May 15, 2026

The Honorable Lee Zeldin
Administrator
Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Re: EPA-HQ-OAR-2019-0178

Dear Administrator Zeldin:

We, the undersigned nursing and health organizations, appreciate the opportunity to provide comments on this proposal. We write to share our opposition to the Environmental Protection Agency's current proposal *National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and*

Technology Review Reconsideration[1] and urge EPA to abandon this course of action and retain the 2024 National Emission Standards for Hazardous Air Pollutants (NESHAP) Ethylene Oxide (EtO) emissions standards for sterilization facilities.

The current proposal seeks to roll back much of the progress and public health protections adopted in 2024 that would benefit communities with close proximity of commercial sterilizer facilities that use ethylene oxide (EtO) to sterilize medical equipment and spices. In 2024, the Environmental Protection Agency (EPA) updated the Clean Air Act standards[2] for ethylene oxide (EtO) requiring multiple protections including expanded air monitoring, installing available technology to reduce emissions, and seeking viable alternatives to EtO gas. The adoption of these standards strengthened the Clean Air Act standards for EtO emitted into the air from commercial sterilization facilities and sought to limit EtO gas exposure affecting community members. The 2024 rule reflected the latest science on EtO. This current proposal will allow higher EtO emissions at almost all facilities resulting in an additional 7.8 tons of EtO emissions annually that would have been omitted under the 2024 rule. This proposal comes on the heels of the July 2025 announcement by President Trump which already exempted more than 40% of sterilizers in the U.S. for two years from complying with the 2024 rule.[3]

According to the FDA, around 50% of medical devices in the U.S.[4] are sterilized with EtO – about 20 billion devices each year. The very product used to sterilize critical medical equipment poses a danger to people who live, work, or attend school near the facilities that emit EtO. Nearly 14 million people[5,6] in the United States, including Puerto Rico, living within five miles of a commercial sterilizer. Many commercial sterilizer facilities are situated in low-income neighborhoods and communities of color, and compound existing health risks from other local sources of pollution.

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[1] Federal Register. (2026). *National emission standards for hazardous air pollutants: Ethylene oxide emissions standards for sterilization facilities residual risk and technology review reconsideration.* EPA-HQ-OAR-2019-0178. https://www.federalregister.gov/documents/2026/03/17/2026-05167/national-emission-standards-for-hazardous-air-pollutants-ethylene-oxide-emissions-standards-for

[2] Federal Register. (2024). *National emission standards for hazardous air pollutants: Ethylene oxide emissions standards for sterilization facilities residual risk and technology review.* EPA-HQ-OAR-2019-0178. https://www.federalregister.gov/documents/2024/04/05/2024-05905/national-emission-standards-for-hazardous-air-pollutants-ethylene-oxide-emissions-standards-for

[3] Proclamation, President of the United States of America (July 17, 2025). *Regulatory relief for certain stationary sources to promote American security with respect to sterile medical equipment.* https://www.whitehouse.gov/presidential-actions/2025/07/regulatory-relief-for-certain-stationary-sources-to-promote-american-security-with-respect-to-sterile-medical-equipment/

[4] U.S. Food and Drug Administration (FDA). (Last updated November 26, 2024). *Sterilization for Medical Devices.* https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/sterilization-medical-devices

[5] Minovi, D. (2023). *Invisible threat, inequitable impact: Communities impacted by cancer-causing ethylene oxide pollution.* Union of Concerned Scientists (UCS). https://www.ucsusa.org/resources/invisible-threat-inequitable-impact#read-online-content

[6] Minovi, D. (February 7, 2023). Ethylene oxide: New interactive map shows communities impacted by cancer-causing chemical. Union of Concerned Scientists. https://blog.ucs.org/dminovi/ethylene-oxide-interactive-map/

Ethylene oxide is one of the most toxic air pollutants that EPA regulates. Under the Clean Air Act, EtO is listed as a hazardous air pollutant or "air toxic." Despite its wide usage, EPA,[7] National Toxicology Program,[8] and International Association of Research on Cancer [9] all classify EtO as a carcinogen. EtO is capable of damaging DNA even in small doses and inhaling it can increase the risk of cancer, including breast cancer and cancer of white blood cells. Exposure to toxic EtO emissions can worsen respiratory conditions and cause health harms for patients and healthcare workers. Chronic exposure through inhaling EtO is associated with the development of cancers of white blood cells, such as non-Hodgkin's lymphoma, as well as breast cancer in women.[10] Children are particularly vulnerable: their bodies experience frequent cell divisions as they grow, and they are susceptible to DNA mutations caused by EtO exposure. Acute inhalation of EtO can also contribute to respiratory issues, headaches, nausea, vomiting, and fatigue.[11]

