

TEMPORARY CHANGE REQUEST

TCR NO. **TCR-ESHD 5008, Sect. 8,
Chapt 2, R3-002**

(e.g., TCR-ENG-021,R0-001)

The Temporary Change Request (TCR) Form is to be used to process urgent or minor changes for PPPL Policies, Organization/Mission Statements and Procedures. The TCR should be used when changes are:
1) urgent, and can not wait the 2-4 week period for Department Head review/comment, or
2) minor, and do not warrant Department Head review.

Person Requesting Change: Jerry Levine Phone Ext: 3439

Department Name: ES&H

Document Number: ESHD 5008 Section 8 Chapter 2 Revision No.: 3

Document Title: Carcinogens, Mutagens and Teratogens

Reason for change:

Minor revisions to capture organization changes

Change description: (Summarize and attach changed pages, with changes clearly indicated)

Changed Maintenance & Operations to Facilities and Site Services, and M&ES to ESD. See attachment.

1. Does this TCR significantly alter the intent or scope of the document? YES: NO: X

2. Does this TCR significantly impact **ES&H**? YES: NO: X

If 1 or 2 is **YES**, Explain why the changes should not be routed for Department Head review:

Jerry Levine 6/28/16

Department/Division Head Approval **Date**

John DeLooper 6/30/16

Head, Best Practices and Outreach/designee **Date**

Release/Effective date of this TCR: 7/1/16

Incorporate this TCR into next revision of this document? YES: X NO:

CHAPTER 2 CARCINOGENS, MUTAGENS, AND TERATOGENS

2.1 INTRODUCTION

The purpose of this chapter is to outline guidelines for the use and handling of carcinogens, suspected carcinogens, mutagens, and teratogens at the Laboratory. Only those carcinogenic, mutagenic, or teratogenic materials for which there is no suitable substitute shall be permitted on site. NOTE: The substances discussed in this chapter can have a more severe effect on an unborn fetus than on an adults. Pregnant women and other adults (both male and female) planning on reproducing should exercise extreme caution. Consultation with Industrial Hygiene (IH) and the Occupational Medicine Office (OMO) is recommended for these individuals working with materials covered in this chapter.

2.2 SCOPE

This section of the Environment, Safety, and Health Manual applies to all chemicals which have been classified a carcinogen, suspect carcinogen, teratogen, or mutagen by any of the agencies listed in the References, Section 2.7.

2.3 DEFINITIONS

Carcinogen - An agent which may produce cancer (uncontrolled cell growth), either by itself or in conjunction with another substance (see ACGIH classifications A1, A2, and A3).

Suspect Carcinogen - An agent which is suspected of being a carcinogen based on chemical structure, animal research studies, or mutagenicity studies.

Controlled area -For this section refers to an area (either permanent or temporary) in which a carcinogen, suspect carcinogen, mutagen, or teratogen is used.

IARC - International Agency for Research on Cancer - Classifies carcinogens in the following manner:

- 1 -Carcinogenic to humans with sufficient human evidence.
- 2A -Probably carcinogenic to humans with some human evidence.
- 2B -Probably carcinogenic to humans with no human evidence.
- 3 -Sufficient evidence of carcinogenicity in experimental animals.

NIOSH - National Institute for Occupational Safety and Health - Classifies carcinogens as either carcinogenic or non-carcinogenic with no further categorization.

NTP - National Toxicology Program - Classifies carcinogens in the following manner:

- a -Carcinogenic with human evidence.
- b -Carcinogenic with limited human evidence but sufficient animal evidence.

ACGIH - American Conference of Governmental Industrial Hygienists - Classifies carcinogens in its TLV's (Threshold Limit Values) as:

- A1 -Confirmed Human Carcinogen: The agent is carcinogenic to humans based on the weight of evidence from epidemiologic studies (see Table 8.2.1).
- A2 -Suspected Human Carcinogen: Human data are accepted as adequate in quality but are conflicting or insufficient to classify the agent as a confirmed human carcinogen; OR, the agent is carcinogenic in experimental animals at doses, by routes of exposure, at sites, of histologic types, or by mechanisms considered relevant to worker exposure. The A2 is used primarily when there is limited evidence of carcinogenicity in humans and sufficient evidence of carcinogenicity in experimental animals with relevance to humans (see Table 8.2.2).
- A3 -Confirmed Animal Carcinogen with Unknown Relevance to Humans: The agent is carcinogenic in experimental animals at a relatively high dose, by routes of administration, at sites, or histologic types, or by mechanisms that may not be relevant to worker exposure. Available epidemiologic studies do not confirm an increased risk of cancer in exposed humans. Available evidence does not suggest that the agent is likely to cause cancer in humans except under uncommon or unlikely routes or levels of exposure (see Table 8.2.3).
- A4 -Not Classifiable as a Human Carcinogen: Agents which cause concern that they could be carcinogenic for humans but which cannot be assessed conclusively because of a lack of data.
- A5 -Not Suspected as a Human Carcinogen: The agent is not suspected to be a human carcinogen on the basis of properly conducted epidemiologic studies in humans.

