APPENDIX 112H

ETHYLENE OXIDE COMMERCIAL STERILIZATION AND FUMIGATION OPERATIONS NESHAP (40 CFR 63 Subpart O)

CAA SECTION 112 NESHAP

REGULATION STATUS

EPA issued the NESHAP for Commercial Sterilization and Fumigation Facilities on 06 Dec 94 (59 FR 62585). Subsequent corrections and amendments are reflected in the latest version of the Code of Federal Regulations, Volume 40, Part 63, Subpart O and are also listed in Appendix 112B.

RULE SUMMARY

Applicability

Presently this NESHAP applies to all sterilization facilities (both major and area HAP sources) that use ethylene oxide (EO) in sterilization or fumigation operations except for the following exempt operations:

- Beehive fumigators.
- Research or laboratory facilities whose primary purpose is to conduct research and development of new processes and products, where such facilities are operated under the close supervision of technically trained personnel and are not engaged in the manufacture of products for commercial sale in commerce, except in a de-minimis manner.
- Stationary sources such as hospitals, doctors' offices, clinics, or other facilities that exist to provide medical services to humans or animals.

Important! EPA may expand the applicability of this NESHAP to affect medical facility sterilizers in order to meet the CAA §112(k) requirements for urban area sources. EPA's Draft Urban Air Toxics Strategy identified Hospital Sterilizers on the urban area source category list. Refer to Appendix C for more information on the Urban Air Toxics Strategy.

Key Definitions

Aeration room means any vessel or room that is used to facilitate off-gassing of ethylene oxide at a sterilization facility.

Aeration room vent means the point(s) through which the evacuation of ethylene oxide-laden air from an aeration room occurs.

Chamber exhaust vent means the point(s) through which ethylene oxide-laden air is removed from the sterilization chamber during chamber unloading following the completion of sterilization and associated air washes.

Manifolding emissions means combining ethylene oxide emissions from two or more different vent types for the purpose of controlling these emissions with a single control device.

Sterilization chamber means any enclosed vessel or room that is filled with ethylene oxide gas, or an ethylene oxide/inert gas mixture, for the purpose of sterilizing and/or fumigating at a sterilization facility.

Sterilization chamber vent means the point (prior to the vacuum pump) through which the evacuation of ethylene oxide from the sterilization chamber occurs following sterilization or fumigation, including any subsequent air washes.

Sterilization facility means any stationary source where ethylene oxide is used in the sterilization or fumigation of materials.

Standards

Table 1 shows the emission standards.

This appendix does not contain a detailed overview of the NESHAP requirements since we are not aware of any affected military sterilization operations. For more information, refer to EPA's Unified Air Toxics Website page for this rule at http://www.epa.gov/ttn/uatw/eo/eopg.html. The EPA Implementation Guide which can be viewed on this website contains a comprehensive summary of the NESHAP requirements.

Table 1: Standards for Ethylene Oxide Commercial Sterilizers/Fumigators

Existing and New Sources			
Source Size (EO use)*	Sterilization Chamber Vent	Aeration Room Vent	Chamber Exhaust Vent
<1 ton	No controls required; minimal recordkeeping requirements apply.		
≥1 ton and <10 tons	99% emission reduction	no control	5,300 ppm maximum chamber concentration prior to activation of the chamber exhaust
≥10 tons	99% emission reduction	1 ppm maximum outlet concentration or 99% emission reduction	Manifold or 99% emission reduction

*Ethylene oxide use applies to all consecutive 12-month periods after 06 Dec 96.

Compliance Deadlines

The compliance deadline for all affected sources (new and existing) is 06 Dec 97 or upon startup, whichever is later. This is unique. Most NESHAPs require all sources installed after the promulgation date to comply immediately upon startup. According to this rule, no source need comply until 06 Dec 97.

MILITARY SOURCES

Commercial Sterilizers (Non-medical)

The HAP Subcommittee is not aware of any nonmedical military EO sterilization or fumigation facilities. Therefore, presently this rule should not affect the military.

Medical Facility Sterilizers

The military does have numerous medical facility sterilizers. Although this rule does not presently affect medical facility sterilizers, it is inevitable that these type of units will be covered in the future. EPA was reluctant to exempt medical facility units in the final rule. The preamble of this final rule states, *"Section 112(c) specifies that the source category list will periodically be revised, and hospitals (with EO emissions greater than 1 ton/yr) may be added to the source category list at a future date. Hospital sterilization sources (under 1 ton/yr ethylene oxide emissions) will likely be assessed as part of § 112(k) of the Act."*

EPA has already identified hospital sterilizers on their list of area source categories to be regulated under their Integrated Urban Air Toxics Strategy. (Appendix C)

Some states already regulate medical facility sterilizers. For example, California SCAQMD Rule 1405 requires 99%+ ethylene oxide control efficiency for medical facility sterilizers. Other states regulate ethylene oxide based on ambient air quality standards, but do not have source-specific sterilizer standards.

Medical facilities should plan for the cost to control EO emissions on their existing units or implement alternative sterilization processes. A project to install controls on a 6 ft. x 4 ft. x 4 ft. EO sterilizer at a Navy facility in California reportedly cost $160,000. The earliest EPA would issue a national regulation for area source hospital sterilizers is 2002 but could be as late as 2006. Facilities will be given from 1 to 3 years after the rule is issued to comply.

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