

R 325.51151 Scope, application, adoption, and availability of standards.

Rule 1. (1) These rules apply to all occupational exposures to ethylene oxide (EtO), chemical abstracts service registry no. 75 21 8, except as provided in subrule (2) of this rule.

(2) These rules do not apply to the processing, use, and handling of products that contain EtO if 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 under the expected conditions of processing, use, or handling that will cause the greatest possible release.

(3) If products containing EtO are exempted under subrule (2) of this rule, 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 29 CFR 1910.1047(k)(1), which is adopted by reference in subrule (4) of this rule.

(4) The following federal Occupational Safety and Health Administration (OSHA) regulations are adopted by reference in these rules:

(a) 29 CFR 1910.1047 "Ethylene oxide," as amended May 14, 2019.

(b) 29 CFR 1910.1047, appendix A "Substance safety data sheet for ethylene oxide (non-mandatory)," as amended January 8, 1998.

(c) 29 CFR 1910.1047, appendix B "Substance technical guidelines for ethylene oxide (non-mandatory)," as in effect as of the effective date of these rules.

(d) 29 CFR 1910.1047, appendix C "Medical surveillance guidelines for ethylene oxide (non-mandatory)," as in effect as of the effective date of these rules.

(e) 29 CFR 1910.1047, appendix D "Sampling and analytical methods for ethylene oxide (non-mandatory)," as amended February 13, 1996.

(5) A reference to 29 CFR 1910.38 and 1910.39 means General Industry Safety and Health Standard Part 6. "Fire Exits."

(6) A reference to 29 CFR 1910.132 and 1910.133 means General Industry Safety and Health Standard Part 33. "Personal Protective Equipment."

(7) A reference to 29 CFR 1910.1200 means Occupational Health Standard Part 430. "Hazard Communication."

(8) A reference to 29 CFR 1910.134 means General Industry and Construction Safety and Health Standard Part 451. "Respiratory Protection."

(9) A reference to 29 CFR 1910.1020 means General Industry and Construction Safety and Health Standard Part 470. "Employee Medical Records and Trade Secrets."

(10) The adopted federal regulations have the same force and effect as a rule promulgated under the Michigan occupational safety and health act, 1974 PA 154, MCL 408.1001 to 408.1094.

(11) The OSHA regulations adopted in these rules are available from the United States Department of Labor, Occupational Safety and Health Administration website, www.osha.gov, at no charge, as of the time of adoption of these rules.

(12) The regulations adopted in these rules are available for inspection at the Department of Labor and Economic Opportunity, MIOSHA, Standards and FOIA Section, 530 West Allegan Street, P.O. Box 30643, Lansing, Michigan, 48909-8143.

(13) The regulations adopted in these rules may be obtained from the publisher or the Department of Labor and Economic Opportunity, MIOSHA, Standards and FOIA Section, 530 West Allegan Street, P.O. Box 30643, Lansing, Michigan, 48909 8143, at the cost charged in this rule, plus \$20.00 for shipping and handling.

(14) The following Michigan occupational safety and health administration (MIOSHA) standards are referenced in these rules. Up to 5 copies of these standards may be obtained at no charge from the Department of Labor and Economic Opportunity, MIOSHA, Standards and FOIA Section, 530 West Allegan Street, P.O. Box 30643, Lansing, Michigan, 48909 8143 or via the internet at the following website: www.michigan.gov/mioshastandards. For quantities greater than 5, the cost, at the time of adoption of these rules, is 4 cents per page.

(a) Occupational Health Standard Part 430. "Hazard Communication," R 325.77001 to R 325.77004.

(b) General Industry and Construction Safety and Health Standard Part 451. "Respiratory Protection," R 325.60051 to R 325.60052.

(c) General Industry Safety and Health Standard Part 6. "Fire Exits," R 408.10601 to R 408.10697.

(d) General Industry Safety and Health Standard Part 33. "Personal Protective Equipment," R 408.13301 to R 408.13398.

(e) General Industry and Construction Safety and Health Standard Part 470. "Employee Medical Records and Trade Secrets," R 325.3451 to R 325.3476.

1910.1047 - ETHYLENE OXIDE

1910.1047(a) "Scope and application."

1910.1047(a)(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.

1910.1047(a)(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 under the expected conditions of processing, use, or handling that will cause the greatest possible release.

1910.1047(a)(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.

1910.1047(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 C(2)H(4)O.

1910.1047(c) "Permissible exposure limits".

1910.1047(c)(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).

1910.1047(c)(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.

1910.1047(d) "Exposure monitoring".

1910.1047(d)(1) "General."

1910.1047(d)(1)(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.

1910.1047(d)(1)(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.

1910.1047(d)(1)(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.

1910.1047(d)(2) "Initial monitoring."

1910.1047(d)(2)(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.

1910.1047(d)(2)(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.

1910.1047(d)(2)(iii) Where the employer has previously monitored for the excursion limit 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.

1910.1047(d)(3) "Monitoring frequency (periodic monitoring)."

1910.1047(d)(3)(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.

1910.1047(d)(3)(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.

1910.1047(d)(3)(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.

1910.1047(d)(3)(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.

1910.1047(d)(4) "Termination of monitoring."

1910.1047(d)(4)(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.

1910.1047(d)(4)(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.

1910.1047(d)(4)(iii) If the initial monitoring required by paragraph (d)(2)(i) 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.

1910.1047(d)(4)(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.

1910.1047(d)(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.

1910.1047(d)(6) "Accuracy of monitoring."

1910.1047(d)(6)(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.

1910.1047(d)(6)(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.

1910.1047(d)(7) "Employee notification of monitoring results."

1910.1047(d)(7)(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.

1910.1047(d)(7)(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.

1910.1047(e) "Regulated Areas."

1910.1047(e)(1) The employer shall establish a regulated area wherever occupational exposures 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.

1910.1047(e)(2) Access to regulated areas shall be limited to authorized persons.

1910.1047(e)(3) Regulated areas shall be demarcated in any manner that minimizes the number of employees within the regulated area.

1910.1047(f) "Methods of compliance."

1910.1047(f)(1) "Engineering controls and work practices."

1910.1047(f)(1)(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.

1910.1047(f)(1)(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.

1910.1047(f)(1)(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.

1910.1047(f)(2) "Compliance program."

1910.1047(f)(2)(i) Where the TWA or excursion limit is exceeded, the employer shall establish and implement a written program to reduce employee 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.

1910.1047(f)(2)(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.

1910.1047(f)(2)(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.

1910.1047(f)(2)(iv) The employer shall not implement a schedule of employee rotation as a means of compliance with the TWA or excursion limit.

1910.1047(g) Respiratory protection and personal protective equipment.

1910.1047(g)(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:

1910.1047(g)(1)(i) Periods necessary to install or implement feasible engineering and work-practice controls.

1910.1047(g)(1)(ii) Work operations, such as maintenance and repair activities and vessel cleaning, for which engineering and work-practice controls are not feasible.

1910.1047(g)(1)(iii) Work operations for which feasible engineering and work-practice controls are not yet sufficient to reduce employee exposure to or below the TWA.

1910.1047(g)(1)(iv) Emergencies.

1910.1047(g)(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.

1910.1047(g)(3) Respirator selection. Employers must:

1910.1047(g)(3)(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.

1910.1047(g)(3)(ii) Equip each air-purifying, full facepiece respirator with a front-or back-mounted canister approved for protection against ethylene oxide.

1910.1047(g)(3)(iii) For escape, provide employees with any respirator permitted for use under paragraphs (g)(3)(i) and (ii) of this standard.

1910.1047(g)(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.

1910.1047(h) "Emergency situations."

1910.1047(h)(1) "Written plan."

1910.1047(h)(1)(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.

1910.1047(h)(1)(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.

1910.1047(h)(1)(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.

1910.1047(h)(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.

1910.1047(i) "Medical Surveillance".

1910.1047(i)(1) "General".

1910.1047(i)(1)(i) "Employees covered."

1910.1047(i)(1)(i)(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.

1910.1047(i)(1)(i)(B) The employer shall make available medical examinations and consultations to all employees who have been exposed to EtO in an emergency situation.

1910.1047(i)(1)(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.

1910.1047(i)(2) "Medical examinations and consultations."

1910.1047(i)(2)(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:

1910.1047(i)(2)(i)(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.

1910.1047(i)(2)(i)(B) At least annually each employee exposed at or above the action level for at least 30 days in the past year.

1910.1047(i)(2)(i)(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.

1910.1047(i)(2)(i)(D) As medically appropriate for any employee exposed during an emergency.

1910.1047(i)(2)(i)(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.

1910.1047(i)(2)(i)(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.

1910.1047(i)(2)(ii) "Content."

1910.1047(i)(2)(ii)(A) Medical examinations made available pursuant to paragraphs (i)(2)(i)(A) through (D) of this section shall include:

1910.1047(i)(2)(ii)(A)(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.

1910.1047(i)(2)(ii)(A)(2) A physical examination with particular emphasis given to the pulmonary, hematologic, neurologic, and reproductive systems and to the eyes and skin.

1910.1047(i)(2)(ii)(A)(3) A complete blood count to include at least a white cell count (including differential cell count), red cell count, hematocrit, and hemoglobin.

1910.1047(i)(2)(ii)(A)(4) Any laboratory or other test which the examining physician deems necessary by sound medical practice.

1910.1047(i)(2)(ii)(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.

1910.1047(i)(3) "Information provided to the physician." The employer shall provide the following information to the examining physician:

1910.1047(i)(3)(i) A copy of this standard and Appendices A, B, and C.

