



**Michigan Department of Environmental Quality
Air Quality Division – Permit Section**

**General Permit to Install Applicability Criteria for
Ethylene Oxide (EtO) Sterilizers**

EtO sterilizers are commonly used at hospitals to sterilize and fumigate medical equipment. The general permit to install may be used for multiple EtO sterilizers at a given stationary source.

The following state and federal requirements are applicable to EtO sterilizers and were considered in the development of the general permit to install. These requirements are addressed in the Special Conditions of the permit.

<u>Citation</u>	<u>Description</u>
R 336.1205	State rule that requires a permit to limit the amount of potential emissions.
R 336.1702(1)	State rule that outlines general provisions for new sources of volatile organic compounds. This rule requires Best Available Control Technology (BACT) be applied to control VOC emissions from new sources.
R 336.1225	State rule that applies to sources of air toxics. This rule requires the application of Best Available Control Technology for toxics (T-BACT) to sources emitting air toxics, and requires the emissions from the process meet the allowed impact levels. In the case of EtO sterilizers to be covered by this general permit to install, the use of control technology, which reduces EtO emissions by 99.9%, is necessary to meet the allowed impact levels.
40 CFR 63.365	Federal test method for stack testing for EtO emissions.
40 CFR Part 63, Subpart WWWW	National Emission Standards for Hospital Ethylene Oxide Sterilizers.

The following state and federal requirements have been reviewed and are considered not applicable to EtO sterilizers which may use the general permit to install.

<u>Citation</u>	<u>Description</u>
40 CFR Part 82	Protection of Stratospheric Ozone. This regulation limits the production and consumption of substances that deplete the ozone layer according to specified schedules. Though sterilizers use some of these substances, this requirement does not apply because the source does not meet the applicability criteria.
40 CFR Part 63, Subpart O	Ethylene Oxide Emissions Standards for Sterilization Facilities. All sterilization sources using one or more tons of EtO in sterilization or fumigation operations are subject to emission standards, recordkeeping, compliance and performance testing, and monitoring requirements. The regulation does not apply to sterilization operations covered by this general permit because the source will be limited to using less than one ton of EtO per year. However, the protocol for performance testing specified in this federal regulation is incorporated in this general permit to install.

APPLICABILITY CRITERIA

To qualify for the general permit to install based on the listed applicable requirements; the EtO sterilizers must meet the following criteria:

- The general permit to install shall apply to EtO sterilizers with a capacity not to exceed 30 cubic feet per unit, and associated aeration equipment.

- The general permit to install may be used for multiple EtO sterilizers at a stationary source. A separate Process Information form (EQP5730) must be completed for each sterilizer to be covered by the general permit. Each sterilizer must meet the criteria set forth in this general permit to install and must comply with all terms and conditions of this general permit.
- The sterilization and aeration processes must include an acid-water scrubber or catalytic oxidation unit that is guaranteed by the manufacturer to reduce EtO emissions to the atmosphere by at least 99.9%.
- The combined EtO usage rate for all sterilization processes at the stationary source shall not exceed 6.5 pounds per day, or 141.1 pounds per month.
- The exhaust gases from the process must be discharged unobstructed vertically upwards to the ambient air at an exit point not less than 25 feet above ground level. The discharge must be located a minimum of 25 feet from any window, air intake vent, or any location accessible by the general public.
- The process must use a closed loop recirculating-fluid vacuum pump, an air ejector system, or other method of drawing a vacuum and evacuating the sterilizer chamber that prevents any discharge of EtO to a wastewater stream.
- The sterilant gas must consist of either 100% EtO, or an EtO/inert gas mixture. Acceptable inert gases include 2-chloro-1,1,1,2-tetrafluoroethane (HCFC-124), carbon dioxide, or a hydrochloro-fluorocarbon (HCFC) blend, which includes only toxic air contaminants (TAC) for which the initial threshold screening level (ITSL) as defined in R 336.1109(e) is equal to or greater than 5000 micrograms per cubic meter on a 24 hour average.
- The facility shall have no outstanding unresolved violations of any of the Michigan Department of Environmental Quality Air Pollution Control rules, orders, or permits; or Federal air quality regulations.
- The general permit shall not apply to a source, process, or process equipment that is covered by an existing permit to install pursuant to Rule 201 and is further referenced in an outstanding consent order or consent judgment.

