UofR Chemical Safety Manual for Laboratory Carcinogens & Reproductive Agents

July 22, 2011

I. Introduction

Exposures to some chemicals can cause severe health effects that can include cancer and reproductive effects. Often, the potential health effects from some chemicals are unknown. With the millions of chemicals and chemical mixtures found in laboratory locations, it is paramount to prevent exposures to minimize potential health effects.

Chemical carcinogens are substances that are known or suspected of causing cancer in animals and/or man. This manual covers:

- OSHA carcinogens (APPENDIX 1);
- Chemicals recognized by the International Agency for Research on Cancer (IARC) as human carcinogens (Group 1) (APPENDIX 2).

The list of recognized chemical carcinogens can be found in the appendix of this manual. This list may not be all inclusive, and will be updated as needed.

Reproductive hazards can affect either male or female reproductive systems. Reproductive effects may be noted after a short period of time, may be delayed, may not become apparent for years, or may not be manifested until a later generation. A conservative view is to assume an adverse effect in animals indicates the potential for risk to humans, although not necessarily the same types of effect(s). A list of recognized chemical reproductive agents can be found in APPENDIX 3 of this manual.

Although this safety manual was established to comply with federal regulations, the main intention was to provide guidance on recognized safe workplace practices, to minimize potential exposures to chemical carcinogens and reproductive agents to as low as reasonably achievable, and document locations where these agents are used.

II. Responsibilities

A. The Department Chair or Unit Head is responsible for ensuring those in their department/unit use chemical carcinogens and reproductive agents safely.

B. The Principal Investigator (PI) must ensure employees under his/her direction:
   - use chemical carcinogens and reproductive agents in accordance with this Safety Manual and the University's Chemical Hygiene Program;
   - maintain an inventory of chemical carcinogens and reproductive;
   - maintain a log of use for OSHA chemical carcinogens;
   - conduct an annual self-inspection of those locations and use of carcinogens and reproductive agents; and,
   - label locations where carcinogens and reproductive agents are stored and used.

C. Faculty, students, and staff must comply with all laboratory safety rules, regulations and procedures and attend annual required Lab Safety training.

D. The Occupational Safety Unit (OSU) of Environmental Health and Safety (EH&S) is responsible for assisting users of chemical carcinogens and reproductive agents. OSU is also responsible for maintaining general records of work areas where these agents are used, conducting periodic evaluations to determine if monitoring for these agents is warranted, and for following up of employee incident reports for these agents.

III. Training

Site-specific safety procedures and hazard information for handling chemical carcinogens and reproductive agents need to be reviewed and updated annually by the PI. Training records need to be documented with the name and signature of each attendee, name of the trainer, content of the class and the date. These records need to be retained in the laboratory.

A. Lab Personnel: All training provided to staff needs to be documented by the PI. The PI is responsible to ensure laboratory personnel under his/her supervision have been provided training that includes:
   - A review of the laboratory's standard operating procedures (SOP) manual that addresses protocols that utilize the chemical carcinogens and reproductive hazards.
   - A review of the procedures that could result in exposures.
   - The physical and health hazards (for example, flammability, toxicity, carcinogenicity) associated with the possible exposures of the chemical carcinogens and reproductive hazards.
   - The required engineering controls, administrative controls, and personal protective equipment needed to prevent/limit exposures.
   - A review of the Material Safety Data Sheets for the chemical carcinogens and reproductive agents, especially addressing the potential health effects for both acute and chronic exposures to these agents.
   - Training is required prior to the employee's initial work with chemical carcinogens and reproductive agents. Refresher training is to be completed and documented at least annually.

B. Facilities Personnel: Environmental Services and Facilities maintenance personnel receive annual training on general chemical and biological safety issues. Lab personnel need to handle carcinogens and reproductive agents to minimize surface contamination issues so these workers are not at risk of exposure. Should these workers need to work on a potentially contaminated system in the lab, the lab staff needs to advise the individuals of any risk of contamination from a chemical carcinogen so they can safely perform their duties.

