
29 C.F.R. § 1910.1047

Ethylene oxide.

(a) *Scope and application.* (1) This section applies to all occupational exposures to ethylene oxide (EtO), Chemical Abstracts Service Registry No. 75-21-8, except as provided in paragraph (a)(2) of this section.

(2) This section does not apply to the processing, use, or handling of products containing EtO where objective data are reasonably relied upon that demonstrate that the product is not capable of releasing EtO in airborne concentrations at or above the action level, and may not reasonably be foreseen to release EtO in excess of the excursion limit, under the expected conditions of processing, use, or handling that will cause the greatest possible release.

(3) Where products containing EtO are exempted under paragraph (a)(2) of this section, the employer shall maintain records of the objective data supporting that exemption and the basis for the employer's reliance on the data, as provided in paragraph (k)(1) of this section.

(b) *Definitions:* For the purpose of this section, the following definitions shall apply:

Action level means a concentration of airborne EtO of 0.5 ppm calculated as an eight (8)-hour time-weighted average.

Assistant Secretary means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.

Authorized person means any person specifically authorized by the employer whose duties require the person to enter a regulated area, or any person entering such an area as a designated representative of employees for the purpose of exercising the right to observe monitoring and measuring procedures under paragraph (l) of this section, or any other person authorized by the Act or regulations issued under the Act.

Director means the Director of the National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, or designee.

Emergency means any occurrence such as, but not limited to, equipment failure, rupture of containers, or failure of control equipment that is likely to or does result in an unexpected significant release of EtO.

Employee exposure means exposure to airborne EtO which would occur if the employee were not using respiratory protective equipment.

Ethylene oxide or *EtO* means the three-membered ring organic compound with chemical formula C₂H₄O.

(c) *Permissible exposure limits—(1) 8-hour time weighted average (TWA).* The employer shall ensure that no employee is exposed to an airborne concentration of EtO in excess of one (1) part EtO per million parts of air (1 ppm) as an 8-hour time-weighted average (8-hour TWA).

(2) *Excursion limit.* The employer shall ensure that no employee is exposed to an airborne concentration of EtO in excess of 5 parts of EtO per million parts of air (5 ppm) as averaged over a sampling period of fifteen (15) minutes.

(d) *Exposure monitoring*—(1) *General.* (i) Determinations of employee exposure shall be made from breathing zone air samples that are representative of the 8-hour TWA and 15-minute short-term exposures of each employee.

(ii) Representative 8-hour TWA employee exposure shall be determined on the basis of one or more samples representing full-shift exposure for each shift for each job classification in each work area. Representative 15-minute short-term employee exposures shall be determined on the basis of one or more samples representing 15-minute exposures associated with operations that are most likely to produce exposures above the excursion limit for each shift for each job classification in each work area.

(iii) Where the employer can document that exposure levels are equivalent for similar operations in different work shifts, the employer need only determine representative employee exposure for that operation during one shift.

(2) *Initial monitoring.* (i) Each employer who has a workplace or work operation covered by this standard, except as provided for in paragraph (a)(2) or (d)(2)(ii) of this section, shall perform initial monitoring to determine accurately the airborne concentrations of EtO to which employees may be exposed.

(ii) Where the employer has monitored after June 15, 1983 and the monitoring satisfies all other requirements of this section, the employer may rely on such earlier monitoring results to satisfy the requirements of paragraph (d)(2)(i) of this section.

(iii) Where the employer has previously monitored for the excursion limit and the monitoring satisfies all other requirements of this sections, the employer may rely on such earlier monitoring results to satisfy the requirements of paragraph (d)(2)(i) of this section.

(3) *Monitoring frequency (periodic monitoring).* (i) If the monitoring required by paragraph (d)(2) of this section reveals employee exposure at or above the action level but at or below the 8-hour TWA, the employer shall repeat such monitoring for each such employee at least every 6 months.

(ii) If the monitoring required by paragraph (d)(2)(i) of this section reveals employee exposure above the 8-hour TWA, the employer shall repeat such monitoring for each such employee at least every 3 months.

(iii) The employer may alter the monitoring schedule from quarterly to semiannually for any employee for whom two consecutive measurements taken at least 7 days apart indicate that the employee's exposure has decreased to or below the 8-hour TWA.

(iv) If the monitoring required by paragraph (d)(2)(i) of this section reveals employee exposure above the 15 minute excursion limit, the employer shall repeat such monitoring for each such employee at least every 3 months, and more often as necessary to evaluate exposure the employee's short-term exposures.

