

Office of Research Services

Ethylene Oxide

2019

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Technical Assistance Branch

**National Institutes of Health
Office of Research Services
Division of Occupational Health and Safety**

ETHYLENE OXIDE SURVEILLANCE PROGRAM

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**National Institutes of Health
Office of Research Services
Division of Occupational Health and Safety**

ETHYLENE OXIDE SURVEILLANCE PROGRAM

1.0 INTRODUCTION

1.1 Purpose

The Office of Research Services, [Division of Occupational Health and Safety](#) (DOHS), Technical Assistance Branch (TAB), has established an ethylene oxide (EtO) surveillance program at the National Institutes of Health (NIH). The EtO program is designed to:

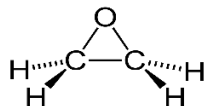
- a) Identify and quantify potential exposure levels for employees who work in EtO sterilization facilities
- b) Document the effectiveness of the controls that are being used to minimize exposures.

1.2 Scope and Application

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, Ethylene oxide](#). This program is administered by the DOHS and applies to all occupational exposures to EtO at the NIH. The EtO program outlines key provisions of the standard and provides procedures in place at the NIH for employee exposure monitoring, methods of compliance/controls, respirators and protective clothing, emergency situations, medical surveillance, communication of EtO hazards (labeling and posting hazards), training and record keeping.

All EtO sterilizers, aerators, and gas sources used at the NIH are 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.

1.3 Background



EtO is a highly flammable, colorless liquid or gas with an ether-like or sweet odor that is detectable only above the Permissible Exposure Limit (PEL). It is a cyclic ether, consisting of an alkane with an oxygen atom bonded to two carbon atoms of the alkane, forming a ring. EtO is produced in large volumes and is used to make other chemicals, such as ethylene glycol. It is a component in things such as detergents, thickeners, solvents, plastics, and various organic chemicals such as ethanolamines, complex glycols, and other compounds. Control of insects on stored agricultural products, such as nuts and spices, is achieved with small amounts of EtO. Hospitals use very small amounts of EtO to sterilize medical equipment and supplies. Synonyms for EtO include Dimethylene oxide; 1,2-Epoxy ethane; and oxirane (IUPAC).

EtO is irritating to the respiratory tract, skin, and eyes. Inhalation is the most common route of EtO exposure and high concentrations may cause coughing, dizziness, drowsiness, headache, nausea, sore throat, and vomiting. Repeated or prolonged contact may cause skin sensitization. Eye contact may cause redness, pain, or blurred vision. At room temperature, it is flammable, carcinogenic, mutagenic, irritating, and an anesthetic gas. 2.0 DEFINITIONS

For evaluating employee exposures to EtO, the NIH uses exposure criteria established by both OSHA and the American Conference of Governmental Industrial Hygienists (ACGIH), as defined below:

NIOSH REL – TWA <0.1 ppm (0.18 mg/m³)

OSHA Permissible Exposure Limit (PEL) – A limit on workplace exposure of one (1) part EtO per million parts of air (1 ppm) as an eight-hour time-weighted average (8-hour TWA). Note: The Threshold Limit Value (TLV), an ACGIH workday exposure level, is the same as the OSHA PEL: 1 ppm.

OSHA Action Level (AL) – An airborne concentration of 0.5 ppm EtO average as an 8-hour TWA.

OSHA Short Term Exposure Limit (STEL) – An excursion limit of 5 ppm EtO averaged over a sampling period of 15 minutes.

OSHA Regulated Area – Areas identified where occupational exposures may exceed the TWA. These areas must be clearly marked and only authorized personnel allowed to enter.

ACGIH Threshold Limit Value (TLV) – 0.1 ppm as an 8-hour TWA

3.0 KEY PROVISIONS

3.1 Exposure Monitoring/Frequency

Routine monitoring of EtO sterilizers and associated equipment, the work environments, and NIH employees is performed to evaluate employee exposures and to ensure the continuing effectiveness of engineering control measures, work practices, and equipment maintenance. An EtO surveillance program has been developed to monitor occupational exposures to EtO at NIH.

In areas of the NIH where EtO is used, employees will be monitored annually to determine their exposure relative to the AL and the PEL (8-hr TWA and STEL). Employee monitoring will be extrapolated to represent other employees performing the identical job task in the same laboratory (similar exposure groups). Employees and their designated representatives may observe all monitoring.

