

MEMORANDUM

TO: Docket for the National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emission Standards for Sterilization Facilities Residual Risk and Technology Review Reconsideration (Docket ID Number: EPA-HQ-OAR-2019-0178)

DATE: March 11, 2026

SUBJECT: Regulatory Impact Analysis for the Proposed National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emission Standards for Sterilization Facilities Residual Risk and Technology Review Reconsideration

1 Introduction

The United States Environmental Protection Agency (EPA) is proposing a reconsideration of the amendments to the National Emission Standards for Hazardous Air Pollutants (NESHAP) for Ethylene Oxide (EtO) Commercial Sterilization and Fumigation Operations (40 CFR Part 63, Subpart O) that were finalized in 2024.¹ The EPA is proposing to repeal and revise several standards from the 2024 Final Rule. This memorandum provides the estimated impacts of the proposed reconsideration.

Commercial sterilization and fumigation operations, or “commercial sterilizers”, that are impacted by this rulemaking use EtO, a flammable and colorless gas, to remove or reduce the presence of bacteria, fungi, and viruses in a variety of products to decrease risks of infection to users of these products. Affected facilities in this source category (subpart O) mostly sterilize medical devices and medical equipment, since many of these products must meet high safety standards before they can be made available to healthcare providers, patients, and other consumers. Commercial sterilizers also use EtO to sterilize some types of food products, such as spices. Sterilization with EtO is primarily conducted by facilities that specialize in sterilization (*i.e.*, ‘contract’ sterilizers) rather than the manufacturers of the products themselves, though some manufacturers perform sterilization with EtO in-house.

The regulatory impact analysis (RIA) for the 2024 final NESHAP amendments assessed the incremental costs and impacts of implementing the rule’s standards against a “baseline”.² A

¹ The 2024 final rule titled *National Emission Standards for Hazardous Air Pollutants (NESHAP) for Ethylene Oxide Commercial Sterilization and Fumigation Operations* (40 CFR Part 63, Subpart O) is referred to as the “2024 Final Rule” in the preamble and in this RIA.

² The 2024 Final Rule RIA is titled *Regulatory Impact Analysis for the Final National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Commercial Sterilization and Fumigation Operations* and is in the docket here: <https://www.regulations.gov/document/EPA-HQ-OAR-2019-0178-1557>.

baseline is a “business-as-usual” scenario that represents the behavior of the regulated sector(s) under market and regulatory conditions in the absence of the regulatory action being analyzed in a policy scenario. From the perspective of this proposed reconsideration action, the standards analyzed in the 2024 Final Rule RIA are considered in the baseline, and this proposed action is the “policy case”.

The EPA is conducting a voluntary reconsideration of the 2024 Final Rule. The EPA is proposing revisions to the standards promulgated under the Clean Air Act (CAA) sections 112(d)(6) and 112(f)(2), the requirement to demonstrate compliance using a continuous emissions monitoring system (CEMS), and the requirement to use permanent total enclosure (PTE) to comply with the emission reduction standards.

The 2024 Final Rule finalized amendments to the subpart O NESHAP requiring existing and new sources in the category to reduce emissions of EtO, a hazardous air pollutant (HAP) that can cause adverse human health impacts, such as cancer, for exposed individuals. The EPA finalized actions concerning the risk and technology review (RTR), including amendments pursuant to the technology review for certain point sources and amendments pursuant to the risk review to specifically address EtO emissions from point sources and fugitive sources from certain groups of facilities. The EPA also finalized amendments to add and clarify regulatory provisions related to emissions during periods of startup, shutdown, and malfunction (SSM). Lastly, the EPA revised monitoring and performance testing requirements and added provisions for electronic reporting of performance test results and reports, performance evaluation reports, and compliance reports.

As a result of this reconsideration action, the EPA is proposing the following:

- To revise the standards for new aeration room vents (ARVs) at facilities where EtO use is at least 10 tpy down to 99.6 percent from 99.9 percent EtO reduction.
- To reduce CEMS to a compliance option and allow facilities to choose either performance testing combined with parametric monitoring or CEMS to demonstrate compliance.
- To remove the requirement to use PTE to ensure capture of EtO to comply with the emission reduction standards.

- To remove all risk-based standards finalized in the 2024 Final Rule under CAA section 112(f)(2) for all five emission sources (SCVs, ARVs, chamber emission vents (CEVs), and Group 1 and 2 room air emissions) and new facility categories based on the amount of EtO used, that included stricter emission reduction requirements for facilities using more EtO based on a post-control risk assessment.

