Environmental Health and Safety
Title: SOP for Cytotoxic Agent and Chemotherapeutic drugs use in research
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I. Purpose:

The purpose of this document is to provide guidelines to staff and students for handling and disposal of Cytotoxic Agent, including chemotherapeutic drugs use in Research at UNT Health campus.

Chemotherapeutic drugs are by nature cytotoxic and often carcinogenic. Studies that use chemotherapeutic drugs in animals can put researchers and DLAM staff at risk from acute and chronic exposure.

NIOSH recommends that all hazardous drugs be handled safely and has published guidelines in their 2004 *NIOSH Alert: Preventing Occupational Exposures to Antineoplastic and Other hazardous Drugs in Health Care Settings.* This applies primarily to workers in health care settings, but also applies to those who work with hazardous drugs in research laboratories, which is the focus in this document.

II. Scope:

This document applies to Cytotoxic Agent, including chemotherapeutic drugs use in in-vitro and in-vivo research.

a. List of commonly used chemotherapeutic agents:

Chemotherapy drugs include, but are not limited to: Amascrine, Bleomycin, Bromo-Deoxyuridine (BrdU), Carboplatin, Carmustine, Chlorambucil, Cisplatin, Cyclophosphamide, Cyclosporin A, Dacarbazine, Dactinomycin, Daunorubicin, Docetaxel, Doxorubicin, Epirubicin, Etoposide, Ifosfamide, Mechlorethamine, Methothrexate, Mithramycin-A, Mitomycin-C, Oxaliplatin, Paclitaxel, Streptozotocin, Tamoxifen, Topotecan, Vincristine, Vinorelbine.

III. Responsibility:

Principal Investigator (PI) is responsible to ensure that all staff and students are trained on the proper handling, and disposal of cytotoxic agents. The PI is responsible to ensure that all procedures are followed to while working with Cytotoxic Agents in the laboratory.

Principal Investigators (PIs) are required to assess and document the exposure hazards of their work with chemotherapy and other hazardous drugs to determine the appropriate precautions and controls to be taken. The assessment includes, at a minimum, the types, forms and volumes of hazardous drugs used, the procedures performed, engineering controls, personal protective equipment (PPE), decontamination and cleaning, spill response, waste handling and emergency procedures in case of possible exposure or other emergencies. EHS will assist PIs as needed in their exposure hazard assessment.

PIs must provide personnel laboratory-specific chemical training for the specific agents they are working with. The hazardous chemical training must include but is not limited to the health and physical hazards of the agents, signs and symptoms associated with exposure, appropriate work practices, PPE, work practices and emergency procedures in case of spill or possible exposure. Review of the safety data sheet/ (SDS) is required and practice with less hazardous materials is recommended prior to work with the agents.

Laboratory personnel/ Staff have the responsibility to be familiar with the SDS for the cytotoxic agent and adhere to the process outlined in this SOP while working with Cytotoxic Agents in the laboratory. All personnel who handle chemotherapy drugs or any other cytotoxic drugs should follow the methods outlined in this document.

IV. Hazards: Cytotoxic agents (Hazardous drugs and chemotherapeutic agents)

Cytotoxic agents have the following potential health hazards,

a. Possible carcinogen- may cause cancer in humans
b. Possible teratogen- may cause birth defects
c. Possible reproductive hazard- may affect the ability to have healthy children
d. Organ toxicity at low doses
e. Genotoxicity
f. Structure and toxicity profiles of new drugs that mimic existing drugs determined hazardous by the above criteria

V. Exposure risk and mitigation

In a research laboratory setting, researchers may be exposed to chemotherapy or other hazardous drugs by inhalation of agent powder or aerosol produced during preparation, administration or cleanup activities. Skin exposure with agents may occur during preparation or administration of the agent, contact with contaminated work surfaces, clothing and equipment, or by needlestick incidents.

Exposure risks can be greatly reduced by (1) making sure that engineering controls such as fume hoods, exhausted biological safety cabinets (BSC) and other exhausted enclosures are used and (2) using proper procedures and protective equipment for handling chemotherapy and other hazardous drugs.