C. Visitors: Laboratory personnel must advise visitors of any risk of exposure they may encounter during their visit.

IV. Purchasing, Storage and Transportation of Chemical Carcinogens and Reproductive Agents

Lab personnel must minimize the quantity of chemical carcinogens and reproductive agents purchased and stored in a lab. Only that quantity needed for a particular project is to be ordered. The Principal Investigator is responsible for the safe storage of these agents. EH&S recommends these agents be stored in a "labeled" location separate from other chemicals. Chemical carcinogens and reproductive agents that have a health hazard rating of 4 are to be stored in ventilated glove boxes unless EH&S approves alternate storage.

All chemicals need to be entered into the University's Chemical Inventory / MSDS System, a web-based system available at http://www.safety.rochester.edu/restricted/msds.html . In addition, the lab

needs to maintain a **current** "quantity" inventory for OSHA carcinogens. The "quantity" inventory must list the dates of use and who uses these agents and needs to be maintained in the Laboratory's Standard Operating Manual or in a lab notebook. Transferring of OSHA carcinogens to other laboratory locations must be recorded.

Should a chemical carcinogen or reproductive agent be transported to another section of the building for use (for example, to be administered to an animal), the agent must be packaged in secondary containment to prevent a spill. Should any of these agents be shipped to an off-site location, personnel must follow all US Department of Transportation shipping regulations. For example, the package must withstand shock, pressure changes, and other conditions that may cause leakage and the package be properly labeled. The packaging must be designed to hold leaks if the primary container breaks.

V. Chemical Carcinogen and Reproductive Agent Use

A written safety protocol including laboratory-specific procedures must be prepared for the use of chemical carcinogens and reproductive agents. The Safety Protocol must address all of the elements included in this section. Protocols for the use of formaldehyde (used for tissue preservation) are listed separately in this manual.

Chemical carcinogens and reproductive agents need to be handled using Good Laboratory Practices. The following activities must be performed in a glove box, a ducted chemical fume hood, or a ducted biological safety cabinet:

- When working with any solid chemical carcinogen or reproductive agent (for example, mixing, weighing, etc.);
- When working with a chemical carcinogen or reproductive agent in concentrations greater than 1% by weight or volume; and,
- When performing high risk operations presenting a greater risk of exposure (for example, aerosolizing, sonicating, or working with highly concentrated stock solutions).

A. Labels and Signs

Doors to locations where carcinogens are used/stored must be posted with a warning sign stating carcinogens and/or reproductive hazards are present. Signage can include the traditional ANSI warning signs or the new GHS Signage.

These signs are available in the appendix of this manual and can be downloaded from the EH&S web site. All containers, storage cabinets and glove boxes containing chemical carcinogens are to be labeled with:

The name of the carcinogen
Caution: Cancer Suspect Agent
[Other hazard warnings such as corrosive, flammable etc.]

Containers must also have one of the following on the labels:

- The original product label listing the name and address of the manufacturer (unless the label is damaged, then lab personnel can make a replacement label listing the same information).
- For mixtures prepared in the lab, the name of the solution and the concentration as well as the date and initials of the person preparing the mixtures.

Doors to locations where reproductive agents are used/stored must be posted with a warning sign stating "**CAUTION: Reproductive Agents**". Signage can include the traditional ANSI warning signs or the new GHS Signage. These signs are available in the appendix of this manual and can be downloaded from the EH&S web site. All containers and storage cabinets containing reproductive agents are to be labeled with:

The name of the reproductive agent
Caution: Reproductive Agent
[Other hazard warnings such as corrosive, flammable etc.]

Containers must also have one of the following on the labels:

- The original product label listing the name and address of the manufacturer (unless the label is damaged, then lab personnel can make a replacement label listing the same information).
- For mixtures prepared in the lab, the name of the solution and the concentration as well as the date and initials of the person preparing the mixtures.

B. Eating/Drinking in Laboratories using or storing Chemical Carcinogens or Reproductive Agents

The storage or consumption of food/beverages, medicines, tobacco, chewing gum, as well as the application of cosmetics or handling of contact lenses are prohibited in areas where these agents are used or stored.

