State of the Art (SOTA)
Manual for Commercial Sterilizers and Fumigators using Ethylene Oxide

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State of New Jersey
Department of Environmental Protection
Air Quality Permitting Program

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Section 3.8

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3.8.i TABLES

3.8.ii Abbreviations

BACT	Best Achievable Control Technology
BID	Background Information Document
CFR	Code of Federal Regulations
GACT	Generally Available Control Technology
HAPS	Hazardous Air Pollutants
MACT	Maximum Achievable Control Technology
NESHAP	National Emission Standard for Hazardous Air Pollutant
N.J.A.C.	New Jersey Administrative Code
NSPS	New Source Performance Standards
RACT	Reasonably Available Control Technology
SOTA	State of the Art
USEPA	United States Environmental Protection Agency
VOC	Volatile Organic Compounds

3.8 SOTA MANUAL FOR COMMERCIAL STERILIZERS AND FUMIGATORS USING ETHYLENE OXIDE

3.8.1 Scope

The state of the art (SOTA) performance levels outlined below apply to newly constructed and reconstructed commercial sterilization/fumigation sources using ethylene oxide in sterilization or fumigation operations, with annual ethylene oxide usage of greater than or equal to 1 ton per year. The performance levels specify emission rates and control technologies applicable to each class of sterilizers based on annual ethylene oxide usage. Emission levels and control technologies are specified for sterilizer sterilization chamber vents, aeration room vents and chamber exhaust vents.

Sterilizers using ethylene oxide are subject to the New Jersey Air Pollution Control Regulations codified at N.J.A.C. 7:27-1 et seq. and Federal requirements at 40 CFR Part 63, Subpart A (General Provisions) and Subpart O (National Emission Standards for Hazardous Air Pollutants - Ethylene Oxide Emissions From Commercial Sterilization/fumigation Operations).

3.8.2 SOTA Performance Levels

As specified in at N.J.A.C. 7:27-22, for sources for which there is a promulgated MACT standard, SOTA equals MACT. This manual presents a summary of the standards included in the MACT for ethylene oxide emissions from commercial sterilization/fumigation operations (40 CFR Part 63, Subpart O). If there are any conflict between this manual and the MACT standard, the actual MACT standard applies. The following table represents the state of the art ethylene oxide emission levels and/or control efficiency levels for commercial sterilizers and fumigators as outlined in the MACT.

In reviewing permit applications for these sources, the applicant must also address health risk concerns. Should the health risk assessment indicate that there are unacceptable risks associated with ethylene oxide emissions which meet the SOTA standard, the Department may require control devices or control efficiencies which are more stringent than the SOTA standard to address these risks.

Table 1. SOTA Standards for Ethylene Oxide Commercial Sterilizers and Fumigators

Sources Type	Source Size[1]	Sterilization Chamber Vent[2]	Aeration Room Vent[3]	Chamber Exhaust Vent[4]
Existing and New Sources	<1 ton	No controls required[5]	No controls required[5]	No controls required[5]
	≥ 1 ton and ≤ 10 tons	99% emission reduction	No control[5]	Maximum chamber concentration limit of 5,300 ppm prior to activation of the chamber exhaust[6]

Table 1. SOTA Standards for Ethylene Oxide Commercial Sterilizers and Fumigators

Sources Type	Source Size[1]	Sterilization Chamber Vent[2]	Aeration Room Vent[3]	Chamber Exhaust Vent[4]
	$\geq$ 10 tons	99% emission reduction	1 ppm maximum outlet concentration or 99% emission reduction	Manifold to a control device used to comply with 40 CFR Part 63.362 (c) or (d) or 99% emission reduction

[1] Based on ethylene oxide use within any consecutive 12-month period.
[2] The vent on the sterilization chamber vacuum pump gas/liquid separator.
[3] The vent on the aeration room ventilation system.
[4] The vent on the exhaust system that evacuates the sterilization chamber prior to unloading.
[5] Additional measures such as increased stack height, controls, etc. may be required to address unacceptable health risks associated with uncontrolled emissions. Refer to Section 3.8.2 of this manual.
[6] Affected sources may show compliance by manifolding emissions to control device used to comply with 40 CFR Part 63.362(c) or (d) by reducing emissions by at least 99%.

3.8.3 Technical Basis

3.8.3.1 Number of Approved Permits Evaluated and the Covered Period

During the covered period of 1994 through 1995, the Department issued four (4) permits for ethylene oxide sterilization operations. Section 3.8.3.2 of this manual lists the typical information extracted from these permits, permitted allowable ethylene oxide emissions and control efficiencies. In addition, numerous other permitted sources nationwide were evaluated by the USEPA when developing the MACT for these sources.

