

**DIRECTOR'S OFFICE BUREAU OF SAFETY AND REGULATION**

OCCUPATIONAL HEALTH STANDARDS COMMISSION

ETHYLENE OXIDE

**FILED WITH THE SECRETARY OF STATE ON FEBRUARY 24, 2015**

These rules become effective immediately upon filing with the Secretary of State unless adopted under sections 33, 44, 45a(6), or 48 of 1969 PA 306.

Rules adopted under these sections become effective 7 days after filing with the Secretary of State.

(By authority conferred on the director of the department of licensing and regulatory affairs by sections 14 and 24 of 1974 PA 154, MCL 408.1014 and 408.1024, and Executive Reorganization Order Nos. 1996-1, 1996-2, 2003-1, 2008-4, and 2011-4, MCL 330.3101, 445.2001, 445.2011, 445.2025, and 445.2030.)  
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 325.51152, R 325.51156, R 325.51158, R 325.51162, R 325.51163, R 325.51164, R 325.51166, R 325.51167, R 325.51169, R 325.51172, R 325.51173, R 325.51174, and R 325.51175 of the Michigan Administrative Code are amended, and R 325.51151a, R 325.51156a, and R 325.51168a are added, and R 325.51177 is rescinded, as follows:

**PART 304 ETHYLENE OXIDE**

**R 325.51151a. Reference of standards.**

**Rule 1a. (1) The following Michigan occupational safety and health standards are referenced in these rules. Up to 5 copies of these standards may be obtained at no charge from the Michigan Department of Licensing and Regulatory Affairs, MIOSHA Regulatory Services Section, 7150 Harris Drive, P.O. Box 30643, Lansing, Michigan 48909-8143, or via the internet at website: [www.michigan.gov/mioshastandards](http://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) Construction Safety Standard Part 18 "Fire Prevention and Prevention," R 408.41801 to R 408.41884.**
- (b) General Industry Safety Standard Part 6 "Fire Exits," R 408.10601 to R 408.10697.**
- (c) General Industry Safety Standard Part 33 "Personal Protective Equipment," R 408.13301 to R 408.13398.**
- (d) Occupational Health Standard Part 430 "Hazard Communication," R 325.77001 to R 325.77003.**
- (e) Occupational Health Standard Part 433 "Personal Protective Equipment," R 325.60001 to R 325.60013.**
- (f) Occupational Health Standard Part 451 "Respiratory Protection," R 325.60051 to R 325.60052.**
- (g) Occupational Health Standard Part 470 "Employee Medical Records and Trade Secrets," R 325.3451 to R 325.3476.**

**(2) 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.**

**R 325.51152. Definitions.**

Rule 2. (1) As used in these rules:

- (a) "Act" means Michigan occupational safety and health act of Act No. 154 of the Public Acts of 1974 PA 154, as amended, being § MCL 408.1001 to MCL §408.1094. 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 licensing and regulatory affairs 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 that 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 C<sub>2</sub>H<sub>4</sub>O.**

~~(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.~~

R 325.51156. Exposure monitoring; frequency.

Rule 6. (1) If ~~the an initial determination or subsequent~~ **monitoring required by R 325.51155** reveals employee exposure to be at or above the action level, but below the **8-hour TWA, permissible employee exposure limits**, an employer shall repeat **such monitoring for each such employee** 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 required by R 325.51155** reveals that employee exposure is above the **8-hour TWA, or the STEL**, an employer shall repeat **such monitoring for each affected employee at least every 3 months**. ~~at least quarterly.~~

(3) ~~The employer may alter the shall continue monitoring~~ **schedule from quarterly to semiannually for any employee for whom at the required frequency until not less than 2 consecutive measurements, taken not less than 7 days apart, indicate that the employee's exposure has decreased to are at or below the 8-hour 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.~~

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

**R 325.51156a. Termination of monitoring, 'action level,' excursion limit.**

**Rule 6a. (1) If the initial monitoring required by R 325.51155 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.**

**(2) If the periodic monitoring required by R 325.51156 reveals that employee exposures, as indicated by at least 2 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.**

**(3) If the initial monitoring required by R 325.51155 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.**

**(4) If the periodic monitoring required by R 325.51156 reveals that employee exposures, as indicated by at least 2 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.**

R 325.51158. Employee notification of monitoring results.

Rule 8. (1) **The employer must**, within 15 working days after the receipt of **the results of any** monitoring results, ~~an employer shall~~ notify each **affected** employee of the results, **either individually** 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.

R 325.51162. Respirators; selection; respiratory protection program.

Rule 12 (1) For employees who use respirators required by these rules, the employer shall **select and provide each employee an appropriate respirator s** that **complies** ~~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.

