HAZARDOUS DRUG HANDLING AND DISPOSAL SOP

The purpose of this program is to ensure that University of Delaware researchers, students and staff are not exposed to hazardous drugs that could potentially cause adverse health effects with occupational exposure.

A. SCOPE

This program applies to all locations at University of Delaware that use and dispose of hazardous drugs.

B. RESPONSIBILITIES

1. Department of Occupational Health and Safety (DOHS) is responsible for:

- developing and implementing a University-wide program;
- monitoring compliance with the OSHA Guidelines for Hazardous Drugs (HD);
- conducting exposure assessments and evaluating exposure control measures as necessary;
- investigating accidents
- maintaining employee exposure records.
- Aiding in spill/contamination clean up or guidance

2. Deans, Directors and Department Heads are responsible for:

- ensuring departmental compliance with all procedures outlined in this program.

3. Principle Investigators/Supervisors' responsibilities include:

- ensuring compliance with this SOP in their work areas;
- developing Standard Operating Procedures (SOP) that address specific safety measures to be implemented when using hazardous drugs;
- monitoring personnel exposures with the assistance of DOHS staff and recordkeeping, as required;
- ensuring employees with potential exposure to hazardous drugs receive the appropriate training prior to working with the substances (all personnel in the lab area should be trained regardless of direct work with HD's);
- arranging for immediate emergency response, if necessary, for chemical spills, injuries and overexposures;
- maintaining Material Safety Data Sheets (MSDSs) for the hazardous drugs used in the work area; and
- notifying DOHS when there is a change in equipment, processes or controls which may result in additional exposure to hazardous drugs.

4. Employees are required to:

- know and comply with the provisions of this program;
- report accidents, possible overexposures or unsafe conditions to their supervisor; and
- wear Personal Protective Equipment and use engineering controls as recommended.

C. GENERAL HAZARDS

1. **Mechanisms of Action** Most HD's either bind directly to genetic material in the cell nucleus or affect cellular protein synthesis. Cytotoxic drugs may not distinguish between normal and cancerous cells. The growth and reproduction of the normal cells are often affected during treatment of cancerous cells.

2. **Animal Data**. Numerous studies document the carcinogenic, mutagenic, and teratogenic effects of HD exposure in animals. They are well summarized in the pertinent IARC publications. Alkylating agents present the strongest evidence of carcinogenicity (e.g., cyclophosphamide, mechlorethamine hydrochloride [nitrogen mustard]). However, other classes, such as some antibiotics, have been implicated as well. Extensive evidence for mutagenic and reproductive effects can be found in all antineoplastic classes. The antiviral agent ribavirin has additionally been shown to be teratogenic in all rodent species tested. The American Society of Health-Systyem Pharmasists (ASHP) recommends that all pharmaceutical agents that are animal carcinogens be handled as human carcinogens.

a. **Cytotoxic (Chemotherapeutic) Drugs**

Although little research has been done on the long-term risk of occupational exposure to cytotoxic drugs, these drugs have been associated with human cancers at high (therapeutic) levels of exposure. These drugs have been shown to be carcinogens, mutagens and teratogens in many animal species. There is evidence that hazardous drugs may cause spontaneous abortions and increase the risk of congenital malformations. In addition, some of these drugs have been shown to cause acute effects in humans, such as localized skin necrosis (death of tissue) damage to normal skin after surface contact, dizziness, lightheadedness, headache and nausea.

b**. Ribavirin/Pentamidine**

Limited research has been conducted to determine the long-term risk of occupational exposure to Ribavirin and Pentamidine. Ribavirin has been shown to be a teratogen in some animal studies. Human studies on nurses who administer the drug have shown minor pulmonary function abnormalities. Pentamidine exposure may cause coughing, sneezing, mucous membrane irritation, headache

and bronchospasm. Pulmonary function tests performed on healthcare workers have demonstrated transitory decreases in carbon monoxide diffusing capacity.

3. **Employee Exposures.** Employees can be exposed to hazardous drugs through inhalation of drug dust or droplets, absorption through the skin directly, injection through the skin or ingestion through contaminated food. The following present opportunities for employee exposure during use in research.

- Withdrawal of needles from drug vials
- Drug transfers using syringes and needles
- Breaking open ampoules
- Expulsion of air from drug-filled syringe
- Spills or accidents (i.e., needle sticks)

Care must be taken when performing these procedures or handling spills and sharps to reduce employee exposures to hazardous agents.

D. HAZARDOUS DRUG SAFETY AND HEALTH GUIDELINES

This section provides general guidelines to be followed when working with hazardous drugs. Areas that use hazardous drugs must develop and implement procedures specific to the work area.

