

SAFE HANDLING OF HAZARDOUS DRUGS

Updated 10/8/2007

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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 is based on the [Occupational Safety and Health Administration's Technical Manual Section on Hazardous Drugs](#). Further information on specific drugs can be found on the Materials Safety Data Sheet, which can be obtained by calling the Pharmacy that supplied the drug or visiting the [Pharmacy-sponsored Micromedex web page](#) (micromedex.mc.duke.edu).

DEFINITION:

Hazardous Drug: Defined by the American Society of Health System Pharmacists 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. [Appendix A](#) of this policy lists some common drugs that are considered hazardous by the above criteria. There is no standardized reference for this information nor is there complete consensus on all agents listed. 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 Materials Safety Data Sheets are available for all drugs in liquid, powdered, and gaseous form. (Departments may use the [Pharmacy-sponsored Micromedex web page](#) (micromedex.mc.duke.edu) or contact the Pharmacy or manufacturer for MSDSs 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 is available to and worn by employees.
- Ensure that tasks involving hazardous drugs in powdered form are performed in a controlled area inside a chemical fume hood or biological safety cabinet (vertical flow hood). 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 personal protective equipment 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 following 7 drugs, which are regulated by the EPA:

CHLORAMBUCIL
CYCLOPHOSPHAMIDE
DAUNOMYCIN (DAUNORUBICIN)
MELPHALAN
MITOMYCIN C
STREPTOZOTOCIN
URACIL MUSTARD
Arsenic Trioxide
Diethylstilbestrol

The Pharmacy will

- Provide access to Materials Safety Data Sheets for hazardous drugs that it distributes. These MSDSs are available by calling the pharmacy that distributed the drug or by visiting the [Pharmacy-sponsored Micromedex web page](http://micromedex.mc.duke.edu) (micromedex.mc.duke.edu).
- 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 must wear powder-free surgical latex or disposable nitrile gloves (4 mil minimum thickness) in appropriate size. Gloves are required during 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, double gloves are recommended if they do not interfere with technique.
- If there is a potential for splashing, employees must also wear a cuffed gown and a face shield or splash goggles. 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 Biological Safety Cabinet (BSC) at the Pharmacy
- Air will be expelled from syringes by the Pharmacy in their BSC.

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 bottles, syringes, IV bags, and tubing will be placed in a BFI biohazard box (red bags).
- Contaminated gloves and other disposable PPE will be placed in a BFI box. Protective goggles (if worn) will be cleaned with detergent and properly rinsed before reuse.
- Gloves and other disposable PPE that is 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 the A-016 form for report of occupational injury or illness and send to Employee Health.
 - If patient injury occurs, notify Pharmacy Quality Improvement (**pager 970-2494**) and Risk Management (**pager 970-2404**) immediately.
 - If a family member or visitor is exposed, notify Risk Management.
 - 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 on a Medication Incident Report Form and submitted to Pharmacy Quality Improvement.

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](http://micromedex.mc.duke.edu) (micromedex.mc.duke.edu).
- Whenever possible, spills of LIQUID hazardous drugs will be handled by employees in the area of the spill.
- 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. See note [below](#).

Equipment Needed:

Chemotherapy/hazardous drug spill kit* (available from pharmacy IV room at 681-5398), including:

- Tyvek gown or coveralls
- Shoe covers
- Splash goggles
- Two pairs surgical latex or disposable nitrile gloves (minimum 4 mil thickness) (Thicker utility gloves may be substituted for one pair.)
- Absorbent Pads

Scoop with detachable scraper for collecting glass fragments
Two 5 gallon red biohazard waste disposal bags
One Ziploc bag for returning contaminated splash goggles to Pharmacy

Procedure:

1. Alert nearby persons about the spill.
2. Deal with patient or personnel exposure as instructed [above](#).
3. Take necessary steps to prevent risk of further exposure to the patient.
4. Obtain chemotherapy/hazardous drug spill kit.
5. Put on safety goggles and double gloves. 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). The sleeves should be tucked into the outer pair of gloves.
6. Use detachable scraper to carefully “sweep” broken glass fragments or other sharps into the scoop. Place these sharps in a needle box.
7. Use the absorbent pads to gently cover and then wipe up the spilled material. If additional absorbent material is needed, chux, paper towels, or other materials from the unit may be used. Place used absorbent material in one of the 5-gallon red biohazard bags from the spill kits.
8. Clean the area thoroughly with water. Put any paper towels or other disposable materials used in this step into any red biohazard bag. . .
9. Additional decontamination of the spill area is not necessary; however, if housekeeping services are available, have someone clean the area using a detergent solution then rinse the area with clean water.
10. If any bedding, patient gowns, towels, or other hospital laundry is contaminated, place it in a hospital laundry bag. All hospital laundry is treated as contaminated.
11. Other (personal) contaminated clothing should be placed in a sealed plastic bag. If it is to be laundered, it should be prewashed at least twice before being combined with other laundry. If it will be thrown away, it must be placed into a red biohazard bag.
12. Remove the shoe covers (if used) and outer pair of gloves. Place these into the open 5-gallon red biohazard bag from the spill kit.
13. Remove the safety goggles and place them in one of the ziploc bags. These need to be returned to the pharmacy with the depleted spill kit, where they will be decontaminated and returned for reuse.
14. Knot the biohazard bag, then place it inside the second 5-gallon biohazard bag.
15. Remove the Tyvek gown (or coveralls) and inner gloves. Place these into the second biohazard bag.
16. Place this second bag into any biohazard waste container UNLESS the spill involves one of the EPA-regulated chemotherapy materials named below or those substances

listed in Table 1 or 3 in “Procedures to Properly Manage Pharmaceutical Waste” which can be found at www.safety.duke.edu/EnvPrograms/default.asp. In these cases, contact the Occupational and Environmental Safety Office (684-2794) during business hours* to arrange for disposal.

CHLORAMBUCIL

CYCLOPHOSPHAMIDE

DAUNOMYCIN (DAUNORUBICIN)

MELPHALAN

MITOMYCIN C

STREPTOZOTOCIN

URACIL MUSTARD

Arsenic trioxide

Diethylstilbestrol

*After hours, a message should be left on voice mail at 684-2794. This message should state the name of the spilled drug and the location (building and room number) where the waste can be picked up the next business day. The container of spill waste should be labeled "(Name of Drug) Spill Waste: To be picked up by OESO, 684-2794."

17. Wash hands thoroughly.
18. Call the pharmacy IV room at 681-5398 to replace the chemotherapy/hazardous drug spill kit. Be sure to leave the used goggles with the kit so that they can be decontaminated and reused.

Note: It is not necessary to report hazardous drug spills to the Occupational and Environmental Safety Office 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. 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 the Occupational and Environmental Safety Office.

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 the Occupational and Environmental Safety Office. These areas must follow the safety procedures outlined in [Appendices B](#) and [C](#) of this Supplement and the spill clean-up procedures in [Appendix D](#).

Tablets of hazardous drugs which may produce dust or potential exposure to the handler must be counted in the pharmacy in a Biological Safety Cabinet (BSC). (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 BSC.

Aerosolized hazardous drugs, including Ribavirin and Pentamidine, require special handling. Refer to [Appendices E \(Ribavirin\)](#) and [F \(Pentamidine\)](#) 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 Materials Safety Data Sheet 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

- 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"

Appendix A: Some Common Drugs that are Considered Hazardous

This Appendix is taken verbatim from Appendix VI:2-1 of the Occupational Safety and Health Administration's Technical Manual, Section VI: Chapter 2, "[Controlling Occupational Exposure to Hazardous Drugs](#)".

Appendix VI:2-1 is not all-inclusive, should not be construed as complete, and represents an assessment of some, but not all, marketed drugs at a fixed point in time. Appendix VI:2-1 was developed through consultation with institutions that have assembled teams of pharmacists and other health care personnel to determine which drugs should be handled with caution. These teams reviewed product literature and drug information when considering each product.

Sources for this appendix are the "Physicians Desk Reference," Section 10:00 in the American Hospital Formulary Service Drug Information, IARC publications (particularly Volume 50), the Johns Hopkins Hospital, and the National Institutes of Health, Clinical Center Nursing Department. No attempt to include investigational drugs was made, but they should be prudently handled as hazardous drugs until adequate information becomes available to exclude them.

