

DEPARTMENT OF CONSUMER AND INDUSTRY SERVICES

BUREAU OF SAFETY AND REGULATION

OCCUPATIONAL HEALTH STANDARDS COMMISSION

ETHYLENE OXIDE

(By authority conferred upon the occupational health standards commission by section 24 of Act No. 154 of the Public Acts of 1974, as amended, being S408.1024 of the Michigan Compiled Laws)

R 325.51151 Scope and application.

Rule 1. (1) These rules apply to all occupational exposures to ethylene oxide (EtO), chemical abstracts service registry no. 75-21-8, except that these rules do not apply to the processing, use, and handling of products that contain EtO if objective data are reasonably relied upon to demonstrate that the product is not capable of releasing EtO in airborne concentrations at or above the action level and that it cannot reasonably be foreseen that the product will release EtO in excess of the short-term exposure limit (STEL) under the expected conditions of processing, use, and handling that will cause the greatest possible release.

(2) An employer who relies on the product exemption of this rule shall maintain records of the objective data supporting that exemption and of the basis of the employer's reliance on the data, as provided in R 325.51171.

History: 1988 AACCS; 1993 AACCS.

R 325.51152 Definitions.

Rule 2. As used in these rules:

(a) "Act" means Act No. 154 of the Public Acts of 1974, as amended, being §408.1001 et seq. of the Michigan Compiled Laws.

(b) "Action level" means a concentration of EtO of 0.5 parts EtO per million parts of air (0.5 ppm) calculated as an 8-hour, time-weighted average.

(c) "Authorized person" means any person specifically authorized by the employer whose duties require the person to enter a regulated area, any person entering such an area as a designated representative of employees for the purpose of exercising the right to observe monitoring procedures under R 325.51176, or any other person authorized by the act.

(d) "Director" means the director of the Michigan department of consumer and industry services or his or her designee.

(e) "Emergency" means any occurrence which is likely to or does result in an unexpected release of ethylene oxide, such as equipment failure, rupture of containers, or failure of control equipment.

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

(g) "Ethylene oxide" or "EtO" means a 3-membered ring organic compound, chemical formula C₂H₄O.

(h) "O.H. rule" means an occupational health rule adopted by reference pursuant to section 14 of the act or promulgated pursuant to section 24 of the act. Copies of these rules are available from the Michigan department of consumer and industry services.

History: 1988 AACCS; 2000 AACCS.

R 325.51153 Airborne concentrations; permissible employee exposure limits.

Rule 3. (1) An employer shall ensure that an employee is not exposed to an airborne concentration of EtO of more than 1 part EtO per million parts of air (1 ppm) as an 8-hour, time-weighted average (TWA).

(2) An employer shall ensure that an employee is not exposed to an airborne short-term exposure limit (STEL) concentration of EtO of more than 5 ppm as averaged over any 15-minute period during the working day.

History: 1988 AACS; 1993 AACS.

R 325.51154 Exposure monitoring generally.

Rule 4. (1) Determinations of employee exposure shall be made from breathing zone air samples that are representative of the 8-hour TWA and 15-minute STEL of each employee.

(2) Representative 8-hour TWA employee exposures shall be determined on the basis of 1 or more samples that represent 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 1 or more samples that represent 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.

(3) If an 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 1 shift.

History: 1988 AACS; 1993 AACS.

R 325.51155 Exposure monitoring; initial determination.

Rule 5. (1) An employer who has a workplace or work operation that is subject to these rules shall perform initial monitoring to accurately determine the TWA and STEL airborne concentrations of EtO to which an employee may be exposed.

(2) Any measurements of airborne EtO concentrations that are determined after June 15, 1983, may be used to satisfy the requirement to monitor specified in subrule (1) of this rule, if the sampling and analytical methods that are used meet the accuracy and confidence levels required by

R 325.51157.

(3) If an employer has previously monitored for the STEL by sampling and analytic methods that meet the accuracy and confidence levels of R 325.51157, the employer may rely on the monitoring results to satisfy the requirements of subrule (1) of this rule.

History: 1988 AACS; 1993 AACS.

R 325.51156 Exposure monitoring; frequency.