1. **Designated Work Area**

a. All hazardous drugs will be used in a centralized area .
b. The area will be posted with warning signs that state: "**Hazardous Drug Area (use/storage/waste)**."
c. Hazardous drug spill guidelines will be available in the work area.
d. The MSDS's for the Drugs used in the area will be kept in the area as well.

2. **Biological Safety Cabinet (BSC)**

a. All hazardous drug work will be conducted in a Class II Biological Safety Cabinets that meet the current National Sanitation Foundation Standard. This cabinet must be authorized by DOHS for hazardous drug use.
b. The cabinet will be certified every six (6) months by a certified technician.
c. The blower on the cabinet will be left on at all times.
d. Decontamination should consist of surface cleaning with water and detergent followed by thorough rinsing. The use of detergent is recommended because there is no single accepted method of chemical deactivation for all agents involved.
e. Ethyl alcohol or 70% isopropyl alcohol may be used with the cleaner if the contamination is soluble only in alcohol. **Alcohol vapor build-up has also been a concern, so the use of alcohol should be avoided in BSC's where air is recirculated.**

f. The BSC will be decontaminated prior to certification.

3. **Personal Protective Equipment**

a. Double gloving is required. Double gloving with nitrile or neoprene is acceptable.

- Gloves should be changed one time per hour and immediately if torn, punctured or contaminated.

b. Body protective wear will include one of the following:

1. Protective disposable gown with closed front, long sleeves and elastic or knit-closed cuffs must be worn with the cuffs tucked under the gloves. The gown should be low-permeability.

2. Polyethylene coated tyvek-sleeved apron.

Note: The cuffs should be tucked into the outer gloves and the inner glove should be under the sleeve.

c. Safety splash goggles (ANSI approved). Goggles should be cleaned with a mild detergent and water for re-use.

d. Personal Protective Equipment used for preparation will not be worn outside of the preparation area.

e. All disposable PPE will be discarded in the **"Hazardous Drug Area (use/storage/waste)"** container in the work area.

4. General Work Procedures

a. All items should be placed in the BSC before work begins.
b. A plastic-backed absorbent pad should be placed under the work area during the process. This should be changed at the end of each process or when a spill occurs.
c. No eating, drinking, smoking or applying cosmetics in the use area.
d. Syringes and IV sets with Luer-lock fittings should be used.
e. Syringes should be large enough so that they are never more than ¾ full.
f. The BSC will be cleaned before and after use with a mild detergent and water.
g. Work should be done in the middle of the hood to prevent contamination and to protect the employee.
h. All contaminated equipment should be wiped clean a mild detergent and water.
i. Needles and syringes must be placed in a sharps containers labeled **"Hazardous Drug Are (use/storage/waste)"** without being bent, recapped or removed.
j. Hands should be washed before gloves are put on and after removal of gloves.

5. Handling Vials of Hazardous Drugs

a. Vials should not be vented unless a BSC is used.

b. Dilutent should be added slowly by injecting small amounts and allowing air to escape the syringe (adding all of the dilutent at once will cause the syringe plunger to back up and possibly spray the drug or cause leakage around the needle).

c. Maintain negative pressure in the vial if chemo pin is not employed.

6. Handling Ampules of Hazardous Drugs

a. Tap down any material at the top of the ampule.
b. Wrap gauze pad around the neck of the ampule before breaking for protection from cuts and catch aerosols.
c. Open ampule away from face.
d. Inject dilutent slowly down the inside wall of the ampule.
e. Tap syringe to remove air bubbles and expel air into sterile gauze, not into the air.

E. EMPLOYEE INFORMATION AND TRAINING

1. All employees involved in any aspect of the handling of hazardous drugs, including shipment-receiving personnel, nurses, researchers, students and staff housekeepers and employees that transport the drugs, must receive training that covers the following:

- explanation of University of Delaware Hazardous Drug Handling program;
- contents of the Material Safety Data Sheets (MSDSs);
- description of the health hazards associated with exposure to hazardous drugs;
- signs and symptoms of exposure;
- instructions to report any signs or symptoms that may be attributable to hazardous drug exposure;
- description of the operations in the work area where exposure may occur to hazardous drugs;
- work practices to reduce exposure, including engineering controls (such as the biological safety cabinet) and Personal Protective Equipment required; and hygiene practices.
- instructions for handling spills and emergency procedures.
- the SOP specific for the process and work area

2. This training should be included as part of Hazard Communication training and must be conducted at least annually or whenever a new hazard is introduced into the work area or the employee demonstrates behavior that indicates a lack of understanding of the safe handling of hazardous drugs.