C. Engineering Controls

1. Laboratory Supply Ventilation

The laboratory ventilation system should be checked by Facilities before use of chemical carcinogens or reproductive agents. Facilities can supply a written report of ventilation that meets the following requirements:

- Six air changes per hour (minimum);
- The laboratory air is not recirculated in the lab or to other work locations; and,
- The laboratory is under negative pressure relative to hallways and non-laboratory areas.

2. Exhaust from Local Ventilation Control Systems

Chemical carcinogens and reproductive agents must to be used in a manner that minimizes their release into the lab or the environment. OSU will determine, based on the lab's SOP, if special exhaust treatments are needed for these agents based on the frequency of use, the quantity used, and the hazard of the individual agents. Examples of treatment could include HEPA filters (particulates only), activated charcoal filters, and chemical scrubbers. The exhaust discharge from a local ventilation control system must be located to prevent re-entrainment into the building.

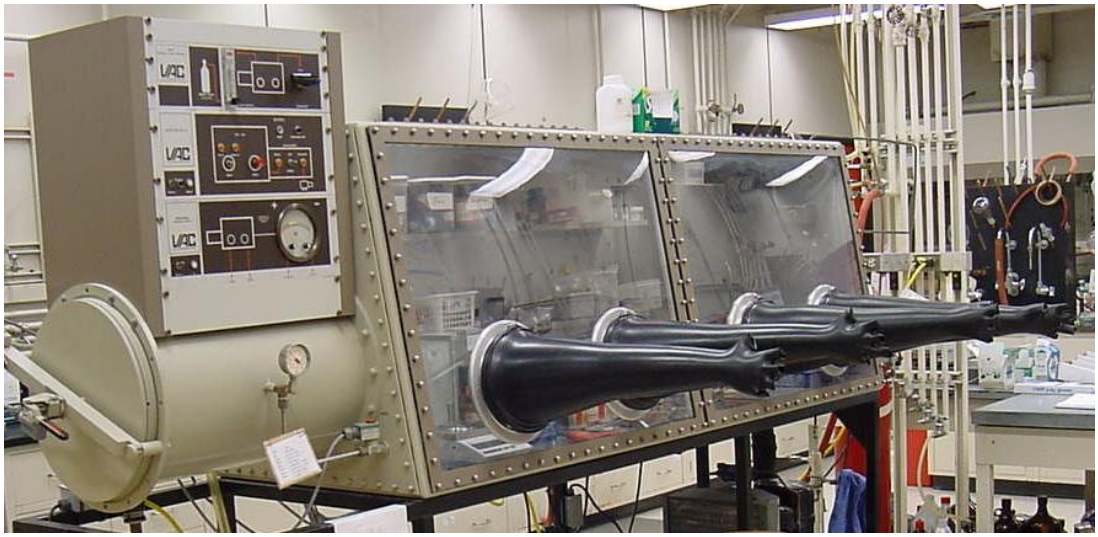
Best practices for handling these agents require laboratory local exhaust ventilation systems use that can include glove boxes, laboratory fume hoods and ducted biological safety cabinets.

a. Glove boxes

Glove boxes are fully enclosed, ventilated containment devices. They have attachable flexible gloves that allow manipulation of agents inside the unit. The units

are ventilated by passing nitrogen into the unit with the exhaust gas running through an approved exhaust treatment system, such as a chemical fume hood.

Glove boxes should be used for storing and diluting OSHA carcinogens. Users should replace gloves when worn or damaged. Glove boxes are to be checked at least annually by the PI or his/her designated representative.