1910.1047(i)(3)(ii) A description of the affected employee's duties as they relate to the employee's exposure.

1910.1047(i)(3)(iii) The employee's representative exposure level or anticipated exposure level.

1910.1047(i)(3)(iv) A description of any personal protective and respiratory equipment used or to be used.

1910.1047(i)(3)(v) Information from previous medical examinations of the affected employee that is not otherwise available to the examining physician.

1910.1047(i)(4) "Physician's written opinion."

1910.1047(i)(4)(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:

1910.1047(i)(4)(i)(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;

1910.1047(i)(4)(i)(B) Any recommended limitations on the employee or upon the use of personal protective equipment such as clothing or respirators; and

1910.1047(i)(4)(i)(C) A statement that the employee has been informed by the physician of the results of the medical examination and of any medical conditions resulting from EtO exposure that require further explanation or treatment.

1910.1047(i)(4)(ii) The employer shall instruct the physician not to reveal in the written opinion given to the employer specific findings or diagnoses unrelated to occupational exposure to EtO.

1910.1047(i)(4)(iii) The employer shall provide a copy of the physician's written opinion to the affected employee within 15 days from its receipt.

1910.1047(j) Communication of hazards.

1910.1047(j)(1) Hazard communication—general.

1910.1047(j)(1)(i) Chemical manufacturers, importers, distributors and employers shall comply with all requirements of the Hazard Communication Standard (HCS) (§ 1910.1200) for EtO.

1910.1047(j)(1)(ii) In classifying the hazards of EtO at least the following hazards are to be addressed: Cancer; reproductive effects; mutagenicity; central nervous system; skin sensitization; skin, eye and respiratory tract irritation; acute toxicity effects; and flammability.

1910.1047(j)(1)(iii) Employers shall include EtO in the hazard communication program established to comply with the HCS (§ 1910.1200). Employers shall ensure that each employee has access to labels on containers of EtO and to safety data sheets, and is trained in accordance with the requirements of HCS and paragraph (j)(3) of this section.

1910.1047(j)(2) Signs and labels.

1910.1047(j)(2)(i) Signs.

1910.1047(j)(2)(i)(A) The employer shall post and maintain legible signs demarcating regulated areas and entrances or access ways to regulated areas that bear the following legend:

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

1910.1047(j)(2)(i)(B) Prior to June 1, 2016, employers may use the following legend in lieu of that specified in paragraph (j)(2)(i)(A) of this section:

DANGER ETHYLENE OXIDE CANCER HAZARD AND REPRODUCTIVE HAZARD AUTHORIZED PERSONNEL ONLY RESPIRATORS AND PROTECTIVE CLOTHING MAY BE REQUIRED TO BE WORN IN THIS AREA

1910.1047(j)(2)(ii) Labels.

1910.1047(j)(2)(ii)(A) The employer shall ensure that labels are affixed to all containers of EtO whose contents are capable of causing employee exposure at or above the action level or whose contents may reasonably be foreseen to cause employee exposure above the excursion limit, and that the labels remain affixed when the containers of EtO leave the workplace. For the purposes of this paragraph (j)(2)(ii), reaction vessels, storage tanks, and pipes or piping systems are not considered to be containers.

1910.1047(j)(2)(ii)(B) Prior to June 1, 2015, employers may include the following information on containers of EtO in lieu of the labeling requirements in paragraph (j)(1)(i) of this section:

1910.1047(j)(2)(ii)(B)(1)

<p>DANGER CONTAINS ETHYLENE OXIDE CANCER HAZARD AND REPRODUCTIVE HAZARD</p>

1910.1047(j)(2)(ii)(B)(2) A warning statement against breathing airborne concentrations of EtO.

1910.1047(j)(2)(ii)(C) The labeling requirements under this section do not apply where EtO is used as a pesticide, as such term is defined in the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.), when it is labeled pursuant to that Act and regulations issued under that Act by the Environmental Protection Agency.

1910.1047(j)(3) "Information and training."

1910.1047(j)(3)(i) The employer shall provide employees who are potentially exposed to EtO at or above the action level or above the excursion limit with information and training on EtO at the time of initial assignment and at least annually thereafter.

1910.1047(j)(3)(ii) Employees shall be informed of the following:

1910.1047(j)(3)(ii)(A) The requirements of this section with an explanation of its contents, including Appendices A and B;

1910.1047(j)(3)(ii)(B) Any operations in their work area where EtO is present;

1910.1047(j)(3)(ii)(C) The location and availability of the written EtO final rule; and

1910.1047(j)(3)(ii)(D) The medical surveillance program required by paragraph (i) of this section with an explanation of the information in Appendix C.

1910.1047(j)(3)(iii) Employee training shall include at least:

1910.1047(j)(3)(iii)(A) Methods and observations that may be used to detect the presence or release of EtO in the work area (such as monitoring conducted by the employer, continuous monitoring devices, etc.);

1910.1047(j)(3)(iii)(B) The physical and health hazards of EtO;

1910.1047(j)(3)(iii)(C) The measures employees can take to protect themselves from hazards associated with EtO exposure, including specific procedures the employer has implemented to protect employees from exposure to EtO, such as work practices, emergency procedures, and personal protective equipment to be used; and

1910.1047(j)(3)(iii)(D) The details of the hazard communication program developed by the employer, including an explanation of the labeling system and how employees can obtain and use the appropriate hazard information.

1910.1047(k) "Recordkeeping".

1910.1047(k)(1) "Objective data for exempted operations."

1910.1047(k)(1)(i) Where the processing, use, or handling of products made from or containing EtO are exempted from other requirements of this section under paragraph (a)(2) of this section, or where objective data have been relied on in lieu of initial monitoring under paragraph (d)(2)(ii) of this section, the employer shall establish and maintain an accurate record of objective data reasonably relied upon in support of the exemption.

1910.1047(k)(1)(ii) This record shall include at least the following information:

1910.1047(k)(1)(ii)(A) The product qualifying for exemption;

1910.1047(k)(1)(ii)(B) The source of the objective data;

1910.1047(k)(1)(ii)(C) The testing protocol, results of testing, and/or analysis of the material for the release of EtO;

1910.1047(k)(1)(ii)(D) A description of the operation exempted and how the data support the exemption; and

1910.1047(k)(1)(ii)(E) Other data relevant to the operations, materials, processing, or employee exposures covered by the exemption.

1910.1047(k)(1)(iii) The employer shall maintain this record for the duration of the employer's reliance upon such objective data.

1910.1047(k)(2) "Exposure measurements."

1910.1047(k)(2)(i) The employer shall keep an accurate record of all measurements taken to monitor employee exposure to EtO as prescribed in paragraph (d) of this section.

1910.1047(k)(2)(ii) This record shall include at least the following information:

1910.1047(k)(2)(ii)(A) The date of measurement;

1910.1047(k)(2)(ii)(B) The operation involving exposure to EtO which is being monitored;

1910.1047(k)(2)(ii)(C) Sampling and analytical methods used and evidence of their accuracy;

1910.1047(k)(2)(ii)(D) Number, duration, and results of samples taken;

1910.1047(k)(2)(ii)(E) Type of protective devices worn, if any; and

1910.1047(k)(2)(ii)(F) Name, number and exposure of the employees whose exposures are represented.

1910.1047(k)(2)(iii) The employer shall maintain this record for at least thirty (30) years, in accordance with 29 CFR 1910.1020.

1910.1047(k)(3) "Medical surveillance."

1910.1047(k)(3)(i) The employer shall establish and maintain an accurate record for each employee subject to medical surveillance by paragraph (i)(1)(i) of this section, in accordance with 29 CFR 1910.1020.

1910.1047(k)(3)(ii) The record shall include at least the following information:

1910.1047(k)(3)(ii)(A) The name and number of the employee;

1910.1047(k)(3)(ii)(B) Physicians' written opinions;

1910.1047(k)(3)(ii)(C) Any employee medical complaints related to exposure to EtO; and

1910.1047(k)(3)(ii)(D) A copy of the information provided to the physician as required by paragraph (i)(3) of this section.

1910.1047(k)(3)(iii) The employer shall ensure that this record is maintained for the duration of employment plus thirty (30) years, in accordance with 29 CFR 1910.1020.

1910.1047(k)(4) "Availability."

1910.1047(k)(4)(i) The employer, upon written request, shall make all records required to be maintained by this section available to the Assistant Secretary and the Director for examination and copying.

1910.1047(k)(4)(ii) The employer, upon request, shall make any exemption and exposure records required by paragraphs (k)(1) and (2) of this section available for examination and copying to affected employees, former employees, designated representatives and the Assistant Secretary, in accordance with 29 CFR 1910.1020 (a) through (e) and (g) through (i).

1910.1047(k)(4)(iii) The employer, upon request, shall make employee medical records required by paragraph (k)(3) of this section available for examination and copying to the subject employee, anyone having the specific written consent of the subject employee, and the Assistant Secretary, in accordance with 29 CFR 1910.1020.

1910.1047(k)(5) "Transfer of records." The employer shall comply with the requirements concerning transfer of records set forth in 29 CFR 1910.1020(h).

1910.1047(l) "Observation of monitoring".

1910.1047(l)(1) "Employee observation." The employer shall provide affected employees or their designated representatives an opportunity to observe any monitoring of employee exposure to EtO conducted in accordance with paragraph (d) of this section.

1910.1047(l)(2) "Observation procedures." When observation of the monitoring of employee exposure to EtO requires entry into an area where the use of protective clothing or equipment is required, the observer shall be provided with and be required to use such clothing and equipment and shall comply with all other applicable safety and health procedures.

1910.1047(m) [Reserved]

1910.1047(n) "Appendices."

