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Society of Interventional Radiology
The vision to heal

June 19, 2023

Mr. Michael S. Regan
Administrator
U.S. Environmental Protection Agency
EPA Docket Center
Mail Code 28221T
1200 Pennsylvania Avenue NW
Washington, DC 20460

RE: Docket ID No. EPA–HQ–OAR–2013– 0244- 0044

Dear Administrator Regan:

The Society of Interventional Radiology (SIR) is a professional medical association representing approximately 8,000 members, including most US physicians practicing in the specialty of vascular and interventional radiology. The Society is dedicated to improving public health through pioneering advances in minimally invasive, image-guided therapies.

SIR applauds the efforts of the EPA to address the unintended consequences of sterilization of medical devices with ethylene oxide (EtO). SIR endorses all efforts to minimize employee risk and to reduce the environmental impact of disinfectants 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 pacemakers and leads, angioplasty balloons, cardiac catheters, stents, guiding sheaths, and other supplies and equipment used in the care of our patients currently rely upon EtO for proper sterilization to ensure patient safety. These complex medical devices currently have limited alternative sterilization processes available while others are suboptimal. Therefore, when considering the overall impact of regulatory changes, we urge the Agency to ensure continued patient access to critical devices used by our interventional radiologists.

We acknowledge the complexity and cost that comes with replacing any sterilization process. Given that the FDA mandates that medical device approval applications for these complex devices contain appropriate data to support the required sterilization process, any change would require an appropriate period to develop the necessary protocols, test those protocols,

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then replicate them throughout various supply chains with an acknowledgment that these additional steps are likely to increase costs to our patients.

Thank you again for your pursuit of increased safety for the workers and neighbors living near sterilization facilities using EtO. We recognize that this is a vital public health safety concern, and we fully support this shared goal. However, we urge caution in considering the limitations of the use of EtO for medical device sterilization until there is a feasible action plan in place to ensure appropriate patient access to critical medical devices.

We appreciate your attention to the concerns of the Society of Interventional Radiology. Should you have any questions on any of the above comments, please do not hesitate to contact Judi Buckalew, Director of Government Affairs at jbuckalew@sirweb.org or (202)253-4183.

Sincerely,

Alda L. Tam, MD, MBA, FSIR
President, Society of Interventional Radiology

cc:
Keith M. Hume, Executive Director, Society of Interventional Radiology