VI. Personal Protective equipment

1. Wear disposable, powder-free chemotherapy gloves that are approved by the Food and Drug Administration (FDA) and have been tested for use with chemotherapy drugs. These gloves are also recommended for handling other hazardous drugs. These gloves should meet the specific requirements of the ASTM D6978-05 standard for chemotherapy drug permeation resistance, according to the American Society of Testing and Materials. See appendix 3

2. Wear two pairs of gloves for most activities working with hazardous drugs. A single pair of gloves should provide adequate protection when working with intact tablets or capsules.

3. Wear a protective gown or equivalent that is lint-free, non-permeable with a solid front, long sleeves, and tight-fitting elastic or knit cuffs. Wear long pants or long skirt, and fully closed shoes.

4. Wear safety glasses with side shields or goggles.

5. Wear face protection, such as a face shield, when splash/splatter is possible.

6. Respiratory protection (requires enrollment in UNT Health's respirator program) may be required if an airborne hazard is present when work is done outside of approved containment or when cleaning up a spill. Surgical masks do not provide adequate protection. Contact EHS for assistance.

VII. Safe Laboratory Practices

1. All agent preparation must be performed in a chemical fume hood, glove box, exhausted BSC or other approved containment. Contact EHS for assistant in determining the correct containment device needed.

2. Perform preparations over plastic backed absorbent pads. Dispose of pads after completion of tasks or immediately upon contamination as chemotherapy waste.

3. Transport agents only in labeled, leak/spill-proof, non-breakable secondary containers.

4. Decontaminate surfaces by cleaning with 10% freshly prepared bleach and water followed by thorough rinsing.

5. Clean work surfaces before and after each activity and at the end of the work shift. Establish periodic cleaning routines for all work surfaces and equipment that may become contaminated.

6. Develop a spill cleanup plan specific for the Hazardous drug you work with (please refer to SDS for the drug and consult with EHS team if you have any questions). Document training of all personnel handling the material.

7. Decontaminate the chemical fume hood, BSC or glove box, and other work surfaces before and after each task and at the end of the work shift.

8. Surface decontaminate containers before they are removed from the fume hood, and BSC. Also decontaminate the exterior of the closed primary container and place it in a clean secondary container.

9. When work is completed, remove gloves and wash hands with soap and water.

10. Store chemotherapy and other hazardous drugs in an area labeled chemotherapeutic/hazardous drugs.

VIII. Animal Experiments

1. Research staff must inform DLAM in advance that cytotoxic agents will be used, and arrangements will be made for appropriate animal housing.

2. Animals must be injected with cytotoxic agents within a Class II Type B Biosafety cabinet or designated fume hood.

3. Animal handler must wear PPE as above with a 2nd pair of gloves (double-glove).

4. All needles must be disposed of in sharps container – do not recap or bend needles.

5. Dispose of waste as described above.

   Cage handling:

6. DLAM staff should be made aware of cytotoxic agents use and cage cards should be labeled with “Cytotoxic agents” after injection.

7. Animal cages and bedding are considered hazardous for a minimum of 3 days (72hours) after an injection. The first cage change after each drug administration is to be done no sooner than 3 days after the administration.

8. The bedding is considered contaminated and requires special handling. The first bedding change after drug administration should be handled using procedures that minimize aerosolization in a biosafety cabinet.

9. After this first cage change there is no need for further special precautions to be taken regarding the animals or the cages as long as the animals have not received any more cytotoxic agents.

10. Dispose of all contaminated bedding and animal carcasses in waste container to be incinerated.

IX. Exposure Plan

Follow the steps below for any exposures to chemotherapy or other hazardous drugs.

1. Provide First Aid Immediately

- Inhalation

Move out of contaminated area.

- Sharps injury (needlestick and subcutaneous exposure)

Scrub exposed area thoroughly for 15 minutes using warm water and soap.

- Skin exposure

Use the nearest safety sink or shower for 15 minutes. Stay under the shower and remove contaminated clothing. Use a clean lab coat or spare clothing for cover-up.