The information contained in the appendices is not intended by itself to create any additional obligations not otherwise imposed or to detract from any existing obligation.

[61 FR 5507, Feb. 13, 1996; 63 FR 1152, Jan. 8, 1998; 67 FR 67965, Nov. 7, 2002; 70 FR 1143, Jan. 5, 2005; 71 FR 16672 and 16673, April 3, 2006; 71 FR 50190, August 24, 2006; 73 FR 75586, Dec. 12, 2008; 76 FR 33609, June 8, 2011; 77 FR 17783, March 26, 2012; 84 FR 21477, May 14, 2019]

1910.1047 APPENDIX A
SUBSTANCE SAFETY DATA SHEET FOR ETHYLENE OXIDE
(Non-Mandatory)

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I. SUBSTANCE IDENTIFICATION

- A. Substance: Ethylene oxide (C₂H₄O).
- B. Synonyms: dihydrooxirene, dimethylene oxide, EO, 1,2-epoxyethane, EtO, ETO, oxacyclopropane, oxane, oxidoethane, alpha/beta-oxidoethane, oxiran, oxirane.
- C. Ethylene oxide can be found as a liquid or vapor.
- D. EtO is used in the manufacture of ethylene glycol, surfactants, ethanalamines, glycol ethers, and other organic chemicals. EtO is also used as a sterilant and fumigant.
- E. Appearance and odor: Colorless liquid below 10.7 deg. C (51.3 deg. F) or colorless gas with ether-like odor detected at approximately 700 parts EtO per million parts of air (700 ppm).
- F. Permissible Exposure: Exposure may not exceed 1 part EtO per million parts of air averaged over the 8-hour workday.

II. HEALTH HAZARD DATA

- A. Ethylene oxide can cause bodily harm if you inhale the vapor, if it comes into contact with your eyes or skin, or if you swallow it.
- B. Effects of overexposure:
 - 1. Ethylene oxide in liquid form can cause eye irritation and injury to the cornea, frostbite, and severe irritation and blistering of the skin upon prolonged or confined contact. Ingestion of EtO can cause gastric irritation and liver injury. Acute effects from inhalation of EtO vapors include respiratory irritation and lung injury, headache, nausea, vomiting, diarrhea, shortness of breath, and cyanosis (blue or purple coloring of skin). Exposure has also been associated with the occurrence of cancer, reproductive effects, mutagenic changes, neurotoxicity, and sensitization.
 - 1. EtO has been shown to cause cancer in laboratory animals and has been associated with higher incidences of cancer in humans. Adversere productive effects and chromosome damage may also occur from EtO exposure.
 - a. Reporting signs and symptoms: You should inform your employer if you develop any signs or symptoms and suspect that they are caused by exposure to EtO.

III. EMERGENCY FIRST AID PROCEDURES

- A. Eye exposure:** If EtO gets into your eyes, wash your eyes immediately with large amounts of water, lifting the lower and upper eyelids. Get medical attention immediately. Contact lenses should not be worn when working with this chemical.
- B. Skin exposure:** If EtO gets on your skin, immediately wash the contaminated skin with water. If EtO soaks through your clothing, especially your shoes, remove the clothing immediately and wash the skin with water using an emergency deluge shower. Get medical attention immediately. Thoroughly wash contaminated clothing before reusing. Contaminated leather shoes or other leather articles should not be reused and should be discarded.
- C. Inhalation:** If large amounts of EtO are inhaled, the exposed person must be moved to fresh air at once. If breathing has stopped, perform cardiopulmonary resuscitation. Keep the affected person warm and at rest. Get medical attention immediately.
- D. Swallowing:** When EtO has been swallowed, give the person large quantities of water immediately. After the water has been swallowed, try to get the person to vomit by having him or her touch the back of the throat with his or her finger. Do not make an unconscious person vomit. Get medical attention immediately.
- E. Rescue:** Move the affected person from the hazardous exposure. If the exposed person has been overcome, attempt rescue only after notifying at least one other person of the emergency and putting into effect established emergency procedures. Do not become a casualty yourself. Understand your emergency rescue procedures and know the location of the emergency equipment before the need arises.

IV. RESPIRATORS AND PROTECTIVE CLOTHING

A. Respirators. You may be required to wear a respirator for nonroutine activities, in emergencies, while your employer is in the process of reducing EtO exposures through engineering controls, and in areas where engineering controls are not feasible. As of the effective date of this standard, only air-supplied, positive-pressure, full-facepiece respirators are approved for protection against EtO. If air-purifying respirators are worn in the future, they must have a label issued by the National Institute for Occupational Safety and Health under the provisions of 42 CFR part 84 stating that the respirators have been approved for use with ethylene oxide. For effective protection, respirators must fit your face and head snugly. Respirators must not be loosened or removed in work situations where their use is required.

EtO does not have a detectable odor except at levels well above the permissible exposure limits. If you can smell EtO while wearing a respirator, proceed immediately to fresh air. If you experience difficulty breathing while wearing a respirator, tell your employer.

B. Protective clothing: You may be required to wear impermeable clothing, gloves, a face shield, or other appropriate protective clothing to prevent skin contact with liquid EtO or EtO-containing solutions. Where protective clothing is required, your employer must provide clean garments to you as necessary to assure that the clothing protects you adequately.

Replace or repair protective clothing that has become torn or otherwise damaged.

EtO must never be allowed to remain on the skin. Clothing and shoes which are not impermeable to EtO should not be allowed to become contaminated with EtO, and if they do, the clothing should be promptly removed and decontaminated. Contaminated leather shoes should be discarded. Once EtO penetrates shoes or other leather articles, they should not be worn again.

C. Eye protection: You must wear splashproof safety goggles in areas where liquid EtO or EtO-containing solutions may contact your eyes. In addition, contact lenses should not be worn in areas where eye contact with EtO can occur.

V. PRECAUTIONS FOR SAFE USE, HANDLING, AND STORAGE

A. EtO is a flammable liquid, and its vapors can easily form explosive mixtures in air.

B. EtO must be stored in tightly closed containers in a cool, well-ventilated area, away from heat, sparks, flames, strong oxidizers, alkalines, and acids, strong bases, acetylide-forming metals such as copper, silver, mercury and their alloys.

C. Sources of ignition such as smoking material, open flames and some electrical devices are prohibited wherever EtO is handled, used, or stored in a manner that could create a potential fire or explosion hazard.

D. You should use non-sparking tools when opening or closing metal containers of EtO, and containers must be bonded and grounded in the rare instances in which liquid EtO is poured or transferred.

E. Impermeable clothing wet with liquid EtO or EtO-containing solutions may be easily ignited. If you are wearing impermeable clothing and are splashed with liquid EtO or EtO-containing solution, you should immediately remove the clothing while under an emergency deluge shower.

F. If your skin comes into contact with liquid EtO or EtO-containing solutions, you should immediately remove the EtO using an emergency deluge shower.

G. You should not keep food, beverages, or smoking materials in regulated areas where employee exposures are above the permissible exposure limits.

H. Fire extinguishers and emergency deluge showers for quick drenching should be readily available, and you should know where they are and how to operate them.

I. Ask your supervisor where EtO is used in your work area and for any additional plant safety and health rules.

VI. ACCESS TO INFORMATION

A. Each year, your employer is required to inform you of the information contained in this standard and appendices for EtO. In addition, your employer must instruct you in the proper work practices for using EtO emergency procedures, and the correct use of protective equipment.

B. Your employer is required to determine whether you are being exposed to EtO. You or your representative has the right to observe employee measurements and to record the results obtained. Your employer is required to inform you of your exposure. If your employer determine that you are being overexposed, he or she is required to inform you of the actions which are being taken to reduce your exposure to within permissible exposure limits.

C. Your employer is required to keep records of your exposures and medical examinations. These exposure records must be kept by the employer for at least thirty (30) years. Medical records must be kept for the period of your employment plus thirty (30) years.

D. Your employer is required to release your exposure and medical records to your physician or designated representative upon your written request.

VII. STERILANT USE OF ETO IN HOSPITALS AND HEALTH CARE FACILITIES

This section of Appendix A, for informational purposes, sets forth EPA's recommendations for modifications in workplace design and practice in hospitals and health care facilities for which the Environmental Protection Agency has registered EtO for uses as a sterilant or fumigant under the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136 et seq. These new recommendations, published in the Federal Register by EPA at 49 FR 15268, as modified in today's Register, are intended to help reduce the exposure of hospital and health care workers to EtO to 1 ppm. EPA's recommended workplace design and workplace practice are as follows:

1. Workplace Design

a. Installation of gas line hand valves. Hand valves must be installed on the gas supply line at the connection to the supply cylinders to minimize leakage during cylinder change.

b. Installation of capture boxes. Sterilizer operations result in a gas/water discharge at the completion of the process. This discharge is routinely piped to a floor drain which is generally located in an equipment or an adjacent room. When the floor drain is not in the same room as the sterilizer and workers are not normally present, all that is necessary is that the room be well ventilated.

The installation of a "capture box" will be required for those work place layouts where the floor drain is located in the same room as the sterilizer or in a room where workers are normally present. A "capture box" is a piece of equipment that totally encloses the floor drain where the discharge from the sterilizer is pumped. The "capture box" is to be vented directly to a non-recirculating or dedicated ventilation system. Sufficient air intake should be allowed at the bottom of the box to handle the volume of air that is ventilated from the top of the box. The "capture box" can be made of metal, plastic, wood or other equivalent material. The box is intended to reduce levels of EtO discharged into the work room atmosphere. The use of a "capture box" is not required if: (1) The vacuum pump discharge floor drain is located in a well ventilated equipment or other room where workers are not normally present or (2) the water sealed vacuum pump discharges directly to a closed sealed sewer line (check local plumbing codes).