In this RIA, we generally follow the same methods used in the 2024 Final Rule RIA to estimate the cost savings of this proposal. However, the costs presented in this memo are in 2024 dollars while the costs in the 2024 Final Rule RIA were in 2021 dollars.³ The “baseline” in an analysis is a business-as-usual scenario that best represents the behavior of the regulated sector under market and regulatory conditions in the absence of the regulatory action under consideration. The baseline for this proposed reconsideration includes the 2024 Final Rule requirements. This memo incorporates certain baseline changes that have occurred since the promulgation of the 2024 Final Rule resulting from exemptions granted under Presidential Proclamation 10959 titled *Regulatory Relief for Certain Stationary Sources to Promote American Security With Respect to Sterile Medical Equipment*.^{4,5} More details on how this affects the baseline are presented later in this section. For more details on the assumptions and methods used to estimate the cost savings, see Section 2.1 on Engineering Costs in this memo or the memorandum titled *Proposed Commercial Sterilizers Reconsideration Cost Analysis*, available in the docket. As in the 2024 Final Rule RIA, the EPA did not monetize the benefits associated with the projected emissions change under the proposed reconsideration, but the potential impacts are characterized qualitatively in Section 4.

³ Values in the 2024 Final Rule analysis were converted from 2021 dollars to 2024 dollars by multiplying by 1.137, which was derived from the annual GDP Implicit Price Deflator from the U.S. Bureau of Economic Analysis (BEA) NIPA Table 1.1.9, found at <https://fred.stlouisfed.org/release/tables?rid=53&eid=41158>.

⁴ Presidential Proclamation 10959, titled *Regulatory Relief for Certain Stationary Sources to Promote Security With Respect to Sterile Medical Equipment* (90 FR 34747, July 17, 2025), is available here: <https://www.federalregister.gov/documents/2025/07/23/2025-13924/regulatory-relief-for-certain-stationary-sources-to-promote-american-security-with-respect-to>.

⁵ Other than updating the dollar year from 2021 to 2024 dollars and effects of the proclamation, changes to the baseline relative to the 2024 Final Rule include updates to the: interest rate used to annualize capital costs (from 7.75 to 7.50 percent), labor cost rates, electricity rates, and the number of total affected facilities. For more details on these assumptions, see the memorandum titled *Cost Impacts and Emission Reductions for the Ethylene Oxide Commercial Sterilization Facilities Source Category – Reconsideration Proposal*, available in the docket.

The cost impacts of this proposed reconsideration are estimated over a 20-year timeframe from 2026 to 2045. The EPA identified 89 EtO commercial sterilization facilities that will be impacted by this proposed reconsideration. Table 1 contains a summary of the cost and emission impacts estimated for this proposed reconsideration. This proposed reconsideration is estimated to result in capital investment cost savings of approximately \$280 million and annualized cost savings of \$50 million (in 2024 dollars).⁶

Table 1. Estimated Cost Savings and Avoided Emissions Reductions from 2026 to 2045 (millions 2024\$)

	Proposed Reconsideration
Present Value of Cost Savings (3%)	\$630
Equivalent Annualized Value (3%)	\$43
Present Value of Cost Savings (7%)	\$510
Equivalent Annualized Value (7%)	\$48
EtO Emissions Change (tpy) ^a	7.8

Note: Values have been rounded to two significant figures.

^a The positive value for the emissions change reflect estimated emissions reductions that will no longer occur under this proposed action.

The present value (PV) of the estimated compliance cost savings from 2026 to 2045 for the proposed reconsideration is \$630 million in 2024 dollars, discounted at a 3 percent rate. The equivalent annualized value (EAV)⁷ of the estimated cost savings is \$43 million, using a 3 percent discount rate. Using a 7 percent discount rate, the PV and EAV of the cost savings are estimated to be \$510 million and \$48 million, respectively. This proposed reconsideration is estimated to result in net compliance cost savings for the impacted source category and impacted small entities as shown in Section 3. The EPA concludes that the estimated impacts of this action will not have a significant economic impact on a substantial number of small entities.

This proposed reconsideration is estimated to forgo emissions reductions of EtO by 7.8 tons per year (tpy) that were estimated to result from the 2024 Final Rule. As mentioned, the

⁶ The total annualized cost savings are the sum of the annualized capital cost savings and other annual cost savings. The capital cost savings were annualized over the lifetime of the equipment at a 7.5 percent interest rate.