3.8.3.2 Typical Information Extracted from Approved Permit Review

The following table represents information from typical permits issued by the Department for commercial ethylene oxide sterilization operations.

Table 2. Approved Permit Information Summary

Source Type	Control Device for Sterilizers	Efficiency, (%) 1 hour average
Sterilization Chambers (2), Aeration Room (1)	Catalytic Oxidizer	99.8
Sterilization Chambers (4)	Sparging Tanks (2), Packed Tower	99.9
Main sterilizers (2), degassing ovens (5)	Scrubber: H2SO4 solution (>5 wt%, pH<3, <60 wt% ethylene oxide in solution)	99.0
Research sterilizer	Scrubber: H2SO4 solution (>5 wt%, pH<3, <60 wt% ethylene oxide in solution)	99.0

NOTE: As listed in the above table, the Department has issued permits for ethylene oxide

sterilization operations which include required control efficiencies greater than the standard specified in Section 3.9.2 of this manual. These control efficiencies reflect the level of control needed to address health risk concerns and are thus greater than the SOTA standard.

3.8.3.3 Basis for Recommended Guidance

The basis for developing this guidance was the information contained in the Background Information Document (BID) prepared by the USEPA for the proposed standards set forth at 40 CFR Part 63 Subpart O. This document was developed upon review and analysis of numerous technical references on the subject of ethylene oxide emissions from commercial sterilization/fumigation operations, the USEPA developed industrial source and control technology databases, cost and economic analyses, and current State and Federal regulations. The BID contains all references used by the USEPA to develop the BID. The MACT standards and the BID can be accessed through the USEPA's Technology Transfer Network (TTN) computer bulletin board at (919) 514-5742.

The bulk sterilization processes can be broken into four (4) principal sources of emissions of ethylene oxide: the sterilizer vent(s); the sterilization chamber vacuum pump drain; the chamber exhaust vent; and the aeration room vent. The following technologies have been determined as being capable of meeting the SOTA emission/control efficiencies for commercial sterilization/fumigation specified in Section 3.8.3 of this manual. Other techniques which assist in the control of low ethylene oxide emissions from these sources are also presented in this section.

Table 3. Summary of USEPA Control Technology Database

Emission Control Technique and Device	Control Efficiency (Percent)	No. of Facilities	No. of Chambers	Cumulative Chamber Size (ft^3)	EO Usage per Facility (lb/yr)
Hydrolysis					
Packed Scrubber	99.0	21	78	350 - 9,900	1,800 - 180,000
Reaction/detoxification Tower	99.0	7	15	300 - 1,600	5,000 - 110,000
Oxidation					
Catalytic Oxidizer	99.0	2	2	130 - 660	1,000 - 15,000
Solid-Phase System					
Gas/Solid Reactor	99.0	** None in Database **			

3.8.4 Control Technologies

Control Technologies for Sterilizer Vent Emissions

A. Packed Scrubber
B. Reaction/detoxification Tower
C. Catalytic Oxidizer
D. Gas/solid Reactor

Control Technologies for Sterilization Chamber Vacuum Pump Drain

Replacement of existing once-through vacuum pumps with closed-loop (recirculating-fluid) vacuum pumps. The recirculating fluid can be water, oil or ethylene glycol.

Control Technologies for Chamber Exhaust Vents

A. Acid-water Scrubber
B. Catalytic Oxidizer
C. Gas/solid Reactor

Control Technologies for Aeration Room Vents

Recirculation of the aeration room air through an emission control device and back to the aeration room. Catalytic oxidation and the gas/solid reactor control devices are applicable for this alternative. Hydrolysis, thermal oxidation and condensation/reclamation are not applicable control techniques because ethylene oxide concentrations are too low (<20 ppmv) for these techniques to be practicable. However, newer control systems allow for more dilute streams (1-20 ppmv) to be mixed with higher concentration streams to allow the control of these dilute streams.

Replacement of the large warehouse-type aeration rooms with smaller (2,500 ft^3 or less), heated aeration chambers with control of the emissions from the chambers using technologies described above (Control Technologies for Sterilizer Vent Emissions).

Modification of the evacuation/air wash phase of the sterilization cycle to reduce residual ethylene oxide in the product by performing additional sterilization chamber purges.

Control Technologies for Aeration Cabinets

When small (<40 ft^3) aeration cabinets are used instead of aeration rooms, catalytic oxidation and the gas/solid reactor are applicable to control ethylene oxide emissions from these cabinets.

3.8.5 Recommended Review Schedule

The next scheduled date for review of this manual will be as warranted due to changes in the promulgated MACT, or five (5) years from the date of this manual, whichever is first.