(2) For respirator selection, an employer must do all of the following:

(a) Select, and provide to employees, the appropriate respirators in accordance with Occupational Health Standard Part 451 "Respiratory Protection," as referenced in R 325.51151a, however, an employer must not select or use half masks of any type because EtO may cause eye irritation or injury.

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

(c) For escape, provide employees with any respirator permitted for use under subdivisions (a) and (b) of this subrule.

(3) The employer must implement a respiratory protection program in accordance with **Occupational Health Standard Part 451 "Respiratory Protection,"** 29 C.F.R. §1910.134 (b) to (d), and (f) to (m), except for (d)(1)(iii), as adopted by referenced in R 325.51151a, ~~R-325.60051.~~ which covers each employee required by this rule to use a respirator.

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 **General Industry Safety Standard Part 33 "Personal Protective Equipment,"** and Occupational Health **Standard Part 433 "Personal Protective Equipment,"** and as referenced in R 325.51151a, ~~rule R-325.60004 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.

R 325.51164. Emergency situations; written plans; alerting employees.

Rule 14. (1) **The employer shall develop a** A written plan for emergency situations ~~shall be developed~~ for each workplace where EtO is used. **The employer shall implement appropriate** 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 **Construction Safety Standard Part 18 Fire Protection and Prevention and General Industry Safety Standard Part 6 Fire Exits,** as referenced in R 325.51151a. ~~of 29 C.F.R. §1910.38, entitled "Employee emergency plans and fire prevention plans."~~

(4) Where there is the possibility of employee exposure to EtO due to an emergency, **the employer shall develop and use** 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.

R 325.51166. Medical examinations and consultation; frequency and content.

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 **each employee exposed at or above the action level for at least 30 days in the past year.**

(c) At termination **of employment** or reassignment to an area where exposure to EtO is not at or above the action level 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.

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 **licensing and regulatory affairs.** ~~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 **that** ~~which~~ is not otherwise available to the examining physician.

R 325.51168a. Hazard communication.

Rule 18a. (1) **Chemical manufacturers, importers, distributors and employers shall comply with all requirements of the Occupational Health Standard Part 430 "Hazard Communication," as referenced in R 325.51151a, for EtO.**

(2) **In classifying the hazards of EtO, at least all of the following hazards shall be addressed:**

(a) **Cancer.**

(b) **Reproductive effects.**

(c) **Mutagenicity.**

(d) **Central nervous system.**

(e) **Skin sensitization.**

(f) **Skin.**

(g) **Eye and respiratory tract irritation.**

(h) **Acute toxicity effects.**

(i) **Flammability.**

(3) **An employer shall include EtO in the hazard communication program established to comply with the Occupational Health Standard Part 430 "Hazard Communication." An employer 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 R 325.51170 and Occupational Health Standard Part 430 "Hazard Communication," as referenced in R 325.51151a.**

R 325.51169. Signs and **labels.** labeling-

Rule 19. (1) An employer shall post **and maintain legible signs demarcating regulated areas and entrances or access ways to regulated areas that bear the following legend:** ~~the following warning sign in each regulated area and entrances or access ways to regulated areas:~~

**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**

(2) Prior to June 1, 2016, an employer may use the following legend in lieu of that specified in subrule (1) of this rule:

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

(3)~~(2)~~ 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 shall ensure that the labels remain affixed when the containers of EtO leave the workplace. For the purposes of this subrule; reaction vessels, storage tanks, and pipes or piping systems are not considered to be containers. ~~An employer shall assure that signs required by this rule are illuminated and cleaned as necessary to remain legible.~~

(4)~~(3)~~ Prior to June 1, 2015, an employer may include the following information on containers of EtO in lieu of the labeling requirements in subrule (1) of this rule: ~~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. §1910.1200(f) and shall include both of the following statements:

(a)

**DANGER  
CONTAINS ETHYLENE OXIDE  
CANCER HAZARD AND REPRODUCTIVE HAZARD**

(b) A **warning** 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. §136 et seq., when it is labeled pursuant to that ~~act~~ **act** and regulations issued under the **act by the environmental protection agency.** ~~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. §1910.1200(g).~~

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 **Occupational Health Standard Part 470 "Employee Medical Records and Trade Secrets," as referenced in R 325.51151a.** ~~R 325.3451 et seq.~~

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 **Occupational Health Standard Part 470 "Employee Medical Records and Trade Secrets," as referenced in R 325.51151a.** ~~R 325.3451 et seq.~~

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 **Occupational Health Standard Part 470 "Employee Medical Records and Trade Secrets," as referenced in R 325.51151a.** ~~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.

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

Rule 25. ~~(1) The employer shall comply with the requirements concerning transfer of records set forth in Occupational Health Standard Part 470 "Employee Medical Records and Trade Secrets," as referenced R 325.51151a. 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.~~

R 325.51177. **Rescinded.** ~~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.~~