⁷ The EAV represents a flow of constant annual values that, had they occurred in each year from 2026 to 2045, would yield a sum equivalent to the present value.

potential health impacts associated with these emissions changes are not monetized in this memorandum.

EtO sterilization services are a critical input in the provision of safe medical devices. According to the U.S. Food and Drug Administration (FDA), more than 20 billion medical devices used in the U.S. every year are sterilized with EtO, accounting for approximately 50 percent of medical devices that require sterilization. In the 2024 Final Rule RIA, the industry profile in Section 2 discusses the role of EtO in providing a significant number of healthcare products to the public and the complexities of substituting other sterilization methods that can be used for a wide variety of common medical devices.⁸ The EPA was not able to quantitatively assess potential market impacts for this proposed rule. However, it is possible that this proposed reconsideration would reduce the risk of capacity constraints in the sterilization sector. In the 2024 RIA, the EPA examined a scenario where the 2024 Final Rule requirements lead to facilities needing to temporarily reduce their capacity and thus lose revenue during that time. To the extent that this proposed reconsideration avoids the need for facilities to reduce capacity, the cost savings of this action are estimated to be higher than the estimates of the examined scenario in the 2024 Final Rule RIA.

As discussed earlier in this section, certain regulatory changes have occurred since the promulgation of the 2024 Final Rule and have been accounted for in this analysis. Presidential Proclamation 10959 titled *Regulatory Relief for Certain Stationary Sources to Promote American Security With Respect to Sterile Medical Equipment* is an action that impacts the baseline of this proposed reconsideration and is reflected in the results presented in this RIA. The Proclamation exempts certain stationary sources, as identified in Annex I, from compliance with the 2024 Final Rule requirements.⁹ As set out in the Proclamation, the exemption lasts for a period of two years beyond the 2024 Final Rule compliance date, which is the period beginning April 5, 2026, and concluding April 5, 2028. During this two-year period, the stationary sources

⁸ U.S. EPA. (2024). *Regulatory Impact Analysis for the Final National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Commercial Sterilization and Fumigation Operations*. Available at: <https://www.regulations.gov/document/EPA-HQ-OAR-2019-0178-1557>.

⁹ Presidential Proclamation 10959, titled *Regulatory Relief for Certain Stationary Sources to Promote Security With Respect to Sterile Medical Equipment* (90 FR 34747, July 23, 2025), is available here: <https://www.federalregister.gov/documents/2025/07/23/2025-13924/regulatory-relief-for-certain-stationary-sources-to-promote-american-security-with-respect-to>.

identified in Annex I will continue to be subject to the pre-2024 Final Rule compliance obligations.

Prior to the Proclamation, all commercial sterilizers emitting EtO were subject to the revised requirements in the 2024 Final Rule. We compared this list of potentially impacted units to the list in Annex I. Based on this analysis, the EPA determined that 34 units are impacted by the exemptions, which accounts for 38 percent of the uniquely affected facilities. We also note that Annex I includes 5 units that the EPA did not anticipate being incrementally impacted by the 2024 Final Rule or are co-located with units already captured by this analysis.

2 Emissions Impacts, Costs, Benefits of Proposed Action

As indicated in Section 1, the cost savings and emission impacts of this proposed reconsideration were assessed relative to a regulatory baseline. From the perspective of this proposed action, the baseline is characterized as a world with the requirements analyzed in the 2024 Final Rule RIA, and the policy case is characterized a world with the incremental changes that would be anticipated as a consequence of this proposed action. The cost impacts were estimated by multiplying facility and source counts by engineering cost estimates for the various requirements in the rule. The engineering costs are also tailored to the configurations of many facilities, while assumed configurations were applied for some facilities. The EPA estimated costs for 89 commercial EtO sterilization facilities.

Under this proposed action, some of the controls identified to reduce EtO emissions in the 2024 Final Rule RIA would no longer be applied, and some other requirements would be reduced. Many facilities would no longer need to install and maintain solid or gas reactor systems to comply with the room air emissions requirements in the 2024 Final Rule. Additionally, the revised monitoring and testing requirements are estimated to result in cost savings.

2.1 Engineering Costs

Some of the requirements in the 2024 Final Rule that were estimated to result in compliance costs will no longer be incurred as a result of this proposed action. We estimate compliance cost savings related to the installation of gas/solid reactors, monitoring and testing

requirements, and reporting and recordkeeping requirements. The annualized cost savings of this proposed rule are estimated to be \$50 million.