- Eye exposure

Use the eye wash for 15 minutes while holding eyelids open.

2. **Immediately notify EHS and PI**

3. **Seek Medical care in the event of personal exposure**
    - Please refer to the exposure plan https://www.unthsc.edu/safety/occupational-health-services/
    - Please provide the information listed below (details of exposure) to the emergency care team. **Bring to the clinic or emergency department the SDS/MSDS and SOP for specific agent.**
        i. Agent
        ii. Dose
        iii. Route of exposure
        iv. PPE worn at the time of exposure
        v. Time since exposure
        vi. First aid response performed

X. AGENT SPILL CLEANUP

Chemotherapy and other hazardous drug spills must be cleaned up as soon as possible by properly protected and trained personnel. All other persons should leave the area. Spill response procedures must be developed based on the hazardous agent present and potential spill or release conditions. All personnel must be trained on spill responses. Do not attempt to clean up any spill if not trained or comfortable. Evacuate the area and contact EHS or police (after hours) for help.

1. **Spills inside a BSC, fume hood, glove box or approved containment**

1. Personnel must wear a lab coat or smock, safety goggles, two pairs of disposable chemotherapy gloves (or one pair of non-disposable nitrile or butyl gloves (minimum 10 mil thickness) or Silver Shield gloves), when cleaning up spills.

2. Liquids: Wipe up spilled liquids with absorbent pads.

3. Powders: Gently cover powder spill with wetted paper towels or absorbent pads to avoid raising dust and then wipe up.

4. Clean the spill area thoroughly with detergent solution followed by clean water.

5. If spill is extensive within the containment, clean all interior surfaces after completion of the spill cleanup.

6. Double bag all waste in plastic bags labeled with the contents. Submit request to EHS for waste pickup.

2. Small Spills (less than 5 ml) outside of containment

1. Personnel must wear a gown or coveralls with solid front, safety goggles, shoe covers as needed and two pairs of disposable chemotherapy gloves (or one pair of non-disposable nitrile or butyl gloves (minimum 10 mil thickness) or Silver Shield gloves), when cleaning up spills.

2. Wear an N95 or equivalent respirator for either powder or liquid spills where airborne powder or aerosol is or has been generated. Spills of volatile agents require the use of an appropriate combination particulate/chemical cartridge-type respirator. Most chemotherapy drugs are not volatile, but some are. Assess the volatility of the agent. Please contact the EHS Respiratory Protection Program to discuss respiratory protection or to enroll in the program. Program enrollment includes medical evaluation, training and fit testing for an appropriate respirator. For information see EHS Respiratory Protection Program

3. Liquids: Wipe up spilled liquids with absorbent pads.

4. Powders: Gently cover powder spill with wetted paper towels or absorbent pads to avoid raising dust and then wipe up.

5. Clean the spill area thoroughly with detergent solution followed by clean water.

6. Double bag all waste in plastic bags labeled with the contents. Submit request to EHS for waste pickup.

3. Large spills (greater than 5 ml) outside of containment

1. Evacuate all personnel from the laboratory and restrict access.

2. As soon as possible report the spill by notifying EHS during business hours, outside business hours contact campus police; tell them that a spill has occurred, and that you need help managing the spill. EHS will contact a spill cleanup contractor if needed. Notify supervisor.

3. Be prepared to provide the following information:

4. Name and phone number of knowledgeable person that can be contacted

5. Name of agent spilled, concentration and amount spilled, liquid or solid type spill

6. Number of injured, if any

7. Location of spill

8. This information should also be reported to the Emergency Department (ED) after a potential exposure.

9. Only if staff are trained, have the proper PPE and are comfortable with cleaning up the spill, they may proceed to clean it up. Personnel must wear a gown or coveralls with solid front, safety goggles, shoe covers as needed, and two pairs of disposable chemotherapy gloves (or one pair of non-disposable nitrile or butyl gloves (minimum 10 mil thickness) or Silver Shield gloves), when cleaning up spills.

