pennsylvania
DEPARTMENT OF ENVIRONMENTAL PROTECTION

February 10, 2020

Mr. Andrew R. Wheeler
Administrator
U.S. Environmental Protection Agency
Air and Radiation Docket and Information Center Mail code: 28221T
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Attn: Docket No. EPA–HQ–OAR–2019–0178

Re: Advance Notice of Proposed Rulemaking for National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Commercial Sterilization and Fumigation Operations 84 FR 67889 (December 12, 2019)

Dear Administrator Wheeler:

The Pennsylvania Department of Environmental Protection (DEP) appreciates the opportunity to provide comments on the United States Environmental Protection Agency's (EPA) advance notice of proposed rulemaking (ANPRM) for National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Commercial Sterilization and Fumigation Operations.

The EPA is soliciting information that will aid in potential future revisions to the Ethylene Oxide Emission Standards for Sterilization Facilities. More specifically, the EPA is soliciting information and requesting comment on potential control measures for reducing ethylene oxide (EtO) emissions from commercial sterilization facilities.

General

Pennsylvania has a facility, B. Braun Medical Inc. (B. Braun), which operates a medical instrument apparatus manufacturing and sterilization facility located in Allentown. At B. Braun, EtO emissions from eight existing sterilization units are currently controlled by an existing, permitted wet scrubber Deoxx unit, and EtO emissions from the aeration room are currently controlled by a catalytic oxidizer. Additionally, B. Braun has installed a dry bed unit control device for EtO emissions from the sterilization unit back vents. The dry bed unit is an additional, voluntary EtO control device that may further reduce actual EtO emissions. The dry bed unit is stated to achieve greater than 99 percent emissions reduction, which is expected to be confirmed through future stack testing. For reference, please see the Process Flow Diagram, on page 2-3, in B. Braun's attached plan approval (operating permit) application.

B. Braun submitted a plan approval application in November 2019, to replace the existing wet scrubber Deoxx unit and catalytic oxidizer with the Anguil System. Based on information provided by Anguil, the Anguil System is expected to achieve a 99.9 percent emissions destruction or, for a lower concentration inlet stream, an exhaust concentration below 1 part per million by volume (ppmv). The Anguil System consists of a peak shaver and catalytic oxidizer. The peak shaver works to normalize the concentration of EtO sent to the catalytic oxidizer. The

peak shaver recirculates water from a holding tank over a packed scrubber bed. The sterilizer exhaust runs countercurrent to the water and the EtO will be absorbed into the water. After the sterilization cycle is finished, the EtO is stripped from the water via a fresh air source at a controlled rate and directed to the catalytic oxidizer. In the exhaust stream to the catalytic oxidizer, the peak shaver exhaust would mix with aeration room air in the interconnecting ductwork. B. Braun will determine the specific emissions control efficiency via stack testing upon installation. For additional information, please see the attached plan approval application. DEP issued B. Braun a State Only Operating Permit on January 21, 2020.

EPA Request C–1

In order to ensure the accuracy of the data that could be used for any future rulemaking for this source category, the EPA is soliciting comment on available EtO usage data for individual facilities and on additional data contained in the modeling file that the EPA intends to use to evaluate the impacts of EtO emissions. EPA has indicated that the modeling files are available at website.

DEP's Comment to C–1: DEP is interested in reviewing the aforementioned modeling files for the two commercial sterilization facilities located in Pennsylvania. However, the modeling files cannot be found, and DEP recommends that these files should be included in the docket.

EPA Request C–2a, C–2b, C–2c

The EPA is requesting comment on the use of an emission factor of 0.5 percent of EtO usage for the calculation of fugitive emissions from this source category.

DEP's Comments on C–2a, C–2b, C–2c: DEP does not agree with using an emission factor of 0.5 percent of the EtO usage to calculate fugitive emissions as an industrywide practice. Using a fixed emission factor does not work for all facilities because each facility is designed and built differently. In other words, one size does not fit all when estimating fugitive emissions from sterilization facilities.

EPA Request C–7

The EPA is aware that emissions may occur from water that comes into contact with EtO during the sterilization process. Potential emissions may come from, but are not limited to, disposal of water used in once-through liquid-ring vacuum pumps, as well as water used in recovering EtO for re-use in sterilization. The EPA solicits comment on the circumstances in which EtO may come into contact with water within commercial sterilization facilities; the frequency with which such water is or should be disposed; methods of disposal; any operational practices that are or may be used to mitigate emissions from waste water; the feasibility of implementing such operational practices; and costs associated with disposal and with specific operational practices, the time required to implement wastewater EtO emissions reductions; the number of facilities currently implementing wastewater EtO emissions reductions; and the extent to which aspects of wastewater EtO emissions reductions might differ for small business facilities.

DEP's Comment on C–7: B. Braun operates an elementary neutralization unit (ENU) under a Permit by Rule in accordance with the federally authorized Commonwealth of Pennsylvania Hazardous Waste Regulations. The ENU consists of a 3,000-gallon above ground storage tank, two towers, and a reaction tank. The unit is completely enclosed with cinder block walls on three sides, an approximately 1.5 feet tall concrete curb on the forth side, and a concrete floor.

The ENU began operation in 1985 and is used to neutralize ethylene glycol process wastewater generated by the facility's closed-loop ethylene oxide sterilization emissions control system (i.e., Deoxx wet scrubber system). Prior to neutralization using sodium hydroxide, the facility's ethylene glycol process wastewater is hazardous for the characteristic of corrosivity. Following neutralization, the facility's process wastewater is shipped off-site to be reused in the manufacture of antifreeze.

Conclusion

DEP appreciates the opportunity to provide comments and technical information for EPA's ANPRM for National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Commercial Sterilization and Fumigation Operations. If you have any questions or comments, please contact Mr. Viren Trivedi, Acting Director of the Bureau of Air Quality, by e-mail at vtrivedi@pa.gov or by telephone at 717.783.9476.

Sincerely,

Patrick McDonnell
Secretary

Attachment: B. Braun's Sterilization Control Device Plan Approval Application