

INFORMATION FOR TECHNICAL REVIEW – ETHYLENE OXIDE STERILIZERS

Guidance for Permit Applicants

The following information will be used for the technical review of a Permit to Install application for an **ethylene oxide sterilizer**. This information is in addition to the general requirements outlined in the AQD document “Information for an Administratively Complete Permit to Install Application,” Part 2 - Additional Supporting Information, Items A through F. Please note that all the information may not be needed for each application, nor is this document necessarily all inclusive. Additional information beyond what is identified in this guidance may be necessary to complete the technical review of any individual application. In the event a determination is made that new additional information is needed for all technical reviews, this document will be updated.

All referenced guidance documents are available on the Air Quality Division (AQD) website at [AQD Permits to Install / New Source Review](#) or you may contact the Permit Section at 517-284-6802.

A. Process Description

Provide the following:

1. The type of sterilizer, including make and model.
2. The chamber size in cubic feet.
3. The amount of ethylene oxide (EtO), and any other carrier gases or sterilants (i.e., carbon dioxide, Freon, HCFCs) which will be used for each sterilizing load.
4. The length of time, in minutes, for each cycle of a load (i.e., charging, holding evacuation).
5. The maximum operating schedule for the sterilizer, in hours per day and days per year.
6. A description of the vacuum pump used. A closed-loop recirculating fluid vacuum pump or other method of drawing a vacuum, which prevents any discharge of EtO to a wastewater stream, should be used in conjunction with the air pollution control device. The EtO should be exhausted through the vacuum pump and then discharged through the control device.

B. Regulatory Discussion

The following state air pollution control regulations may be applicable. Please review these regulations carefully to determine if they apply to your process and summarize the results in the application. The [Air Pollution Control Rules](#) may be viewed from the [AQD website](#). Click on “State Air Laws and Rules.”

1. State of Michigan, Department of Environment, Great Lakes, and Energy, Act 451 of 1994, Natural Resources and Environmental Protection Act, Part 55 Air Pollution Control and the following promulgated rules:
 - a) Rules 215 and 216 apply to an existing facility which has a current Renewable Operating Permit (ROP). A Permit to Install issued for the installation of new equipment or modifications to existing equipment is incorporated into an ROP pursuant to Rules 215 and 216.
 - b) If the process or equipment was installed or modified after April 17, 1992, Rules 224 – 230 apply. Rule 224 requires the application of Best Available Control Technology for toxics (T-BACT) for all non-volatile organic compound (VOC) toxic air contaminants (TACs). T-BACT does not apply to emissions of VOCs. Rule 225 limits the emission impacts of TACs and requires a demonstration that the proposed emission of each TAC complies with a health-based screening level. Compliance can be demonstrated using any of three methods described in Rule 227(1) including the use of computerized dispersion modeling. Refer to “Guidelines for Conducting a Rule 224 T-BACT Analysis,” “TACs-Demonstrating Compliance with Rule 225,” and “Dispersion Modeling Guidance” for additional detailed information.

- c) If the process or equipment was installed or modified after August 1, 1979, Rule 702 applies. This rule requires Best Available Control Technology (BACT) for new sources of VOCs. Refer to “Instructions for Conducting a BACT Analysis” for additional detailed information.
 - d) Rule 901 prohibits emissions of an air contaminant in quantities that cause either a) injurious effects to human health or safety, animal life, plant life of significant economic value, or property; or b) unreasonable interference with the comfortable enjoyment of life and property.
2. National Emission Standards for Hazardous Air Pollutants for Source Categories (NESHAP), 40 CFR Part 63, Subpart O, Ethylene Oxide Emissions Standards for Sterilization Facilities. The regulation is available on the United States Environmental Protection Agency (USEPA) Website at [Ethylene Oxide Sterilizer NESHAP](#). Additionally, there is a separate NESHAP for Hospital Ethylene Oxide Sterilizers which can be found at [Hospital Ethylene Oxide Sterilizer NESHAP](#). These regulations should be consulted carefully to determine applicability to your process.

C. Control Technology Analysis

1. Provide a description of the emission control device, the emission reduction efficiency for each pollutant, and the basis for the claimed efficiency.
2. Indicate whether a bypass of the collection system is provided. If a bypass exists, include a complete description of the circumstances and duration for which the process would operate in the bypass mode.
3. Rule 702 BACT applies to all sources of VOCs proposed to be installed within the State of Michigan. A Rule 702 BACT analysis is very similar to a PSD top-down BACT analysis. Michigan’s air pollution control rules also define BACT as an emission limit. Rule 702 BACT should be applied on a flexible grouping of equipment – subdivisions of emission units and/or groupings of emission units – if it is logical to do so. Logical means that the principles on which the groupings (or subdivisions) are made are consistent with federal guidance and sound engineering practices. Refer to “Instructions for Conducting a BACT Analysis” for additional detailed information.
4. Best Available Control Technology for Toxics (T-BACT) means the maximum degree of emission reduction which the Department determines is reasonably achievable for each process that emits toxic air contaminants (TACs) considering energy, environmental and economic impacts, and other costs. T-BACT does not apply to VOCs. The analysis must be specific to the process and the TACs subject to a T-BACT review. T-BACT limits can be expressed as an emission limit, control equipment requirements, and/or work practice standards. Refer to “Guidelines for Conducting a Rule 224 T-BACT Analysis” for additional detailed information.
5. Lowest achievable emission rate (LAER) applies to a major source and/or a major modification at a source located in a nonattainment area. Please see the [Attainment Status Map](#) on the [AQD website](#) for the current nonattainment status in Michigan. LAER is defined as the lowest emission limitation contained in any State Implementation Plan (SIP) or the lowest emission limitation achieved in practice. Such an emission limit is presumed to be LAER for that source class and category. If an applicant proposes to meet this presumptive LAER, no site-specific control technology determination will be necessary. When an applicant believes the presumptive LAER limit is not achievable, a site-specific determination is required. This determination should include consideration of raw material changes, process changes, and add-on control equipment. The cost of these changes is not considered. Raw material and process changes should be evaluated through technology transfer (i.e., the likelihood that such a change will transfer from one industry to another), based on the manufacture of similar products or use of similar raw materials or fuels. Add-on controls should be evaluated based on the physical and chemical characteristics of the pollutant-bearing exhaust stream.

D. Site Description and Process Equipment Location Drawings

Provide a scaled plot plan of the site, showing building locations and dimensions (width, length and height); stack location, diameter and height; distances to all property lines; locations of all air intakes and windows within 25 feet and all structures within 150 feet.

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