If it is impractical to install a vented "capture box" and a well ventilated equipment or other room is not feasible, a box that can be sealed over the floor drain may be used if: (1) The floor drain is located in a room where workers are not normally present and EtO cannot leak into an occupied area, and (2) the sterilizer in use is less than 12 cubic feet in capacity (check local plumbing codes).

c. Ventilation of aeration units

i. Existing aeration units. Existing units must be vented to a non-recirculating or dedicated system or vented to an equipment or other room where workers are not normally present and which is well ventilated. Aerator units must be positioned as close as possible to the sterilizer to minimize the exposure from the off-gassing of sterilized items.

ii. Installation of new aerator units (where none exist). New aerator units must be vented as described above for existing aerators. Aerators must be in place by July 1, 1986.

d. Ventilation during cylinder change. Workers may be exposed to short but relatively high levels of EtO during the change of gas cylinders. To reduce exposure from this route, users must select one of three alternatives designed to draw off gas that may be released when the line from the sterilizer to the cylinder is disconnected:

i. Location of cylinders in a well ventilated equipment room or other room where workers are not normally present.

ii. Installation of a flexible hose (at least 4" in diameter) to a non-recirculating or dedicated ventilation system and located in the area of cylinder change in such a way that the hose can be positioned at the point where the sterilizer gas line is disconnected from the cylinder.

iii. Installation of a hood that is part of a non-recirculating or dedicated system and positioned no more than one foot above the point where the change of cylinders takes place.

e. Ventilation of sterilizer door area. One of the major sources of exposure to EtO occurs when the sterilizer door is opened following the completion of the sterilization process. In order to reduce this avenue of exposure, a hood or metal canopy closed on each end must be installed over the sterilizer door. The hood or metal canopy must be connected to a non-recirculating or dedicated ventilation system or one that exhausts gases to a well ventilated equipment or other room where workers are not normally present. A hood or canopy over the sterilizer door is required for use even with those sterilizers that have a purge cycle and must be in place by July 1, 1986.

f. Ventilation of sterilizer relief valve. Sterilizers are typically equipped with a safety relief device to release gas in case of increased pressure in the sterilizer. Generally, such relief devices are used on pressure vessels. Although these pressure relief devices are rarely opened for hospital and health care sterilizers, it is suggested that they be designed to exhaust vapor from the sterilizer by one of the following methods:

i. Through a pipe connected to the outlet of the relief valve ventilated directly outdoors at a point high enough to be away from passersby, and not near any windows that open, or near any air conditioning or ventilation air intakes.

ii. Through a connection to an existing or new non-recirculating or dedicated ventilation system.

iii. Through a connection to a well ventilated equipment or other room where workers are not normally present.

g. Ventilation systems. Each hospital and health care facility affected by this notice that uses EtO for the sterilization of equipment and supplies must have a ventilation system which enables compliance with the requirements of section (b) through (f) in the manner described in these sections and within the timeframes allowed. Thus, each affected hospital and health care facility must have or install a non-recirculating or dedicated ventilation equipment or other room where workers are not normally present in which to vent EtO.

h. Installation of alarm systems. An audible and visual indicator alarm system must be installed to alert personnel of ventilation system failures, i.e., when the ventilation fan motor is not working.

2. Workplace Practices

All the workplace practices discussed in this unit must be permanently posted near the door of each sterilizer prior to use by any operator.

a. Changing of supply line filters. Filters in the sterilizer liquid line must be changed when necessary, by the following procedure:

- i. Close the cylinder valve and the hose valve.
- ii. Disconnect the cylinder hose (piping) from the cylinder.
- iii. Open the hose valve and bleed slowly into a proper ventilating system at or near the in-use supply cylinders.
- iv. Vacate the area until the line is empty.
- v. Change the filter.
- vi. Reconnect the lines and reverse the valve position.
- vii. Check hoses, filters, and valves for leaks with a fluorocarbon leak detector (for those sterilizers using the 88 percent chlorofluorocarbon, 12 percent ethylene oxide mixture (12/88)).

b. Restricted access area.

- i. Areas involving use of EtO must be designated as restricted access areas. They must be identified with signs or floor marks near the sterilizer door, aerator, vacuum pump floor drain discharge, and in-use cylinder storage.
- ii. All personnel must be excluded from the restricted area when certain operations are in progress, such as discharging a vacuum pump, emptying a sterilizer liquid line, or venting a non-purge sterilizer with the door ajar or other operations where EtO might be released directly into the face of workers.

c. Door opening procedures.

- i. Sterilizers with purge cycles. A load treated in a sterilizer equipped with a purge cycle should be removed immediately upon completion of the cycle (provided no time is lost opening the door after cycle is completed). If this is not done, the purge cycle should be repeated before opening door.
- ii. Sterilizers without purge cycles. For a load treated in a sterilizer not equipped with a purge cycle, the sterilizer door must be ajar 6" for 15 minutes, and then fully opened for at least another 15 minutes before removing the treated load. The length of time of the second period should be established by peak monitoring for one hour after the two 15-minute periods suggested. If the level is above 10 ppm time-weighted average for 8 hours, more time should be added to the second waiting period (door wide open). However, in no case may the second period be shortened to less than 15 minutes.

d. Chamber unloading procedures.

- i. Procedures for unloading the chamber must include the use of baskets or rolling carts, or baskets and rolling tables to transfer treated loads quickly, thus avoiding excessive contact with treated articles, and reducing the duration of exposures.
- ii. If rolling carts are used, they should be pulled not pushed by the sterilizer operators to avoid off-gassing exposure.

e. Maintenance. A written log should be instituted and maintained documenting the date of each leak detection and any maintenance procedures undertaken. This is a suggested use practice and is not required.

i. Leak detection. Sterilizer door gaskets, cylinder and vacuum piping, hoses, filters, and valves must be checked for leaks under full pressure with a Fluorocarbon leak detector (for 12/88 systems only) every two weeks by maintenance personnel. Also, the cylinder piping connections must be checked after changing cylinders. Particular attention in leak detection should be given to the automatic solenoid valves that control the flow of EtO to the sterilizer. Specifically, a check should be made at the EtO gasline entrance port to the sterilizer, while the sterilizer door is open and the solenoid valves are in a closed position.

ii. Maintenance procedures. Sterilizer/aerator door gaskets, valves, and fittings must be replaced when necessary as determined by maintenance personnel in their bi-weekly checks; in addition, visual inspection of the door gaskets for cracks, debris, and other foreign substances should be conducted daily by the operator.

[63 FR 1152, Jan. 8, 1998]

1910.1047 APPENDIX B
SUBSTANCE TECHNICAL GUIDELINES FOR ETHYLENE OXIDE
(Non-Mandatory)

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I. Physical and Chemical Data

A. Substance identification:

1. Synonyms: Dihydrooxirene, dimethylene oxide, EO, 1,2-epoxyethane, EtO, ETO, oxacyclopropane, oxane, oxidoethane, alpha/beta-oxidoethane, oxiran, oxirane.
2. Formula: (C₂H₄O).
3. Molecular weight: 44.06

B. Physical data:

1. Boiling point: (760 mm Hg): 10.70°C (51.3°F);
2. Specific gravity (water = 1): 0.87 (at 20°C or 68°F)
3. Vapor density (air = 1): 1.49;
4. Vapor pressure (at 20°C): 1,095 mm Hg;
5. Solubility in water: complete;
6. Appearance and odor: colorless liquid; gas at temperature above 10.7°F or 51.3°C with ether-like odor above 700 ppm.

II. Fire, Explosion, and Reactivity Hazard Data

A. Fire:

1. Flash point: less than 0°F (open cup);
2. Stability: decomposes violently at temperatures above 800°F;
3. Flammable limits in air, percent by volume: Lower: 3, Upper: 100;
4. Extinguishing media: Carbon dioxide for small fires, polymer or alcohol foams for large fires;
5. Special fire fighting procedures: Dilution of ethylene oxide with 23 volumes of water renders it non-flammable;
6. Unusual fire and explosion hazards: Vapors of EtO will burn without the presence of air or other oxidizers. EtO vapors are heavier than air and may travel along the ground and be ignited by open flames or sparks at locations remote from the site at which EtO is being used.
7. For purposes of compliance with the requirements of 29 CFR 1910.106, EtO is classified as a flammable gas. For example, 7,500 ppm, approximately one-fourth of the lower flammable limit, would be considered to pose a potential fire and explosion hazard.
8. For purposes of compliance with 29 CFR 1910.155, EtO is classified as a Class B fire.
9. For purposes of compliance with 29 CFR 1919.307, locations classified as hazardous due to the presence of EtO shall be Class I.

B. Reactivity:

1. Conditions contributing to instability: EtO will polymerize violently if contaminated with aqueous alkalies, amines, mineral acids, metal chlorides, or metal oxides. Violent decomposition will also occur at temperatures above 800°F;
2. Incompatibilities: Alkalines and acids;
3. Hazardous decomposition products: Carbon monoxide and carbon dioxide.

III. Spill, Leak, and Disposal Procedures

A. If EtO is spilled or leaked, the following steps should be taken:

1. Remove all ignition sources.
2. The area should be evacuated at once and re-entered only after the area has been thoroughly ventilated and washed down with water.

B. Persons not wearing appropriate protective equipment must be restricted from areas of spills or leaks until cleanup has been completed.

