Guidelines for the Use of Cytotoxic or Chemotherapeutic Drugs

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Introduction

What are Cytotoxic Drugs?
Cytotoxic drugs (CDs) are primarily used as anti-cancer drugs because they are toxic to cells. These drugs have been associated with human cancers at high (therapeutic) levels of exposure and are carcinogens and teratogens in many animal species. Under current work practices, CDs have demonstrated the ability to cause elevations in sister chromatid exchanges and chromosome breakage in circulating lymphocytes and mutagenic activity in urine. In addition, many of these drugs have been shown to cause a variety of acute effects in humans, such as localized skin necrosis (death of tissue) after surface contact with abraded skin or damage to normal skin.

What are the Routes of Exposure?
- Inhalation – drug dusts or droplets
- Absorption – via skin or mucous membranes
- Ingestion – via contact with contaminated food, drink, cigarettes, etc.

How can you protect yourself when working with Cytotoxic Drugs?

Engineering Controls
- Biological Safety Cabinet (Class II vertical flow, Type A2, ducted)
- Chemical Fume Hood

Personal Protective Equipment
- Gloves appropriate for the chemical being handled and double glove
- Protective Disposable gown
  - Lint free, low permeability
  - Closed front, long sleeves, elastic/ knit closed cuffs
  - Cuffs tucked under gloves
  - Wear only in prep area
- Safety Glasses
- Respiratory Protection
  - N95 HEPA Mask when local exhaust ventilation is not available

Work Practices
Standard Procedures
- Work in a Biological Safety Cabinet (Class II vertical flow, Type A2, ducted), or chemical fume hood.
- No Eating or Drinking
- Label contaminated containers with CHEMO labels.
- Store all waste in covered receptacles
- Minimize aerosols by taking care when:
  - Withdrawing needles from drug vials
  - Transferring drugs via needles/syringes
  - Breaking ampoules
  - Expelling the drugs from needles
- Use a plastic lined absorbent sheet to cover work area
- Clean all surfaces including containers with detergent when procedure complete
Handling of Cytotoxic Drug Treated Animals and Cages

- Must be reviewed and approved by the Institute Animal Care and Use Committee prior to start.
- Animals dosed with cytotoxic drugs must have a completed Cytotoxic/Chemo in Use Cage Card.
  - The following information must be completed on the card:
    - The date of dose
    - Dosage
    - Name of Drug
- Any handling of the animal or opening of the cage must be done in a fume hood or biosafety cabinet until a cage change has occurred (minimum time 72 hours, maximum time 1 week).
- The cage card may be removed after the initial bedding change and regular handling procedures can resume.
- Dirty bedding must be placed in a red biohazard bag or yellow trace chemo waste bag for disposal.

How to Dispose of Cytotoxic Waste?

Waste Cytotoxic Drugs

- Dispose of as hazardous waste. Place all drugs in boxes that are marked clearly as “INCINERATION ONLY”. Complete a hazardous waste tag and call the Caltech Environment, Health and Safety Office at x6727 for pick up.

Items Contaminated with Cytotoxic Drugs

- Dispose of as “Trace Chemotherapeutic Waste”
  - Examples include gloves, pads, empty vials, tubes, excreta.
  - Disposed of in a yellow rigid, leak proof container with chemotherapeutic waste labels on all sides of the container that is lined with a yellow trace chemotherapeutic waste bag. The yellow trace chemotherapeutic bag must meet ASTM D1709 and D1922 for impact and tear resistance. The ASTM test markings should be on both parallel and perpendicular planes.
  - Contact the Caltech Environment, Health and Safety Office at x6727 for assistance.

Trace Chemotherapeutic Solid Waste:

- Need separate waste container for chemo waste (any rigid leak-proof container with lid can be used as long as the container is labeled as "Trace Chemo")
- A yellow trace chemo waste bag will line the waste container (Safety Office will provide)
- All contaminated gloves, tubes, pads, etc should go into this container.

Trace Chemotherapeutic Bedding:

- Due to limited shedding and regulatory exemptions trace chemo bedding can be disposed of in red biohazard waste bags.

Trace Chemotherapeutic Sharps Waste:

- Segregate chemo sharps into chemo sharps containers.
Trace Chemo and/or Biohazard carcasses:
  o Triple bag and mark for incineration only.
  o Place in designated freezer.
  o Safety Office will pick up.

What to Do in an Emergency?

Cleanup of Small Spills
  - Spills of less than 5 ml or 5 gm outside a hood should be cleaned immediately by personnel wearing gowns and double surgical latex gloves and eye protection.
  - Liquids should be wiped with absorbent gauze pads; solids should be wiped with wet absorbent gauze. The spill areas then should be cleaned (three times) using a detergent solution followed by clean water.
  - Any broken glass fragments should be placed in a small cardboard or plastic container and then into a CD disposal bag, along with the used absorbent pads and any non-cleanable and contaminated items.
  - Glassware or other contaminated reusable items should be placed in a plastic bag and washed in a sink with detergent by a trained employee wearing double surgical latex gloves.

Cleanup of Large Spills
  - Contact Safety Office for assistance at x6727 or after hours at x5000.
  - For spills of amounts larger than 5 ml or 5 gm, spread should be limited by gently covering with absorbent sheets or spill-control pads or pillows or, if a powder is involved, with damp cloths or towels.
  - Be sure not to generate aerosols. Access to the spill areas should be restricted. Protective apparel should be used with the addition of a respirator when there is any danger of airborne powder or an aerosol being generated. The dispersal of CD particles into surrounding air and the possibility of inhalation is a serious matter and should be treated as such.

Personnel Contamination
  - Overt contamination of gloves or gowns, or direct skin or eye contact should be treated as follows:
    o Immediate removal of the gloves or gown
    o Wash the affected skin area immediately with soap (not germicidal cleaner) and water.
    o For eye exposure, immediately flood the affected eye with water or isotonic eyewash designated for that purpose for at least 15 minutes
    o Obtain medical attention immediately by calling Security at x5000.