Rule 6. (1) If an initial determination or subsequent monitoring reveals employee exposure to be at or above the action level, but below the permissible employee exposure limits, an employer shall repeat monitoring in accordance with this rule, R 325.51154, R 325.51155, R 325.51157, and R 325.51158 at least every 6 months. The employer shall continue monitoring at the required frequency until not less than 2 consecutive measurements, taken not less than 7 days apart, are below the action level, at which time the employer may discontinue monitoring for that employee, except as provided pursuant to subrule (3) of this rule.

(2) If initial monitoring reveals that employee exposure is above the TWA or the STEL, an employer shall repeat monitoring at least quarterly. The employer shall continue monitoring at the required frequency until not less than 2 consecutive measurements, taken not less than 7 days apart, are at or below the TWA and STEL. At that time, the employer shall repeat monitoring for that employee at the frequency prescribed by subrule (1) of this rule, except as otherwise provided pursuant to subrule (3) of this rule.

(3) If there has been a production, process, control, personnel, or work practice change which might result in new or additional employee exposure to EtO, or if an employer has any other reason to suspect a change which might result in new or additional exposures to EtO, additional monitoring pursuant to this rule and R 325.51154, R 325.51155, R 325.51157, and R 325.51158 shall be conducted.

History: 1988 AACS; 1993 AACS.

R 325.51157 Exposure monitoring; accuracy of measurement.

Rule 7. An employer shall use a method of monitoring which is accurate, to a confidence level of 95%, to within plus or minus 25% for airborne concentrations of EtO at the 1 ppm TWA, to within plus or minus 35% for airborne concentrations of EtO at the action level of 0.5 ppm, and to within plus or minus 35% for airborne concentrations of EtO at the 5 ppm STEL.

History: 1988 AACS.

R 325.51158 Employee notification of monitoring results.

Rule 8. (1) Within 15 working days after the receipt of monitoring results, an employer shall notify each employee of the results, in writing, either individually or by posting the results in an appropriate location that is accessible to affected employees.

(2) If the monitoring results indicate that employee exposure, without regard to respirators, exceeds 1 or both of the permissible employee exposure limits, an employer shall include, in the written notice required

by subrule (1) of this rule, a statement that the permissible employee exposure limit was exceeded and a description of the corrective action taken or to be taken to reduce exposure to or below the permissible employee exposure limit.

History: 1988 AACS.

R 325.51159 Regulated areas.

Rule 9. (1) An employer shall establish a regulated area wherever employee exposure to airborne concentrations of EtO may exceed either of the permissible employee exposure limits specified in R 325.51153.

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

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

History: 1988 AACS; 1993 AACS.

R 325.51160 Methods of compliance; engineering controls and work practices.

Rule 10. (1) An employer shall institute engineering and work practice controls to reduce and maintain employee exposures to EtO to or below the permissible exposure limits, except to the extent that such controls are not feasible.

(2) If the engineering and work practice controls that can be instituted are not sufficient to reduce employee exposures to or below the permissible exposure limits, an employer shall nonetheless use them to reduce exposures to the lowest levels achievable by these controls and shall supplement the controls by the use of respiratory protection which complies with the requirements of R 325.51162.

(3) Engineering controls are generally infeasible for the following operations:

- (a) Collection of quality assurance sampling from sterilized materials.
- (b) Removal of biological indicators from sterilized materials.
- (c) Loading and unloading of tank cars.
- (d) Changing of ethylene oxide tanks on sterilizers.
- (e) Vessel cleaning.

(4) Engineering controls are required for operations in subrule (3) of this rule where the director demonstrates that such controls are feasible.

(5) Employee job rotation shall not be used as a means of compliance with the permissible exposure limits.

History: 1988 AACS.

R 325.51161 Methods of compliance; written compliance program.

Rule 11. (1) If the TWA or STEL exposure limits are exceeded, an employer shall establish and implement a written compliance program to reduce and maintain employee exposures at or below the permissible employee exposure limits prescribed by R 325.51153(1) and (2) solely by means of engineering and work practice controls pursuant to 325.51160 and by the use of respiratory protection where required or permitted by R R 325.51162.

(2) The written compliance program shall, at a minimum, include both of the following:

(a) A schedule for periodic leak detection surveys.

(b) A written plan for emergency situations pursuant to R 325.51164.