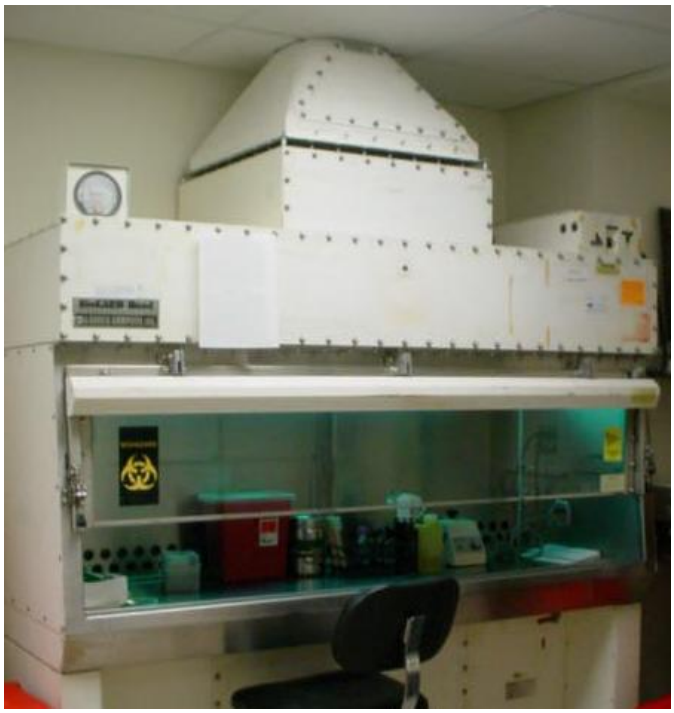


b. Chemical Fume Hoods

Chemical fume hoods provide a work area where the air inside the hood is exhausted from the building using a dedicated exhaust system. Fume hoods are tested annually by EH&S or Facilities and are to have an average face velocity of 100 $\pm$ 10 feet per minute with the sash 2/3 open. High performance fume hoods are to have an average face velocity of 80 $\pm$ 10 feet per minute with the sash 2/3 open. **Ductless hoods are not approved for use with chemical carcinogens or reproductive agents.**

c. Biological Safety Cabinets

Ducted biological safety cabinets can be used for chemical carcinogens and reproductive agents. However, non-ducted biological safety cabinets are not be used for these agents without prior approval from OSU.



d. Clean Benches

Clean Benches, a type of laminar flow hoods, provide product protection but does not provide worker protection. These units must never be used for chemical carcinogen or reproductive agent work.

7. **Vacuum Lines**

   Building vacuum systems should not be used for chemical carcinogen work. Dedicated laboratory vacuum pumps with special traps for chemical carcinogens need to be used.

D. Personal Protective Equipment

PIs and/or supervisors are responsible for performing a job hazard assessment (link for this is available at http://www.safety.rochester.edu/pdf/hazardassessment.pdf) to determine the appropriate personal protective equipment needed for staff handing carcinogens and reproductive agents. Requirements for personal protective equipment must be incorporated into each SOP. Although PPE is needed, individuals must wear appropriate clothing. PPE and clothing should include fully fastened lab coat, pants (no dresses or shorts permitted), closed-toe/heel shoes, goggles and/or face shield if there is a risk of a splash hazard, and gloves to prevent exposures to the hands.

Additional PPE may be required when administering carcinogens and reproductive agents to animals. Any needed PPE will be stated in the UCAR reviews of the individual protocols.

Clothing contaminated with chemical carcinogens and reproductive agents need to be removed immediately, placed into a heavy-duty plastic bag, and labeled with the name of the agent. OSU can be contacted to determine if there is an approved industrial laundry or if the clothing needs to be disposed of as hazardous waste.

Gloves need to be selected based on the properties of the chemicals being used. Double gloving may be needed to prevent the permeation of the chemical through the glove. Disposable gloves need to be discarded after each use and immediately should they become contaminated with a chemical carcinogen or reproductive agent. Gloves must be removed before touching environmental surfaces such as telephones, doorknobs, computers, and elevator controls.

Regular prescription glasses do not provide adequate eye protection. Eye protection must be worn whenever a splash could occur. The type of eye protection depends on the hazard

presented. For example, splash goggles are appropriate for most laboratory procedures. Face shields may be required for some activities. EH&S can provide recommendations on appropriate eye protection.

Respiratory protection may be required if OSU's assessment indicates elevated airborne levels or carcinogens or reproductive agents may be present. Contact OSU for an evaluation for the use of respirators. The use of a respirator is considered a temporary measure until appropriate engineering controls are implemented/provided.

