Introduction

Purpose:
In accordance with applicable regulations and Temple University, this policy was developed to minimize exposure to Ethylene Oxide.

Applicability

This policy is applicable to all Temple University employees, to all work conducted under the authority of Temple University, and to all equipment and property managed by Temple University. Non-Temple and contractor personnel must follow the provisions of this policy while at Temple University facilities.

Definition Of Terms:

Ethylene Oxide: A colorless gas with a characteristic ether-like odor that is used by various facets of the health care industry for the sterilization of delicate instruments and heat or moisture sensitive devices.

Action Level (AL): A concentration of airborne Ethylene Oxide of 0.5-parts per million (ppm) calculated as an 8-hour time weighted average.

Permissible Exposure Limits (PEL): A concentration of airborne Ethylene Oxide of 1 parts per million (ppm) calculated as an 8-hour time weighted average.

Short Term Exposure Limit (STEL) or Excursion limit- A concentration of airborne Ethylene Oxide of 5 parts per million (ppm) averaged over a sampling period of 15 minutes.

Responsibilities

Environmental Health and Radiation Safety Department (EHRS)
The EHRS has the following responsibilities related to Ethylene Oxide activities:

- Policy implementation.
- Surveillance as requested by responsible supervisor.
- Training as requested by responsible supervisor
- Exposure monitoring when requested responsible supervisor.
- Establish procedures for the use and operation of respiratory protective devices.

Supervisors and Managers

- Assess their site and operations to determine whether ethylene oxide is present or used.
- All persons designated as ethylene oxide users shall be issued a copy of this section by their supervisor. The copy should be kept in the user’s work place for reference. Additional copies are available through EHRS.
- Ensure that all required (area and personal) monitoring is performed.
• Maintain all required documentation (exposure monitoring, hazards assessment, medical monitoring, etc)
• Inform all individuals who work with ethylene oxide regarding health risks and safety precautions. They must also be provided a copy of the ethylene oxide policy.
• If the supervisor or manager provides the training, this training must be documented. The supervisor may forward the training documentation to EHRS.
• Review and approve proposed uses of ethylene oxide in the areas within their jurisdiction. Such approval signifies that management will provide the resources necessary to comply with OSHA, EPA, and other government regulations. Such compliance may include the following actions:
  • Provide employee training regarding the safe use, storage, and disposal of ethylene oxide.
  • Maintain an adequate stock of required personal protective equipment.
  • Provide equipment such as eyewash stations, showers, and ventilation devices when required.
  • Make requests to the EHRS department for required exposure monitoring and surveillance of work activities.
  • Maintain relevant Material Safety Data Sheets (MSDSs) for ethylene oxide.
  • Arrange for transportation and disposal of ethylene oxide waste gas.
  • Make regular visual inspections for leaks and spills.
  • Maintain ethylene oxide leak detection equipment.
  • Maintain an inspection log of leak detection equipment.

Ethylene Oxide Users
Ethylene oxide users are those workers who work with or handle ethylene oxide in their job. These workers have the following responsibilities related to ethylene oxide use:
• Attend required training classes
• Properly use and maintain PPE
• Comply with Temple University, OSHA, and EPA and other government regulations as they pertain to ethylene oxide use.

Director of Maintenance
• Ensure that his staff is trained in the safe handling of Ethylene Oxide.
• Ensure the availability of safety equipment and clothing for his employees.
• Notify the Director of Supply, Processing and Distribution, the Operating Room Head Nurse, the Manager of Central Supply, and the EHS whenever a change to the ventilation system may effect the exhausting of the Ethylene Oxide from the work area(s).

Exposure Monitoring

Initial:

The level of ethylene oxide exposure for a particular work activity dictates the regulatory requirements for exposure monitoring, engineering controls, PPE, training, and medical surveillance. Initial exposure monitoring must be conducted to determine the likely exposure for a work activity. A representative sampling of employees exposures are permitted. When initial exposure monitoring results show that
airborne ethylene oxide is below the OSHA levels specified below, the facility may discontinue monitoring. However, any time there is a change in the work activity, personnel, equipment, or control measures that may result in new or additional exposure to ethylene oxide, monitoring must be resumed. Furthermore, if an employee indicates signs or symptoms of ethylene oxide exposure, additional monitoring must be conducted. For certain exposure situations, the air monitoring requirements can be relieved if it can be proven with objective data that an employee is exposed below the Action Level. For example, if a chemist is exposed below the Action Level while performing continuous ethylene oxide activities, objective data might indicate that a second worker in the same area, who does not work with ethylene oxide, is also exposed below the Action Level.