(3) Written compliance programs shall be submitted, upon request, to the director and shall be available at the workplace for examination and copying by the director, an affected employee, or an authorized employee representative.

(4) A written compliance program shall be reviewed and updated at least once every 12 months to reflect the current status of the compliance program.

History: 1988 AACS; 1993 AACS.

R 325.51162 Respirators; selection; respiratory protection program.

Rule 12. (1) For employees who use respirators required by these rules, the employer shall provide respirators that comply with the requirements of these rules. Respirators must be used during all of the following:

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

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

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

(d) Emergencies.

(2) The employer shall select the appropriate respirator from table 1.

TABLE 1--MINIMUM REQUIREMENTS FOR RESPIRATORY PROTECTION FOR AIRBORNE ETHYLENE OXIDE

Condition of use or concentration of airborne EtO (ppm)	Minimum Required Respirator
Equal to or less than 50	Full facepiece respirator with EtO approved canister, front- or back-mounted.
Equal to or less than 2,000	(a) Positive-pressure, supplied-air respirator equipped with full facepiece, hood, or helmet, or (b) Continuous-flow, supplied-air respirator(positive-pressure) equipped with hood, helmet, or suit.
Concentration above 2,000 or unknown concentration (such as in emergencies).	(a) Positive-pressure, self-contained breathing apparatus(SCBA) equipped with full facepiece, or (b) Positive-pressure, full facepiece, supplied-air respirator equipped with auxiliary positive-pressure,

	self-contained breathing apparatus.
Firefighting	Positive-pressure, self-contained breathing apparatus equipped with full facepiece.
Escape	Any respirator described in this table.

Note: Respirators approved for use in higher concentrations are permitted to be used in lower concentrations.

(3) The employer must implement a respiratory protection program in accordance with 29 CFR §1910.134 (b) to (d), and (f) to (m), except for (d)(1)(iii), as adopted by reference in R 325.60051.

History: 1988 AACS; 1993 AACS; 2000 AACS.

R 325.51163 Protective clothing and equipment.

Rule 13. If it is possible that employees could have eye or skin contact with EtO or EtO solutions, then the employer must select and provide, at no cost to the employee, appropriate protective clothing or other equipment in accordance with occupational health rule R 325.6001 et seq. 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.

History: 1988 AACS; 2000 AACS.

R 325.51164 Emergency situations; written plans; alerting employees.

Rule 14. (1) A written plan for emergency situations shall be developed for each workplace where EtO is used. Appropriate portions of the plan shall be implemented in the event of an emergency.

(2) The plan shall specifically provide that an employee who is engaged in correcting emergency conditions shall be equipped with respiratory protection as required in R 325.51162 until the emergency has abated.

(3) The plan shall include the elements prescribed in the provisions of 29 C.F.R. S1910.38, entitled "Employee emergency plans and fire prevention plans."

(4) Where there is the possibility of employee exposure to EtO due to an emergency, means shall be developed and used to promptly alert potentially affected employees of such occurrences.

(5) Affected employees who are not engaged in correcting the emergency shall be immediately evacuated from the area and shall not be permitted to return until the emergency has abated.

History: 1988 AACS.

R 325.51165 General medical surveillance.

Rule 15. (1) An employer shall institute a medical surveillance program for each employee who is or may be exposed to concentrations of EtO at or above the action level or short-term exposure limit, without regard to the use of respirators, for at least 30 days a year.

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

(3) The employer shall ensure that all medical examinations and procedures are performed by, or under the supervision of, a licensed physician.

(4) An employer shall ensure that the required medical surveillance is provided without cost to employees, without loss of pay, and at a reasonable time and place.

History: 1988 AACS.

R 325.51166 Medical examinations and consultations; frequency and contact.

Rule 16. (1) An employer shall make medical examinations and consultations available to each employee covered in R 325.51165 as follows:

(a) Before assignment to a work area where exposure may be at or above the action level or short-term exposure limit for at least 30 days a year.

(b) At least annually.

(c) At termination or reassignment to an area where exposure to EtO is not at or above the action level or short-term exposure limit for at least 30 days a year.

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

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

(f) An employer shall provide additional medical examinations to affected employees at the frequency recommended by the examining physician.

(2) Medical examinations made available pursuant to subrule (1) of this rule shall include all of the following:

(a) A medical and work history, with emphasis given to eyes, skin, and pulmonary, hematologic, neurologic, and reproductive systems.