Any determination of the hazard status of a drug should be periodically reviewed and updated as new information becomes available. Importantly, new drugs should routinely undergo a hazard assessment.

CHEMICAL/GENERIC NAME	SOURCE*
Altretamine	C
Aminoglutethimide	A
Azathioprine	ACE
L-Asparaginase	ABC
Bleomycin	ABC
Busulfan	ABC
Carboplatin	ABC
Carmustine	ABC
Chlorambucil	ABCE
Chloramphenicol	E
Chlorotrianisene	B
Chlorozotocin	E
Cyclosporin	E
Cisplatin	ABCE
Cyclophosphamide	ABCE
Cytarabine	ABC
Dacarbazine	ABC
Dactinomycin	ABC
Daunorubicin	ABC
Diethylstilbestrol	BE
Doxorubicin	ABCE
Estradiol	B

Estramustine	AB
Ethinyl estradiol	B
Etoposide	ABC
Floxuridine	AC
Fluorouracil	ABC
Flutamide	BC
Ganciclovir	AD
Hydroxyurea	ABC
Idarubicin	AC
Ifosfamide	ABC
Interferon-A	BC
Isotretinoin	D
Leuprolide	BC
Levamisole	C
Lomustine	ABCD
Mechlorethamine	BC
Medroxyprogesterone	B
Megestrol	BC
Melphalan	ABCE
Mercaptopurine	ABC
Methotrexate	ABC
Mitomycin	ABC
Mitotane	ABC
Mitoxantrone	ABC
Nafarelin	C
Pipobroman	C
Plicamycin	BC
Procarbazine	ABCE
Ribavirin	D
Streptozocin	AC
Tamoxifen	BC
Testolactone	BC
Thioguanine	ABC
Thiotepa	ABC
Uracil mustard	ACE
Vidarabine	D
Vinblastine	ABC
Vincristine	ABC
Zidovudine	D

* Sources

A: The National Institutes of Health, Clinical Center Nursing Department

B: Antineoplastic drugs in the Physicians' Desk Reference

C: American Hospital Formulary, Antineoplastics

D: Johns Hopkins Hospital

E: International Agency for Research on Cancer

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 Materials Safety Data Sheet, available from the Pharmacy or through the Pharmacy-sponsored [Micromedex website](http://micromedex.mc.duke.edu) (micromedex.mc.duke.edu).

Personal Protective Equipment:

- Powder free surgical latex or disposable nitrile gloves (minimum thickness of 4 mils) must be worn.
 - A double layer of gloves will resist permeation considerably longer than a single layer. Double gloves should be used if the second pair does not interfere with technique.
 - 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, at which time they will be thrown away (in the BFI 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 BFI 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.

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 Class II or III Biological Safety Cabinets (BSCs, also known as Vertical Flow Hoods) designated for that purpose. 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 BSC must be covered with a disposable plastic-backed paper 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 BSC.
- A BFI box 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 BFI box. The reusable materials should be cleaned in a designated sink with mild detergent and water, then rinsed thoroughly with clean water for reuse.
- The cabinet will be cleaned daily with 70 percent alcohol.
- The cabinet will be decontaminated weekly, whenever spills occur, or 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 BSC.

- All necessary items will be placed within the BSC 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 work surface.
 - 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, name and address of the manufacturer, and warnings about hazards associated with the drug.
- 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 BSC 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 BSC, 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 BSC. (Capsules, i.e., gel-caps or coated tablets, are unlikely to produce dust unless broken in handling.) These are counted in a BSC 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).
 - Any hazardous drug tablets which must be crushed before administration will be handled in the Pharmacy's biological safety cabinet.

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, or when the cabinet requires moving, service or certification.

Personal Protective Equipment

- Personnel must wear double surgical latex or disposable nitrile gloves (minimum thickness of 4 mils).
- 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.)
- 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 worktrays, if present, will be removed, and the back of the worktray 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 BFI box.

Appendix D: 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, it must be decontaminated 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 under the section, "[Spills of Liquid Hazardous Drugs](#)".

- 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 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. The respirator should be put in a ziploc bag and decontaminated before it is reused. The cartridges should not be reused.

