

SAFE HANDLING & DISPOSAL OF CYTOTOXIC & OTHER HAZARDOUS DRUGS

I. INTRODUCTION

Cytotoxic and some other agents have the potential for causing chromosomal damage, with teratogenic and carcinogenic effects. Acute effects include severe soft-tissue damage, fetotoxicity, headaches, lightheadedness, dizziness and nausea. Health care personnel involved with the preparation, handling, administration and disposal of these and other hazardous drugs may be at increased health risk, with exposure occurring through inhalation of dusts and aerosols, skin absorption and ingestion.

The following information is intended to reduce the number of opportunities for unnecessary contact with cytotoxic agents by health care personnel and prevent contamination of the hospital and community environment. Consult Michigan Occupational Safety and Health Administration for more specific details.

See References for OSHA Technical Manual, Section VI, Chapter 2, from which the following has been taken. Note that it also covers hazardous drugs, in addition to cytotoxic (antineoplastic) agents.

http://www.osha.gov/dts/osta/otm/otm_vi/otm_vi_2.html

II. DRUGS COVERED

Drugs, which are considered hazardous, include, but are not limited to, cyclophosphamide (Cytoxan), fluorouracil, doxorubicin (Adriamycin), mechlorethamine (nitrogen mustard), carmustine, bleomycin, methotrexate, procarbazine, cisplatin, vincristine, etc. See Appendix 1 for a list published by Occupational Safety and Health Administration.

Most act by binding to genetic material in the cell nucleus or by affecting cellular protein synthesis.

III. HAZARDOUS DRUG SAFETY AND HEALTH PLAN

A Hazardous Drug Safety and Health Plan should be available and accessible to all employees, including temporary employees, contractors and trainees who might encounter these agents. It should address the preparation, administration, and disposal of hazardous drugs and be developed to minimize exposure of personnel to, and contamination of the environment by hazardous drugs.

The plan should address at least the following:

1. Standard operating procedures relevant to safety and health considerations to be followed when health care workers are exposed to hazardous drugs.
2. Criteria that the employer uses to determine and implement control measures to reduce employee exposure to hazardous drugs, including engineering controls, use of personal protective equipment, and hygiene practices.
3. A requirement that ventilation systems and other protective equipment function properly, and specific measures to ensure performance of such equipment.
4. Provision for information and training, including spill management.
5. The circumstances under which the use of specific FDA investigational drugs require prior approval from the employer, before use.
6. Provision for medical examinations of potentially exposed personnel.
7. Designation of personnel responsible for implementation of the Hazardous Drug Safety and Health Plan, including the assignment of a Hazardous Drug Officer (who is an industrial hygienist, nurse or pharmacist health and safety representative) and, if needed, establishment of a Hazardous Drug Committee or a joint Hazardous Drug Committee/Chemical Committee.

Where appropriate:

8. Establishment of a designated hazardous drug handling area
9. Use of containment devices such as biological safety cabinets
10. Procedure for safe removal of contaminated waste
11. Decontamination procedures

The Hazardous Drug Safety and Health Plan should be reviewed and its effectiveness reevaluated at least annually. It should be updated as necessary. The development of the plan should be a collaborative effort of all hospital departments involved with hazardous drugs, and all employees, including temporary staff and trainees, should have access to it.

IV. PERSONNEL

All personnel involved with hazardous drugs must receive training regarding the possible health risks associated with exposure to these agents and be instructed in their safe handling and disposal. They should be aware of contents of the Hazardous Drug Safety and Health Plan.

Staff members who may be pregnant or breast-feeding may not prepare, administer or otherwise handle hazardous drugs. Activities related to hazardous drugs should be distributed among available trained personnel, in order to minimize each employee's daily exposure.

[Workers who are potentially exposed to chemical hazards should be monitored in a systematic program of medical surveillance intended to prevent occupational injury and disease. For detection and control of work-related health effects, job-specific medical evaluations should be performed before job placement, at certain times during employment, following acute exposures and at the time of job termination.]

V. DRUG PREPARATION

A. Work Area: Hazardous drugs preparation should be done in a restricted, centralized area, with signs limiting access of unauthorized personnel. Eating, drinking, smoking, chewing gum, applying cosmetics and storing food in the preparation area is prohibited. Written procedures for spills and emergencies, such as eye or skin contact, should be readily available to workers, preferably posted in the immediate area.