(4) *Termination of monitoring.* (i) If the initial monitoring required by paragraph (d)(2)(i) of this section reveals employee exposure to be below the action level, the employer may discontinue TWA monitoring for those employees whose exposures are represented by the initial monitoring.

(ii) If the periodic monitoring required by paragraph (d)(3) of this section reveals that employee exposures, as indicated by at least two consecutive measurements taken at least 7 days apart, are below the action level, the

employer may discontinue TWA monitoring for those employees whose exposures are represented by such monitoring.

(iii) If the initial monitoring required by paragraph (d)(2)(1) of this section reveals employee exposure to be at or below the excursion limit, the employer may discontinue excursion limit monitoring for those employees whose exposures are represented by the initial monitoring.

(iv) If the periodic monitoring required by paragraph (d)(3) of this section reveals that employee exposures, as indicated by at least two consecutive measurements taken at least 7 days apart, are at or below the excursion limit, the employer may discontinue excursion limit monitoring for those employees whose exposures are represented by such monitoring.

(5) *Additional monitoring.* Notwithstanding the provisions of paragraph (d)(4) of this section, the employer shall institute the exposure monitoring required under paragraphs (d)(2)(i) and (d)(3) of this section 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 the employer has any reason to suspect that a change may result in new or additional exposures.

(6) *Accuracy of monitoring.* (i) Monitoring shall be accurate, to a confidence level of 95 percent, to within plus or minus 25 percent for airborne concentrations of EtO at the 1 ppm TWA and to within plus or minus 35 percent for airborne concentrations of EtO at the action level of 0.5 ppm.

(ii) Monitoring shall be accurate, to a confidence level of 95 percent, to within plus or minus 35 percent for airborne concentrations of EtO at the excursion limit.

(7) *Employee notification of monitoring results.* (i) The employer must, within 15 working days after the receipt of the results of any monitoring performed under this section, notify each affected employee of these results either individually in writing or by posting the results in an appropriate location that is accessible to employees.

(ii) The written notification required by paragraph (d)(7)(i) of this section shall contain the corrective action being taken by the employer to reduce employee exposure to or below the TWA and/or excursion limit, wherever monitoring results indicated that the TWA and/or excursion limit has been exceeded.

(e) *Regulated areas.* (1) The employer shall establish a regulated area wherever occupational exposure to airborne concentrations of EtO may exceed the TWA or wherever the EtO concentration exceeds or can reasonably be expected to exceed the excursion limit.

(2) Access to regulated areas shall be limited to authorized persons.

(3) Regulated areas shall be demarcated in any manner that minimizes the number of employees within the regulated area.

(f) *Methods of compliance—(1) Engineering controls and work practices.* (i) The employer shall institute engineering controls and work practices to reduce and maintain employee exposure to or below the TWA and to or below the excursion limit, except to the extent that such controls are not feasible.

(ii) Wherever the feasible engineering controls and work practices that can be instituted are not sufficient to reduce employee exposure to or below the TWA and to or below the excursion limit, the employer shall use them to reduce employee exposure to the lowest levels achievable by these controls and shall supplement them by the use of respiratory protection that complies with the requirements of paragraph (g) of this section.

(iii) Engineering controls are generally infeasible for the following operations: collection of quality assurance

sampling from sterilized materials removal of biological indicators from sterilized materials: loading and unloading of tank cars; changing of ethylene oxide tanks on sterilizers; and vessel cleaning. For these operations, engineering controls are required only where the Assistant Secretary demonstrates that such controls are feasible.

(2) *Compliance program.* (i) Where the TWA or excursion limit is exceeded, the employer shall establish and implement a written program to reduce exposure to or below the TWA and to or below the excursion limit by means of engineering and work practice controls, as required by paragraph (f)(1) of this section, and by the use of respiratory protection where required or permitted under this section.

(ii) The compliance program shall include a schedule for periodic leak detection surveys and a written plan for emergency situations, as specified in paragraph (h)(i) of this section.

(iii) Written plans for a program required in paragraph (f)(2) shall be developed and furnished upon request for examination and copying to the Assistant Secretary, the Director, affected employees and designated employee representatives. Such plans shall be reviewed at least every 12 months, and shall be updated as necessary to reflect significant changes in the status of the employer's compliance program.

(iv) The employer shall not implement a schedule of employee rotation as a means of compliance with the TWA or excursion limit.

