ETHYLENE OXIDE SURVEILLANCE PROGRAM

l. Background:

Ethylene Oxide (EtO) is a highly flammable, colorless gas with an ether-like, sweet odor at toxic levels. EtO is found in the production of solvents, antifreeze, textiles, detergents, adhesives, polyurethane foam, and pharmaceuticals. Smaller amounts are present in fumigants, sterilant for spices and cosmetics, as well as during sterilization of surgical equipment. EtO is irritating to the respiratory tract, skin, and eyes. Inhalation is the most common route of EtO exposure.

Exposure to high concentrations of EtO can cause eye pain, blurred vision, sore throat, difficulty breathing, dizziness, nausea, headache, convulsions, blisters, and can result in vomiting. Both human and animal studies have shown EtO to be a carcinogen.

Below are permissible exposure limits for Ethylene Oxide:

- **Action Level (AL):** 0.5 part EtO per million parts of air (0.5 ppm)
- **8-hour Time Weighted Average (TWA):** 1 part EtO per million parts of air (1 ppm)
- **Excursion Limit:** 5 parts of EtO per million parts of air (5 ppm)

2. Purpose:

The EtO program establishes guidelines for implementation and compliance with the requirements of the Occupational Safety and Health Administration (OSHA) standard 29 CFR Part 1910.1047. This program is administered by the University of Pittsburgh's Department of Environmental Health & Safety and applies to all occupational exposures to EtO at the University. The EtO program outlines key provisions of the standard and provides procedures in place at the University for employee exposure monitoring, methods of compliance/controls, Personal Protective Equipment (PPE), emergency situations, medical surveillance, communication of EtO hazards (posting hazards and labeling), training and recordkeeping.

All EtO sterilizers used at the University should be evaluated and monitored to ensure that they have been designed, installed, or modified to help the facility meet the OSHA standard and to otherwise minimize personnel exposure to EtO.

3. Methods of Compliance/Controls:

a) **Engineering Controls:**
Engineering controls will be implemented to reduce and maintain employee exposures at or below the Action Level (AL), Time Weighted Average (TWA), and Excursion Limit. EtO exhaust must be vented to a dedicated exhaust or non-recirculating ventilation system.

b) Administrative Controls:
Supervisors should reduce the amount of time an employee may spend in the area where the EtO sterilizer is located, to the extent possible.

c) Personal Protective Equipment:
When employees could have eye or skin contact with EtO or EtO solutions, the University of Pittsburgh will select and provide, at no cost to the employee, appropriate Personal Protective Equipment (PPE) in accordance with 29 CFR 1910.132 and 1910.133. Appropriate PPE may include butyl rubber gloves, chemical resistant aprons, protective clothing (impermeable), full face shields, and safety goggles. Supervisors will ensure the use and maintain Personal Protective Equipment (PPE). Contact EH&S if further assistance is needed for PPE selection.

d) Respiratory Protection:
Full face respirators equipped with a cartridge approved for protection against EtO may be used to control EtO exposure only under the following circumstances: during maintenance, repairs, and other operations for which engineering controls are not feasible; in work situations where feasible engineering and work practice controls do not reduce exposures below the TWA and Excursion Limit. In situations where respiratory protection is required, the EH&S Respiratory Protection Program must be instituted.

Note: The use of half masks of any type is prohibited as EtO may cause eye irritation or injury.

4. Continuous EtO Monitors:

a) It is recommended that at least one EtO detector/monitor should be continuously utilized in spaces where EtO sterilizers are actively being used outside of an EH&S approved engineering control.
b) To ensure the detector/monitor operates and alarms as programmed, bump tests should be performed in accordance with the manufacturer's requirements.
c) The operation of the detectors/monitors should be checked prior to use and calibrated in accordance to the manufacturer's requirements (example: monthly).