A major component of the total costs estimated for the 2024 Final Rule was the cost of implementing the room air emissions requirements. In many cases, affected facilities would have needed to install a PTE and/or solid or gas reactor systems to comply with the room air emissions requirements. While not monetized within this document, stakeholders raised significant concerns about the feasibility of PTE in all facilities. If a facility is unable to install PTE and meet the requirements, not only would the facility lose the costs associated with compliance but it would result in increased strain on the limited supply chain. The secondary effects would result in shifting sterilization to other commercial sterilizers and/or loss of properly sterilized medical equipment – leading to delays in necessary medical procedures and/or increased infections from medical procedures.

A second major component was the cost to install, operate, and maintain solid or gas reactor systems to meet the CAA 112(f)(2) standards for SCVs, ARVs, and CEVs.

Another major cost was associated with the monitoring and testing requirements, which includes capital and annual costs associated with a CEMS or the recurring costs associated with annual performance testing, depending on the facility.

The engineering costs estimated for the requirements of the 2024 Final Rule, and this proposed reconsideration, the number of facilities affected by those requirements, and the difference in costs between the 2024 Final Rule and the proposed reconsideration are presented in Table 2. The “total annualized costs” are the sum of the annualized capital costs and other annual costs (e.g., operating and maintenance costs, and recordkeeping and reporting costs). The EPA also included the costs to complete new cycle validations and initial performance tests in the total annualized costs, even though these costs are only expected to be incurred once in Year 1 (2026).¹⁰ This was done to simplify the presentation by providing one consistent total annualized cost estimate, since the total annual costs would be different in Year 1 than in Years 2-20 due to the one-time costs. Capital costs are generally assumed to be incurred in year 1 (2026) of the analytical timeframe. However, the stream of cost savings for facilities covered

¹⁰ The new validation and initial testing costs are not considered capital costs, so they are not annualized and spread out over the time horizon.

under the Proclamation two-exemption (discussed in Section 1.1) are assumed to begin two years later in the analytical timeframe. To see how the costs vary across the years in the analytical timeframe (2026 to 2045), see Table 4.

Annualization of capital costs involves establishing an annual, representative “payment” sufficient to finance the investment over the expected lifetime of the equipment or loan period. This payment is typically referred to as the “capital recovery cost.” To obtain annualized capital costs, a capital recovery factor is applied to capital costs. The capital recovery factor is based on the lifetime of the capital equipment as well as the interest rate. To annualize the capital costs, the EPA assumed a 7.50 percent interest rate,¹¹ a 20-year lifetime for a PTE, a 20-year lifetime for a gas or solid reactor system, and a 10-year lifetime for the capital associated with CEMS for the emissions monitoring requirements.

¹¹ The 7.50 percent interest rate was obtained from <https://fred.stlouisfed.org/series/PRIME> on July 10, 2025.

Table 2. Engineering Costs Savings by Emissions Point or Cost Component (millions of 2024\$)

	2024 Final Rule	Proposed Reconsideration	Cost Savings
Permanent Total Enclosure			
Facilities Affected	28	0	
Capital Costs	\$88.1	\$0.0	\$88.1
Annual O&M Costs	\$0.8	\$0.0	\$0.8
Total Annualized Costs	\$9.4	\$0.0	\$9.4
Gas/Solid Reactors			
Facilities Affected	72	54	
Capital Costs	\$181.8	\$51.4	\$130.4
Annual O&M Costs	\$30.2	\$13.9	\$16.3
Total Annualized Costs	\$48.0	\$18.9	\$29.1
Monitoring and Testing			
Facilities Affected	88	88	
Capital Costs	\$58.1	\$0.0	\$58.1
Annual O&M Costs	\$14.9	\$5.3	\$9.6
Total Annualized Costs	\$23.4	\$5.3	\$18.1
Recordkeeping and Reporting			
Facilities Affected	89	89	
Total One-time Costs	\$0.6	\$0.6	\$0.0
Annual O&M Costs	\$2.1	\$2.3	-\$0.2
Total Annualized Costs	\$2.8	\$2.9	-\$0.2
Cycle Revalidations^a			
Facilities Affected	0	86	
Total One-time Costs	\$0.0	\$6.3	-\$6.3
TOTAL COSTS			
Facilities Affected	89	89	
Capital Costs	\$328.0	\$51.4	\$276.6
Annual O&M Costs	\$48.0	\$21.5	\$26.5
Total One-time Costs	\$0.6	\$6.9	-\$6.3
Total Annualized Costs	\$83.6	\$33.4	\$50.1

Note: Total annualized costs include annualized capital costs, annual operating and maintenance costs, and one-time costs. Dollar values are presented to one decimal place. Values may not appear to sum correctly due to rounding.