If representative samples are used to determine the employee's exposure to EtO, the measurements obtained will be representative of the employee's full workday, or a fraction thereof. Short-term or grab samples, except for the STEL determination, will be considered screening samples to be followed up with sampling for the duration of the workday exposures.

An employee health complaint related to EtO exposure, e.g., symptoms of respiratory, gastrointestinal or dermal conditions, will initiate personal monitoring of that employee and background monitoring of the job task. Monitoring of employees reporting signs or symptoms will be done promptly.

Monitoring will be repeated annually and each time there has been a significant change in the production, process, control equipment, personnel or work practices that may result in new or additional exposures to

EtO or when the employer has any reason to suspect that a change may result in new or additional exposures. Monitoring will cease if EtO sterilization is no longer used in the facility.

(See Appendix 1)

3.2 Monitoring Results

The need for further action is determined by the EtO monitoring results. Further action may include periodic monitoring, development of a compliance plan, participation into a medical surveillance program, and implementation of engineering and/or administrative control methods.

3.2.1 Initial Monitoring

If initial monitoring reveals employee exposures at or above the AL, periodic exposure monitoring and medical surveillance will be implemented; and, employees will be provided information and training on EtO at the time of initial assignment and at least annually thereafter.

3.2.2 Compliance Plan

If employee exposure exceeds the TWA or STEL, a written compliance program should be implemented to reduce exposures to below the TWA and or the STEL by means of engineering and work practice controls, supplemented with the use of respiratory protection on an interim basis.

3.2.3 Overexposures

In areas where EtO monitoring has been conducted and the EtO TWA or STEL levels have been exceeded, the NIH will:

- a. Use engineering controls and work practices to reduce and maintain employee exposures at or below the TWA or STEL. These controls and practices may be supplemented by the use of respirators where necessary.
- b. Establish and implement a written compliance program to achieve employee exposure at or below the TWA or STEL. Exposures above the AL, but below the TWA, will constitute repeat monitoring at least every six (6) months. Exposures above the TWA will constitute repeat monitoring at least every three (3) months.
- c. Establish exposure monitoring and training programs for employees with EtO exposure above the STEL. Repeat employee monitoring at least every 3 months until the exposure is below the AL.
- d. Identify as a regulated area, any location where the airborne concentration of EtO is expected to exceed the TWA or STEL.
- e. Place warning labels on containers capable of releasing EtO to the extent that an employee's potential exposure would exceed the TWA or STEL.

Note: Employee rotation is prohibited as a means of compliance with the TWA or STEL.

3.2.4 Employee Notification of Monitoring Results

The DOHS will provide the affected employee and his or her supervisor a written report of the results of the monitoring conducted by DOHS within 15 working days.

3.3 Methods of Compliance/Controls

3.3.1 Engineering Controls

Engineering and work practice controls will be implemented to reduce and maintain employee exposures at or below the AL, TWA, and STEL. Ventilation is the principal means for controlling EtO emissions at the NIH. EtO exhaust is vented to a dedicated exhaust or non-recirculating ventilation system.

3.3.2 Personal Protective Equipment

Where eye or skin contact with liquid EtO or EtO solutions may occur, the NIH will select and provide, at no cost to the employee, appropriate personal protective equipment (PPE) in accordance with [29 CFR Part 1910.132 and 1910.133](#). Appropriate PPE may include: neoprene or butyl rubber gloves, vinyl aprons, or protective clothing (impermeable), full face shields, and safety goggles to protect any part of the body that may come in contact with EtO. The supervisor will provide and ensure that the employee properly wears the PPE.

3.3.3 Respiratory Protection

Respirators may be used to control EtO exposures only under the following circumstances: during the installation of feasible engineering and work practice controls; 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 STEL; and in emergencies. In situations where respiratory protection is required, the [NIH Respiratory Protection Program](#) (RPP) will be instituted.

3.3.4 Administrative Controls

Safe working conditions in NIH EtO facilities are obtained through proper work practices and adequately designed and maintained equipment. Supervisors should reduce the amount of time an employee may spend in the area where the EtO sterilizer is located, to the extent possible.