According to EPA, when fully implemented, the 2024 standards would have eliminated over 90% of ethylene oxide emissions from commercial sterilizer facilities[12] and reduced the number of people exposed to unacceptable cancer risks from ethylene oxide by 92%.[13] The requirement to reduce EtO emissions came after decades of communities and workers shouldering the burden[14,15] of harmful exposure. Community members and workers should not have to carry the burden of ensuring that facilities control cancer-causing air emissions. Without the health-based safeguards finalized in 2024, EPA's current proposal will leave communities exposed to cancer risks from commercial sterilizers at least as high as 6,000-in-1-million (6-in-1,000; 3-in-500).[16] EPA deems cancer risk from a toxic air pollutant greater than 100-in-1 million as "unacceptable" and the proposed rule could pose risks at

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[7] Environmental Protection Agency (EPA). (2016). Evaluation of the inhalation carcinogenicity of ethylene oxide (CASRN 75-21-8): In support of summary information on the integrated risk information system (IRIS). https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/1025tr.pdf

[8] National Toxicology Program, Department of Health and Human Services. (2021). Report on carcinogens, (15th ed.) Ethylene oxide, CAS No. 75-21-8. https://ntp.niehs.nih.gov/sites/default/files/ntp/roc/content/profiles/ethyleneoxide.pdf

[9] International Agency for Research on Cancer (IARC). (2012). *Chemical agents and related occupations, 100F.* IARC Monographs on the Evaluation of Carcinogenic Risks to Humans. https://publications.iarc.who.int/Book-And-Report-Series/Iarc-Monographs-On-The-Identification-Of-Carcinogenic-Hazards-To-Humans/Chemical-Agents-And-Related-Occupations-2012#:~:text=Coal%2Dtar%20Distillation-,Coal%2Dtar%20Pitch,8%2DPeCDF%2C%20and%20PCB%20126

[10] Environmental Protection Agency (EPA). (2016). Ethylene oxide 75-21-8. https://www.epa.gov/sites/default/files/2016-09/documents/ethylene-oxide.pdf

[11] EPA, 2016.

[12] Environmental Protection Agency (EPA). (March 14, 2024). EPA announces final rule to slash toxic emissions of ethylene oxide and reduce cancer risk. https://www.epa.gov/newsreleases/epa-announces-final-rule-slash-toxic-emissions-ethylene-oxide-and-reduce-cancer-risk

[13] Lewis, C. (January 28, 2026). Our communities can't wait for clean air. Southern Environmental Law Center (SELC). https://www.selc.org/news/our-communities-cant-wait-for-clean-air/#:~:text=New%20science%2C%20new%20protections,this%20industry%20by%20approximately%2092%25

[14] Minovi, D. (2023). *Invisible threat, inequitable impact.*

[15] O'Kelley, L. (2025) *Nurses can still take action on ethylene oxide.* The Alliance of Nurses for Healthy Environments. https://envirn.org/nurses-can-still-take-action-on-ethylene-oxide/

[16] Environmental Protection Agency (EPA). (January 2024). Residual risk assessment for the commercial sterilization facilities source category at 6, EPA-HQ-OAR-2019-0178-1576 (with only technology-based standards under CAA Section 112(d), the maximum cancer risk faced by an individual exposed to EtO from commercial sterilizers is 6,000-in-1 million, based on allowable emissions.) https://downloads.regulations.gov/EPA-HQ-OAR-2019-0178-1576/content.pdf

least 60 times higher. The current proposal would leave at least 85,000 more people subject to a cancer risk greater than EPA's "acceptable" cancer risk benchmark of 100-in-1million[17] and at least 38,000,000 more people would be subject to a greater than 1-in-1million cancer risk, which is the Agency's aspirational cancer risk target.[18]

Fugitive emissions are a major driver of cancer risks posed by commercial sterilizer facilities.[19] In 2024, EPA required sterilizers to control fugitive emissions for the first time. To assure compliance with fugitive emission limits, EPA required facilities to implement permanent total enclosure (PTE) which makes a facility airtight to ensure all EtO emissions are captured. While EPA is not proposing to eliminate all fugitive emission limits from the 2024 rule, EPA is proposing to eliminate health risk-based fugitive emission limits and the requirement for PTE. PTE is EPA's "established protocol" for ensuring complete capture of fugitive emissions, but in this proposal, the Agency did not identify any other ways for sterilizers to meet fugitive emission limits.[20]

In the current proposal, facilities would be allowed to choose continuous emissions monitoring systems (CEMS) or parametric monitoring. Parametric monitoring is not as accurate as CEMS because it merely tracks operational parameters such as temperature, pressure, and flow rate in order to infer the performance of the pollution control equipment. In the 2024 rule, communities and Members of Congress called for fenceline monitoring in order to know the true amounts of EtO escaping facilities. EPA required CEMS for most facilities but did not finalize a fenceline monitoring requirement, so the CEMS requirement was already a compromise. Part of EPA's rationale was that by requiring PTE, fugitive emissions would all be captured, controlled, and monitored by CEMS. By no longer requiring PTE or CEMS in this current proposal communities will be exposed to more EtO and communities will not be made aware of their exposure.