^a To implement the change to lower the in-chamber EtO concentration to 1 ppm prior to chamber emission vents (CEVs) activation, the validation cycle must be confirmed. The associated cycle revalidation costs are considered a one-time annual cost.

Additional information about the development of the cost estimates and assumptions can be found in the memorandum titled *Cost Impacts and Emission Reductions for the Ethylene*

Oxide Commercial Sterilization Facilities Source Category - Reconsideration Proposal in the docket.

2.2 Benefits

If finalized as proposed, this reconsideration will result in an estimated 7.8 tpy of avoided EtO emissions reductions that would have resulted from the 2024 Final Rule.¹² Due to methodological and data limitations, the EPA was not able to quantify and monetize the potential human health impacts of the changes in EtO emissions in this analysis. This does not imply that there are no impacts associated with the EtO emission changes estimated for this proposed rule. Instead, this section provides a qualitative discussion of the health effects associated with EtO exposure.

The Department of Health and Human Services and the International Agency for Research on Cancer have classified EtO as a known human carcinogen.¹³ The EPA has concluded that EtO is carcinogenic to humans by the inhalation route of exposure. Evidence in humans indicates that exposure to EtO increases the risk of lymphoid cancer (including non-Hodgkin lymphoma, myeloma, and lymphocytic leukemia) and, for females, breast cancer.¹⁴ Noncancer health endpoints affected by chronic exposure to EtO include irritation of the eyes, skin, nose, throat, and lungs, and damage to the brain and nervous system. There is also some evidence linking EtO exposure to reproductive and developmental effects.¹⁵ EtO is a mutagen,

¹² This value for avoided EtO emissions reductions is calculated by taking the difference between the estimated nationwide EtO emissions reductions resulting from the 2024 Final Rule promulgated standards and the reductions resulting from the proposed reconsideration standards (both scenarios are relative to a baseline under the standards promulgated under the preexisting 1994 rule (59 FR 62585, December 6, 1994). This estimate also incorporates the delay in implementation of the 2024 Final Rule as a result of the Proclamation two-year exemption.

¹³ NTP. (2016). Ethylene oxide. Report on carcinogens, 14th edition. Research Triangle Park, NC: National Toxicology Program. Found at <https://ntp.niehs.nih.gov/ntp/roc/content/profiles/ethyleneoxide.pdf>.

¹⁴ U.S. 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)*. National Center for Environmental Assessment, Office of Research and Development. Washington, DC. EPA/635/R-16/350Fa. Found at https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/1025tr.pdf.

¹⁵ Agency for Toxic Substances and Disease Registry (ATSDR). Toxicological Profile for Ethylene Oxide. U.S. Public Health Service, U.S. Department of Health and Human Services, Atlanta, GA. 2022. <https://www.atsdr.cdc.gov/toxprofiles/tp137.pdf>.

meaning it acts directly on DNA and causes chromosome damage. Children may be particularly susceptible to the harmful effects of mutagenic substances.¹⁶

3 Small Entity Analysis

The Regulatory Flexibility Act (RFA) requires an agency to prepare a regulatory flexibility analysis for any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions. The EPA determined that this action will not have a significant economic impact on a substantial number of small entities (SISNOSE) under the RFA. In making this determination, the impact of concern is any significant adverse economic impact on small entities. This proposed reconsideration is estimated to have a net cost savings for the affected facilities (shown in Section 2) and will relax certain requirements relative to the 2024 Final Rule.

The EPA identified 89 EtO sterilization facilities currently operating in the U.S. that will be impacted by this action. There are 49 ultimate parent companies that own the 89 commercial sterilization facilities affected by this final rule, as several parent companies own multiple facilities. About 39 percent (19) of the 49 parent companies are small entities. Out of the 89 facilities expected to be affected by the reconsideration, 23 facilities, or about 26 percent of facilities, are owned by ultimate parent companies that are small entities based on the business size standards defined by the SBA.¹⁷

See Table 3 for average entity-level requirement costs, annualized cost savings, and entity sales estimates under the proposed reconsideration by entity size. The average annualized cost savings is about \$0.68 million for small entities and about \$0.35 million for large entities. Average annual sales for the 19 small entities is \$38 million, while the remaining 30 entities have average annual sales of \$15 billion.