3.4 Regulated Areas

Employers must identify areas where occupational exposures exceed the TWA. These areas must be clearly marked and only authorized personnel allowed to enter. Supervisors should ensure employees are aware of these areas and understand the signs, postings, and requirements.

3.5 Communication of EtO Hazards

Personnel that work in or near locations where ethylene oxide is used must be informed of EtO exposure hazards, potential adverse health effects, and methods for protecting themselves from exposure to EtO. This information is communicated in accordance with OSHA regulations as stipulated in [29 CFR Part 1910.1047, Ethylene oxide](#), and in [29 CFR Part 1910.1200, Hazard communication and shall include a](#)

[discussion of the following hazards:](#) cancer; reproductive effects; mutagenicity; central nervous system; skin sensitization; skin, eye and respiratory tract irritation; acute toxicity effects; and flammability.. In addition, signs and labels should be posted that clearly indicate EtO's carcinogenic and reproductive hazards and outline good work practices. Such signs and labels are posted: 1) in the immediate area of the sterilizers, 2) above EtO supply cylinders, and 3) areas with associated equipment.

The [OSHA Fact Sheet on Ethylene Oxide](#) (Appendix 2) provides a means for communicating this information and can be posted at the worksite, and its availability will be verified during the monitoring survey.

3.6 Employee Training

ICs must ensure that personnel that use ethylene oxide sterilization equipment at NIH have been trained regarding the proper use, handling of ethylene oxide canisters, and information in the OSHA Fact Sheet on Ethylene Oxide.

The DOHS will provide initial and annual training to all employees potentially exposed to EtO at or above the AL and/or STEL.

The training will include:

- The requirements of the OSHA EtO standard with an explanation of its contents, including [Appendix A](#) and [Appendix B](#)
- Any operations in the employee's work area where EtO is present
- The location and availability of the written EtO Final Rule
- The medical surveillance program with an explanation of the information in [Appendix C](#)
- Methods and observations that may be used to detect the presence or release of EtO
- The physical and health hazards of EtO
- The measures employees may take to protect themselves from hazards associated with EtO exposures, such as proper use of PPE
- The specific procedures the NIH has implemented to protect employees from exposures to EtO, such as work practices and emergency procedures
- The details of the hazard communication program developed by the NIH, including an explanation of the labeling system and how employees may obtain and use the appropriate hazard information.

(See Appendix 3)

3.7 Medical Surveillance

An Occupational Medical Service (OMS) licensed health care provider will carry out the OMS Medical Surveillance Protocol, once activated. Employees will receive a medical examination: 1) before assignment to an area where exposure is at or above the AL; 2) annually, if they are exposed at this level for 30 days or more during the year; 3) upon request, if an employee has developed symptoms suggesting overexposure or wants medical advice concerning the effects of EtO exposure on his or her ability to produce a healthy child; and 4) at the time an employee's employment ends in an area of potential exposure. Employees, who are exposed to EtO at or above the AL or in an emergency situation, are automatically enrolled in the OMS Medical Surveillance Protocol.

When results of successive monitoring of EtO locations show documented, ambient EtO concentrations well below the established AL, the OMS Medical Surveillance Protocol will be deactivated. Notice will be given to the employee, explaining that the ambient EtO concentrations are low enough for their exit from the program. If the monitoring identifies employee exposures at or above the AL, as noted above, the OMS Medical Surveillance Protocol will be reactivated. Notice will be given to the employee, explaining the reactivation.

(See Appendix 4)

3.8 Emergency Situations

A written plan for EtO emergency situations has been developed for each workplace where there is a possibility of an emergency. The plan should be posted in the work areas and implemented in the event of an emergency.

Alarms are installed on the EtO sterilizing units to alert employees of an EtO emergency. The Institute or Center (IC) shall ensure that the alarms and EtO sterilizer unit area both calibrated and inspected annually (or more frequent if recommended by the manufacturer) to verify proper operations. The calibration and inspection record will be reviewed during the annual exposure monitoring assessment.

Storage of EtO sterilizing gas cylinders and/or containers should be in accordance with the manufacturer's recommendations and storage regulations. Efforts should be made to keep any 'extra' containers to a minimal. Storage of EtO cylinders and containers will be reviewed during the annual exposure monitoring assessment.