As required by OSHA, within 15 days of the employer receiving the results of exposure monitoring, the employer shall notify the affected employees of the results in writing. If monitoring results reveal exposure levels above the OSHA defined Permissible Exposure Limit (PEL), the employer shall implement a written plan that describes what actions will be taken to reduce employee exposure to or below the PEL. This written plan shall be distributed to all affected employees.

In addition to personal exposure monitoring, area air monitoring should also be performed to document levels within the work area. Area air monitoring data can be a worst-case exposure indicator for casually exposed workers. The EHRS department should be contacted to conduct both personal and area air monitoring activities.

*Periodic Exposure Monitoring*

This section only applies when employee exposure monitoring results are at or above the

1. Action level (AL) of 0.5 ppm;
2. Permissible Exposure Limit (PEL) of 1 ppm; or
3. Short-term Exposure limit (STEL) or Excursion limit of 5 ppm
The frequency of employee exposure monitoring is specified in the following table:

<table>
<thead>
<tr>
<th>If employee exposure monitoring results:</th>
<th>Then</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are above the Action level (AL) of 0.5 ppm and below Permissible Exposure Limit (PEL) of 1 ppm</td>
<td>Conduct additional exposure monitoring every 6 months</td>
</tr>
<tr>
<td>Are above the PEL of 1 ppm or STEL or Excursion limit of 5 ppm</td>
<td>Conduct additional exposure monitoring every 3 months.</td>
</tr>
<tr>
<td>Have been obtained at least every 3 months and have 2 consecutive monitoring results, taken at least 7 days apart, showing 8 hour employee exposure monitoring results that have dropped below the PEL but remain at or above the AL</td>
<td>You may decrease your frequency for PEL to every 6 months.</td>
</tr>
<tr>
<td>Have 2 consecutive evaluations, taken at least 7 days apart, showing 8-hour employee exposure monitoring results that have dropped below the AL and STEL.</td>
<td>You may stop periodic exposure evaluations.</td>
</tr>
</tbody>
</table>

Exposures above the Action Level

The Action Level (AL) for ethylene oxide is 0.5-ppm, as an eight-hour time weighted average (8-hr TWA). If the initial exposure monitoring indicates that an employee exposure is at or above the Action Level, the supervisor must ensure that the following activities are implemented:

1. Periodic personal exposure monitoring must be conducted according to the specified frequencies in the above table 1 under the worst conditions.
2. Establish an ethylene oxide medical monitoring program for affected employees.

Exposures above the Time-Weighted Average PEL or STEL (Excursion limit)

The OSHA-defined time-weighted average (TWA) PEL for ethylene oxide is 1.0-ppm, which is the maximum allowable exposure concentration, calculated as an 8-hr TWA. The STEL or Excursion limit for Ethylene Oxide is 5 ppm averaged over a 15 minute sampling period.

If the initial exposure monitoring indicates that an employee exposure is at or above the TWA PEL, the supervisor must ensure that the following activities are implemented:

1. Establish and implement a written compliance program to reduce exposures below the PEL and STEL.
2. Periodic exposure monitoring must be conducted according to the specified frequencies in the above table 1 under the worst conditions.
3. Establish regulated areas by posting ethylene oxide danger signs.
4. Train employees to recognize the danger of ethylene oxide exposure.
5. Provide respiratory protection adequate to reduce the employees' exposure too less than the TWA PEL.
6. Implement engineering controls and improved work practices to reduce employee exposures to less than the PEL or STEL.