3. Supervisors are responsible for ensuring that employees with potential exposure to hazardous drugs receive the appropriate training ***prior*** to working with the substance.

4. All training must be documented by the individual presenting the training session, and a copy of the training records will be submitted to DOHS.

F. MEDICAL SURVEILLANCE

1. All employees exposed to hazardous drugs must receive medical attention under the following circumstances:

- whenever an employee has developed signs or symptoms associated with exposure to hazardous drugs; and/or
- whenever an employee is involved in a spill, leak or other occurrence (i.e., needle stick) resulting in a possible overexposure to hazardous drugs.

2. It is the intent of the University to provide a work environment which does not compromise the reproductive health of any employee or student, regardless of gender, or the health of a fetus. Counseling on reproductive health matters may be obtained by contacting DOHS.

G. STORAGE AND RECEIVING

1. Storage Areas: All hazardous drugs should be stored in an area that is limited to only authorized personnel and should have the signs designating the area as a **"Hazardous Drug Area (use/storage/waste)"**. A list of all hazardous drugs covered by this policy and information on spill and emergency procedures should be posted or easily available to employees. Facilities used for storing hazardous drugs should not be used for other drugs and should be designed to prevent containers from falling. Warning labels should be applied to all hazardous drug containers, as well as the shelves and bins where these containers are stored.

2. Receiving Damaged Packages: Damaged shipping cartons should not be opened. Broken containers/contaminated packages should be placed in the hazardous drug waste disposal pail. Appropriate Personal Protective Equipment and waste disposal materials should be kept in this area and employees trained in their use and the risks of exposure to hazardous drugs.

H. SPILLS/PERSONAL CONTAMINATION PROCEDURE

1. Equipment - All areas handling chemotherapy drugs should have a spill kit available in the area where the work is being conducted. Information concerning the spill kit can be obtained by contacting DOHs at (x8475)

2. Clean Up

a. Spills should be identified with a warning sign to limit access to the area until decontamination has been completed.

b. All spills occurring in the BSC:

1. Spills should be cleaned up immediately by a properly protected employee who has been trained in the appropriate procedures regarding the handling and disposal of hazardous drugs.

2. Spills should be cleaned up by utilizing materials that are available in a clearly identified spill kit. All contaminated areas should be thoroughly cleaned with a mild detergent and rinsed twice with water.

3.All contaminated cleanup materials should be disposed of in the appropriately labeled waste container. Please refer to the Waste section for details

Note: ***Spills in Biological Safety Cabinets****:* Decontamination of all interior cabinet surfaces may be required after the above procedures have been followed first. Do not turn off the hood while decontaminating interior surfaces. If the HEPA filter of a cabinet is contaminated, the unit should be labeled **"Do Not Use–Contaminated"**, and the unit should be sealed in plastic until the filter can be changed and properly disposed of in the hazardous drug disposal container by trained personnel wearing appropriate Personal Protective Equipment.

c. All other spills outside of the BSC:

1. Alert others in the area.
2. Leave the lab area immediately, closing the door behind you
3. Contact 911 for immediate assistance

3. Personal Contamination Procedure

a. Personnel Contamination*:* Overt contamination of gloves or gowns, or direct skin or eye contact, should be treated as follows:

- Immediately remove gloves or gown.

- Immediately wash the affected skin area with soap (not germicidal cleaner) and water.
- Immediately flood the affected eye with water for fifteen (15) minutes.
- Immediately obtain medical attention.

K. WASTE DISPOSAL

1. Procedures

a. All hazardous drug contaminated waste should be placed in yellow bags that are labeled with the appropriate hazard warning **"Hazardous Drug Area (use/storage/waste**). The bag must be placed in a covered 5 gallon pail with lid and sealed whenever waste is not actively being added.

b. At least one (1) covered hazardous drug waste disposal container should be located in every area where the drugs are being used. Prudent practice dictates that every precaution must be taken to prevent contamination of the exterior of the containers.

c. All items contaminated by hazardous drugs including gloves, syringes, gowns, vials, needles, and solution containers should be considered as regulated medical waste and disposed of accordingly.

d. When the white hazardous drug waste disposal container is almost full, seal the bag in the **BSC** and place the sealed bag in a bio-waste box. Replace the yellow bag in the **HD** waste container.

e. Gloves should be worn when handling all waste containers.

2. Sharps

a. Place needles, syringes with needles attached and other breakable items into a red, rigid plastic sharps container that has been labeled **"Hazardous Drug Area (use/storage/waste)"**.

b. When the sharps container is full, seal it in the **BSC** and place it into a bio-waste box.