Laboratory employees should not engage in correcting emergency conditions. The [NIH Fire Department](#) provides this service and responds to all emergencies at the NIH campus. (See Appendix 3)

The emergency response procedures are sent along with the annual monitoring reports.

The DOHS provides the NIH Fire Department an EtO locations table on an annual basis.

(See Appendix 1)

3.9 Record Keeping

Exposure records will be retained for 30 years; medical records must be kept for the employee's duration of employment, plus 30 years. Employees, former employees, and their designated representatives may have access to records, upon request.

The TAB, DOHS maintains and updates records of all monitoring data obtained to measure employee exposures to EtO. The records include:

- Date measurements are obtained
- Operations of process being monitored
- Method of sampling and analysis used
- Number, duration, time, and results of samples taken
- Employee name, Institute or Center and Department (ICD), area supervisor, job classification/title, employee ID, and exposure estimate of the employee whose exposures are represented by the actual monitoring results

4.0 APPLICABILITY

The OSHA EtO standard generally applies to all occupational exposures to EtO. Exceptions, and therefore excluded workplaces, include those in which the processing, use, or handling of products containing EtO will not result in airborne concentrations at or above the AL. An employer who claims exemption from the standard must keep records that document this determination.

5.0 REFERENCES

U.S. Department of Labor [OSHA Safety and Health Standards \(29 CFR Part 1910\)](#). U.S. Government Printing Office, Washington, D.C.

Lamontagne, A.D., Kelsey, K., Christiani, D. and Plantamura, D. “Ethylene Oxide Health and Safety Manual: Training and Reference Materials on the Safe Use of Ethylene Oxide in Sterilization Facilities,” 2nd edition.

APPENDIX 1: ETHYLENE OXIDE SURVEILLANCE PROTOCOL AND LOCATIONS

1.0 ETHYLENE OXIDE SURVEILLANCE PROTOCOL

1.1 Purpose

To evaluate NIH employee occupational exposures to ethylene oxide (EtO) resulting from EtO sterilization or servicing procedures.

1.2 Introduction

Presently, there are two types of EtO gas sterilizers used at the NIH: (1) automatic, general purpose sterilizers that are supplied by compressed-gas cylinders or single-dose cartridges, and (2) sterilizers that use glass ampules.

The Division of Occupational Health and Safety (DOHS), Technical Assistance Branch (TAB) annually conducts surveys of all ethylene oxide sterilization facilities at NIH to determine if the employees who operate the sterilizers and those who work in the immediate area are exposed to excessive levels of EtO. The goal of the program is to reduce personal exposures to the lowest level possible through the use of approved equipment, adequate engineering controls, and good work practices.

The survey results serve to evaluate the effectiveness of engineering controls and work practices. The results also provide documentation of surveillance activities for The Joint Commission for Accreditation of Health Care Organizations (JCAHO) and demonstrates compliance with Occupational Safety and Health Administration (OSHA) statutes.

1.3 Criteria

The current OSHA permissible exposure limit (PEL) for EtO is 1 part per million (ppm) based on an 8-hour time weighted average (TWA) exposure ([29 CFR Part 1910.1047, Ethylene oxide](#)). There is also a short-term exposure limit (STEL) of 5 ppm for 15 minutes. This means that the average EtO concentration during any 15-minute period of the workday should not exceed 5 ppm. An EtO concentration that is one half of the PEL is defined as the "action level" (0.5 ppm).

Employees exposed to EtO at and above this level for at least thirty days a year are required to participate in a medical surveillance program and monitoring must be done every six months. There are additional compliance requirements if employee exposure exceeds the PEL or STEL. Detailed information on these, requirements are found in the OSHA standard 29 CFR 1910.1047, [Appendix A](#).

1.4 Analytical Methods

The current method employed by NIH involves the use of passive dosimeters (3M 3551). These dosimeters adsorb EtO vapors on chemically treated activated charcoal. The contaminants are then desorbed and quantified by gas chromatography. Samples will be sent to an [American Industrial Hygiene Association accredited laboratory](#) for analysis.

1.5 Sampling Strategy

A sampling strategy will be developed for each location monitored because of the specific conditions and uniqueness of each sampling situation. The employee with the highest risk of exposure will be sampled and samples will be obtained during periods of maximum EtO concentration by using all available knowledge about the area, employees and process being monitored.