C. Waste disposal methods: Waste material shall be disposed of in a manner that is not hazardous to employees or to the general population. In selecting the method of waste disposal, applicable local, State, and Federal regulations should be consulted.

IV. Monitoring and Measurement Procedures

A. Exposure above the Permissible Exposure Limit;

1. Eight-hour exposure evaluation: Measurements taken for the purpose of determining employee exposure under this section are best taken with consecutive samples covering the full shift. Air samples must be taken in the employee's breathing zone (air that would most nearly represent that inhaled by the employee.)

2. Monitoring techniques: The sampling and analysis under this section may be performed by collection of the EtO vapor on charcoal adsorption tubes or other composition adsorption tubes, with subsequent chemical analysis. Sampling and analysis may also be performed by instruments such as real-time continuous monitoring systems, portable direct reading instruments, or passive dosimeters as long as measurements taken using these methods accurately evaluate the concentration of EtO in employees' breathing zones.

Appendix D describes the validated method of sampling and analysis which has been tested by OSHA for use with EtO. Other available methods are also described in Appendix D. The employer has the obligation of selecting a monitoring method which meets the accuracy and precision requirements of the standard under his unique field conditions. The standard requires that the method of monitoring must be accurate, to a 95 percent confidence level, to plus or minus 25 percent for concentrations of EtO at 1 ppm, and to plus or minus 35 percent for concentrations at 0.5 ppm. In addition to the method described in Appendix D, there are numerous other methods available for monitoring for EtO in the workplace. Details on these other methods have been submitted by various companies to the rulemaking record, and are available at the OSHA Docket Office.

B. Since many of the duties relating to employee exposure are dependent on the results of measurement procedures, employers must assure that the evaluation of employee exposures is performed by a technically qualified person.

V. Protective Clothing and Equipment

Employees shall be provided with and required to wear appropriate protective clothing wherever there is significant potential for skin contact with liquid EtO or EtO-containing solutions. Protective clothing shall include impermeable coveralls or similar full-body work clothing, gloves, and head coverings, as appropriate to protect areas of the body which may come in contact with liquid EtO or EtO-containing solutions.

Employers must ascertain that the protective garments are impermeable to EtO. Permeable clothing, including items made of rubber, and leather shoes should not be allowed to become contaminated with liquid EtO. If permeable clothing does become contaminated, it should be immediately removed, while the employee is under an emergency deluge shower. If leather footwear or other leather garments become wet from EtO they should be discarded and not worn again, because leather absorbs EtO and holds it against the skin.

Any protective clothing that has been damaged or is otherwise found to be defective should be repaired or replaced. Clean protective clothing should be provided to the employee as necessary to assure employee protection. Whenever impermeable clothing becomes wet with liquid EtO, it should be washed down with water before being removed by the employee. Employees are also required to wear splash-proof safety goggles where there is any possibility of EtO contacting the eyes.

VI. Miscellaneous Precautions

A. Store EtO in tightly closed containers in a cool, well-ventilated area and take all necessary precautions to avoid any explosion hazard.

B. Non-sparking tools must be used to open and close metal containers. These containers must be effectively grounded and bonded.

C. Do not incinerate EtO cartridges, tanks or other containers.

D. Employers shall advise employees of all areas and operations where exposure to EtO occurs.

VII. Common Operations

Common operations in which exposure to EtO is likely to occur include the following: Manufacture of EtO, surfactants, ethanolamines, glycol, ethers, and specialty chemicals, and use as a sterilant in the hospital, health product and spice industries.

1910.1047 APPENDIX C
MEDICAL SURVEILLANCE GUIDELINES FOR ETHYLENE OXIDE
(Non-Mandatory)

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I. Route of Entry

Inhalation.

II. Toxicology

Clinical evidence of adverse effects associated with the exposure to EtO is present in the form of increased incidence of cancer in laboratory animals (leukemia, stomach, brain), mutation in offspring in animals, and resorptions and spontaneous abortions in animals and human populations respectively. Findings in humans and experimental animals exposed to airborne concentrations of EtO also indicate damage to the genetic material (DNA). These include hemoglobin alkylation, unscheduled DNA synthesis, sister chromatid exchange chromosomal aberration, and functional sperm abnormalities.

Ethylene oxide in liquid form can cause eye irritation and injury to the cornea, frostbite, severe irritation, and blistering of the skin upon prolonged or confined contact. Ingestion of EtO can cause gastric irritation and liver injury. Other effects from inhalation of EtO vapors include respiratory irritation and lung injury, headache, nausea, vomiting, diarrhea, dyspnea and cyanosis.

III. Signs and Symptoms of Acute Overexposure

The early effects of acute overexposure to EtO are nausea and vomiting, headache, and irritation of the eyes and respiratory passages. The patient may notice a "peculiar taste" in the mouth. Delayed effects can include pulmonary edema, drowsiness, weakness, and incoordination. Studies suggest that blood cell changes, an increase in chromosomal aberrations, and spontaneous abortion may also be causally related to acute overexposure to EtO.

Skin contact with liquid or gaseous EtO causes characteristic burns and possibly even an allergic-type sensitization. The edema and erythema occurring from skin contact with EtO progress to vesiculation with a tendency to coalesce into blebs with desquamation. Healing occurs within three weeks, but there may be a residual brown pigmentation. A 40-80% solution is extremely dangerous, causing extensive blistering after only brief contact. Pure liquid EtO causes frostbite because of rapid evaporation. In contrast, the eye is relatively insensitive to EtO, but there may be some irritation of the cornea.

Most reported acute effects of occupational exposure to EtO are due to contact with EtO in liquid phase. The liquid readily penetrates rubber and leather, and will produce blistering if clothing or footwear contaminated with EtO are not removed.

IV. Surveillance and Preventive Considerations

As noted above, exposure to EtO has been linked to an increased risk of cancer and reproductive effects including decreased male fertility, fetotoxicity, and spontaneous abortion. EtO workers are more likely to have chromosomal damage than similar groups not exposed to EtO. At the present, limited studies of chronic effects in humans resulting from exposure to EtO suggest a causal association with leukemia. Animal studies indicate leukemia and cancers at other sites (brain, stomach) as well. The physician should be aware of the findings of these studies in evaluating the health of employees exposed to EtO.

Adequate screening tests to determine an employee's potential for developing serious chronic diseases, such as cancer, from exposure to EtO do not presently exist. Laboratory tests may, however, give evidence to suggest that an employee is potentially overexposed to EtO. It is important for the physician to become familiar with the operating conditions in which exposure to EtO is likely to occur. The physician also must become familiar with the signs and symptoms that indicate a worker is receiving otherwise unrecognized and unacceptable exposure to EtO. These elements are especially important in evaluating the medical and work histories and in conducting the physical exam. When an unacceptable exposure in an active employee is identified by the physician, measures taken by the employer to lower exposure should also lower the risk of serious long-term consequences.

The employer is required to institute a medical surveillance program for all employees who are or will be exposed to EtO at or above the action level (0.5 ppm) for at least 30 days per year, without regard to respirator use. All examinations and procedures must be performed by or under the supervision of a licensed physician at a reasonable time and place for the employee and at no cost to the employee.

Although broad latitude in prescribing specific tests to be included in the medical surveillance program is extended to the examining physician, OSHA requires inclusion of the following elements in the routine examination:

(i) Medical and work histories with special emphasis directed to symptoms related to the pulmonary, hematologic, neurologic, and reproductive systems and to the eyes and skin.

(ii) Physical examination with particular emphasis given to the pulmonary, hematologic, neurologic, and reproductive systems and to the eyes and skin.

(iii) Complete blood count to include at least a white cell count (including differential cell count), red cell count, hematocrit, and hemoglobin.

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

If requested by the employee, the medical examinations shall include pregnancy testing or laboratory evaluation of fertility as deemed appropriate by the physician.

In certain cases, to provide sound medical advice to the employer and the employee, the physician must evaluate situations not directly related to EtO. For example, employees with skin diseases may be unable to tolerate wearing protective clothing. In addition those with chronic respiratory diseases may not tolerate the wearing of negative pressure (air purifying) respirators. Additional tests and procedures that will help the physician determine which employees are medically unable to wear such respirators should include: An evaluation of cardiovascular function, a baseline chest x-ray to be repeated at five year intervals, and a pulmonary function test to be repeated every three years. The pulmonary function test should include measurement of the employee's forced vital capacity (FVC), forced expiratory volume at one second (FEV(1)), as well as calculation of the ratios of FEV(1) to FVC, and measured FVC and measured FEV(1) to expected values corrected for variation due to age, sex, race, and height.

The employer is required to make the prescribed tests available at least annually to employees who are or will be exposed at or above the action level, for 30 or more days per year; more often than specified if recommended by the examining physician; and upon the employee's termination of employment or reassignment to another work area. While little is known about the long term consequences of high short-term exposures, it appears prudent to monitor such affected employees closely in light of existing health data. The employer shall provide physician recommended examinations to any employee exposed to EtO in emergency conditions. Likewise, the employer shall make available medical consultations including physician recommended exams to employees who believe they are suffering signs or symptoms of exposure to EtO.

The employer is required to provide the physician with the following information: a copy of this standard and its appendices; a description of the affected employee's duties as they relate to the employee exposure level; and information from the employee's previous medical examinations which is not readily available to the examining physician. Making this information available to the physician will aid in the evaluation of the employee's health in relation to assigned duties and fitness to wear personal protective equipment, when required.