10. Wear an N95 or equivalent respirator when cleaning large spills. Spills of volatile agents require the use of an appropriate combination particulate/chemical cartridge-type respirator. Most chemotherapy agents are not volatile, but some are. Assess the volatility of the agent. Please contact the EHS Respiratory Protection Program to discuss respiratory protection or to enroll in the program. Program enrollment includes medical evaluation, training and fit testing for an appropriate respirator. For information see EHS Respiratory Protection Program.

11. Liquids: Wipe up spilled liquids with absorbent pads.

12. Powders: Gently cover powder spill with wetted paper towels or absorbent pads to avoid raising dust and then wipe up.

13. Clean the spill area thoroughly with detergent solution followed by clean water.

14. Double bag all waste in plastic bags labeled with the contents. Submit request to EHS for waste pickup.

Any spill incident requires the involved person or supervisor to complete and submit the Incident reporting form to EHS within 24 hours.
For questions on spill cleanup, contact EHS.

XI. Waste Disposal

1. Dispose of leftover/unused excess chemotherapy and hazardous drug and the contaminated disposable items in a plastic bag labelled with “Cytotoxic Wate” (see appendix 1) and placed in the proper waste container. Submit online request to EHS for waste pickup.

2. All disposable materials contaminated with the chemical, residual chemical and PPE used with P listed drugs must be disposed of as hazardous waste. See appendix 2

3. All disposable materials contaminated with the chemical, residual chemical and PPE used can be disposed as normal.

4. Re-useable glassware and other non-porous materials can be decontaminated by soaking in 10% bleach for 24 hours.

5. Used needles/syringes should be disposed in a sharps container destined for incineration.

For questions regarding chemotherapy/hazardous drug waste collection and disposal, contact Safety Office at SafetyOffice@unthsc.edu

XII. RESOURCES

- *NIOSH Alert: Preventing Occupational Exposures to Antineoplastic and Other hazardous Drugs in Health Care Settings.* DHHS (NIOSH) Publication Number 2004−165, September 2004.
- NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings (2024)

XIII. Version Revision

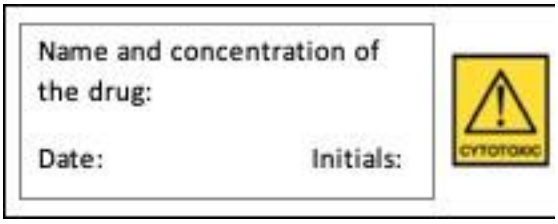
Approved 12 May 2020

Revised 29 July 2025 update to new branding, made accessible, added safety information.

Appendix 1: Cytotoxic agent waste Label

Example of label for secondary containers. Avery labels
Avery5167EasyPeelReturnAddressLabels

Premade sheet available on EHS website https://www.unthsc.edu/safety/standard-operating-procedures/.



Appendix 2: P listed drugs

Waste Code	Constituent of Concern	Product Name Examples:
P001	Warfarin & salts (concentration > 0.3%)	Coumadin; Warfarin
P012	Arsenic trioxide	Trisenox
P042	Epinephrine	Adrenalin; EpiPen; Eppy/N; Epifrin; Epinal; Anaphalaxis kit; Epinephrine (inhalants, injectables, kits); Racepinephrine; Racord; Primatene aerosol inhaler
P046	Phentermine	Phentermine (CIV)
P075	Nicotine & salts	Nicotine patches; Habitrol; Nicoderm; Nicorette; Nicotrol; Tetrahydronicotyrine
P188	Physostigmine salicylate	aka Eserine salicylate
P204	Physostigmine	aka Eserine