1.6 Monitoring Procedure

The monitoring schedule for each facility will be developed with the supervisor of each area (see Table 1). Routine monitoring of the sterilizer and associated equipment, as well as the work environment, will be conducted to check for employee exposure and to ensure the continuing effectiveness of engineering control measures, work practices, and equipment maintenance.

Consecutive area and personnel sampling will be conducted during the entire work shift. All samples will be taken in areas that are representative of the concentrations to which employees are exposed during normal and routine use of EtO. If closely representative samples are not achievable for some reason, at a minimum, the areas with greater likelihood of higher concentrations need to be sampled so that protective measures are conservative.

At a minimum, representative personal samples will be taken for each employee category. These categories, or Similar Exposure Groups (SEGs) will be developed by the specialist conducting the sampling. The specialist will review the types of tasks the employees are doing, the duration of the work performed, the PPE utilized, and other considerations (such as particularly sensitive populations; e.g. pregnant workers, immunocompromised individuals, etc.), and will parse the groups out and assign sampling badges accordingly. Personal samples will be taken in the "breathing zone" of the employee. The employee will wear a small badge clipped to his/her collar for the expected period of potential exposure, especially during operations with the highest potential for exposures. Employees who change the EtO cylinders will be included in periodic STEL checks. Area monitoring will be conducted at various fixed locations within the workplace.

A sampling data sheet will be completed for each area monitored. These data sheets will indicate the locations of area monitors and identify the operator who works regularly in the EtO sterilization area. The employee will be notified of his/her monitoring results within 15 days of receipt from laboratory.

Passive dosimeters will be stored in a cool place away from chemical contaminants until used. After use, the manufacturer or an American Industrial Hygiene Association accredited laboratory will analyze the dosimeters as soon as possible. Samples will be shipped no later than one day after the sample is collected. Samples will be kept under refrigeration until ready for analysis.

1.7 Report

Supervisors or their authorized designees of areas being monitored will be promptly informed of equipment deficiencies and unsafe work practices that may contribute to potential harmful exposures. It is the responsibility of the supervisors in each facility to initiate and follow to completion the recommendations made in the final report. Copies of all final reports will be sent to the responsible supervisor(s) in each area (see Table 1); and to the Safety Specialist assigned to the Institute or Center (IC) that is responsible for the operation of the EtO facility. Final reports, which indicate employee exposures above the STEL, AL or TWA, will be sent to the [Occupational Medical Service](#) (OMS) Medical Director.

In the Clinical Center (CC), corrective actions requiring engineering support are coordinated through the Building Services Manager. The following persons will be notified of findings that need immediate

attention and will also receive copies of the final report of the survey conducted in the Central Hospital Supply facility:

Environmental Safety Officer, CC
Chief, Materials Management Department, CC
Chief, Central Hospital Supply Section, MM, CC

In all other areas of NIH, engineering support will be coordinated through the appropriate [Office of Research Facilities Development and Operations](#) (ORF) coordinator. Safety and health consultants assigned to the IC where facility changes are needed will provide assistance and will monitor the progress of the project to completion.

It is the responsibility of the CC ESO and/or Safety Committee to provide the DOHS with an annual (or more frequently if necessary) updated list of EtO gas usage areas within the CC. In other areas, this information will be provided by the IC's safety and health consultant or by other appropriate mechanism

1.8 Reference

U.S. Department of Labor, [29 CFR Part 1910, OSHA Safety and Health Standards](#).