Teratogen - A substance which can cause physical defects in a developing embryo.

Mutagen - A material that induces genetic changes (mutations) in the DNA.

Asbestos - A generic term applied to a wide variety of naturally occurring fibrous mineral silicates which occur as bundles of minute fibers and can be separated into fibers that are smaller than human hair.

Friable Asbestos - Asbestos containing material that can be broken up by hand pressure and consequently release fibers into the air. **Non-Friable Asbestos** - Asbestos containing materials bonded into a form which will not easily release fibers to the air.

2.4 RESPONSIBILITIES

2.4.1 Department /Division Heads are responsible for ensuring the implementation of this section.

2.4.2 Line Supervisors are responsible for:

- A. Informing the Industrial Hygienist (IH) of the proposed use of a carcinogen, mutagen, or teratogen.

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- B. Searching for a suitable substitute for the present or proposed use of a carcinogen, mutagen, or teratogen with assistance from the IH.
 - C. Installing and maintaining the proper engineering controls to control exposure to carcinogens, mutagens, or teratogens.
 - D. Ensuring that subordinates have been trained in the proper handling, storage, and hazards of carcinogens, mutagens, or teratogens.
 - E. Enforcing the use of personal protective equipment (PPE), as per Section 8.6, where its use is required.
 - F. Ensuring that the proper PPE is on hand in sufficient quantities for employees and visitors required to wear it.
 - G. Ensuring that subordinates are handling the carcinogens, mutagens, or teratogens in the manner outlined and approved by the IH.
 - H. Posting a written and IH approved procedure for the handling of the carcinogen, mutagen, or teratogen contaminated PPE.
 - I. Ensuring the integrity of a controlled area.
 - J. Posting warning signs in controlled areas.

2.4.3 Industrial Hygiene (IH) is responsible for:

- A. Assisting supervisors in the search for a suitable substitute for the present or proposed use of a carcinogen, mutagen, or teratogen.
- B. Specifying the correct procedures to be used in handling a carcinogen, mutagen, or teratogen to supervisors, and employees.
- C. Training supervisors and workers on the correct handling and storing of carcinogens, mutagens, and teratogens.
- D. Assisting maintenance and supervisors in the design and installation of engineering controls, including ventilation.
- E. Reviewing and giving approval for design specifications for facilities and the handling and storage procedures for carcinogens, mutagens, and teratogens.
- F. Periodically monitoring for air contaminants to ensure worker safety.
- G. Periodically inspecting the handling and storage areas and procedures to ensure worker safety.

2.4.4 The Facilities and Site Services Division is responsible for: designing, installing, and maintaining engineering controls, including ventilation systems (Chapter 4), and incorporating the criteria developed by the IH and supervisors.

2.4.5 Procurement is responsible for complying with Section 8, Chapter 13, “ES&H Review of Procurements” for chemical requisition review and not ordering any chemical before it is approved by the IH.

2.4.6 Quality Assurance is responsible for auditing compliance with this Chapter.

2.4.7 All other employees are responsible for:

- A. Wearing and using the PPE issued to them in accordance with instructions and training provided by the IH and their supervisors.
- B. The proper cleaning, maintenance, and storage of the PPE as per instructions from the IH and their supervisors.
- C. Using only those types of PPE that have been recommended to them by their supervisors or the IH.
- D. Reporting malfunctioning engineering controls and ventilation systems to their supervisors.
- E. Following the handling instructions in accordance with procedures set down by the IH and their supervisors.

2.5 REQUIREMENTS

2.5.1 All Laboratory use of carcinogens, mutagens and teratogens shall meet or exceed the requirements and regulations of the Occupational Safety and Health Administration (OSHA), the U.S. Department of Energy (DOE), the Environmental Protection Agency (EPA), and the guidelines set by the American Conference of Governmental Industrial Hygienists (ACGIH) and the National Institute for Occupational Safety and Health (NIOSH).

2.5.2 All proposed and present use and handling of carcinogens, mutagens, and teratogens must be approved by the IH. A requisitioner must get approval from the IH before a carcinogen, mutagen or teratogen can be purchased (see Chapter 13). The IH will assist in the identification of a material as to its carcinogenicity, mutagenicity, or teratogenicity.

2.5.3 All uses and handling of carcinogens, mutagens, and teratogens will meet the most stringent regulations set down by any regulatory agency. This includes regulations or recommendations from the agencies mentioned in Section 2.5.1. A list of carcinogens identified by an agency is available from the IH.

