



June 26, 2023

U.S. Environmental Protection Agency
EPA Docket Center, Docket ID No. EPA-HQ-OAR-2019-0178
Mail code: 28221T
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Attention: Docket No. EPA-HQ-OAR-2019-0178

Re: National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review 88 FR 22790 (April 13, 2023)

To Whom It May Concern:

The Pennsylvania Department of Environmental Protection (DEP, Department) appreciates the opportunity to provide comments on the United States Environmental Protection Agency (EPA) proposed amendments to the National Emission Standards for Hazardous Air Pollutants (NESHAP) for the Commercial Sterilization Facilities source category.

DEP believes that the current requirement to conduct initial performance testing within 180 days of the compliance date for an emission source is appropriate. A performance test is equipment intensive and time consuming to arrange and perform. It may not be possible for an owner or operator to contract a company to perform a stack test within a timeframe less than 180 days.

DEP agrees with EPA that it is not appropriate to exempt area source ethylene oxide (EtO) commercial sterilizers from the requirement to obtain a Title V permit under section 502(a). The owner or operator of any sterilization facility subject to Subpart O should obtain a Title V permit. Area MACT sources, including EtO commercial sterilizers, were previously deferred from permitting. This deferral ended December 9, 2004. Since then, these facilities were required to have operating permits. Facilities that have Title V permits tend to be inspected on a more frequent basis than those with state-only operating permits. Additionally, Title V permits include more intensive monitoring, recordkeeping, and reporting requirements, which are warranted for EtO commercial sterilizer facilities.

There are three facilities in Pennsylvania that would be subject to the proposed rulemaking. Two of them currently have state-only operating permits and one has a plan approval whose conditions will be incorporated into a new operating permit. DEP believes that the owners and operators of these facilities should obtain Title V permits.

EPA is proposing different emission limitations based on the format of the standard (i.e., removal efficiency or emission rate) with which the facility is complying. If complying with a removal efficiency standard, EPA is proposing that the facility must comply with the removal

efficiency standard for the emission source in the composite stream that has the most stringent removal efficiency. If complying with an emission rate standard, EPA is proposing that the facility must comply with an emission rate standard that is equal to the sum of the emission rate standards for each emission source type in the composite stream. DEP agrees with EPA's proposed standards for composite emissions streams because these standards provide flexibility for the owners and operators to comply with the standards based on the best approach for their facility, and the standards are equally protective to the standards for individual emissions streams. The option chosen by the owner or operator would be memorialized in the operating permit.

In addition, EPA is proposing an expedited timeline for regulated sterilization facilities to meet the new emission and operating requirements. If finalized as proposed, sterilizer facilities would be required to install pollution controls within 18 months of issuance of the final rule. DEP agrees with EPA's proposed compliance timeline of 18 months. The three facilities in Pennsylvania that are expected to be subject to the proposed rule have already installed additional EtO controls although not required by the current regulation, 40 CFR 63 Subpart O.

Additionally, DEP agrees with the proposed standards for sterilization chamber vents, aeration room vents, chamber exhaust vents, and two types of room air emissions (Group 1, consisting of pre-aeration emissions from EtO storage, dispensing, vacuum pump operations, and handling of sterilized material, and Group 2, consisting of post-aeration handling of sterilized material). The owners and operators of the three facilities in Pennsylvania that are expected to be subject to the proposed rule have already installed additional or replacement EtO controls. These controls should be in compliance with the proposed EtO standards.

Below are the controls that are installed by the three facilities in Pennsylvania:

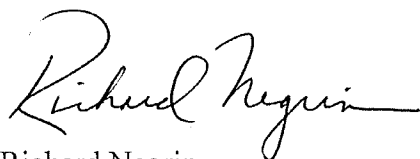
B. Braun: Prior to 2019, EtO emissions from the sterilization chambers and aeration room were controlled by a catalytic oxidizer and scrubber as required by regulation. These controls reduced EtO emissions by 99% or below 1ppm. However, the EtO emissions from the sterilizer back vents are not currently required to be controlled. However, in 2019, B. Braun voluntarily installed a dry bed scrubber to significantly reduce back vent EtO emissions by 99%. Furthermore, in 2020, B. Braun voluntarily replaced its existing catalytic oxidizer and scrubber controls with a new, more efficient upgraded catalytic oxidizer which has demonstrated an EtO destruction efficiency of 99.98%.

American Contract Systems, Inc. (ACS): Although not required by regulation, ACS voluntarily installed dry sorbent EtO controls with a 99% control efficiency that meets the 40 CFR 63 Subpart O control requirement for larger sources using 1-10 tons/year EtO. The plan approval includes the EtO usage limitation of 1,500 lbs. (0.75 tons) per consecutive 12-month rolling total. Post-control EtO (VOC/HAP) potential to emit is estimated as 15 lb/yr on a consecutive 12-month rolling total. The installation and operation of the dry sorbent beds reduces the potential threat to public health, welfare, and the environment from the EtO emissions from the facility. The voluntary installation of EtO controls on this minor source ensures that EtO emissions are minimized in the area.

Cosmed Group, Inc. (Cosmed): Cosmed has installed two new dry bed adsorber emission control devices which will control EtO emissions from the sterilizer chamber back exhaust vents. Ethylene oxide emitted from the existing four sterilizers' main vents is currently controlled by a wet scrubber control device.

DEP appreciates the opportunity to provide comments on EPA's proposal for National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review. Should you have questions or need additional information, please contact Mark Hammond, Director of the Bureau of Air Quality, by e-mail at mahammond@pa.gov.

Sincerely,

A handwritten signature in black ink that reads "Richard Negrin". The signature is written in a cursive style with a long horizontal flourish at the end.

Richard Negrin
Acting Secretary