The employer is required to obtain a written opinion from the examining physician containing the results of the medical examinations; the physician's opinion as to whether the employee has any detected medical conditions which would place the employee at increased risk of material impairment of his or her health from exposure to EtO; any recommended restrictions upon the employee's exposure to EtO, or upon the use of protective clothing or equipment such as respirators; and a statement that the employee has been informed by the physician of the results of the medical examination and of any medical conditions which require further explanation or treatment. This written opinion must not reveal specific findings or diagnoses unrelated to occupational exposure to EtO, and a copy of the opinion must be provided to the affected employee.

The purpose in requiring the examining physician to supply the employer with a written opinion is to provide the employer with a medical basis to aid in the determination of initial placement of employees and to assess the employee's ability to use protective clothing and equipment.

1910.1047 APPENDIX D
Sampling And Analytical Methods For Ethylene Oxide
(Non-Mandatory)

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A number of methods are available for monitoring employee exposures to EtO. Most of these involve the use of charcoal tubes and sampling pumps, followed by analysis of the samples by gas chromatograph. The essential differences between the charcoal tube methods include, among others, the use of different desorbing solvents, the use of different lots of charcoal, and the use of different equipment for analysis of the samples.

Besides charcoal, methods using passive dosimeters, gas sampling bags, impingers, and detector tubes have been utilized for determination of EtO exposure. In addition, there are several commercially available portable gas analyzers and monitoring units.

This appendix contains details for the method which has been tested at the OSHA Analytical Laboratory in Salt Lake City. Inclusion of this method in the appendix does not mean that this method is the only one which will be satisfactory. Copies of descriptions of other methods available are available in the rulemaking record, and may be obtained from the OSHA Docket Office. These include the Union Carbide, Dow Chemical, 3M, and DuPont methods, as well as NIOSH Method S-286. These methods are briefly described at the end of this appendix.

Employers who note problems with sample breakthrough using the OSHA or other charcoal methods should try larger charcoal tubes. Tubes of larger capacity are available. In addition, lower flow rates and shorter sampling times should be beneficial in minimizing breakthrough problems. Whatever method the employer chooses, he must assure himself of the method's accuracy and precision under the unique conditions present in his workplace.

ETHYLENE OXIDE

Method No.: 30.

Matrix: Air.

Target Concentration: 1.0 ppm (1.8 mg/m³).

Procedure: Samples are collected on two charcoal tubes in series and desorbed with 1 percent CS(2) in benzene. The samples are derivatized with HBr and treated with sodium carbonate. Analysis is done by gas chromatography with an electron capture detector.

Recommended Air Volume and Sampling Rate: 1 liter and 0.05 Lpm.

Detection Limit of the Overall Procedure: 13.3 ppb (0.024 mg/m³) (Based on 1.0 liter air sample).

Reliable Quantitation Limit: 52.2 ppb (0.094 mg/m³) (Based on 1.0 liter air sample).

Standard Error of Estimate: 6.59 percent (See Backup Section 4.6).

Special Requirements: Samples must be analyzed within 15 days of sampling date.

Status of Method: The sampling and analytical method has been subjected to the established evaluation procedures of the Organic Method Evaluations Branch.

Date: August 1981.

Chemist: Wayne D. Potter.

ORGANIC SOLVENTS BRANCH, OSHA ANALYTICAL LABORATORY, SALT LAKE CITY, UTAH

1. General Discussion.

1.1 Background.

1.1.1 History of Procedure.

Ethylene oxide samples analyzed at the OSHA Laboratory have normally been collected on activated charcoal and desorbed with carbon disulfide. The analysis is performed with a gas chromatograph equipped with a FID (Flame ionization detector) as described in NIOSH Method S286 (Ref. 5.1). This method is based on a PEL of 50 ppm and has a detection limit of about 1 ppm.

Recent studies have prompted the need for a method to analyze and detect ethylene oxide at very low concentrations.

Several attempts were made to form an ultraviolet (UV) sensitive derivative with ethylene oxide for analysis with HPLC. Among those tested that gave no detectable product were: p-anisidine, methylimidazole, aniline, and 2,3,6-trichlorobenzoic acid. Each was tested with catalysts such as triethylamine, aluminum chloride, methylene chloride and sulfuric acid but no detectable derivative was produced.

The next derivatization attempt was to react ethylene oxide with HBr to form 2-bromoethanol. This reaction was successful. An ECD (electron capture detector) gave a very good response for 2-bromoethanol due to the presence of bromine. The use of carbon disulfide as the desorbing solvent gave too large a response and masked the 2-bromoethanol. Several other solvents were tested for both their response on the ECD and their ability to desorb ethylene oxide from the charcoal. Among those tested were toluene, xylene, ethyl benzene, hexane, cyclohexane and benzene. Benzene was the only solvent tested that gave a suitable response on the ECD and a high desorption. It was found that the desorption efficiency was improved by using 1 percent CS₂ with the benzene. The carbon disulfide did not significantly improve the recovery with the other solvents. SKC Lot 120 was used in all tests done with activated charcoal.

1.1.2 Physical Properties (Ref. 5.2-5.4).

Synonyms:	Oxirane; dimethylene oxide, 1,2-epoxy-ethane; oxane; C(2)H(4)O; ETO;
Molecular Weight:	44.06
Boiling Point:	10.7 deg. C (51.3 deg.)
Melting Point:	111 deg. C
Description:	Colorless, flammable gas
Vapor Pressure:	1095 mm. at 20 deg. C
Odor:	Ether-like odor
Lower Explosive Limits:	3.0 percent (by volume)
Flash Point (TOC):	Below 0 deg. F
Molecular Structure:	CH(2)-CH(2)

1.2 Limit Defining Parameters.

1.2.1 Detection Limit of the Analytical Procedure.

The detection limit of the analytical procedure is 12.0 picograms of ethylene oxide per injection. This is the amount of analyte which will give a peak whose height is five times the height of the baseline noise. (See Backup Data Section 4.1).

1.2.2 Detection Limit of the Overall Procedure.

The detection limit of the overall procedure is 24.0 ng of ethylene oxide per sample.

This is the amount of analyte spiked on the sampling device which allows recovery of an amount of analyte equivalent to the detection limit of the analytical procedure. (See Backup Data Section 4.2).

1.2.3 Reliable Quantitation Limit.

The reliable quantitation limit is 94.0 nanograms of ethylene oxide per sample. This is the smallest amount of analyte which can be quantitated within the requirements of 75 percent recovery and 95 percent confidence limits. (See Backup Data Section 4.2).

It must be recognized that the reliable quantitation limit and detection limits reported in the method are based upon optimization of the instrument for the smallest possible amount of analyte. When the target concentration of an analyte is exceptionally higher than these limits, they may not be attainable at the routine operating parameters. In this case, the limits reported on analysis reports will be based on the operating parameters used during the analysis of the samples.

1.2.4 Sensitivity.

The sensitivity of the analytical procedure over a concentration range representing 0.5 to 2 times the target concentration based on the recommended air volume is 34105 area units per µg/mL. The sensitivity is determined by the slope of the calibration curve (See Backup Data Section 4.3).

The sensitivity will vary somewhat with the particular instrument used in the analysis.

1.2.5 Recovery.

The recovery of analyte from the collection medium must be 75 percent or greater. The average recovery from spiked samples over the range of 0.5 to 2 times the target concentration is 88.0 percent (See Backup Section 4.4). At lower concentrations the recovery appears to be non-linear.

1.2.6 Precision (Analytical Method Only).

The pooled coefficient of variation obtained from replicate determination of analytical standards at 0.5X, 1X and 2X the target concentration is 0.036 (See Backup Data Section 4.5).

1.2.7 Precision (Overall Procedure).

The overall procedure must provide results at the target concentration that are 25 percent of better at the 95 percent confidence level. The precision at the 95 percent confidence level for the 15 day storage test is plus or minus 12.9 percent (See Backup Data Section 4.6).

This includes an additional plus or minus 5 percent for sampling error.

1.3 Advantages.

- 1.3.1 The sampling procedure is convenient.
- 1.3.2 The analytical procedure is very sensitive and reproducible.
- 1.3.3 Reanalysis of samples is possible.
- 1.3.4 Samples are stable for at least 15 days at room temperature.
- 1.3.5 Interferences are reduced by the longer GC retention time of the new derivative.

1.4 Disadvantages.

- 1.4.1 Two tubes in series must be used because of possible breakthrough and migration.
- 1.4.2 The precision of the sampling rate may be limited by the reproducibility of the pressure drop across the tubes. The pumps are usually calibrated for one tube only.
- 1.4.3 The use of benzene as the desorption solvent increases the hazards of analysis because of the potential carcinogenic effects of benzene.
- 1.4.4 After repeated injections there can be a buildup of residue formed on the electron capture detector which decreases sensitivity.
- 1.4.5 Recovery from the charcoal tubes appears to be nonlinear at low concentrations.

2. Sampling Procedure.

2.1 Apparatus.

2.1.1 A calibrated personal sampling pump whose flow can be determined within plus or minus 5 percent of the recommended flow.

2.1.2 SKC Lot 120 Charcoal tubes: glass tube with both ends flame sealed, 7 cm long with a 6 mm O.D. and a 4 - mm I.D., containing 2 sections of coconut shell charcoal separated by a 2 - mm portion of urethane foam. The adsorbing section contains 100 mg of charcoal, the backup section 50 mg. A 3 - mm portion of urethane foam is placed between the outlet end of the tube and the backup section. A plug of silylated glass wool is placed in front of the adsorbing section.

2.2 Reagents.

- 2.2.1 None required.

2.3 Sampling Technique.

2.3.1 Immediately before sampling, break the ends of the charcoal tubes. All tubes must be from the same lot.

2.3.2 Connect two tubes in series to the sampling pump with a short section of flexible tubing. A minimum amount of tubing is used to connect the two sampling tubes together. The tube closer to the pump is used as a backup. This tube should be identified as the backup tube.