APPENDIX 1: ETHYLENE OXIDE SURVEILLANCE PROTOCOL AND LOCATIONS

EtO Sterilizer Locations					
Location	Type	Number	Contact	Title	Report Recipients (most recent monitoring date)
Active					
10/B1N238 IC: CC	Amsco	2	Norman Hall	Lead Technologist, CHS	Norman Hall, Dr. Michele Evans (12/16)
14D/232	3M 4XL	1	Dr. Robert Hoyt		Dr. Robert Hoyt (11/15) Unit was offline for most of 2016
14E/114C	3M 5XL and GS5	2	Dr. Tom (Marvin) Thomas	Chief,	Dr. Tom Thomas (1/18)
49/B1S43	Anderson	1	Ted Plemons		Ted Plemons (3/17)
NIHAC (Poolesville) – 102	3M 4XL	1	Kris Eckard	Facility Manager	Kris Eckard (12/16)
NIDA Baltimore	3M (5XL)	1	Dr. Ira Baum Philip White Delores Dobson		Ira Baum; Delores Dobson (2/15)
Inactive					
5RC / B1-33 IC: NCRR/VRP/NIHAC	3M (4XL)	1	Dr. Jim McGehee Sandy Clements		Dr. Jim McGehee, NHLBI (9/12 last survey; location closed 1/14 – moving to PNRC II and plan to use Building 49 for any sterilization.
14F/S102 IC: NCRR/VRP	Castle (3647)	1	Mr. David Dorsey Mr. David Brightwell	Facility Manager	David Dorsey (removed from facility in 2012)
14G / West Corridor IC: NCI	Amsco (2055)	1	Mr. David Dorsey	Facility Manager	David Dorsey (removed from facility in 2012)
Twinbrook II (136) NIAID IC: NIAID	3M (4XL-523T20)	1	Marnie Walker		No longer an ETO unit here
Twinbrook II (224) IC: NHLBI	Castle (MDT)	1	Marnie Walker		No longer an ETO unit here
NIHAC (Poolesville) – 110	Anderson	1	Julie Jacobs	Facility Manager	Julie Jacobs (11/15) – unit was rarely used and facility is closed in 2017.
GRC / 312	Anprolene (AN74C)	1	Scott Koehler	Researcher	Scott Koehler (Sterilizer not in use)

APPENDIX 2: OSHA Fact Sheet - Ethylene oxide

[OSHA Fact Sheet - Ethylene Oxide](#)

APPENDIX 3: EMERGENCY PROCEDURES FOR ETHYLENE OXIDE RELEASES

EMERGENCY PROCEDURES FOR ETHYLENE OXIDE (EtO) RELEASE

A. PURPOSE

The purpose of this document is to establish a written plan of action to follow in the event of an EtO release (leak/spill) in buildings occupied by NIH employees and others utilizing NIH facilities.

B. REFERENCES

1. 29 CFR 1910.1047 - "Ethylene Oxide Standard"
2. 29 CFR 1910.38 - "Employee Emergency Plans and Fire Prevention Plans"
3. NIH Policy Manual - 1430 NIH Occupant Evacuation Plan

C. POLICY

The Occupational Safety and Health Administration (OSHA) states that a written plan for emergency situations shall be developed for each workplace where there is a possibility of an emergency.

D. EMERGENCY ACTION TO FOLLOW

Steps to take in the event of an EtO release:

- 1) If you become aware of, or suspect, an ethylene oxide release, alert all personnel in the room to the problem, leave the room immediately, and close all doors and windows as you leave in order to contain the gas as much as possible. Evacuate the immediate area. **ONLY TRAINED EMERGENCY RESPONDERS SHOULD ATTEMPT TO CORRECT EMERGENCY CONDITIONS.**
- 2) If EtO comes in contact with the skin or eyes, flush the area immediately with large amounts of water using the closest emergency shower or eye wash station.
- 3) Once clear of the area, immediately use the nearest phone to report the release to the NIH Fire Department by calling 911. Be sure to provide the following information:
 - a) The exact location of the release, if known
 - b) Whether or not there are any injured personnel
 - c) Whether or not there is a risk of fire
 - d) Your name, location and number from where you are calling
- 4) If building evacuation is necessary, evacuate the area using the established routes
- 5) Injured personnel will be transported to the nearest hospital, if necessary.
- 6) Do not attempt to re-enter the area until the appropriate authorities determine the area is safe to enter.

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- 2) If EtO comes in contact with the skin or eyes, flush the area immediately with large amounts of water using the closest emergency shower or eye wash station.
- 3) Once clear of the area, immediately use the nearest phone to report the release to the City/County Department of Fire and Rescue Services by calling 911. Be sure to provide the following information:
 - a) The exact location of the release, if known
 - b) Whether or not there are any injured personnel
 - c) Whether or not there is a risk of fire
 - d) Your name, location and number from where you are calling from
- 4) If building evacuation is necessary, evacuate the area using the established routes
- 5) Injured personnel will be transported to the nearest hospital, if necessary.
- 6) Do not attempt to re-enter the area until the appropriate authorities determine the area is safe to enter.