PERMIT CONDITION

Attachment A lists the terms and special conditions of the general permit to install. These terms and conditions include the applicable emission limits; material usage limits; process/operational limits; equipment restrictions; testing, monitoring, and recordkeeping requirements; and stack restrictions which are necessary to ensure that an EtO sterilizer subject to a general permit to install will comply with all state and federal applicable requirements.

**ATTACHMENT A
GENERAL CONDITIONS**

1. The process or process equipment covered by this general permit to install shall not be reconstructed, relocated, or modified unless a Permit to Install pursuant to Rule 201 authorizing such action is issued by the Department, or an application for coverage under a General Permit to Install pursuant to Rule 201a, is submitted to and approved by the Department. For the purpose of a general permit to install, the permittee is defined as any person who owns or operates a process or process equipment at the source for which coverage under the general permit has been granted.
2. Operation of any process or process equipment shall not result in the emission of an air contaminant which causes injurious effects to human health or safety, animal life, plant life of significant economic value, or property, or which causes unreasonable interference with the comfortable enjoyment of life and property. **(R 336.1901)**
3. Operation of this equipment shall not interfere with the attainment or maintenance of the air quality standard for any air contaminant. **(R 336.1207(1)(b))**
4. The permittee shall provide notice of an abnormal condition, start-up, shutdown, or malfunction that results in emissions of a hazardous or toxic air pollutant which continue for more than one hour in excess of any applicable standard or limitation, or emissions of any air contaminant continuing for more than two hours in excess of an applicable standard or limitation, as required in Rule 912, to the Department. The notice shall be provided not later than two business days after start-up, shutdown, or discovery of the abnormal condition or malfunction. Written reports, if required, must be filed with the Department within 10 days after the start-up or shutdown occurred, within 10 days after the abnormal conditions or malfunction has been corrected, or within 30 days of discovery of the abnormal conditions or malfunction, whichever is first. The written reports shall include all of the information required in Rule 912(5).
5. Coverage under this general permit to install does not exempt the permittee from complying with any future regulation, which may be promulgated under Part 55 of 1994 PA 451.
6. Coverage under this general permit to install does not obviate the necessity of obtaining such permits or approvals from other units of government as required by law.
7. The permittee shall notify any public utility of any excavation, tunneling and discharging of explosives or demolition of buildings which may affect said utility's facilities in accordance with Act 53 of the Public Acts of 1974, being sections 460.701 to 460.718 of the Michigan Compiled laws and comply with each of the requirements of that Act.
8. The restrictions and conditions of this general permit to install shall apply to any person or legal entity which now or shall hereafter own or operate the equipment for which coverage under this general permit to install is issued. A written request to the Department for a change in ownership or operational control of the process or process equipment shall be made pursuant to Rule 219.
9. If the installation of the equipment for which coverage under this general permit to install has been issued, has not commenced within, or has been interrupted for, 18 months, then the general permit to install shall become void unless otherwise authorized by the Department as a condition of the permit. Furthermore, the permittee shall notify the Department via the Supervisor, Permit Section, Air Quality Division, Michigan Department of Environmental Quality, P.O. Box 30260, Lansing, Michigan 48909, if it is decided not to pursue the installation or construction of the equipment allowed by this general permit to install. **(R 336.1201(4))**