E. Spills and Emergencies

Before beginning a procedure using a chemical carcinogen or reproductive agent, standard operating procedures for the safe handling of the agent needs to be created. For example, placing paper backed plastic onto a work surface minimizes the cleanup of an area should a spill occur. The protocol needs to include a response plans for exposures and small spills. Such emergency planning is to include:

- Taking the needed first aid measures for an exposure (removal of PPE, clothing and the use of an eyewash or safety shower);
- Seeking medical assistance for the exposure;
- Restricting access to the area for spills;
- For minor spills, using the appropriate PPE and follow the established protocols to clean and decontaminate the affected area to eliminate the hazard; and,
- For major spills, assisting the University Spill Team by providing information of the chemical carcinogen that was spilled and other hazards present in the work location.

F. Medical consultations

If a suspected or know exposure (inhalation, contact, needle stick, ingestion) occurs during working hours (8 AM-4:30 PM), take the necessary first aid measures then contact University Health Service at x5-1160 for a medical evaluation and go to 1-5000 for a consultation/medical assistance. For after hours exposures, utilize the SMH Emergency Department, located at SMH G-1800.

G. Emergency Phone Numbers

Security	x13	Emergencies (spills, medical assistance)
Security	x5-3333	Non-emergencies
University Health Service	x5-1164	Exposures (8 am – 4:30 PM), medical assistance, located at MC 1-5000
SMH Emergency Room	x5-4551	Exposures (after hours), severe injuries, located at G-1800
Poison Center	800-222-1222	Emergency information for chemical exposures.
Hazardous Waste Management	x5-2056	Hazardous Waste pickups
Environmental Health & Safety	x5-3241	Protocol assistance, emergency MSDSs

H. Hazardous Waste Management

Plans must be developed for the handling and disposal of contaminated wastes and surplus chemical carcinogens and reproductive agents. Waste containing or contaminated with any

amount of these agents is considered hazardous waste. OSU **does not** recommend the chemical inactivation of these agents prior to disposal as hazardous waste. However, for those locations where deactivation is done, the Principal Investigator is responsible to document the validity of the inactivation method and provide the training to his/her employees to follow the inaction method.

Wastes containing chemical carcinogens or reproductive agents must be contained to prevent exposures to personnel. For example, an impermeable container with a tight fitting top must be used for liquid waste. Contaminated plastic backed paper must be placed into a heavy-duty plastic bag. The collected waste receptacle must be labeled with a completed Hazardous Waste Tag to identify the contents and quantity present. Contact the Hazardous Waste Management Unit at x5-2056 for a pick up.

I. Chemical Carcinogen and Reproductive Agent Work with Animals

OSU evaluates UCAR Protocols for chemical carcinogens and reproductive agents, as well as other hazardous agents, administered to animals. The review will list the precautions for both the research personnel and Vivarium staff to follow. Those not observing the precautions could have a significant risk of exposure.

Researchers must complete the Vivarium's form "Notification of Intention to Use Hazardous Substances in the Vivarium". The name of the chemical carcinogen or reproductive agent must be listed on this form as well as the start date and end date. Researchers then place a special label on the cage identifying that a "HAZARDOUS DRUG/CHEMCIAL" has been administered to the animals and the date of the last administration. These labels are available through the Vivarium.

Research animals are protected from possible contaminants from research personnel and Vivarium staff because of the personal protective equipment (PPE) they are required to wear. This PPE provides a level of safety for personnel when examining or caring for the animals. Cage dumping activities can present an exposure potential remote from the animal housing rooms. To minimize employee exposure when this activity is done, Vivarium personnel moving animals from a used cage, listing a "HAZARDOUS DRUG/CHEMICAL" was administered, to a clean cage must stack the used cages and place them into plastic bags. The plastic bags are to be labeled with the "Caution: HAZARDOUS DRUG/CHEMICAL" label. Vivarium employees dumping cages, utilizing a N95 respirator, can observe appropriate precautions for the handling these cages and the ultimate disposal of the bedding.

