



March 27, 2025

RE: Clear Air Act Section 112 (i)(4) Presidential Exemption

To whom it may concern:

Exemption request from Ethylene Oxide Emissions Standards for Sterilization Facilities: National Emission Standards for Hazardous Air Pollutants (NESHAP) - 40 CFR 60 and 63 subpart O standards that were final April 5, 2024.

Facilities affected:

1. Windstone Medical Packaging Inc. 1602 4th Ave. North Billings, MT 59102
2. Windstone Medical Packaging Inc. 1400 Montana Ave. Billings, MT 59102

Windstone Medical Packaging, Inc. dba Aligned Medical Solutions is a small business located in Billings, Montana that packages and sterilizes custom convenience kits sold to hospitals and surgery centers throughout the United States. We employ a total of 240 people, so we believe we meet the small business size standard for companies that make or process surgical appliances and supplies. NAICS Code 339113. Due to our use of ethylene oxide, we are subject to NESHAP 40 CRF 60 and 63 subpart O. We are requesting an additional 2-year compliance extension until April 5, 2029 for our facilities.

On March 21, 2025, EPA stated that it will reconsider the EtO sterilization rules. In that reconsideration, Windstone will invite EPA's attention to the low-polluting nature of Windstone's EtO sterilization process, something EPA inadequately considered in the prior rulemaking process.

Windstone Medical Packaging Inc. uses ethylene oxide (EtO) to sterilize custom convenience kits, kits which contain the sterilized medical supplies and devices tailored for specific kinds of surgical procedures according to the customer's detailed requirements. The use of these custom kits streamlines time in surgery, enhancing patient safety and improving the capacity of existing hospital surgical units.

Windstone's sterilization method differs from its large volume competitors, which use large chambers to sterilize medical supplies in bulk. By contrast, Windstone uses "flexible chamber" technology, in other words, it encases each custom kit in a plastic bag and injects Ethylene Oxide (EtO) into the bag. Windstone believes that it uses far less EtO per item sterilized than its large volume competitors use. Windstone's method is inherently

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low polluting, reducing EtO usage per item sterilized by as much as 90% compared to more common EtO sterilization methods.

EPA failed to consider these efficiencies adequately in the rulemaking process when it set percentage reduction limits on EtO emissions. Indeed, as nearly as Windstone can determine, EPA failed to consider Windstone's facilities at any time in this rulemaking process. As a consequence, the percentage limits EPA set effectively punish rather than reward Windstone for Windstone's reduced usage of EtO per item sterilized.

We believe the following additional cost, timing, and mortality factors further justify the request for an extension for compliance with the rule:

1. After the rule was finalized Windstone Medical Packaging engaged with an engineering company to develop the basis of design (BOD) for compliance. The BOD was performed and determined the cost to comply would require a capital expenditure of **Ex. 4 CBI**. As a small business with 2024 sales of only **Ex. 4 CBI** this enormous regulatory compliance cost is not feasible within the current compliance timeline and presents a significant hurdle for growth, job creation and potentially reduced sterilization capacity. Due to the extremely high cost of compliance, we believe an extension is justified. Under the circumstances, the technology needed to achieve the required percentage emission reductions (beyond those already accomplished by Windstone's low polluting sterilization method), is not reasonably available to Windstone within the meaning of section 112(i)(4) of the Clean Air Act. 42 U.S.C. Section 7412(i)(4)
2. Windstone believes that the current percentage reduction requirements, once adjusted to reflect the low-polluting nature of Windstone's sterilization process, will result in far less costly requirements, and avoid spending large sums on equipment and monitoring with negligible environmental and health benefits.
3. By the same token, an extension will provide more adequate time to implement carefully tailored EtO controls and allow expansion rather than contraction of surgical supply sterilization capacity. That expansion may help reduce hospital acquired infections (HAIs), a major public health challenge for the United States. In a peer-reviewed study, the CDC estimated that the United States suffers 99,000 deaths annually from HAIs.
<https://pmc.ncbi.nlm.nih.gov/articles/PMC3528178/#:~:text=The%20Centers%20of%20Disease%20Control,obtained%20from%20multiple%20healthcare%20databases.>
According to this peer-reviewed study, two of the four most deadly HAIs are surgical site infection and central line-associated bloodstream infection. Nearly half of



these HAIs in the study were multi-drug resistant, making surgical sterilization even more important than before such multi-drug resistance became so common.

4. Windstone submits that expanding effective surgical supply sterilization will help combat the substantial United States death and illness toll from HAIs. Reducing that toll of HAI deaths and illnesses is very much in the national security interests of the United States, within the meaning of Section 112(i)(4) of the Clean Air Act, 42 U.S.C. Section 7412(i)(4).

We appreciate the opportunity to present our case for an exemption and would be happy to discuss the details of our situation if necessary.

Regards,

A handwritten signature in black ink, appearing to read 'Jeff Jensen', written over a circular stamp or seal.

Jeff Jensen
VP of Operations

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