthermic Intraperitoneal Chemotherapy

†For nonsterile preparation, a ventilated engineering control such as Containment Ventilated Enclosure (CVE), fume hood or Class I BSC or HEPA-filtered enclosure (such as powder hood) is sufficient if the control device exhaust is HEPA filtered or appropriately exhausted to the outside of the building. It is recommended that these activities be carried out in a control device, but is recognized that under some circumstances, it is not possible. If the activity is performed in a ventilated engineering control that is used for sterile intravenous preparations, a thorough cleaning is required following the activity. The Containment Primary Engineering Control (C-PECs) used for manipulation of nonsterile HDs must be either externally vented (preferred) or have redundant–HEPA filters in series. Nonsterile HD compounding must be performed in a C-PEC that provides personnel and environmental protection, such as a Class I Biological Safety Cabinet (BSC) or Containment Ventilated Enclosure (CVE). A Class II BSC or a compounding aseptic containment isolator (CACI) may also be used. For occasional nonsterile HD compounding, a C-PEC used for sterile compounding (e.g., Class II BSC or CACI) may be used but must be decontaminated, cleaned, and disinfected before resuming sterile compounding in that C-PEC.

‡Required if patient may resist (infant, unruly patient, patient pre-disposed to spitting out, patient who has difficulty swallowing) or if the formulation is hard to swallow.

§Sterile gloves are required for aseptic drug preparation in BSC or CACI.

References

1. NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2014 [Internet] U.S. Department of Health and Human Services. Last Updated September 2014. Available from http://www.cdc.gov/niosh/docs/2014-138/pdfs/2014-138.pdf
2. NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2016 [Internet] U.S. Department of Health and Human Services. Last Updated September 2016. Available from http://www.cdc.gov/niosh/topics/antineoplastic/pdf/hazardous-drugs-list_2016-161.pdf
3. Duke University Health System Policy on Hazardous Drug Management Waste and Disposal
4. Hazardous Drugs – Handling in Healthcare Settings (general information chapter 800) [Internet] U.S. Pharmacopeial Convention. http://www.usp.org/sites/default/files/usp_pdf/EN/m7808_pre-post.pdf

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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.

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.
    - 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. Work must never be performed outside a BSC or other appropriate containment primary engineering control (C-PEC) as defined in USP 800.

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.)
- 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 variety.
  - 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, 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.
  - All syringes and needles used in the course of preparation will be placed in the needle box for disposal without being crushed, clipped or capped.
- Vials
  - 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, 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. (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. 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.

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 Cleanup Instructions

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

- Tyvek gown or coveralls
- Shoe covers
- Splash goggles
- Two pairs chemotherapy tested disposable gloves
- Absorbent pads
- Scoop with detachable scraper for collecting glass fragments
- Two 5 gallon plastic waste disposal bags
- One Ziploc bag for returning contaminated splash goggles to Pharmacy
- Hazardous Drug Waste labels

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 page 29.
3. Prevent risk of additional skin contact with the spilled drug.
4. Obtain chemotherapy/hazardous drugs spill kit.
5. Put on safety goggles 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 Tyvek gown and shoe covers (or coveralls) 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 needle box.
7. Use the absorbent pads to gently cover and wipe up the spilled material. If additional absorbent material is needed, use plastic lined blue pads (chux) or other available materials. Place used absorbent in one of the clear 5-gallon 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 clear 5-gallon bag from the spill kit.
15. Remove the Tyvek gown (or coveralls) and inner gloves. Place these into the second bag from the spill kit. Close the outer bag.
16. Wash hands thoroughly.
17. **For instructions regarding proper waste disposal please refer to the next page** *(Improper disposal can mean large fines)*
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 procedure outlined on page 29.

READ PREVIOUS PAGE FIRST!

Disposal Instructions for Spills of Chemotherapeutic or Regulated Hazardous Drugs

If the spill involved a chemotherapy 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:

1. 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.

2. 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.

3. 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
Choral Hydrate
Chloroform
Dichlorodifluoromethane
Epinephrine (Adrenaline)
Formaldehyde
Hexachlorophene
Lindane
Mercury
Nicotine
Nitroglycerine
Paraldehyde
Phenacetin
Phentermine (CIV)
Physostigmine
Physotigmine Salicylate
Reserpine
Resorcinol
Selenium Sulfide
Sodium Azide
Streptozoticin (Streptozotocin)
Strychnine
Warfarin (Coumadin)

If the drug is not a chemotherapy drug OR on the above list, put the knotted bag of spill waste directly into a biohazard container (WITHOUT hazardous waste label).

READ PREVIOUS PAGES FIRST!

SUPPLEMENTAL INFORMATION

FOR EMPLOYEES CLEANING UP SPILLS OF HAZARDOUS DRUGS

OBVIOUS 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. For eye exposure, immediately flush the affected eye with water or isotonic eyewash (or normal saline) 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 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 and send to Employee Health.
     - If patient injury occurs, notify Pharmacy Quality Improvement (**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.

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 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**. If you call 911, 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 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**

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 N-95 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 (unless wearing full-face respirator or PAPR), 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 the wearer judges that there is no longer a possibility for aerosolization of wet or dry hazardous drugs. N-95 respirators 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 (N-95 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 N-95 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)
- N-95 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:

Administration to intubated patients

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 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 **N-95 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 N-95 respirator.

Post-Administration procedures

If Engineering and Operations is involved in achieving negative pressure in the room, the Respiratory Therapist must call 919-684-3232 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 a competent person from the Occupational and Environmental Safety Office (OESO).
- In the case of tight-fitting respirators (including N-95s), 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 N-95 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.