**Controlling Ethylene Oxide Exposure**

**Engineering Controls - Ventilation Systems**

It is the policy of the Temple University that all ethylene oxide-related work activities with potential for exceeding the Action Level shall implement feasible engineering controls. Examples of engineering controls include ventilation systems, air pollution control devices, laboratory hoods, enclosures, shields, barriers, isolation chambers, automatic emergency shut off valves, and remote-control equipment.

The following considerations should be included in the design and installation process for such equipment:

1. On an annual basis, laboratory fume hoods must be evaluated for proper operation and airflow. The EHS department provides these services upon request.
2. To minimize ethylene oxide exposure and control the buildup of gases and vapors in the general work area, it is important that adequate room ventilation be provided. The recommended ventilation rate for laboratory areas is 4 to 12 air changes per hour. To prevent gas and vapor migration into adjacent areas, the ethylene oxide work area should be maintained at a negative air pressure with respect to surrounding rooms. The exhaust duct stack must be located a sufficient distance from any building air intakes to prevent re-introduction of contaminated air.
3. If the facility ventilates containers of contaminated clothing and equipment, the facility shall establish an appropriately labeled storage area for this purpose, and locate and arrange it in a manner that minimizes ethylene oxide exposure. The facility shall allow only persons trained in recognizing the hazards of ethylene oxide to remove containers from the storage area.

**Personal Protective Equipment (PPE)**

Certain types of PPE are effective in controlling ethylene oxide exposure. In normal work situations, PPE should be used only as a supplement to engineering controls. Employees must not take ethylene oxide-contaminated materials, clothing, or equipment home.

*Impermeable Gloves*: Latex gloves are among the appropriate glove choices for protection against skin contact with ethylene oxide. Check with EHS for other material options.

*Eye and Face Protection*: Eye and face protection in the form of goggles will reduce exposure in cases of splash hazards.

*Respiratory Protection*

Ethylene oxide, as it is used in the Temple University Hospital Sterile Processing area, displaces oxygen and creates an oxygen-deficient atmosphere. For this reason, a self-contained breathing apparatus (SCBA) is the minimum level of respiratory protection to be used. When employees are required to wear
respirators to reduce exposure, they must be enrolled in a Respiratory Protection Program, as required by OSHA. The Temple University requires respirator use in the following situations:
1. During emergencies, and entry into areas of unknown ethylene oxide concentration.
2. During the period to evaluate, purchase, and install engineering control equipment and/or modify work practices to achieve compliance with the PELs.
3. In work situations where engineering and work practice controls are not yet capable of reducing employee ethylene oxide exposure to or below the PEL.
4. During cleaning, maintenance, repair, and other work where engineering and work practice controls are not feasible.

**Work Practices**
Each facility shall examine the work practices that employees use, and consider alternative work practices that will minimize exposure.

**Leak and Spill Detection**
Facilities with ethylene oxide shall create and maintain a program to detect leaks and spills. The equipment leak and spill detection program shall include:
1. Regular visual inspections for leaks and spills;
2. Preventative maintenance of equipment, including surveys for leaks, at regular intervals;
3. Regular testing of monitoring equipment to assure proper function;
4. Provisions for ethylene oxide spill containment, surface decontamination, and waste disposal in work areas where spillage may occur;
5. Prompt cleanup of spills and repair of leaks using persons who wear appropriate protective clothing and equipment and are trained in the proper methods for ethylene oxide cleanup and decontamination;

**Container Labels**
The label must list the name and address of the responsible person; and must state that physical and health hazard information is readily available from the employer and from MSDSs.

**Emergency Showers, Eyewash Stations**
If there is an eye splash possibility eyewash stations must be present in the immediate work area. Showers must be present in the immediate work area if there is a splash hazard. The locations of the stations must be close enough so that an injured worker can reach one within ten seconds.

**Emergency Situations**
Leak sensors are in place in Temple Hospitals Sterile Processing area, where ethylene oxide is used to sterilize equipment.

In case of a leak:
- Personnel should immediately evacuate the effected area when the monitor alarm sounds, and assist injured personnel to safety,
• Seek medical assistance for injured personnel,
• Call the EHS department (ext. 707-2520) or Page Operator (ext. 707-4545) immediately,
• Never re-enter contaminated area without fully encapsulated clothing, SCBA, and back-up personnel.