2.6 PRACTICES AND PROCEDURES

2.6.1 General Laboratory Controls - The following practices must be followed whenever confirmed human carcinogens, mutagens, or teratogens (class A1, see Table 8.2.1) and should be followed where class A2 and A3 carcinogens (as determined by the IH) are handled in the Laboratory and no suitable substitutes can be found:

- A. Entrance to the area where the carcinogen, mutagen, or teratogen is being used shall be restricted to personnel directly involved in experimentation or required services, and signs shall be posted at the entrances to the area (see Figure 8.2.1).
- B. Local ventilation in the form of fume hoods and close-capture systems shall be available for any experiment that produces significant amounts of airborne gas, vapor, or particulate. These systems shall be of the "once through" type; no recirculation of exhaust air will be permitted.
- C. Eating, drinking, tobacco or gum chewing, food storage, smoking, and application of cosmetics shall be prohibited in the laboratory work area.
- D. Mechanical pipetting aids shall be used for all pipetting procedures.
- E. Solid and liquid wastes shall be properly labeled and collected separately in non-permeable containers and shall be disposed of through the Environmental Services Division (ESD).
- F. Separate receptacles for non-contaminated broken glass shall be provided in all laboratory work areas.
- G. Hypodermic syringes shall be disposed of in disposal containers designed for sharps.
- H. Laboratory floor and bench-top surfaces shall be made of, or be covered with, a non-permeable material such as stainless steel or polyethylene to facilitate clean-up of spilled materials.
- I. Carcinogens, mutagens, and teratogens are also subject to all other applicable policies in the Environment, Safety and Health (ES&H) Manual such as Section 5.0 for flammable liquids. Where a conflict occurs, the most stringent policy shall apply.
- J. Safety-shower and eye-wash facilities shall be located within, or in close proximity to, the laboratory.
- K. All containers shall be clearly marked as to general hazard and complete chemical contents.
- L. Emergency action plans shall be included in the standard operating procedure.
- M. The workplace shall only be exposed to the amount of material needed to complete the project, and no quantity of material greater than what is needed should be purchased. Excess chemicals and unusable equipment should be disposed of once the project is completed through ESD.

2.6.2 Personal Protective Equipment (PPE) - All persons involved in working with carcinogens, mutagens, or teratogens must wear laboratory coats, gloves, and chemical splash goggles as specified by the Industrial Hygienist. When possible, disposable materials shall be used to prevent decontamination difficulties. Personal protective equipment shall be changed or decontaminated at a minimum of once per week unless known to be contaminated or damaged. If contaminated or damaged, it will be immediately replaced. No PPE shall be worn outside of the work area.

2.6.3 Special requirements for work involving carcinogens, mutagens, or teratogens -central carcinogen, mutagen, or teratogen storage and work areas should be planned for all major laboratory programs using carcinogens, mutagens, or teratogens on a regular basis. All storage and handling of pure carcinogenic, mutagenic, or teratogenic materials should be done in a few primary work areas that are centrally located. This arrangement will minimize duplication of expensive handling facilities and enable better monitoring of the control program's effectiveness. The following are requirements for areas where carcinogens, mutagens, or teratogens are frequently used or stored:

- A. Primary Work Areas - Primary work areas (controlled areas) are locations used for work on or for long-term storage of undiluted, chemical carcinogens, mutagens, or teratogens. Because of the potentially hazardous nature of pure chemical carcinogens, mutagens, or teratogens, the following additional guidelines must be followed:
- 1 The responsible department shall maintain a written record of all persons entering and using the work area. A copy of this record shall be forwarded to the Occupational Medicine Office and the IH to be kept as a medical record. Access to these areas are restricted to authorized personnel only.
 - 2 Signs identifying chemical carcinogen, mutagen, or teratogen work areas shall be posted at all entrances to the work area (see Figure 8.2.1).
 - 3 Glove boxes and fume hoods shall be installed and used as defined by the IH.
 - 4 Air-cleaning devices shall be used to clean exhaust air contaminated by chemical carcinogens, mutagens, or teratogens as specified by the IH. All ventilation systems shall be of the "once through" type; no recirculation of exhaust air is permitted. House or shop vacuums are only permitted if they are equipped with the proper filters and its use is approved by the IH.
 - 5 Liquid waste retention systems shall be maintained where used.
 - 6 Change rooms and shower facilities shall be available for all laboratory users.
 - 7 Proper janitorial, maintenance, and housekeeping practices and procedures shall be observed.
- B. Temporary Primary Work Areas - Certain uses of carcinogens, mutagens, or teratogens can be performed in normal chemical laboratories if these laboratories meet all the requirements outlined above. When one of these laboratories is used as a primary work area, it remains a primary work area until it has been decontaminated and the carcinogen, mutagen, or teratogen is no longer present.