J. Annual Reviews

Principal investigators using chemical carcinogens and reproductive agents must perform an annual review of their use. OSU will schedule an annual audit for the PI's program.

The annual audit must verify that:

- Chemical carcinogens are stored in a location remote from other chemicals. OSHA chemical carcinogens are stored in a glove box, unless EH&S authorized an alternate storage location.
- Locations where chemical carcinogens are stored are labeled with a warning sign "Cancer Suspect Agent".
- Locations where reproductive agents are stored are labeled with a warning sign "Reproductive Agent".
- Personal protective equipment is worn when using chemical carcinogens or reproductive agents.

- Any fume hood used for chemical carcinogen or reproductive agent usage has been checked within the last 12 months.
    - Standard fume hoods have a face velocity of 100 fpm with the sash at 2/3 open.
    - High performance fume hoods have a face velocity of 80 fpm with the sash at 2/3 open.
- Work areas where chemical carcinogens or reproductive agents are handled are protected with plastic lined absorbent paper.
- Vacuum lines are protected by using an in-line vacuum trap to protect the laboratory's vacuum pump (the building's centralized vacuum system is NOT to be used).
- Wastes containing chemical carcinogens or reproductive agents are properly labeled with a Hazardous Waste tag.
- The consumption of food and beverages does not take place within the laboratory.
- Personnel handling chemical carcinogens or reproductive agents received training on the standard operating procedures for the handling of these agents, especially any new issue that is identified in the annual audit.

K. Formaldehyde Use in Laboratories

Pure or concentrated forms of formaldehyde from a gas cylinder are prohibited unless specific use is approved by OSU. Precautions for the safe handling of formaldehyde include:

- Training: Employees must take and successfully complete the EH&S Laboratory Safety Training annually. This training contains the information required to work safely with formaldehyde. The PI must provide training on any special formaldehyde application in his/her lab to work safely with formaldehyde containing materials. For example, animal perfusions must be done in a location equipped with a local exhaust system.

- Exposure Control: OSHA has established exposure limits for employee exposures to formaldehyde. Personnel are to use local exhaust ventilation system to maintain formaldehyde levels below the following:
    - For 15 minutes of exposure, the airborne formaldehyde level must be below 2 parts per million (PPM) in air (the OSHA Permissible Exposure Limit (PEL) for formaldehyde).
    - For 8-hours of exposure, the airborne formaldehyde level must be below 0.75 PPM in air (the OSHA Short Term Exposure Limit (STEL) for formaldehyde).
    - For 8-hours of exposure, the airborne formaldehyde level OSHA must be below 0.5 PPM in air or additional engineering controls and workplace practices must be implemented (the OSHA Action Level for formaldehyde).
    - Laboratory locations known or found to have levels above the OSHA exposure limits will require the use of respirators, as specified in the UofR's Respiratory Protection Program. These locations will be identified with signage:

DANGER: Formaldehyde Authorized Personnel Only [Other hazard warnings such as corrosive, flammable etc.]

However, the use of respirators in these locations is to be considered a temporary solution only until appropriate engineering controls and workplace practices are implemented.

Personnel identified as having the exposures above the OSHA limits will be enrolled in the Formaldehyde Medical Surveillance Program.

- Locations not normally occupied and having formaldehyde levels capable of causing over-exposures must be properly labeled:

> DANGER: Formaldehyde
> Authorized Personnel Only
>
> All Entries Require Appropriate Respirators.
>
> [Other hazard warnings such as corrosive, flammable etc.]

An example of such a location includes the Cadaver Cooler. For these locations, the signage will state whether respirators will be required.

- Exposure Monitoring: OSU must perform a formaldehyde workplace assessment for locations using formaldehyde to determine the potential exposures to formaldehyde.
  - Those surveys identified as having high or moderate level of exposure will be monitored by EH&S and the results will be provided to the PI and the individual monitored.
  - Those results found to exceed the OSHA Action Level for formaldehyde (0.5 ppm) will be reported to UHS.
  - Exposure monitoring records are kept by OSU.