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

(c) A complete blood count, including at least a white cell count with differential, red cell count, hematocrit, and hemoglobin.

(d) Additional tests which, in the opinion of the examining physician, are appropriate.

(e) Pregnancy testing or laboratory evaluation of fertility shall be provided if requested by the employee and deemed appropriate by the physician.

History: 1988 AACS.

R 325.51167 Medical surveillance program; information provided to the physician by employer.

Rule 17. An employer shall provide all of the following information to the examining physician:

(a) A copy of these rules and related appendices which may be obtained from the department of public health.

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

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

(d) A description of any personal protective equipment used or to be used.

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

History: 1988 AACS.

R 325.51168 Medical surveillance program; physician's written opinion.

Rule 18. (1) An employer shall obtain a written opinion from the examining physician, which shall include all of the following information:

(a) The results of the medical examination and tests performed.

(b) The physician's opinion as to whether an employee has any detected medical condition or conditions which would subject the employee to an increased risk of material health impairment from exposure to EtO.

(c) Any recommended limitations on the employee or upon the use of personal protective equipment, such as clothing or respirators.

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

(2) An employer shall instruct the physician not to reveal specific findings or diagnoses unrelated to occupational exposure to EtO in the written opinion.

(3) Within 15 days of receipt, an employer shall provide a copy of the written opinion to the affected employee.

History: 1988 AACCS.

R 325.51169 Signs and labeling.

Rule 19. (1) An employer shall post the following warning sign in each regulated area and entrances or access ways to regulated areas:

DANGER

ETHYLENE OXIDE

CANCER HAZARD AND REPRODUCTIVE HAZARD

AUTHORIZED PERSONNEL ONLY

RESPIRATORS AND PROTECTIVE CLOTHING MAY BE REQUIRED

TO BE WORN IN THIS AREA

(2) An employer shall assure that signs required by this rule are illuminated and cleaned as necessary to remain legible.

(3) An employer shall assure that precautionary labels are affixed to EtO containers and remain affixed when the containers are removed from the workplace. Reaction vessels, storage tanks, and pipes or piping systems are not considered containers.

(4) Labels shall comply with the provisions of 29 C.F.R. S1910.1200(f) and shall include both of the following statements:

(a)

DANGER

CONTAINS ETHYLENE OXIDE

CANCER HAZARD AND REPRODUCTIVE HAZARD

(b) A statement warning against breathing airborne concentrations of EtO.

(5) The labeling requirements in subrules (1) to (4) of this rule 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. S136 et seq., when it is labeled pursuant to that act and regulations issued under the act by the environmental protection agency.

(6) Manufacturers and importers of EtO shall develop material safety data sheets as specified in the provisions of 29 C.F.R. S1910.1200(g).

History: 1988 AACCS.

R 325.51170 Employee information and training.

Rule 20. (1) An employer who has a workplace in which there is a potential exposure to airborne EtO at or above the action level or above the STEL shall provide employees with information and training on EtO at the time of initial assignment and at least annually for each employee.

(2) An employer shall ensure that each employee is informed of all of the following:

- (a) The location, availability, and contents of these rules and appendices A and B to these rules.
- (b) The specific nature of any operations in the employee's work area where EtO is present.
- (c) The purpose and description of the medical surveillance program required in R 325.51165 to R 325.51168 and an explanation of the information in appendix C to these rules.
- (3) An employer shall institute a training program that shall include all of the following areas:
 - (a) Methods and observations that may be used to detect the presence or release of EtO in the work area.
 - (b) The physical and health hazards of EtO.
 - (c) The engineering controls, work practices, personal protective equipment, and emergency procedures used to protect employees.
 - (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 appropriate hazard information.

History: 1988 AACS; 1993 AACS.

R 325.51171 Recordkeeping; objective data for exempted operations.