APPENDIX 4: ETHYLENE OXIDE MEDICAL SURVEILLANCE

Note: Currently, the Ethylene Oxide Medical Surveillance Program is inactive due to consecutive low or less than detected results on the NIH campus. If surveillance results exceed the permissible exposure limit, the Occupational Medical Service will activate Ethylene Oxide Medical Surveillance Program.

I. Background

In the health care setting, ethylene oxide is commonly used for sterilizing medical supplies and equipment. At room temperature and normal atmospheric pressure, it is a colorless gas with a characteristic ether-like odor. The threshold of odor perception is variable with a mean odor concentration of 700 parts per million. The threshold commonly wanes with chronic exposure.

Acute toxicity in humans may consist of irritation of the eyes, respiratory tract and skin, headache, nausea, vomiting, diarrhea, neurological signs and symptoms such as seizures, peripheral neuropathy, gait disturbances, hypoesthesia and changes in lymphocytosis. In addition, many individuals complain of a peculiar taste.

The effects of chronic exposure/toxicity in humans are not as well established. The human studies in the literature are contradictory and the conclusions reached are controversial, but they suggest that ethylene oxide exposure may lead to increased sister chromatic exchange, leukemia, solid tumors of the gastrointestinal and genito-urinary systems, and spontaneous abortions.

Current OSHA recommendations define the "action level" as a mean concentration of airborne ethylene oxide of less than 0.5 parts per million calculated as an eight-hour time-weighted average (TWA) and the permissible exposure limit (PEL) as an airborne concentration of ethylene oxide not to exceed one part ethylene oxide per million parts of air as an eight-hour TWA.

II. Eligibility

All employees who are or may be exposed to ethylene oxide at or above an airborne concentration of 0.5 ppm calculated as an eight-hour TWA for at least 30 days a year.

All employees who have been exposed to ethylene oxide during an emergency.

III. Identification of Eligible Employees

The Division of Occupational Health and Safety (DOHS) will submit a list of employees based on the results of environmental measurements obtained at worksites where ethylene oxide is used.

IV. Frequency of Medical Examinations and Consultations

A. Employees at or above the action level

1. Pre-employment
2. Annually
3. Development of signs or symptoms indicating possible over-exposure to ethylene oxide
4. Termination from an ethylene oxide worksite

- B. Employees exposed during an emergency

As medically indicated

V. Content of Medical Examination

- A. Pre-employment Examination

1. Complete work history with special attention to prior work exposures.
2. Complete medical history with special attention to pulmonary, neurologic, hematologic, hepatic and reproductive systems.
3. Complete physical examination.
4. Laboratory evaluation: CBC with differential and SMAC.
5. Additional tests as medically indicated.

- B. Annual Examination

1. Interim work history with special attention to work practices, job description, estimated exposure and signs or symptoms indicating possible over-exposure to ethylene oxide.
2. Interim medical history with special attention to pulmonary, neurologic, hematologic and reproductive systems and the skin and eyes.
3. Physical examination to include the eyes, lungs, abdomen, skin and neurologic system.
4. Laboratory evaluation: CBC with differential. Additional tests as medically indicated.

- C. Development of Signs or Symptoms of Over-exposure or Exposure During an Emergency

1. Work history with special attention to work practices and/or nature of exposure during the emergency
2. Physical examination to include the eyes, lungs, abdomen, skin and neurologic system.
3. Laboratory evaluation: CBC with differential, SMAC to assess hepatic function, additional tests as medically indicated.
4. Removal from further ethylene oxide exposure until signs and symptoms resolve.
5. Follow-up as medically indicated.
6. Notify DOHS.

- D. Termination from an Ethylene Oxide Worksite per Annual Examination

- E. Reproductive Evaluation, if Medically Indicated.

1. Work history with special attention to ethylene oxide exposure.
2. Medical history with special attention to reproductive and genito-urinary systems.
3. Physical examination.
4. Laboratory evaluation may include pregnancy testing if medically indicated.
5. Referral for fertility evaluation if medically indicated.

