UNIVERSITY OF TOLEDO

SUBJECT: HANDLING OF HAZARDOUS DRUGS (HD) i.e., ANTINEOPLASTIC AND CARCINOGENIC AGENTS

Procedure No: HM-08-005

PROCEDURE STATEMENT

Hazardous drugs shall be handled in a manner so as to ensure the safety of the staff, patients, students, and faculty of the University of Toledo. Occupational Safety and Health Administration (OSHA), National Institute for Occupational Safety and Health (NIOSH) and the United States Pharmacopoeia (USP) guidance have been used as a basis for this procedure.

PURPOSE OF PROCEDURE

To ensure protection of individuals working with hazardous drugs as defined by the “NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings” document.

PROCEDURE

A. PREPARATION OF HAZARDOUS DRUGS

1. Personal Protective Equipment

   a. Personal Protective Equipment recommendations found in the “NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings” document are based on formulation and the activity being conducted.

   b. Gloves: Double chemo-therapy gloves must be worn during all activities with the exception of receiving, unpacking, and placing in storage. During receiving, unpacking and placing in storage single chemo-therapy gloves can be used unless spills occur. Powdered gloves should never be used. Gloves should be changed every 45 minutes. Gloves should be removed and properly disposed of if they have been damaged or have come into contact with a hazardous drug.

   c. Protective Gowns: Chemo protective gowns must be worn at all times with the exception of receiving, unpacking, and placing in storage (unless spills occur). It is strongly recommended that a long sleeved, lint free, low permeability fabric with a closed front and elastic or knit closed cuffs be worn with the cuffs tucked under the gloves.

   d. Eye/Face Protection: Eye/face protection is required if there is a potential if there is a potential for splash or not done in a control device.

   e. Respiratory Protection: Respiratory protection may be required for specific activities and procedures including large spill clean up. Environmental Health and Radiation Safety staffers who are tasked with cleaning up a hazardous drug spills shall utilize a properly fitted and fit tested half mask respirator equipped with combination organic vapor / particulate cartridges.

2. Preparation Area

   Individuals involved in the preparation are required to receive training from Manager, PI's or other qualified designee.

   a. Preparation of all hazardous drugs shall be performed in a biological safety cabinet (BSC), Class II or III type, which meets current National Sanitation Foundation Standard #49. All antineoplastic agents must be prepared in the pharmacy or in approved area utilizing BSC.
b. Drug preparation shall be performed with the biological safety cabinet window in the down position and with the air flow on at all times.

c. Biological safety cabinets should be certified by a qualified technician at least once a year, or any time the cabinet is moved.

d. The biological safety hood should be operated with the blower constantly on, 24 hours a day, seven days a week.

e. Within the biological safety cabinet, work with hazardous drugs must be carried out on a disposable, plastic-backed, paper liner. Syringes and IV sets with Luer-lock fittings should always be used. The biological safety cabinet should be cleaned daily with 70% alcohol and decontaminated on a regular basis, whenever spills occur, and whenever the cabinet requires service or certification. Ordinary decontamination procedures, including fumigation with a germicidal agent, are inappropriate.

f. No food or drink shall be kept or consumed in hazardous drug preparation or storage areas.

B. STORAGE, TRANSPORT AND DISTRIBUTION

1. Hazardous drugs must be packaged in a secured area limited to authorized personnel and clearly labeled in order to prevent contamination to any person distributing the drug from the pharmacy to any clinical area.

2. Department managers or principal investigators will ensure that personnel involved in transporting hazardous drugs are trained in the necessary procedures should a spill occur.

3. The pneumatic tube system should not be used to transport hazardous drugs or any materials containing hazardous drugs.

4. Specimens from patients who have received antineoplastics (chemotherapy, immunotherapy) within the previous 48 hours, should be labeled with a yellow sticker stating "Caution: Antineoplastic Material."

5. Any material generated in the research areas transferred from original containers shall be labeled as a carcinogen or suspected carcinogen (i.e., syringe, diet).

6. Appropriate notification shall be given to DLAR personnel when animals are administered hazardous drugs.

C. DRUG ADMINISTRATION

1. Personal Protective Equipment

a. Personal Protective Equipment recommendations found in the “NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings” document are based on formulation and the activity being conducted.

b. Gloves: Double chemo-therapy gloves must be worn during all activities with the exception of administration of intact tablets or capsules (single chemo-therapy gloves can be used unless spills occur). Powdered gloves should never be used. Gloves should be changed every 45 minutes. Gloves should be removed and properly disposed of if they have been damaged or have come into contact a hazardous drug.

c. Protective Gowns: Chemo protective gowns must be worn at all times with the exception of administration of intact tablets or capsules (unless spills occur). It is strongly recommended that a long sleeved, lint free, low permeability fabric with a closed front and elastic or knit closed cuffs be worn with the cuffs tucked under the gloves.

d. Eye/Face Protection: Eye/face protection is required if there is a potential if there is a potential for splash or not done in a control device.
e. Respiratory Protection: Respiratory protection may be required for specific activities including large spill clean up or during administration of solution for irrigation. Medical procedures involving the open administration of hazardous drugs (irrigation) or situations potentially involving significant leakage of hazardous drugs shall use a properly fitted and fit tested N-95 respirator or Powered Air Purifying respirator to protect the user from exposure to aerosolized hazardous drugs.