According to the Union of Concerned Scientists report on EtO, commercial sterilizers are just one of several types of facilities that emit EtO.[21] Hundreds of facilities in a variety of chemical sectors nationwide emit EtO with 12 communities in the U.S. that are in "sterilizer hotspots"[22] meaning they are exposed to EtO from more than one sterilizer. Rolling back health protections will impact these communities disproportionately. In 2022, after assessing risks to communities near active commercial sterilizers, EPA found an elevated cancer risk in 23 communities[23] related to EtO. The concept of "acceptable risk" must be questioned when people's lives are at stake. Acceptable risk must also be questioned when more than 14 million people live within five miles of the 104 ethylene oxide-emitting

[17] EPA, January 2024.
[18] EPA, January 2024.
[19] 89 Federal Register 24090, 24116 (Apr. 4, 2024). https://www.govinfo.gov/app/details/FR-2024-04-05/2024-05905
[20] Federal Register. (2026). EPA-HQ-OAR-2019-0178.
[21] Minovi, D. (2023). *Invisible threat, inequitable impact.*
[22] Minovi, D. (2023). *Invisible threat, inequitable impact.*
[23] Environmental Protection Agency (EPA). (2020). AirToxScreen frequent questions. https://www.epa.gov/AirToxScreen/airtoxscreen-frequent-questions

facilities[24] in the United States are people of color, people with low incomes, and/or people with limited English language proficiency. In addition, there are more than 10,000 schools and childcare centers[25] in the vicinity of these commercial sterilization facilities. EPA's assessments of EtO from commercial sterilizers do not consider exposure to other chemicals or pollutants that may be in a community. Nor do they consider other cumulative impacts, such as poverty, that can increase susceptibility to poor health outcomes.

The EtO IRIS value is developed by the Integrated Risk Information System (IRIS) program at EPA. The program is a politically independent toxicology program that studies the human health hazards of chemicals[26] with the EtO IRIS value representing the carcinogenicity from chronic inhalation of EtO. EPA and other regulatory agencies can use IRIS values to ensure their regulations protect public health. In 2016, after nearly 10 years of research and analysis, EPA published an updated IRIS assessment of EtO based on the most up-to-date science, concluding that EtO is 30 times more toxic for adults than previously understood and 60 times more toxic for children than previously understood when it promulgated the last set of sterilizer regulations in 2006. EtO is more toxic to children because they cannot clear the chemical out from their bodies as quickly as adults. EPA's 2024 rule incorporated the IRIS assessment to strengthen emission limits and ensure that the regulations would protect public health with an ample margin of safety. However, with this proposal, EPA is flipping its position on the 2016 EtO IRIS value, which reflected the latest science on EtO's potential to cause cancer. EPA is seeking comment on the IRIS assessment as well as an EtO risk assessment conducted by the Texas Commission on Environmental Quality (TCEQ), despite the latter being roundly rejected by the National Academies of Sciences (NAS) with NAS noting that TCEQ's assessment "suffered from numerous flaws that deviated from best practices."[27]

While EPA acknowledges that EtO is a carcinogen, it has declined to calculate any benefits from protecting public health from the chemical. In the current proposal, EPA chose to not calculate the potential impacts on health resulting from increased EtO exposure. The only benefits that EPA has quantified are the cost savings for the industry, even though EPA acknowledges that there would be costs associated with increased EtO

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[24] Minovi, D. (2023). *Invisible threat, inequitable impact.*
[25] Minovi, D. (2023). *Invisible threat, inequitable impact.*
[26] As of this writing, the status of the IRIS program at EPA is unclear. IRIS was housed in EPA's Office of Research and Development (ORD), but EPA announced in July 2025 that it will take action to eliminate ORD. *EPA Announces Reduction in Force, Reorganization Efforts to Save Taxpayers Nearly Three-Quarters of a Billion Dollars*, U.S. EPA (July 18, 2025), https://www.epa.gov/newsreleases/epa-announces-reduction-force reorganization-efforts-save-taxpayers-nearly-three.
[27] National Academies of Sciences Engineering and Medicine. (2025). Consensus study report: Review of Texas Commission on Environmental Quality's ethylene oxide development support document 2025. https://www.nationalacademies.org/publications/28592

exposure due to the proposed rule.[28] EPA calculates the cost savings to industry at $46 million/year which averages to only one penny saved for every five medical devices sterilized. EPA did not attempt to calculate how much these changes would increase Americans' cancer risks and health costs.