Rule 21. (1) If the processing, use, and handling of products made from or containing EtO are exempted pursuant to R 325.51151, or where objective data have been relied on instead of initial monitoring pursuant to R 325.51155(2), an employer shall establish and maintain an accurate record of the objective data reasonably relied upon in support of the exemption, which shall include all of the following information:

- (a) The product qualifying for exemption.
 - (b) The source of the objective data.
 - (c) The testing protocol and the results of the testing or an analysis of the material, or both, for the release of EtO.
 - (d) A description of the operation exempted and how the data supports the exemption.
 - (e) Other data relevant to the operations, materials, processing, or employee exposures covered by the exemption.
- (2) An employer shall maintain the record specified in subrule (1) of this rule for the duration of the employer's reliance upon such objective data.

History: 1988 AACS.

R 325.51172 Monitoring of exposure; records; maintenance.

Rule 22. (1) An employer shall establish and maintain an accurate record of all monitoring required by R 325.51154 to R 325.51156. The exposure monitoring record shall include all of the following information:

- (a) The dates, number, duration, and results of each of the samples taken, including a description of the sampling plan used to determine representative employee exposure.
 - (b) The operation involving exposure to EtO that is being monitored.
 - (c) A description of the sampling and analytical methods used and the data relied upon to establish that the methods used meet the accuracy and precision requirements of R 325.51157.
 - (d) Type of protective devices worn, if any.
 - (e) Name, social security number, and job classification of the employee being monitored and of all other employees whose exposure the measurement is intended to represent.
- (2) An employer shall maintain the record specified in subrule (1) of this rule for not less than 30 years in accordance with the provisions of R 325.3451 et seq.

History: 1988 AACS; 1993 AACS.

R 325.51173 Medical surveillance records; maintenance.

Rule 23. (1) An employer shall establish and maintain an accurate record for each employee subject to medical surveillance as required by R 325.51165. The medical surveillance record shall include all of the following information:

- (a) The name and social security number of the employee.
- (b) A copy of the physician's written opinions.
- (c) Any employee medical complaints related to exposure to EtO.
- (d) A copy of the information provided to the physician as required by R 325.51167.

(2) An employer shall ensure the record is maintained for the duration of employment plus 30 years in accordance with the provisions of R 325.3451 et seq.

History: 1988 AACS; 1993 AACS.

R 325.51174 Availability of records.

Rule 24. (1) Upon written request, an employer shall make all records that are required to be maintained by these rules available to the director for examination and copying.

(2) Upon request, an employer shall make records that are required to be maintained by R 325.51171, R 325.51172, and R 325.51173 available to affected employees, former employees, and designated representatives for examination and copying in accordance with the provisions of R 325.3451 et seq.

(3) An employer shall make records that are required to be maintained by R 325.51173 available for examination and copying to anyone who has the specific written consent of the affected employee or former employee.

History: 1988 AACS; 1993 AACS.

R 325.51175 Retention and disposal of records; successor employer; transmittal and notice to director.

Rule 25. (1) If an employer ceases to do business, the successor employer shall receive and retain all records that are required to be maintained by these rules for the prescribed period.

(2) If an employer ceases to do business and there is no successor employer to receive and retain the records for the prescribed period, these records shall be transmitted to the director.

(3) At the expiration of the retention period for the records that are required to be maintained pursuant to these rules, an employer shall notify the director not less than 3 months before the disposal of the records and shall transmit the records to the director upon request.

History: 1988 AACS.

R 325.51176 Exposure monitoring; employee observation.

Rule 26. (1) An employer shall provide affected employees or their designated representatives an opportunity to observe any monitoring of employee exposure to EtO which is conducted pursuant to R 325.51154 to R 325.51156.

(2) 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.

History: 1988 AACS.

R 325.51177 Availability of rules and appendices; permission to reproduce.

Rule 27. (1) Appendices A to D to these rules are informational and are not intended to create any additional obligations not otherwise imposed or to detract from any existing obligations. Copies of these rules and related appendices entitled "Appendix A--Substance Safety Data Sheet for Ethylene Oxide," "Appendix B--Substance Technical Information for Ethylene Oxide," "Appendix C--Medical Surveillance Information for Ethylene Oxide," and "Appendix D--Sampling and Analytical Methods for Ethylene

Oxide" are available to affected employers and employees at no cost from the Michigan Department of Consumer and Industry Services, Standards Division, 7150 Harris Drive, P.O. Box 30643, Lansing, Michigan 48909.

(2) Permission to reproduce any of the documents specified in subrule (1) of this rule in full is granted by the director.

History: 1988 ACS; 1993 ACS; 2000 ACS.