Ethylene Oxide Waste

Any ethylene oxide waste must be characterized in accordance with EPA regulations. Waste determined to be hazardous will be affixed with a hazardous waste label, and handled on site for proper disposal by a hazardous waste contractor, as arranged by the EHS Chemical Hygiene Officer. Personnel from the EHS department must sign all manifests for hazardous waste disposal.

Intentional discharge of ethylene oxide or other hazardous material into the sewer system or storm drain is prohibited. Similarly, hazardous materials may not be disposed of by evaporation in a fume hood. If such an incident does occur, it may be reportable to local or Federal authorities, and shall be reported immediately to the EHS department.

Where vapors may be exhausted as a by-product of work being done with ethylene oxide (not as a means of disposal), the fume hood will be equipped with filters to prevent atmospheric releases.

Medical Surveillance Program

The medical surveillance program is provided to monitor the health of ethylene oxide-exposed employees, and determine whether continued exposure will adversely affect their health.

1. The medical surveillance program is mandatory for employees who are exposed at or above the AL.
2. The medical surveillance program is required for the following groups of employees; employees who show symptoms of ethylene oxide exposure, or employees who are exposed during an emergency.

Hazard Communication Program

Implementation of a written hazard communication program is required of each branch or division that uses ethylene oxide gas. The hazard communication program must address the following items:

1. Health risks of ethylene oxide
2. Material Safety Data Sheets (MSDSs)
3. Container labeling of ethylene oxide
4. Medical surveillance program
5. Instructions to immediately report signs of ethylene oxide exposure to the supervisor.
6. Uses and limitations of PPE.
7. Instructions for handling spills and emergency situations.
8. Proper work practices and the use of engineering controls.

Employee Training Requirements
Information regarding hazard communication training can be obtained from the EHS department. Training must be provided at the time of the initial job assignment and whenever there is a change to the work process. At a minimum, the topics addressed in the hazard communication training shall include:

1. The contents of the OSHA ethylene oxide standard (29 CFR 1910.1048), as well as the location and availability of these regulations.
2. The contents of MSDSs.
3. Health risks
4. The medical surveillance program.
5. The ethylene oxide work activities that take place at the facility, and the appropriate work practices that will minimize exposure.
6. PPE use and limitations.
7. Instructions for the use of engineering controls in minimizing exposure.
8. Instructions for handling spills and emergency situations.
9. Access and location of training materials for the affected employees.
10. Container labeling

**Record-keeping Requirements**

The EHS department will keep accurate and complete records for all ethylene oxide-related work areas. The records shall consist of:

**Exposure Monitoring Records**

Exposure monitoring will include the following information:

1. The date the measurement was taken.
2. The operation that is being monitored.
3. The sampling and analytical methods used and evidence of their precision and accuracy.
4. The number, duration, time of day, and results of samples obtained.
5. The types of protective devices worn.
6. The names, job classifications, social security numbers, and exposure estimate of employees whose exposure is represented by actual monitoring results.

When it is felt that objective data will relieve exposure-monitoring requirements, records shall consist of the objective data and calculations that demonstrate that no employee is exposed to ethylene oxide at or above the Action Level.

Exposure monitoring records shall be kept for at least 30 years.

**Medical Evaluation Records**

Records shall consist of:

1. The name and social security number of the employee.
2. The physician's written opinion.
3. A list of employee health complaints that may be related to exposure to ethylene oxide.
4. A copy of the employee's medical examination results, medical questionnaires, and results of medical tests that are required by the regulation or mandated by the examining physician.
Medical evaluation records shall be kept for the duration of the employee's employment plus at least 30 years.

**Respirator Fit Test Records**
Respirator fit test records shall consist of:
1. A copy of protocol used to test the fit of negative-pressure respirators.
2. The name and social security number of each employee assigned to wear a negative-pressure respirator.
3. The date of the employee's most recent respirator fit test and a copy of the test results.
4. A list of the brands, types, and sizes of respirators available at the facility from which respirator selection and assignment was made.

Respirator fit test records shall be kept until replaced by a more recent record.

Contractors are responsible for complying with these record-keeping requirements for their own employees.