EOSA

The Ethylene Oxide Sterilization Association, Inc.

Managed by B&C® Consortia Management, L.L.C.

EOSA / OMB Discussion re: EtO NESHAP

February 6, 2024

Agenda

- ❑ List of proposed requirements that will impact medical device supply
- ❑ Clarification on the potential new requirements
- ❑ List of potential concerns from public comments
- ❑ Reemphasize other proposed requirements that are not feasible and will cause compliance issues and disrupt medical device supply

List of Proposed Requirements That Will Impact Medical Device Supply

Proposed Requirement	EOSA Concerns	Ways to Address Concern
Sterilization Chamber Vent (SCV), Existing and New	▪ Emission control device manufacturers do not guarantee a destruction removal efficiency of 99.94% for SCVs ▪ EPA's proposed requirement for the efficiency to be measured across a 24-hr time period makes compliance far more difficult, and likely impossible, to achieve	In order for industry to have the ability to meet an emission standard, it must be based on achievable, **OEM guaranteed destruction removal efficiency (DRE)** of emission control equipment (**99.94% is too high**)
Aeration Room Vent (ARV), Existing and New	▪ Increasing the required abatement efficiency potentially penalizes operations where EtO is already significantly removed during the sterilization cycle via vacuum and/or nitrogen wash cycle prior to moving the sterilized load to aeration ▪ The lack of any alternative outlet concentration makes compliance impossible in many situations due to decreases in abatement device efficiency with low concentration inlet streams ▪ Because EtO inlet concentrations to ARVs are relatively low, demonstrating compliance with the proposed 99.6 or 99.9 percent emission reduction limitation may be extremely difficult or impossible due to the current detection limits available with existing equipment	The current requirements should remain in place as explained An **alternative outlet concentration or some means (i.e., facility-wide DRE)** to ensure compliance can be achieved and demonstrated

List of Proposed Requirements That Will Impact Medical Device Supply

Proposed Requirement	EOSA Concerns	Ways to Address Concern
Chamber Exhaust (Back) Vent (CEV), Existing and New	▪ Setting a mass emission rate is essentially limiting volumetric flow rate when EPA assumes a maximum outlet concentration which equates to the minimum reliable and consistently detectable concentration of the monitoring equipment ▪ EPA must not assume one data set is representative of sterilization facilities operations, especially without considering size or EtO usage at the facility ▪ For all facilities, an alternative outlet concentration (e.g. 1 ppm) or facility-wide DRE must be an option to achieve compliance. Otherwise facilities have no options other than to cut throughput	Emission standards for chamber exhaust vents (CEVs) must be practical/achievable and must not limit airflow rates; suggest **a DRE or alternative outlet concentration or some means (i.e., facility-wide DRE)** to ensure compliance can be achieved and demonstrated
Group 1 & Group 2 Fugitive Emissions; Major and Area Sources; Existing and New	▪ The same airflow and mass rate don't account for different facility sizes or throughput ▪ For the G1 & G2 emission standards to be feasible and effective, they must not rely on a single mass emission rate; they must be based on the guaranteed DRE of the abatement technologies' actual guaranteed destruction efficiency ▪ Setting a mass emission rate is essentially limiting volumetric flow rate when EPA assumes a maximum outlet concentration which equates to the minimum reliable and consistently detectable concentration of the monitoring equipment ▪ For many facilities, to meet the proposed rate, a significant reduction in throughput would be required, including facilities that already capture Group 1 & 2 emissions. These requirements, if implemented, will cripple access to critical medical devices	**A DRE or alternative outlet concentration or some means (i.e., facility-wide DRE)** to ensure compliance can be achieved and demonstrated

List of Proposed Requirements That Will Impact Medical Device Supply

Proposed Requirement	EOSA Concerns	Ways to Address Concern
Title V Permit	▪ Title V permitting is unnecessary, burdensome, costly, and will not result in further decreases in EtO emissions or improved compliance ▪ Facilities may well encounter significant unwarranted opposition during the permit's comment period due to the significant amount of publicity on EtO that may not accurately present potential risk information	Should not be required
Compliance Timeline	▪ Proposed 18-month compliance timeline is not possible or feasible. Widespread facility shutdowns would occur quickly followed by severe medical device shortages ▪ Many of the proposed rule requirements (if possible at all) would require significant facility reconstruction and major equipment procurement and installation. Additional time is needed to allow for detailed engineering and design work, hazard assessments, equipment lead time, and local permitting before construction can begin	Four or more years for those requirements that can be done
Reporting	▪ The proposed requirement for initial reporting to report the cycle calculation approach or the bioburden approach used for each cycle run must be deleted ▪ The need to obtain specific NDO details on a semi-annual basis adds little, if any, value if the facility is already continually monitoring such parameters through flow rate or differential monitoring. ▪ The requested quarterly reporting information is unduly burdensome for facilities, particularly smaller facilities ▪ With regard to the proposed electronic reporting requirements, at a minimum, EPA must address concerns regarding duplication of reporting with state agencies and the undue regulatory burden they impose, which will be compounded by other proposed requirements. Summary reports combined with Title V permits, daily CEMS reporting, and state permit reporting requirements creates several layers of regulatory reporting burdens ▪ In addition, there are major concerns with submitting reports that do not contain summarized aggregate data, such as daily CEMS reports, for all of the reasons stated above. Additionally, acute risk reporting is already required under the Emergency Planning and Community Right-to-Know Act (EPCRA) requirements	Keep existing requirements

Clarification On The Potential New Requirements

- EOSA understands that EPA is considering facility-wide DRE concept and EOSA supports the approach
- EOSA concerns
  - If a facility-wide DRE is proposed, EOSA believes that it should be determined at the Federal level and in line with the emission control equipment manufacturers' guarantees
  - EOSA would be concerned about the prescription of an unachievable DRE and its impact on medical device supply if local/State authorities are delegated for approval of specific facility-wide DRE

List Of Potential Concerns From Public Comments

- Fenceline monitoring
  - The current equipment/technology, as well as the lack of ability to differentiate sterilization facilities vs. other sources, make any fenceline monitoring of sterilization facilities impossible

- Reduced compliance timelines
  - As stated previously, proposed 18-month or shorter compliance timeline is not possible or feasible. Widespread facility shutdowns would occur quickly followed by severe medical device shortages
  - An initial Performance Testing Compliance Timeline of less than 180 Days is not feasible. 180 days is necessary to schedule the test with a stack test company, survey the equipment (e.g., to identify test ports, equipment setup), draft a test plan, obtain approval for the test plan, and implement the test

Other Proposed Requirements That Are Not Feasible

- It is critical to have a performance-based standard and not restrict specific approaches such as:
  - Cycle approaches for validation
  - Cycle EtO concentration limit
  - Mass limits
  - Volumetric flow limits