10. Except as provided in subrules (2) and (3) or unless the special conditions of the general permit to install include an alternate opacity limit established pursuant to subrule (4) of R 336.1301, the permittee shall not cause or permit to be discharged into the outer air from a process or process equipment a visible emission of a density greater than the most stringent of the following. The grading of visible emissions shall be determined in accordance with R 336.1303. **(R 336.1301(1))**
 - a) A six-minute average of 20 percent opacity, except for one six-minute average per hour of not more than 27 percent opacity.
 - b) A visible emission limit specified by an applicable federal new source performance standard.
 - c) A visible emission limit specified as a condition of this general permit to install.
11. Collected air contaminants shall be removed as necessary to maintain the equipment at the required operating efficiency. The collection and disposal of air contaminants shall be performed in a manner so as to minimize the introduction of contaminants to the outer air. Transport of collected air contaminants in Priority I and II areas requires the use of material handling methods specified in R 336.1370(2). **(R 336.1370)**
12. The Department may require the permittee to conduct acceptable performance tests, at the permittee's expense, in accordance with R 336.2001 and R 336.2003, under any of the conditions listed in R 336.2001. **(R 336.2001)**
13. Any required testing protocol shall conform to a format acceptable to the AQD. **(R 336.2003(1))**
14. Any required test results, which must be submitted to the AQD, shall conform to a format acceptable to the AQD. **(R 336.2001(4))**
15. Any air cleaning device shall be installed, maintained, and operated in a satisfactory manner and in accordance with the Michigan Air Pollution Control rules and existing law. **(R 336.1910)**
16. For a stationary source that becomes a major source, as defined by R 336.1211(1)(a), upon receipt of approval for coverage under this general permit to install, an administratively complete application for a renewable operating permit shall be submitted not more than 12 months after the stationary source commences operation as a major source. Commencing operation as a major source occurs upon commencement of trial operation of the new or modified process or process equipment that increased the potential to emit of the stationary source to more than or equal to the applicable major source definition specified in R 336.1211(1)(a).
17. For a stationary source that is already a major source with an existing renewable operating permit, the source shall notify the Department of the installation of the process or process equipment covered by this general permit, pursuant to R 336.1215(3) or apply for a modification pursuant to R 336.1216(2) prior to commencing operation. The notification or application to modify the renewable operating permit shall be made using a form approved by the Department.

ATTACHMENT A SPECIAL CONDITIONS

FLEXIBLE GROUP SUMMARY TABLE

The descriptions provided below are for informational purposes and do not constitute enforceable conditions.

Flexible Group ID	Description - Emission Unit(s) Included in Group
FG-STERILIZERS	One or more ethylene oxide (EtO) sterilizers, with a capacity not to exceed 30 cubic feet per unit, and associated aeration equipment. Each unit shall be controlled by a control device that is guaranteed by the manufacturer to reduce EtO emissions by at least 99.9%.
Changes to the equipment described in this table are subject to the requirements of R 336.1201, except as allowed by R 336.1278 to R 336.1290.	

The following conditions apply to: FG-STERILIZERS

I. EMISSION LIMITS

Pollutant	Limit	Time Period	Equipment	Testing/Monitoring Method	Applicable Requirement
1. EtO	0.006 pph	Hourly	FG-STERILIZERS	SC V.1	R 336.1205, R 336.1225(1)
2. EtO	0.0001 ton/mo (0.141 lb/mo)	Calendar month	FG-STERILIZERS	SC VI.2	R 336.1205, R 336.1225(1)
3. HCFC	62.3 pph	Hourly	FG-STERILIZERS	SC V.1	R 336.1205, R 336.1225(1)
4. HCFC	0.75 ton/mo	Calendar month	FG-STERILIZERS	SC VI.2	R 336.1205, R 336.1225(1)
pph = pound per hour; mo = month; lb = pound HCFC = hydrochlorofluorocarbon					

II. MATERIAL LIMITS

- The permittee shall use a sterilant gas, which consists of 100% EtO or an EtO/inert gas mixture. Acceptable inert gases include 2-chloro-1,1,1,2-tetrafluoroethane (HCFC-124), carbon dioxide (CO₂), or a HCFC blend, which includes only toxic air contaminants for which the initial threshold screening level (ITSL) is equal to or greater than 5000 micrograms per cubic meter on a 24 hour average. **(R 336.1225(1))**
- The permittee shall not use more than 6.5 pounds of EtO per calendar day, or 141.1 pounds of EtO per calendar month in FG-STERILIZERS. **(R 336.1205)**
- The permittee shall not use more than 69.23 pounds of HCFC per calendar day, or 1,500 pounds of HCFC per calendar month in FG-STERILIZERS. **(R 336.1205)**

III. PROCESS/OPERATIONAL RESTRICTIONS

- The permittee shall not operate any sterilizer or aerator associated with FG-STERILIZERS unless the associated control device is installed, maintained and operated properly according to the manufacturer's specifications. Proper operation requires a minimum of 99.9% reduction (by weight) of EtO emissions to the atmosphere. A copy of the manufacturer's specifications for the control device shall be maintained on file. **(R 336.1205, R 336.1225(1), R 336.1910)**