Appendix 3: Chemotherapy Glove Permeation Test Data* ASTM D6978-05**

Chemical	Medline Sensicare 12" MDS 1285 series	Medline Sensicare Ice 9.5" MDS 8802 series	Medline Aloetouch 12" MDS 195185 series	Medline Sensicare 300 9.5" 486802 series	Kimberly Clark KC500 Purple Nitrile 9.5"	Kimberly Clark KC500 Purple Nitrile-XTRA 12"	Kimberly Clark KC300 Sterling or Sterling XTRA 12"	Cardinal Health Esteem Tru-Blu Stretchy 9.7"	Microflex Rogel Nuisance (neoprene) 314	Molnlycke Biogel PI Ultra Touch (polyisoprene) 411	Conolidary/Kendall Chemoattire Nitrile 12" CTS071 series	Cardian Chemosafety Nitrile 12" CTS711 series	Ansell Micro Touch Nitrile 9.4" 6034380 series	Ansell Micro Touch Nitrile 11.6" 6034050 series	Ansell Micro Touch Nitra Free Pink 9.4" 6034510 series
Bleomycin sulfate (Blenoxane)		>240	>240	>240	>240		>240								
Bortezomib (Velcade)		>240	>240	>240											
Busulfan		>240	>240	>240	>240	>240		>240							
Carboplatin (Paraplatin)	>240	>240	>240	>240	>240	>240		>240							
Carmustine (BCNU)	15.1	1.85	47.2	1.85	7.8	30.7	NR	22	15	1	37	1	12.4	71.3	45.3
Cetuximab (Erbitux)		>240	>240	>240											
Cisplatin	>240	>240	>240	>240	>240	>240	>240	>240			>240	>240	>240	>240	
Cyclophosphamide (Cytoxan)	>240	>240	>240	>240	>240	>240	>240	>240	>225	>240	>240	>240	>240	>240	>240
Cytarabine Hydrochloride		>240	>240	>240	>240	>240		>240							
Dacarbazine (DTIC)	>240	>240	>240	>240	>240	>240	>240	>240			>240	>240	>240	>240	
Daunorubicin		>240	>240	>240	>240	>240		>240							
Docetaxel	>240	>240	>240	>240	>240	>240									
Doxorubicin Hydrochloride	>240	>240	>240	>240	>240	>240	>240		>225	>240	>240	>240	>240	>240	>240
Epirubicin (Ellence)	>240	>240	>240	>240	>240	>240		>240							
Etoposide (Toposar)	>240	>240	>240	>240	>240	>240	>240	>240	>225	>240	>240	>240	>240	>240	>240
Fludarabine		>240	>240	>240	>240	>240		>240							
5-Fluorouracil	>240	>240	>240	>240	>240	>240	>240	>240	>225	>240	>240	>240	>240	>240	>240
Gemcitabine (Gemzar)	>240	>240	>240	>240	>240	>240									
Idarubicin		>240	>240	>240	>240	>240		>240							
Ifosfamide (IFEX)		>240	>240	>240	>240	>240	>240	>240							
Irinotecan	>240	>240	>240	>240	>240	>240									
Mechlorethamine HCl (Mustargen)		>240	>240	>240	>240	>240		>240							
Melphalan		>240	>240	>240	>240	>240		>240							
Methotrexate	>240	>240	>240	>240	>240	>240		>240							>240
Mitomycin C	>240	>240	>240	>240	>240	>240		>240	>225	>240					
Mitoxantrone		>240	>240	>240	>240	>240	>240	>240							
Oxaliplatin	>240	>240	>240	>240											
Paclitaxel (Taxol)	>240	>240	>240	>240	>240	>240	>240	>240	>225	>240	>240	>240	>240	>240	>240
Pemetrexed		>240	>240	>240											
Raltitrexed		>240	>240	>240											
Rituximab		>240	>240	>240	>240	>240		>240							
ThioTEPA	30.8	1.01	119.3	1.01	1.6	>240	NR	17	45	6	16	3	19.6	179.5	93.5
Trisenox		>240	>240	>240	>240	>240		>240							
Vidaza (5-Azacytidine)	>240	>240	>240	>240											
Vinblastine		>240	>240	>240											
Vincristine Sulfate	>240	>240	>240	>240	>240	>240	>240	>240	>225	>240					>240
Vinorelbine	>240	>240	>240	>240											

*all nitrile, non-latex, powder free exam or surgical gloves unless noted; data provided from glove manufacturers

**includes 9 chemicals to test: carmustine, cyclophosphamide, doxorubicin hydrochloride, etoposide, 5-fluorouracil, methotrezate, paclitaxel, thioTEPA, vincristine sulfate NR = not recommended