

June 27, 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

RE: National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review, Docket #EPA-HQ-OAR-2019-0178

Submitted electronically via www.regulations.gov

The American College of Cardiology, the Heart Rhythm Society, the Society for Cardiovascular Angiography & Interventions, the Society of Interventional Radiology, and the Society of Thoracic Surgeons appreciate the opportunity to provide feedback to the Environmental Protection Agency (EPA) on the proposed rule for the National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide (EtO) Emissions Standards for Sterilization Facilities Residual Risk and Technology Review.

The undersigned medical organizations support efforts to minimize employee and community risk as well as reduce the environmental impact of sterilants through the minimization of emissions and exposure to EtO. However, as the Food and Drug Administration (FDA) has previously acknowledged, many complex medical devices, including but not limited to pacemakers and leads, angioplasty balloons, cardiac catheters, stents, and guiding sheaths, and other supplies and equipment used in the care of cardiovascular patients currently rely upon EtO for proper sterilization to ensure patient safety. Currently, these complex medical devices have limited alternative sterilization processes available while others are suboptimal.

We are concerned that the proposed rule as written could result in significant disruptions to the medical supply chain and our ability to care for our patients. We urge the EPA to work closely with the FDA and relevant stakeholders to implement updated national standards to reduce EtO emissions that provide sufficient time and flexibility for sterilization facilities to comply in order to ensure continued patient access to critical devices.

The undersigned organizations thank the EPA for the opportunity to submit comments on the proposed rule on national emission standards for EtO. We support efforts to reduce community risk through the minimization of emissions and exposure to EtO. At the same time, it is crucial that the supply chain of critical medical devices and patient care are not put at risk. Please direct any questions or concerns to Amanda Stirling, Regulatory Affairs Associate, at (202) 375-6553 or astirling@acc.org.

Sincerely,

B. Hadley Wilson, MD, FACC
President, American College of Cardiology



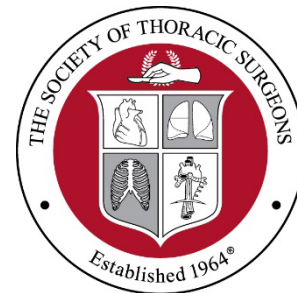
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