(g) *Respiratory protection and personal protective equipment—(1) General.* For employees who use respirators required by this section, the employer must provide each employee an appropriate respirator that complies with the requirements of this paragraph. Respirators must be used during:

(i) Periods necessary to install or implement feasible engineering and work-practice controls.

(ii) Work operations, such as maintenance and repair activities and vessel cleaning, for which engineering and work-practice controls are not feasible.

(iii) Work operations for which feasible engineering and work-practice controls are not yet sufficient to reduce employee exposure to or below the TWA.

(iv) Emergencies.

(2) *Respirator program.* The employer must implement a respiratory protection program in accordance with § 1910.134(b) through (d) (except (d)(i)(iii)), and (f) through (m), which covers each employee required by this section to use a respirator.

(3) *Respirator selection.* Employers must:

(i) Select, and provide to employees, the appropriate respirators specified in paragraph (d)(3)(i)(A) of 29 CFR 1910.134; however, employers must not select or use half masks of any type because EtO may cause eye irritation or injury.

(ii) Equip each air-purifying, full facepiece respirator with a front- or back-mounted canister approved for protection against ethylene oxide.

(iii) For escape, provide employees with any respirator permitted for use under paragraphs (g)(3)(i) and (ii) of this standard.

(4) *Protective clothing and equipment.* When employees could have eye or skin contact with EtO or EtO solutions,

the employer must select and provide, at no cost to the employee, appropriate protective clothing or other equipment in accordance with 29 CFR 1910.132 and 1910.133 to protect any area of the employee's body that may come in contact with the EtO or EtO solution, and must ensure that the employee wears the protective clothing and equipment provided.

(h) *Emergency situations*—(1) *Written plan*. (i) A written plan for emergency situations shall be developed for each workplace where there is a possibility of an emergency. Appropriate portions of the plan shall be implemented in the event of an emergency.

(ii) The plan shall specifically provide that employees engaged in correcting emergency conditions shall be equipped with respiratory protection as required by paragraph (g) of this section until the emergency is abated.

(iii) The plan shall include the elements prescribed in 29 CFR 1910.38 and 29 CFR 1910.39, “Emergency action plans” and “Fire prevention plans,” respectively.

(2) *Alerting employees*. Where there is the possibility of employee exposure to EtO due to an emergency, means shall be developed to alert potentially affected employees of such occurrences promptly. Affected employees shall be immediately evacuated from the area in the event that an emergency occurs.

(i) *Medical Surveillance*—(1) *General*—(i) *Employees covered*. (A) The employer shall institute a medical surveillance program 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.

(B) The employer shall make available medical examinations and consultations to all employees who have been exposed to EtO in an emergency situation.

(ii) *Examination by a physician*. The employer shall ensure that all medical examinations and procedures are performed by or under the supervision of a licensed physician, and are provided without cost to the employee, without loss of pay, and at a reasonable time and place.

(2) *Medical examinations and consultations*—(i) *Frequency*. The employer shall make available medical examinations and consultations to each employee covered under paragraph (i)(1)(i) of this section 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 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.

(ii) *Content.* (A) Medical examinations made available pursuant to paragraphs (i)(2)(i)(A)-(D) of this section shall include:

(1) A medical and work history with special emphasis directed to symptoms related to the pulmonary, hematologic, neurologic, and reproductive systems and to the eyes and skin.

(2) A physical examination with particular emphasis given to the pulmonary, hematologic, neurologic, and reproductive systems and to the eyes and skin.

(3) A complete blood count to include at least a white cell count (including differential cell count), red cell count, hematocrit, and hemoglobin.

(4) Any laboratory or other test which the examining physician deems necessary by sound medical practice.

(B) The content of medical examinations or consultation made available pursuant to paragraph (i)(2)(i)(E) of this section shall be determined by the examining physician, and shall include pregnancy testing or laboratory evaluation of fertility, if requested by the employee and deemed appropriate by the physician.

(3) *Information provided to the physician.* The employer shall provide the following information to the examining physician:

(i) A copy of this standard and Appendices A, B, and C.

(ii) A description of the affected employee's duties as they relate to the employee's exposure.

(iii) The employee's representative exposure level or anticipated exposure level.

(iv) A description of any personal protective and respiratory equipment used or to be used.

(v) Information from previous medical examinations of the affected employee that is not otherwise available to the examining physician.

(4) *Physician's written opinion.* (i) The employer shall obtain a written opinion from the examining physician. This written opinion shall contain the results of the medical examination and shall include:

(A) The physician's opinion as to whether the employee has any detected medical conditions that would place the employee at an increased risk of material health impairment from exposure to EtO;

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