

Message

From: AirAction [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FA78B98923384078995E04A73D258D83-AIRACTION]
Sent: 3/28/2025 3:28:39 PM
To: Shrager, Brian [Shrager.Brian@epa.gov]; McLamb, Marguerite [McLamb.Marguerite@epa.gov]; McGinn, Kevin [mcginn.kevin@epa.gov]; Branning, Amy [Branning.Amy@epa.gov]; South, Peter [South.Peter@epa.gov]; Anderson, Lea [anderson.lea@epa.gov]; Smith, Korbin [smith.korbin@epa.gov]
CC: Noonan, Jenny [Noonan.Jenny@epa.gov]
Subject: FW: Regarding Sterilizer Rule (89 FR 24090): KPR US, LLC d/b/a Kendall Patient Recovery ("KPR")
Attachments: FINAL EOSA Letter to EPA re. NESHAP -- March 17, 2025.pdf

Hi all – We have received another Presidential Exemption request. For awareness, please see email below and attachment.

From: Leach, Arthur <arthur.leach@cardinalhealth.com>
Sent: Friday, March 28, 2025 11:04 AM
To: AirAction <AirAction@epa.gov>
Subject: Regarding Sterilizer Rule (89 FR 24090): KPR US, LLC d/b/a Kendall Patient Recovery ("KPR")

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To: airaction@epa.gov

Re: Sterilizer Rule (89 FR 24090): KPR US, LLC d/b/a Kendall Patient Recovery ("KPR")

I write on behalf of KPR to request that the President issue a two-year exemption pursuant to his authority under CAA Section 112(i)(4) for all emission standards and associated requirements set or revised in EPA's April 4, 2024 *National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review*, 89 FR 24090 (April 5, 2024) (Sterilizer Rule).

KPR requests that the Presidential Exemption apply to the following facility regulated by the Sterilizer Rule and all sources therein:

- KPR US, LLC d/b/a Kendall Patient Recovery
1430 Marvin Griffin Road, Augusta, Georgia 30906

KPR requests that the President issue a two-year exemption as quickly as possible, but designate it as taking effect on the compliance deadlines for the standards in the Sterilizer Rule. Specifically:

- For standards set or revised under CAA Section 112(f) and all corresponding requirements (including monitoring requirements), the exemption should apply as of April 6, 2026 (the compliance deadline for those standards);
- For standards set or revised under CAA Section 112(d) and all corresponding requirements (including monitoring requirements), the exemption should apply as of April 5, 2027 (the compliance deadlines for those standards).

As explained further in the attached letter submitted to EPA on March 17 on behalf of the Ethylene Oxide Sterilization Association (EOSA), the technology necessary to implement the standards is not widely available to the sterilization industry because: manufacturers cannot guarantee that existing emissions control equipment will enable sources to meet the new standards; there is not a sufficient supply of the necessary technology; and

there are not enough experienced installation professional and technical experts to install and test that equipment within the current compliance timeframes.

As also explained further in EOSA's March 17 letter, it is in the national security interests of the United States to issue the requested exemption because if some facilities choose to cease operations rather than attempt compliance (which is likely), that will disrupt the supply of sterilized medical devices, raise the cost of those devices, and/or force medical suppliers or providers to source sterilized medical devices from abroad.

Please don't hesitate to let me know if any additional information is needed. KPR appreciates EPA's attention to this important matter and urges EPA to recommend that the President issue the requested exemption as quickly as possible.

Thanks you for your considerations of this matter,

Arthur



Arthur Leach

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