VI. Medical Documentation

- A. Pre-employment Work and Medical History: Ethylene Oxide Surveillance:
Replacement Work and Medical History, Attachment I.

- B. Interim Work and Medical History: Ethylene Oxide Surveillance:

Interim Medical Work and Medical History, Attachment II.

C. Physical Examination. Ethylene Oxide Surveillance: Physical Exam, Attachment III.

VII. Notification of Employees of Medical Surveillance Results

Physical Examination and Laboratory Results

1. Normal findings: Verbal notification at the end of the physical examination by the examining medical personnel.
2. Findings suggestive of ethylene oxide over-exposure: Verbal notification at the end of the physical examination by the examining medical personnel and written notification within 15 days of the physical examination by the OMS physician heading the surveillance program.

VIII. Ethylene Oxide Surveillance Review

Annual Review with the Appropriate Members from OMS and DOHS

1. Review latest OSHA/NIOSH recommendations.
2. Review environmental sampling data obtained by DOHS with special attention given to an employee's representative exposure level or anticipated exposure level.
3. Review of medical literature.

APPENDIX 5: ETHYLENE OXIDE INFORMATION AND TRAINING

Training and Information Protocol for NIH Personnel Working With Ethylene Oxide (EtO)

This appendix reviews the mandatory information required by OSHA [29 CFR Part 1910.1047 \(j\)\(3\), Communication of EtO hazards to employees; "Information and training"](#).

1.0 PROGRAM OVERVIEW

The NIH has developed an in-service program for personnel who may work with ethylene oxide (EtO) or may be potentially exposed to EtO above the AL and/or STEL. This EtO Safety Training Program is provided through the Technical Assistance Branch, Division of Occupational Health and Safety (DOHS) in cooperation with the Safety Operations Support Branch.

The program consists of three parts. Part I provides a comprehensive overview of the hazards associated with working with EtO, safe work practices, and steps to be taken in the event of an emergency. Part II provides an overview for support staff that may work around but not directly with EtO. Part III is orientation training and supporting materials for new employees working with EtO. The designated, responsible supervisor conducts the orientation training.

All personnel working with EtO, or who may work in close proximity to EtO sterilizers, are required to participate in Part I of the NIH EtO Training Program. This training is provided on an annual basis, with a mid-year update provided every six months.

Part II of the EtO Training Program provides an overview of the use of EtO in clinical and research areas for support staff and others who may work in these areas but are not occupationally exposed. Part II is provided on an as-needed basis.

In each area where EtO is used or stored, the designated, responsible supervisor maintains a site-specific safety orientation package that includes a copy of the written EtO program, standard operating procedures, hazard information and warnings, and steps to be taken in the event of an emergency. All new personnel working with EtO must receive safety orientation training before beginning work. The designated, responsible supervisor will conduct the training and is required to document the orientation. The safety orientation program will be audited on a semi-annual basis during regular scheduled training.

The NIH EtO Safety Training Program is consistent with the [NIH Hazard Communication Program](#).

The Technical Assistance Branch will maintain a complete copy of the training materials. The DOHS will maintain training program documentation and attendance records.

2.0 PROGRAM CONTENT

The information provided in the NIH EtO Safety Training Program includes, but is not limited to:

- a. The availability of the EtO standard to employees. An overview of the NIH Hazard Communication Program and the EtO Medical Surveillance Program conducted by the Occupation Medical Service (see Appendix 4).

- b. The physical and health effects of both acute and chronic exposure to EtO. Methods used to detect the presence of EtO, which are personnel monitoring and area alarms.
- c. The availability of information on EtO. Signs used to indicate the presence of EtO in regulated areas.
- d. The rationale for and results of EtO exposure monitoring done in a particular location.
- e. Accepted work practices with EtO to minimize exposure including behaviors, personal protective equipment, and personal hygiene practices.
- f. The procedures to be followed when changing EtO tanks. General safe work practices with all compressed gases.
- g. The expected behaviors in the event of an emergency or uncontrolled release of gas and personnel contamination.

3.0 PROGRAM EVALUATION

The program will be evaluated on an on-going basis and may be updated and supplemented with additional information in keeping with subsequent changes in the OSHA standard and accepted prudent practices. Evidence of these changes will be maintained with the training materials.