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- C. Carcinogen, Mutagen, or Teratogen Packaging - All carcinogens, mutagens, and teratogens stored on shelves or in refrigerators in the work or storage area must be placed in properly labeled, unbreakable containers. All containers must be properly labeled (see Figure 8.2.2).
 - D. Decontamination and Disposal
 - 1 Processes used to decontaminate materials and surfaces that come in contact with carcinogens, mutagens, or teratogens must be evaluated by the IH. Questions about decontamination processes will be answered by the IH.
 - 2 The decontamination process must ensure that all carcinogenic, mutagenic, or teratogenic materials are destroyed or removed from the materials or surfaces. When necessary, surface-wipe samples will be taken by an Industrial Hygienist to confirm the completeness of the decontamination process.
 - 3 All solid and liquid wastes contaminated with carcinogens, mutagens, or teratogens must be disposed of through ESD.

2.6.4 Medical Surveillance for Carcinogen, Mutagen, or Teratogen Workers

- A. The department head or division head is responsible for informing the Occupational Medicine Office (OMO) in advance when any employee will be routinely working with class A1, A2 or A3 chemical carcinogens, mutagens, or teratogens. This advance notice will enable the OMO to review the employee's file and provide necessary counseling and surveillance.
- B. The OMO's minimum medical surveillance program for carcinogen, mutagen, or teratogen workers includes an annual review of employee medical records, a complete medical history, and an annual physical examination.

2.7 ASBESTOS REMOVAL AND HANDLING

2.7.1 All asbestos removal is to be done by an outside contractor with current certification in all applicable Federal, State and Local requirements.

2.7.2 Asbestos removal projects shall comply with the appropriate OSHA and EPA regulations.

2.7.3 The IH should be consulted to determine the asbestos content of a suspect material before handling.

2.7.4 The IH shall maintain an inventory of asbestos-containing materials in cooperation with ESD.

2.7.5 Materials known to contain asbestos fibers not slated for immediate removal shall be labeled:

DANGER

CONTAINS ASBESTOS FIBERS

AVOID CREATING DUST

CANCER AND LUNG DISEASE HAZARD

AVOID BREATHING AIRBORNE ASBESTOS FIBERS

2.7.6 No asbestos-containing materials shall be purchased unless no suitable substitute can be found.

2.7.7 All employees are required to report any damaged asbestos-containing materials to the IH and ESD.

2.7.8 Asbestos-containing materials which are damaged shall be removed on a hazard level priority basis.

2.7.9 Asbestos-containing material removal shall be coordinated through ESD.

2.7.10 All personnel who could come into contact with asbestos-containing materials on a regular basis, including janitorial staff, must take an Asbestos Awareness training course offered through Human Resources and Training.

2.8 REFERENCES

Occupational Safety and Health Administration, 29 CFR 1910.1000 to -.1045, "General Industry

Standards."

Occupational Safety and Health Administration, 29 CFR 1990, "Identification, Classification and Regulation of Potential Occupational Carcinogens."

American Conference of Governmental Industrial Hygienists, "Threshold Limit Values and Biological Exposure Indices" latest edition, Cincinnati, Ohio.

Environmental Protection Agency, 40 CFR 61, "National Emission Standard for Asbestos." International Agency for Research on Cancer, "Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans."

National Toxicology Program, "Annual Report on Carcinogens."

TABLES

(Note: These lists of Carcinogens are not all inclusive, and do not include any reference to mutagens or teratogens. The lists are compiled from the 1998 TLV's and BEI's published by the ACGIH. The most current available information from ACGIH should be consulted (contact IH).

Table 8.2.1
Select list of A1 Confirmed Human Carcinogens

Asbestos	Coal Tar Pitch Volatiles
Arsenic	Nickel (Insoluble Compounds)
Benzene	Uranium
Beryllium	Vinyl Chloride
Chromium Compounds (Cr VI)	Zinc Chromates

Table 8.2.2
Select list of A2 Suspected Human Carcinogens

Acrylonitrile	Diesel Exhaust
1,3 Butadiene	Ethylene Oxide
Cadmium	Formaldehyde
Carbon Tetrachloride	Silica (Quartz)
Coal Dust	Vinyl Bromide

Table 8.2.3
Select list of A3 Confirmed Animal Carcinogens with Unkown Relevance to Humans

Acetaldehyde	Acrylamide
Chlordane	Chloroform
Cobalt	DDT
Dichlorobenzene	Diesel Fuel
Gasoline	Hydrazine
Hydroquinone	Kerosene
Lead	Methylene Chloride
Vinyl Acetate	VM&P Naphtha

Figure 8.2.1



Figure 8.2.2