The health sector's mission is to protect and promote health; however, EtO emissions can also contribute to health problems occupationally and in patients. As organizations representing nurses and other health professionals, we believe it is critical to emphasize the importance of identifying alternatives to safe cleaning and sterilization equipment that doesn't jeopardize human health and patient care. Those in healthcare shouldn't have to choose between adequate sterilization and health harming emissions. Part of the professional nursing obligation is to address environmental health exposures that can harm patients, healthcare workers and communities. Workers in and communities around sterilizing facilities need and deserve strong protections. EPA should work toward requiring a complete phaseout of EtO at all commercial sterilizers as less toxic alternatives to EtO are available.[29]

The Food and Drug Administration,[30] which regulates medical devices and is working to continue to identify alternatives to EtO for sterilization, should collaborate with EPA. Eliminating EtO is successfully happening at healthcare facilities. Practice Greenhealth is the leading membership organization for sustainable health care, delivering environmental solutions to hospitals and health systems across the United States. In their 2025 Practice Greenhealth Environmental Excellence Awards data, 299 healthcare facilities have reportedly eliminated the use of EtO. Alternatives used on-site include steam sterilization (79% of facilities), low temperature hydrogen peroxide gas plasma (55%), peracetic acid (25%), ozone plasma (10%) and other alternatives (7%).[31] It is critical that we move towards safer alternatives and elevate the alternatives that the FDA has already approved for industry. Sterilization can be done safely without causing health harming emissions. For some medical devices sterilized with EtO, manufacturers must report manufacturing discontinuations or interruptions to the FDA if there may be a meaningful disruption of the supply of that device in the U.S.[32] Medical device manufacturers have

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[28] Environmental Protection Agency (EPA). (March 11, 2026). pp 4-5 "the potential health impacts associated with these emissions changes are not monetized in this memorandum." Regulatory impact analysis, p 14 "Non-monetized disbenefits associated with [EtO] are expected from the health effects from estimated increases of about 7.8 tons of EtO annually."; p 16 "Should the impacts from increased EtO exposure be monetized, they would reduce the overall monetized benefits relative to the anticipated cost savings." https://www.epa.gov/system/files/documents/2026-03/eto_commericial_sterilizers_proposal_ria_memo-2026-03.pdf

[29] Shahbandar, L. (2018). Alternatives to ethylene oxide. https://www.stopsterigenics.com/post/alternatives-to-ethylene-oxide

[30] U.S. Food and Drug Administration (FDA), 2024.

[31] Keroack, J. personal communication, April 1, 2026.

[32] 21 U.S. Code § 356j(a) *Discontinuance or interruption in the production of medical devices.* https://www.law.cornell.edu/uscode/text/21/356j

never reported any device shortages due to delays in sterilization.[33] EPA does not acknowledge this in its proposal.

Rolling back the 2024 standards is not necessary. Of course, there is a need to ensure that medical devices and equipment are sterilized for appropriate use. The 2024 rules included provisions to help ensure that sterilized medical supplies remain available. It is critical that we have both access to medical supplies AND that sterilizing them does not harm human health.

We urge you to retain the life-saving 2024 National Emissions Standards for Hazardous Air Pollutants (NESHAP) for Ethylene Oxide (EtO) Commercial Sterilization Facilities, and protect human health from the cancer risk posed by the use of ethylene oxide in sterilization facilities and in all other uses.

Thank you for your time and consideration of our comments.

Respectfully,

Allergy & Asthma Network

Alliance of Nurses for Healthy Environments

American College of Chest Physicians

American College of Nurse-Midwives

American College of Physicians

American Lung Association

American Nurses Association\California

American Public Health Association

American Thoracic Society

Association of Community Health Nursing Educators

Association of periOperative Registered Nurses (AORN)

Children's Environmental Health Network

[33] Food and Drug Administration (FDA). (March 2026). Medical Device Shortages List. https://www.fda.gov/medical-devices/medical-device-supply-chain-and-shortages/medical-device-shortages-list

Council of Public Health Nursing Organizations

Gerontological Advanced Practice Nurses Association

Health Care Without Harm

Massachusetts Nurses Association

Medical Society Consortium on Climate and Health

Medical Students for a Sustainable Future (MS4SF)

Michigan Clinicians for Climate Action

National Association of Hispanic Nurses

National Association of Nurse Practitioners in Women's Health

National Association of Pediatric Nurse Practitioners

National Association of School Nurses

National Coalition of Ethnic Minority Nurse Associations (NCEMNA)

National Environmental Health Association

National League for Nursing

Oklahoma Indigenous Nurses Association

Orthodox Jewish Nurses Association

Physicians for Social Responsibility