2.3.3 The tubes should be placed in a vertical position during sampling to minimize channeling.

2.3.4 Air being sampled should not pass through any hose or tubing before entering the charcoal tubes.

2.3.5 Seal the charcoal tubes with plastic caps immediately after sampling. Also, seal each sample with OSHA seals lengthwise.

2.3.6 With each batch of samples, submit at least one blank tube from the same lot used for samples. This tube should be subjected to exactly the same handling as the samples (break, seal, transport) except that no air is drawn through it.

2.3.7 Transport the samples (and corresponding paperwork) to the lab for analysis.

2.3.8 If bulk samples are submitted for analysis, they should be transported in glass containers with Teflon-lined caps. These samples must be mailed separately from the container used for the charcoal tubes.

2.4 Breakthrough.

2.4.1 The breakthrough (5 percent breakthrough) volume for a 3.0 mg/m ethylene oxide sample stream at approximately 85 percent relative humidity, 22 deg. C and 633 mm is 2.6 liters sampled at 0.05 liters per minute. This is equivalent to 7.8 mg of ethylene oxide. Upon saturation of the tube it appeared that the water may be displacing ethylene oxide during sampling.

2.5 Desorption Efficiency.

2.5.1 The desorption efficiency, from liquid injection onto charcoal tubes, averaged 88.0 percent from 0.5 to 2.0 x the target concentration for a 1.0 liter air sample. At lower ranges it appears that the desorption efficiency is non-linear (See Backup Data Section 4.2).

2.5.2 The desorption efficiency may vary from one laboratory to another and also from one lot of charcoal to another. Thus, it is necessary to determine the desorption efficiency for a particular lot of charcoal.

2.6 Recommended Air Volume and Sampling Rate.

2.6.1 The recommended air volume is 1.0 liter.

2.6.2 The recommended maximum sampling rate is 0.05 Lpm.

2.7 Interferences.

2.7.1 Ethylene glycol and Freon 12 at target concentration levels did not interfere with the collection of ethylene oxide.

2.7.2 Suspected interferences should be listed on the sample data sheets.

2.7.3 The relative humidity may affect the sampling procedure.

2.8 Safety Precautions.

2.8.1 Attach the sampling equipment to the employee so that it does not interfere with work performance.

2.8.2 Wear safety glasses when breaking the ends of the sampling tubes.

2.8.3 If possible, place the sampling tubes in a holder so the sharp end is not exposed while sampling.

3. Analytical Method.

3.1 Apparatus.

3.1.1 Gas chromatograph equipped with a linearized electron capture detector.

3.1.2 GC column capable of separating the derivative of ethylene oxide (2-bromoethanol) from any interferences and the 1 percent CS(2) in benzene solvent. The column used for validation studies was: 10 ft x 1/8 inch stainless steel 20 percent SP-2100, .1 percent Carbowax 1500 on 100/120 Supelcoport.

3.1.3 An electronic integrator or some other suitable method of measuring peak areas.

3.1.4 Two milliliter vials with Teflon-lined caps.

3.1.5 Gas tight syringe - 500 mL or other convenient sizes for preparing standards.

3.1.6 Microliter syringes - 10 mL or other convenient sizes for diluting standards and 1 mL for sample injections.

3.1.7 Pipets for dispensing the 1 percent CS(2) in benzene solvent. The Glenco 1 mL dispenser is adequate and convenient.

3.1.8 Volumetric flasks - 5 mL and other convenient sizes for preparing standards.

3.1.9 Disposable Pasteur pipets.

3.2 Reagents.

3.2.1 Benzene, reagent grade.

3.2.2 Carbon Disulfide, reagent grade.

3.2.3 Ethylene oxide, 99.7 percent pure.

3.2.4 Hydrobromic Acid, 48 percent reagent grade.

3.2.5 Sodium Carbonate, anhydrous, reagent grade.

3.2.6 Desorbing reagent, 99 percent Benzene/1 percent CS(2).

3.3 Sample Preparation.

3.3.1 The front and back sections of each sample are transferred to separate 2-mL vials.

3.3.2 Each sample is desorbed with 1.0 mL of desorbing reagent.

3.3.3 The vials are sealed immediately and allowed to desorb for one hour with occasional shaking.

3.3.4 Desorbing reagent is drawn off the charcoal with a disposable pipet and put into clean 2-mL vials.

3.3.5 One drop of HBr is added to each vial. Vials are resealed and HBr is mixed well with the desorbing reagent.

3.3.6 About 0.15 gram of sodium carbonate is carefully added to each vial. Vials are again resealed and mixed well.

3.4 Standard Preparation.

3.4.1 Standards are prepared by injecting the pure ethylene oxide gas into the desorbing reagent.

3.4.2 A range of standards are prepared to make a calibration curve. A concentration of 1.0 mL of ethylene oxide gas per 1 mL desorbing reagent is equivalent to 1.0 ppm air concentration (all gas volumes at 25 deg. C and 760 mm) for the recommended 1 liter air sample. This amount is uncorrected for desorption efficiency (See Backup Data Section 4.2. for desorption efficiency corrections).

3.4.3 One drop of HBr per mL of standard is added and mixed well.

3.4.4 About 0.15 grams of sodium carbonate is carefully added for each drop of HBr (A small reaction will occur).

3.5 Analysis.

3.5.1 GC Conditions. Nitrogen flow rate - 10 mL/min. Injector Temperature - 250 deg. C Detector Temperature - 300 deg. C Column Temperature - 100 deg. C Injection size - 0.8 mL Elution time - 3.9 minutes

3.5.2 Peak areas are measured by an integrator or other suitable means.

3.5.3 The integrator results are in area units and a calibration curve is set up with concentration vs. area units.

3.6 Interferences.

3.6.1 Any compound having the same retention time of 2-bromoethanol is a potential interference. Possible interferences should be listed on the sample data sheets.

3.6.2 GC parameters may be changed to circumvent interferences.

3.6.3 There are usually trace contaminants in benzene. These contaminants, however, posed no problem of interference.

3.6.4 Retention time data on a single column is not considered proof of chemical identity. Samples over the 1.0 ppm target level should be confirmed by GC/Mass Spec or other suitable means.

3.7 Calculations

3.7.1 The concentration in $\mu\text{g/mL}$ for a sample is determined by comparing the area of a particular sample to the calibration curve, which has been prepared from analytical standards.

3.7.2 The amount of analyte in each sample is corrected for desorption efficiency by use of a desorption curve.

3.7.3 Analytical results (A) from the two tubes that compose a particular air sample are added together.

3.7.4 The concentration for a sample is calculated by the following equation:

$$\text{ETO, mg/ m}^{(3)} = \frac{\text{AXB}}{\text{C}}$$

Where:

A = $\mu\text{g/mL}$

B = desorption volume in milliliters

C = air volume in liters.

3.7.5 To convert $\text{mg/m}^{(3)}$ to parts per million (ppm) the following relationship is used:

$$\text{ETO, ppm} = \frac{\text{mg/m}^{(3)} \times 24.45}{44.05}$$

Where:

$\text{mg/m}^{(3)}$ = results from 3.7.4

24.45 = molar volume at 25 deg. C and 760mm Hg

44.05 = molecular weight of ETO.

3.8 Safety Precautions

3.8.1 Ethylene oxide and benzene are potential carcinogens and care must be exercised when working with these compounds.

3.8.2 All work done with the solvents (preparation of standards, desorption of samples, etc.) should be done in a hood.

3.8.3 Avoid any skin contact with all of the solvents.

3.8.4 Wear safety glasses at all times.

3.8.5 Avoid skin contact with HBr because it is highly toxic and a strong irritant to eyes and skin.

4. Backup Data.

4.1 Detection Limit Data.

The detection limit was determined by injecting 0.8 uL of a 0.015 µg/mL standard of ethylene oxide into 1 percent CS(2) in benzene. The detection limit of the analytical procedure is taken to be 1.20 X 10⁵ µg per injection. This is equivalent to 8.3 ppb (0.015 mg/m⁽³⁾) for the recommended air volume.

4.2 Desorption Efficiency.

Ethylene oxide was spiked onto charcoal tubes and the following recovery data was obtained.

Amount spiked (µg)	Amount recovered (µg)	Percent recovery
4.5	4.32	96.0
3.0	2.61	87.0
2.25	2.025	90.0
1.5	1.365	91.0
1.5	1.38	92.0
.75	.6525	87.0
.375	.315	84.0
.375	.312	83.2
.1875	151	80.5
.094	.070	74.5
At lower amounts the recovery appears to be non-linear.		

4.3 Sensitivity Data.

The following data was used to determine the calibration curve.

Injection	0.5 X .75 µg/mL	1 X 1.5 µg/mL	2 X 3.0 µg/mL
1	30904	59567	111778
2	30987	62914	106016
3	32555	58578	106122
4	32242	57173	109716
X	31672	59558	108408
Slope = 34.105.			

4.4 Recovery.

The recovery was determined by spiking ethylene oxide onto lot 120 charcoal tubes and desorbing with 1 percent CS(2) in Benzene. Recoveries were done at 0.5, 1.0, and 2.0 X the target concentration (1 ppm) for the recommended air volume.

PERCENT RECOVERY			
Sample	0.5x	1.0x	2.0x
1	88.7	95.0	91.7
2	83.8	95.0	87.3
3	84.2	91.0	86.0
4	88.0	91.0	83.0
5	88.0	86.0	85.0
X	86.5	90.5	87.0
Weighted Average = 88.2.			