B. Equipment: A Class II, Type B, or Class III, vertical laminar flow biological safety cabinet (BSC or "hood"), must be used for the preparation of hazardous drugs. Class II, Type B-2, without air recirculation, is the most protective. External exhaust air must be discharged far from all air intakes. The hood exhaust fan or blower should remain on at all times, except for maintenance or moving. Each cabinet should be equipped with a continuous monitoring device to allow confirmation of adequate airflow and cabinet performance. The hood should be in an area with minimal air turbulence, isolated from traffic patterns of other workstations, and, preferably, located in a separate room. The preparation area should be equipped with a hand wash sink and an eye wash station. (See Michigan Occupational Safety and Health Administration for more information.)

Ventilation and BSC's should be maintained and evaluated for proper performance in accordance with manufacturer's instructions. The cabinet should be cleaned according to the manufacturer's instructions. Some recommend decontamination weekly, as well as whenever spills occur, or when the cabinet requires moving, service or certification.

C. Worker's Apparel and Protection (should be donned before work is started in the BSC)

1. Gloves: Because all are permeable to some extent - and their permeability increases with time - they should be changed hourly, or immediately if they are torn, punctured or contaminated with a spill. Thicker, longer (covering the gown cuff) latex gloves give the best protection, unless the specific hazardous drug manufacturer recommends another type. Gloves with minimal or no powder are preferred. Double gloving is recommended if it does not interfere with an individual's technique.

Gloves should be tucked into the cuffs of the operator's gown. Care must be taken not to cut, puncture or tear gloves. Training should be given to staff regarding proper technique for contaminated glove removal.

2. Gowns: Should be made of disposable, lint-free, low-permeability material with a closed front, long sleeves, and elastic or knit, closed cuffs. Apparel used to prepare hazardous drugs must not be worn out of the prep area. When double gloves are worn, one should be under and one over the cuff.

3. Eye and Face Protection: Whenever splashes, sprays or aerosols of hazardous drugs may be generated that can result in eye, nose or mouth contamination, chemical-barrier face and eye protection must be provided and used in accordance with MIOSHA mandates. Eyeglasses with temporary side shields and surgical masks are not adequate protection.

4. A BSC is essential for preparation of cytotoxic drugs. When an appropriate BSC is temporarily unavailable for cytotoxic agent preparation, a NIOSH-approved respirator must be worn. (This will not substitute for use of the biological safety hood.)

5. Personal Protective Equipment Disposal and Decontamination: All gowns, gloves and disposal materials used in preparation should be disposed of according to the facility's hazardous drug waste procedures. Goggles, face shields and respirators may be cleaned with mild detergent and water, for reuse.

For specifics on technique for preparation and administration, consult OSHA/MIOSHA Technical Manual.)

VI. SPILL MANAGEMENT AND WASTE DISPOSAL
(Consult MIOSHA/OSHA Technical Manual for more information.)

References:

1. It is strongly recommended that those involved consult OSHA Technical Manual, Section VI: Chapter 2, "Controlling Occupational Exposure to Hazardous Drugs", a copy of which may be found at Internet Address http://www.osha.gov/dts/osta/otm/otm_vi/otm_vi_2.html
2. OSHA Regulations (Standards – 29 CFR 1910.1200) on Hazard Communication.

APPENDIX 1 - Some common drugs considered hazardous

ALTRETAMINE	IDARUBICIN
AMINOGLUTETHIMIDE	IFOSFAMIDE
AZATHIOPRINE	INTERFERON-A
L-ASPARAGINASE	ISOTRETINOIN
BLEOMYCIN	LEUPROLIDE
BUSULFAN	LEVAMISOLE
CARBOPLATIN	LOMUSTINE
CARMUSTINE	MECHLORETHAMINE
CHLORAMBUCIL	MEDROXYPROGESTERONE MEGESTROL
CHLORAMPHENICOL	MELPHALAN
CHLOROTIANISENE	MERCAPTOPURINE
CHLOROZOTOCIN	METHOTREXATE
CYCLOSPORIN	MITOMYCIN
CISPLATIN	MITOTANE
CYCLOPHOSPHAMIDE	MITOXANTRONE
CYTARRABINE	NAFARELIN
DACARBAZINE	PIPOBROMAN
DACTINOMYCIN	PLICAMYCIN
DAUNORUBICIN	PROCARBAZINE
DIETHYLSTILBESTROL	RIBAVIRIN
DOXORUBICIN	STREPTOZOCIN
ESTRADIOL	TAMOXIFEN
ESTRAMUSTINE	TESTOLACTONE
ETHINYL ESTRADIOL	THIOGUANINE
ETOPOSIDE	THIOTEPA
FLOXURIDINE	URACIL MUSTARD
FLUOROURACIL	VIDARABINE
FLUTAMIDE	VINBLASTIN
GANCICLOVIR	VINCRISTINE
HYDROXYUREA	ZIDOVUDINE