3. Reagent, Virgin Compound, Solutions

a. Reagent chemical, stock solutions, etc. should not be disposed in a bio-waste box.

b. Seal the container, bottle, etc in a zip-lock bag and place in a cardboard box with ample packing material. Apply a completed DOHS Orange Chemical Waste Label to the box and contact DOHS for disposal.

4. Empty Stock Vials, Reagent Bottles, etc.

a. Triple rinse with copious amounts of water.
b. Deface the label with a black magic marker or scraper
c. Place in a glass only box, take to the dumpster or place in a recycling container.

5. Pharmaceuticals and/or Active Ingredients that are Chemical or Hazardous Wastes

Disposal of pharmaceuticals used for treatment in a hospital or clinic setting, as well as research must be managed properly. Some specific drugs or the active ingredients are hazardous wastes and could harm human health or the environment if disposed of improperly. Other antiseptics, pain killers, antibiotics, etc. still require proper management and must not be disposed into sanity sewer system or normal trash. Always check the Material Safety Data Sheet (MSDS) for indicators that the pharmaceuticals are hazardous and require special management through the chemical waste or biological waste programs. Some indicators are the words carcinogen or potential carcinogen, toxic, flammable, corrosive or hazardous. The National Fire Protection Association Fire Rating Diamond also will indicate if the material is hazardous. Below is a list of common pharmaceuticals, active ingredients or drug classes that are hazardous or chemical wastes. This list in not inclusive and you should always check the active ingredients, MSDS and/or contact DOHS for disposal guidance.

Also go to the U.S. Drug Enforcement Agency's web site for a list of drugs and drug active ingredients that they regulate and which require special management. Contact DOHS if you use any of these compounds in your research or for treatment of patients.

- http://www.usdoj.gov/dea/pubs/scheduling.html

P-Listed (Acutely Hazardous)		**U-Listed (Toxic)**	
Waste Name	**HW #**	**Waste Name**	**HW #**
Arsenic trioxide, CAS#: 1327-53-3	P012	Acetone, CAS#: 67-64-1	U002
Epinephrine (Adrenaline), CAS#: 51-43-3	P042	Chloral Hydrate (CIV), CAS#: 302-17-0	U304
Nicotine, CAS#: 54-11-5	P075	Chlorambucil, CAS#: 305-03-3	U035
Nitroglycerine, CAS#: 55-63-0	P081	Chloroform, CAS#: 67-66-3	U044
Phentermine (CIV), CAS#: 122-09-8	P046	Cyclophosphamide, CAS#: 50-18-0	U058
Physostigmine, CAS#: 57-47-6	P204	Daunomycin, CAS#: 20830-81-3	U059

Physostigmine salicylate, CAS#: 57-64-7	P188	Dichlorodifluoromethane, CAS#: 75-71-8	U075
Sodium Azide, CAS#: 26628-22-8	P105	Diethylstilbestrol, CAS#: 56-53-1	U089
Strychnine, CAS#: 57-54-9	P108	Formaldehyde, CAS#: 50-00-0	U122
Warfarin >.3%, CAS#: 81-81-2	P001	Hexachlorophene, CAS#: 70-30-4	U132
Metals		Lindane, CAS#: 58-89-9	U129
Waste Name	**HW #**	Melphalan, CAS#: 148-82-3	U150
Arsenic	D004	Mercury, CAS#: 7439-97-6	U151
Barium	D005	Mitomycin C, CAS#: 50-07-7	U010
Cadmium	D006	Paraldehyde, CAS#: 123-63-7	U182
Chromium	D007	Phenacetin, CAS#: 62-44-2	U187
Lead	D008	Phenol, CAS#: 108-95-2	U188
Mercury	D009	Reserpine, CAS#: 50-55-5	U200
Selenium	D010	Resorcinol, CAS#: 108-46-3	U201
Silver	D011	Saccharin, CAS#: 81-07-2	U202
Other Compounds or Classes that Require Special Management		Selenium sulfide, CAS#: 7488-56-4	U205
Cisplatin, CAS#: 15663-27-1		Streptozoticin (Streptozotocin), CAS#: 18883-66-4	U206
Etoposide, CAS#: 33419-42-0		Trichloromonofluoromethane, CAS#: 75-66-4	U121
Etoposide Phosphate, CAS#: 117091-64-2		Uracil mustard, CAS#: 66-75-1	U237
Taxotere, CAS#: 114977-28-5		Warfarin <.3% (Coumadin), CAS#: 81-81-2	U248
Thalidomide, CAS#: 50-35-1			
Thalidomide Derived Compounds			
Antineoplastic Drugs			