4.5 Precision of the Analytical Procedure.

The following data was used to determine the precision of the analytical method:

Concentration	0.5x.75 µg/mL	1x1.5 µg/mL	2X3.0 µg/mL
Injection	.7421	1.4899	3.1184
	.7441	1.5826	3.0447
	.7831	1.4628	2.9149
	.7753	1.4244	2.9185
Average.	.7612	1.4899	2.9991
Standard Deviation	.0211	0674	.0998
CV	.0277	.0452	.0333

$$CV = \frac{3(.0277)(2) + 3(.0452)(2) + 3(.0333)(2)}{3 + 3 + 3}$$

$$CV = 0.036$$

4.6 Storage Data.

Samples were generated at 1.5 mg/m³ ethylene oxide at 85 percent relative humidity, 22 deg. C and 633 mm. All samples were taken for 20 minutes at 0.05 Lpm. Six samples were analyzed as soon as possible and fifteen samples were stored at refrigerated temperature (5 deg. C) and fifteen samples were stored at ambient temperature (23 deg. C). These stored samples were analyzed over a period of nineteen days.

PERCENT RECOVERY		
Day analyzed	Refrigerated	Ambient
1	87.0	87.0
1	93.0	93.0
1	94.0	94.0
1	92.0	92.0
4	92.0	91.0
4	93.0	88.0
4	91.0	89.0
6	92.0	--
6	92.0	--
8	--	92.0
8	--	86.0
10	91.7	--
10	95.5	--
10	95.7	--
11	--	90.0
11	--	82.0
13	78.0	--
13	81.4	--
13	82.4	--
14	--	78.5
14	--	72.1
18	66.0	--
18	68.0	--
19	--	64.0
19	--	77.0

4.7 Breakthrough Data.

Breakthrough studies were done at 2 ppm (3.6 mg/m³) at approximately 85 percent relative humidity at 22 deg. C (ambient temperature). Two charcoal tubes were used in series. The backup tube was changed every 10 minutes and analyzed for breakthrough. The flow rate was 0.050 Lpm.

Tube No.	Time (minutes)	Percent break-through
1	10	(1)
2	20	(1)
3	30	(1)
4	40	1.23
5	50	3.46
6	60	18.71
7	70	39.2
8	80	53.3
9	90	72.0
10	100	96.0
11	110	113.0
12	120	133.9
Footnote(1) None.		

The 5 percent breakthrough volume was reached when 2.6 liters of test atmosphere were drawn through the charcoal tubes.

5. References.

5.1 "NIOSH Manual of Analytical Methods," 2nd ed. NIOSH: Cincinnati, 1977; Method S286.

5.2 "IARC Monographs on the Evaluation of Carcinogenic Risk of Chemicals to Man," International Agency for Research on Cancer: Lyon, 1976; Vol. II, p. 157.

5.3 Sax., N.I. "Dangerous Properties of Industrial Materials," 4th ed.; Van Nostrand Reinhold Company. New York, 1975; p. 741.

5.4 "The Condensed Chemical Dictionary", 9th ed.; Hawley, G.G., ed.; Van Nostrand Reinhold Company, New York, 1977; p. 361.

Summary of Other Sampling Procedures

OSHA believes that served other types of monitoring equipment and techniques exist for monitoring time-weighted averages. Considerable research and method development is currently being performed, which will lead to improvements and a wider variety of monitoring techniques. A combination of monitoring procedures can be used. There probably is no one best method for monitoring personal exposure to ethylene oxide in all cases. There are advantages, disadvantages, and limitations to each method. The method of choice will depend on the need and requirements. Some commonly used methods include the use of charcoal tubes, passive dosimeters, Tedler gas sampling bags, detector tubes, photoionization detection units, infrared detection units and gas chromatographs. A number of these methods are described below.

A. Charcoal Tube Sampling Procedures

Qazi-Ketcham method (Ex. 11-133) - This method consists of collecting EtO on Columbia JXC activated carbon, desorbing the EtO with carbon disulfide and analyzing by gas chromatography with flame ionization detection. Union Carbide has recently updated and revalidated this monitoring procedures. This method is capable of determining both eight-hour time-weighted average exposures and short-term exposures. The method was validated to 0.5 ppm. Like other charcoal collecting procedures, the method requires considerable analytical expertise. ASTM-proposed method - The Ethylene Oxide Industry Council (EOIC) has contracted with Clayton Environmental Consultants, Inc. to conduct a collaborative study for the proposed method. The ASTM-Proposed method is similar to the method published by Qazi and Ketcham in the November 1977 American Industrial Hygiene Association Journal, and to the method of Pilney and Coyne, presented at the 1979 American Industrial Hygiene Conference. After the air to be sampled is drawn through an activated charcoal tube, the ethylene oxide is desorbed from the tube using carbon disulfide and is quantitated by gas chromatography utilizing a flame ionization detector.

The ASTM-proposed method specifies a large two-section charcoal tube, shipment in dry ice, storage at less than 5 deg. C, and analysis within three weeks to prevent migration and sample loss. Two types of charcoal tubes are being tested-Pittsburgh Coconut-Based (PCB) and Columbia JXC charcoal. This collaborative study will give an indication of the inter- and intralaboratory precision and accuracy of the ASTM-proposed method. Several laboratories have considerable expertise using the Qazi-Ketcham and Dow methods.

B. Passive Monitors - Ethylene oxide diffuses into the monitor and is collected in the sampling media. The DuPont Pro-Tek badge collects EtO in an absorbing solution, which is analyzed colorimetrically to determine the amount of EtO present. The 3M 350 badge collects the EtO on chemically treated charcoal. Other passive monitors are currently being developed and tested. Both 3M and DuPont have submitted data indicating their dosimeters meet the precision and accuracy requirements of the proposed ethylene oxide standard. Both presented laboratory validation data to 0.2 ppm (Exs. 11-65, 4-20, 108, 109, 130).

C. Tedlar Gas Sampling Bags - Samples are collected by drawing a known volume of air into a Tedlar gas sampling bag. The ethylene oxide concentration is often determined on-site using a portable gas chromatograph or portable infrared spectrometer.

D. Detector tubes - A known volume of air is drawn through a detector tube using a small hand pump. The concentration of EtO is related to the length of stain developed in the tube. Detector tubes are economical, easy to use, and give an immediate readout. Unfortunately, partly because they are nonspecific, their accuracy is often questionable. Since the sample is taken over a short period of time, they may be useful for determining the source of leaks.

E. Direct Reading Instruments - There are numerous types of direct reading instruments, each having its own strengths and weaknesses (Exs. 135B, 135C, 107, 11-78, 11-153). Many are relatively new, offering greater sensitivity and specificity. Popular ethylene oxide direct reading instruments include infrared detection units, photoionization detection units, and gas chromatographs.

Portable infrared analyzers provide an immediate, continuous indication of a concentration value; making them particularly useful for locating high concentration pockets, in leak detection and in ambient air monitoring. In infrared detection units, the amount of infrared light absorbed by the gas being analyzed at selected infrared wavelengths is related to the concentration of a particular component. Various models have either fixed or variable infrared filters, differing cell pathlengths, and microcomputer controls for greater sensitivity, automation, and interference elimination.

A fairly recent detection system is photoionization detection. The molecules are ionized by high energy ultraviolet light. The resulting current is measured. Since different substances have different ionization potentials, other organic compounds may be ionized. The lower the lamp energy, the better the selectivity. As a continuous monitor, photoionization detection can be useful for locating high concentration pockets, in leak detection, and continuous ambient air monitoring. Both portable and stationary gas chromatographs are available with various types of detectors, including photoionization detectors. A gas chromatograph with a photoionization detector retains the photoionization sensitivity, but minimizes or eliminates interferences. For several GC/PID units, the sensitivity is in the 0.1-0.2 ppm EtO range. The GC/PID with microprocessors can sample up to 20 sample points sequentially, calculate and record data, and activate alarms or ventilation systems. Many are quite flexible and can be configured to meet the specific analysis needs for the workplace.

DuPont presented their laboratory validation data of the accuracy of the Qazi-Ketcham charcoal tube, the PCB charcoal tube, Miran 103 IR analyzer, 3M number 3550 monitor and the Du Pont C-70 badge. Quoting Elbert V. Kring:

We also believe that OSHA's proposed accuracy in this standard is appropriate. At plus or minus 25 percent at one part per million, and plus or minus 35 percent below that. And, our data indicates there's only one monitoring method, right now, that we've tested thoroughly, that meets that accuracy requirements. That is the Du Pont Pro-Tek badge. . . . We also believe that this kind of data should be confirmed by another independent laboratory, using the same type dynamic chamber testing (Tr. 1470)

Additional data by an independent laboratory following their exact protocol was not submitted. However, information was submitted on comparisons and precision and accuracy of those monitoring procedures which indicate far better precision and accuracy of those monitoring procedures than that obtained by Du Pont (Ex. 4-20, 130, 11-68, 11-133, 130, 135A).

The accuracy of any method depends to a large degree upon the skills and experience of those who not only collect the samples but also those who analyze the samples. Even for methods that are collaboratively tested, some laboratories are closer to the true values than others. Some laboratories may meet the precision and accuracy requirements of the method; others may consistently far exceed them for the same method.

[49 FR 25796, June 22, 1984, as amended at 50 FR 9801, Mar. 12, 1985; 50 FR 41494, Oct. 11, 1985; 51 FR 25053, July 10, 1986; 53 FR 11436, 11437, Apr. 6, 1988; 53 FR 27960, July 26, 1988; 54 FR 24334, June 7, 1989; 61 FR 5507, Feb. 13, 1996]



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