6. Air Monitoring:

Routine monitoring of EtO sterilizers, the work environment, and University of Pittsburgh employees is performed to evaluate employee exposures and to ensure the continuing effectiveness of engineering control measures, work practices and equipment maintenance. In areas where EtO is used, employees will be monitored to determine their exposure relative to the Action Level (AL) and the Permissible Exposure Limit (PEL) (8-

hr Time Weighted Average (TWA) and Excursion Limit. Costs associated with monitoring may be charged directly to the participating Department or the Principal Investigator (PI).

a) Initial Monitoring

Any workplace or work operations using EtO must perform initial monitoring to determine accurately the airborne concentrations of EtO to which employees may be exposed. If initial monitoring reveals employee exposures at or above the Action Level (AL) (0.5 ppm), periodic monitoring and medical surveillance will be implemented.

b) Periodic Monitoring

If the initial monitoring reveals employee exposure at or above the action level but at or below the 8-hour TWA, monitoring must be repeated at least every six (6) months. If the monitoring reveals employee exposure above the 8-hour TWA, monitoring must be repeated at least every three (3) months. If the monitoring reveals employee exposure above the excursion limit, monitoring shall be repeated at least every 3 months until the exposure is below the excursion limit.

Whenever there has been a change in the production, process, control equipment, personnel or work practices that may result in new or additional exposures to EtO, or when there is any reason to suspect that a change may result in new or additional exposures, additional monitoring will be conducted.

c) Employee Notification

Within 15 working days after receipt of the results from the laboratory analyzing the sample, each affected employee and their supervisor will be notified of these results either individually in writing or by posting the results in an appropriate location that is accessible to employees.

7. Medical Surveillance:

A medical surveillance program will be implemented for all employees who are or may be exposed to EtO at or above the action level, without regard to the use of respirators, for at least 30 days a year. Medical examinations and consultations will also be available to all employees who have been exposed to EtO in an emergency situation.

The University of Pittsburgh will make available medical examinations and consultations to each employee on the following schedules:

a) Prior to assignment of the employee to an area where exposure may be at or above the action level for at least 30 days a year.

b) At least annually each employee is exposed at or above the action level for at least 30 days in the past year.

c) At termination of employment or reassignment to an area where exposure to EtO is not at or above the action level for at least 30 days a year.

d) As medically appropriate for any employee exposed during an emergency.

e) As soon as possible, upon notification by an employee either (1) that the employee has developed signs or symptoms indicating possible overexposure to EtO, or (2) that the employee desires medical advice concerning the effects of current or past exposure to EtO on the employee's ability to produce a healthy child.

f) If the examining physician determines that any of the examinations should be provided more frequently than specified, the employer shall provide such examinations to affected employees at the frequencies recommended by the physician.

8. Regulated Areas:

Regulated areas will be established wherever occupational exposure to airborne concentrations of EtO may exceed the TWA or wherever the EtO concentration exceeds or can be reasonably expected to exceed the excursion limit. Access to regulated areas will be demarcated and limited to authorized personnel.

9. Signs and Labels:

a) Legible signs shall be posted and maintained demarcating regulated areas and entrances or access ways to regulated areas. Signs shall bear the following legend:

DANGER
ETHLYENE OXIDE
MAY CAUSE CANCER
MAY DAMAGE FERTILITY OR THE UNBORN CHILD
RESPIRATORY PROTECTION AND PROTECTIVE CLOTHING MAY BE REQUIRED IN THIS AREA
AUTHORIZED PERONNEL ONLY

b) All labels must be placed on all containers of EtO contents and must remain on when the containers of EtO leave the workplace.

10. Emergency Situations:

If possible and safe, turn off all sources/equipment containing Ethylene Oxide; and close containers of hazardous or infectious materials. Do not turn of ventilation/engineering controls. Close the door behind you and promptly evacuate the building via designated/nearest stairwells and exterior exit doors. When safe to do so, contact University of Pittsburgh Police Dipatch to report the emergency – 412-624-2121. Do not use the elevators. Proceed to an assembly point away from the building. Do not re-enter the building until the "all clear" signal is given. Additional information can be found in the Building Occupant Handbook.

11. Training:

Training is required upon initial assignment to a job where EtO is used and at least annually thereafter. This training will cover the following topics:

- Methods and observations that may be used to detect the presence or release of EtO in the work area;
- The physical and health hazards of EtO;
- The measures employees can take to protect themselves from hazards associated with EtO exposure, including work practices, emergency procedures, and personal protective equipment to be used; and,
- The details of the hazard communication program, including an explanation of the labeling system and how employees can obtain and use the appropriate hazard information.

12. Disposal:

Excess ethylene oxide cartridges and ethylene oxide containing waste materials should be disposed via the University's chemical waste program. Waste cartridges/containers must be properly labeled with a completed orange Waste Chemicals label.

If you have any questions about the handling, storage, or disposal of ethylene oxide, please call EH&S at 412-624-9505 or email safety@ehs.pitt.edu.