2. Administration Equipment
   a. The use of large bore needles, no. 18, or no. 20 for I.V. push and I.V. side-arm administration, is recommended to insure that high pressure syringing of the solutions is avoided.
   b. Syringes and IV sets with Luer-lock fittings must be used in the administration of hazardous drugs.

D. SPILL CONTAINMENT
   1. Very small (incidental) spills which occur during the normal course of preparation, storage, transport, distribution or administration may be managed by employees on-scene. Larger spills must be reported to EHRS via campus police (419-530-2600) for management and cleanup.

   2. Each area in which hazardous drugs are handled shall contain a small spill clean up kit. These kits are available from Central Stores and are made up of the following items: 1 disposable chemo-safety gown, 2 pair chemotherapy gloves, 1 Chux spill absorbent, 1 small scoop/scraper, 1 small sealable and 1 large yellow polyethylene bag for disposal of contaminated absorbent, 1 stack paper towels, and spill procedure sheet.

   2. Overt contamination of gloves or gowns, or direct skin contact should be treated as follows: Immediately remove gloves or gown, wash the affected skin area immediately with soap and water, and complete an injury/incident report. If eye or skin contact or if irritation develops, seek medical attention. If eye contact occurs, flush eyes for at least 15 minutes with water or isotonic eyewash. Seek medical attention immediately.

   3. All contaminated absorbents should be disposed of as described in Section E below.

E. DISPOSAL OF HAZARDOUS DRUG (Carcinogen Waste) WASTE
   1. Contaminated sharps used in the preparation or administration of a hazardous drug shall be placed in sharps containers which are clearly marked chemotherapy waste and/or color-coded yellow. Full sharps containers, I.V. tubings and supplies used in the preparation or administration of hazardous drugs (including post-administration liquid wastes from bladder instillations or interperitoneal) and spent spill clean up supplies shall be placed in 2 mil polypropylene or 4 mil thick polyethylene disposal bags, preferably color-coded yellow. (These supplies are available through Central Stores.) Hazardous drug waste must be placed into a 28-gallon red infectious waste tub. These wastes shall be collected by Environmental Services. Generators of the waste (typically nurses) are responsible for informing Environmental Services that individual containers of infectious waste contain hazardous drug waste and must receive a yellow sticker. Environmental Services will label the waste for incineration by affixing a yellow sticker to the outside of the red container. Carcinogens generated on the college side should either be disposed of in the Department of Lab Animal Research or by contacting Environmental Health and Radiation Safety at 419-530-3600. These wastes will be disposed of by high-temperature incineration through the Environmental Health and Radiation Safety Department.

   2. Personnel dealing with blood, vomitus, or excreta from patients who have received antineoplastic drugs in the last 48 hours should wear latex gloves and disposable gowns, to be discarded after each use. Eye/Face protection should be worn if vomit or potential to spit up is suspected. Standard precautions will provide appropriate protection.
3. Linen contaminated with antineoplastic drugs, blood, vomitus, or excreta from a patient who has received antineoplastic drugs in the last 48 hours should be first bagged in a clear plastic liner, then in a blue linen bag, and then placed in a 4 mil, yellow polyethylene bag for disposal. Bags are available from Central Distribution.

4. Certain classes of hazardous drugs provided through the hospital Pharmacy are considered “hazardous waste” when destined for disposal. These drugs will be identified by the Pharmacy. Nursing will be required to collect the waste and place in a black container found in dirty utility rooms in clinical areas. Nursing staff should contact Environmental Health and Radiation Safety to retrieve these wastes for disposal through a licensed hazardous waste treatment facility. Disposal can be requested at 419-530-3600 or via the chemical waste disposal request form at [http://utoledo.edu/depts/safety/forms.html](http://utoledo.edu/depts/safety/forms.html).

F. DISPOSAL OF NON-HAZARDOUS DRUG WASTE

1. Liquid non-hazardous drug waste (drugs which are not considered “hazardous”, “carcinogen” or “controlled substances”) shall be wasted to the greatest extent possible down a sanitary drain system (sink or toilet), and empty containers disposed of in the solid waste receptacle (trash) or broken glass disposal container as appropriate. Solid non-hazardous drug waste shall be disposed of in the solid waste receptacle or broken glass container as appropriate.

G. PERSONNEL POLICY RECOMMENDATIONS

1. All personnel in affected areas shall receive special training in working with hazardous drugs. Each department manager shall have the responsibility for either obtaining or providing necessary training on an annual basis. Documentation of this training shall be maintained in the department. Training is also available from the Oncology Clinical Nurse Specialist, Department of Nursing Resources and through the Environmental Health and Radiation Safety Department.

2. It is the responsibility of the departmental managers to assure compliance with established procedures/policies for handling of hazardous drugs.

3. Pregnant employees should be informed of the potential reproduction hazard, and if they so request, staff members who are pregnant or breastfeeding should be transferred to comparable duties that do not involve handling hazardous drugs. At the discretion of the department manager, a similar policy may be followed among male or female personnel who are actively trying to conceive a child. (See Procedure HM-08-028.)

Source: Safety & Health Committee

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