IV. DESIGN/EQUIPMENT PARAMETERS

1. The permittee shall not operate any sterilizer associated with FG-STERILIZERS unless a closed loop recirculating-fluid vacuum pump, an air ejector system, or other method of drawing a vacuum and evacuating the sterilizer chamber is installed, maintained, and operated in a satisfactory manner. This equipment is necessary to prevent the discharge of any EtO to a wastewater stream. **(R 336.1201a(1))**

V. TESTING/SAMPLING

Records shall be maintained on file for a period of five years. **(R 336.1201(3))**

1. Verification and quantification of EtO emission rates from FG-STERILIZERS, and control device efficiency, by testing at owner's expense, in accordance with Department requirements, may be required for continued operation. Refer to 40 CFR 63.365 for test methods and procedures. Within 60 days of notification from the AQD, a complete test plan shall be submitted to the AQD. The final plan must be approved by the AQD prior to testing. Verification of emission rates includes the submittal of a complete report of the test results to the AQD within 60 days following the last date of the test. **(R 336.2001(1), R 336.2001(2), R 336.2001(4), R 336.2003, 40 CFR 63.365)**

VI. MONITORING/RECORDKEEPING

Records shall be maintained on file for a period of five years. **(R 336.1201(3))**

1. The permittee shall monitor an operating parameter of the control device, based on either manufacturer's specifications or a performance test, which assures at least 99.9% reduction of EtO emissions. A copy of the manufacturer's specifications for the control device shall be maintained on file. **(R 336.1225, R 336.1910)**
 - a) For processes controlled by an acid-water scrubber: Measure and record once per week, either the maximum ethylene glycol concentration of the scrubber liquor, or the level of the scrubber liquor in the recirculation tank.
 - b) For processes controlled by a catalytic oxidizer: Continuously monitor the oxidation temperature in the catalyst bed.
2. The permittee shall keep, in a satisfactory manner, separate daily and monthly records of the amount of EtO and any inert gas used in each sterilizer, in pounds per cycle. **(R 336.1205, R 336.1225(1))**
3. The permittee shall calculate the EtO emission rates from FG-STERILIZERS for each month as outlined in Appendix A. **(R 336.1205, R 336.1225(1))**
4. The permittee shall keep the following in a satisfactory manner: records of the date, duration, and description of any malfunction of the control equipment; any maintenance performed; replacement of catalyst or scrubber liquor; and any testing results for FG-STERILIZERS. All records shall be kept on file and made available to the Department upon request. **(R 336.1225, R 336.1910)**

VII. REPORTING Not applicable (N/A)

VIII. STACK/VENT RESTRICTIONS

1. The exhaust gases from FG-STERILIZERS shall be discharged unobstructed vertically upwards to the ambient air at an exit point not less than 25 feet above ground level. The discharge must be located a minimum of 25 feet from any window, air intake vent, or any location accessible by the general public. **(R 336.1225(1))**

IX. OTHER REQUIREMENTS

1. The permittee shall not replace or modify any portion of F-STERILIZERS, including control equipment, nor install new equipment unless all of the following conditions are met: **(R 336.1201)**
 - a) The permittee shall update the general permit by submitting a new Process Information Form (EQP5730) to the Permit Section and District Supervisor, identifying the existing and new equipment a minimum of 10 days before the replacement, modification or installation of new equipment.
 - b) The permittee shall continue to meet all general permit to install applicability criteria after the replacement, modification or installation of new equipment is complete.
 - c) The permittee shall keep records of the date and description of the replacement, modification or installation of new equipment. All records shall be kept on file for a period of at least five years and made available to the Department upon request.
2. The permittee shall comply with all applicable provisions of the National Emission Standards for Hazardous Air Pollutants, as specified in 40 CFR Part 63, Subpart A and Subpart WWWW for Hospital Ethylene Oxide Sterilizers by the initial compliance date. **(40 CFR Part 63, Subpart A and Subpart WWWW)**

Permittee (Source Name) _____
General Permit to Install Number _____

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