Appendix E:**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 Program (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 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 684-3232) or by use of pressure controls on the room (isolation rooms).
 - **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 on 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.
- Visitors 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 684-3232 after the administration to have the ventilation returned to normal.

Special Note:

- Respiratory protection for Ribavirin falls under a different Occupational Safety and Health Administration standard than respiratory protection for TB.
- 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 1998 respirator standard. Medical Clearance forms are available from the Occupational Hygiene office (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.

Appendix F:
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 and who have been fit-tested for N-95 respirators by Employee Occupational Health Services (or who have been trained to use a Powered Air Purifying Respirator by Biological Safety).

Safety considerations include the following:

- Patients receiving this drug are often HIV+ and therefore difficult to diagnose with *Mycobacterium tuberculosis* (TB). Therefore, all patients receiving this drug will be treated as though they are positive for TB. This means that employees will wear respiratory protection when in the same room with these patients and take all TB precautions.
- Pentamidine will always be administered in a negative pressure room or inside a Demistifier (or other HEPA-filtered containment tent). Negative pressure will be achieved by consultation with Engineering and Operations or by use of pressure controls on the room. Negative pressure will be confirmed prior to administration by using an installed negative pressure monitor or daily air current smoke tests.
- Patients will be instructed to pinch the tube carrying pentamidine if they remove the RespiGuard from their mouths during treatment. This will prevent the pentamidine from being released directly into the room.
- After setting up the administration, the health care provider will leave the room.
- If the provider has to re-enter the room during treatment, he or she will minimize time in the room. (Note: If a Demistifier is used, this is not necessary.) The health care provider will assure that the patient is using the RespiGuard correctly. If not, s/he or she will pinch the tube or stop the administration to prevent Pentamidine particles from entering the room.
- The provider will minimize time in the room during the 30 minutes immediately following the Pentamidine treatment.
- 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 G:
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.

APPENDIX HHAZARDOUS DRUG SPILL KIT INSTRUCTIONS

1. Alert nearby persons about the spill.
2. If the spilled drug got on anyone's skin, eyes, or clothing, see [Page 2](#) (*).
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 or any red biohazard bag.
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, placed it in the open bag from the spill kit or any biohazard bag.
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. **Read carefully for proper waste disposal** (*Improper disposal can mean large fines*):
 - a. **Nursing & Medical Research**: If the drug is listed below, determine a location where the bag can be left for a few days without being moved or thrown in the trash. Contact the Occupational and Environmental Safety Office (OESO) at 684-2794 to arrange for waste pick-up. 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. Fill in the blanks on the "Hazardous Drug Waste" labels and put them on the bag, then put bag in location described to OESO.

These are the drugs that must be treated as described above:

 - Chlorambucil (Leukeran)**
 - Cyclophosphamide (Cytosin)**
 - Daunorubicin (Daunomycin, Cerubidine)**
 - Melphalan (Alkeran)**
 - Mitomycin (Mitomycin C, Mutamycin)**
 - Streptozocin (Zanosar, Streptozotocin)**
 - Uracil mustard (Uramustine, U-8344)**
 - Arsenic Trioxide**
 - Diethylstilbestrol**

If the drug is not on the above list, put the knotted bag of spill waste directly into a biohazard container (WITHOUT labels).
 - b. **Pharmacy**: refer to "Procedures to Properly Manage Pharmaceutical Waste" to determine if this drug must be treated as hazardous waste and picked up by OESO. Call 684-2794 with questions.
18. Call the pharmacy IV room at 681-5398 to obtain a replacement spill kit.
19. Nursing staff should bag and label any contaminated pumps and send to Pharmacy.
20. Follow reporting procedures ([page 2](#) **).

READ PAGE 1 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 970-2494**) and Risk Management (**pager 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 on a Medication Incident Report Form and submitted to Pharmacy Quality Improvement. Alternately, this report can be made through the pharmacy web site: (<http://ade.mc.duke.edu/pharmacy/ade.nsf>)

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](http://micromedex.duhs.duke.edu) (micromedex.duhs.duke.edu). Ask for or look for a Materials Safety Data Sheet (MSDS) 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.