¹⁶ U.S. EPA. (2005). *Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens*. Found at https://www.epa.gov/sites/default/files/2013-09/documents/childrens_supplement_final.pdf.

¹⁷ U.S. Small Business Administration. (2022). *Table of Small Business Size Standards*. Found at <https://www.sba.gov/document/support-table-size-standards>.

Table 3. Mean Costs, Cost Savings, and Sales (2024\$) by Entity Size

Entity Size	Number of Affected Entities	Percent of Affected Entities	Number of Affected Facilities	Percent of Affected Facilities	Mean Annualized Costs (millions)	Mean Annualized Cost Savings (millions)	Mean Annual Sales (millions)
Small	19	39%	23	26%	\$0.55	\$0.68	\$38
Not Small	30	61%	66	74%	\$0.13	\$0.35	\$15,000
All	49		89		\$0.68	\$1.00	\$9,000

Note: Values have been rounded to two significant figures. Annualized costs and cost savings are summed across facilities owned by a single parent company.

To assess potential impacts on small entities, the EPA calculates cost-to-sales ratios (CSRs), which compare facility-level annualized compliance costs aggregated to the ultimate parent company level to annual sales revenues of the ultimate parent company. This metric for evaluating impacts is known as the “sales test” and is consistent with guidance published by SBA’s Office of Advocacy.¹⁸ As shown in Table 2, this proposed reconsideration does incur cost increases related to one-time costs for cycle revalidations and recordkeeping and reporting costs. However, these cost increases are less than the net cost savings for 16 of the affected 19 small entities. The 16 small entities estimated to experience net cost savings under this proposed reconsideration are expected to have lower CSRs relative to the 2024 Final Rule. Of the 3 small entities projected to incur additional requirement costs relative to 2024 Final Rule, one has an estimated CSR above 3 percent. Consequently, the EPA concludes that the estimated impacts of this action will not present a SISNOSE under the RFA.

4 Results of Regulatory Impact Analysis of Proposed Action

Consistent with guidance for E.O. 12866, the EPA presents PV estimates of the benefits, costs, and net benefits over an analytical timeframe. We have chosen a twenty-year timeframe (from 2026 to 2045) to reflect the equipment life of the control technologies considered in this rulemaking. To calculate the PV, annual benefits and costs are discounted to 2026. The choice of social discount rates reflects the guidance of OMB Circular A-4, which suggests a 3 percent rate

¹⁸ U.S. SBA, Office of Advocacy. (2017). *A Guide for Government Agencies: How to Comply with the Regulatory Flexibility Act*. Retrieved from <https://advocacy.sba.gov/2017/08/31/a-guide-for-government-agencies-how-to-comply-with-the-regulatory-flexibility-act/>.

to represent the social rate of time preference (i.e., the rate at which society discounts future consumption) and a 7 percent rate to represent the opportunity cost of capital.¹⁹ The discounted annual values are then summed over the twenty-year period to calculate the PV. The EPA also presents the EAV, which represents a flow of constant annual values that, had they occurred in each year from 2026 to 2045, would yield a sum equivalent to the PV.

Table 4 shows the cost savings estimates of this proposed reconsideration. The undiscounted costs are shown in the columns for capital cost savings and annual O&M cost savings (the total undiscounted cost savings are obtained from summing the two columns). The costs savings for the subset of units exempted under the Proclamation have been staggered by two years, as presented in the table. This is presented in Table 4 as two simultaneous streams of costs: one starting in the year 2026 (reflecting affected facilities not covered by the Proclamation) and the other staggered two years to 2028 (reflecting the later effective date for affected facilities under the two-year exemption). The PV of the estimated compliance cost savings from 2026 to 2045 for the proposed reconsideration is \$630 million in 2024 dollars, discounted at a 3 percent rate. The EAV of the estimated cost savings is \$43 million, using a 3 percent discount rate. Using a 7 percent discount rate, the PV and EAV of the cost savings are estimated to be \$510 million and \$48 million, respectively.

¹⁹ OMB. *Circular No. A-4*. September 17, 2003. <https://www.federalregister.gov/documents/2003/10/09/03-25606/circular-a-4-regulatory-analysis>. Accessed 7/10/2025

Table 4. Cost Savings of Proposed Reconsideration (millions of 2024\$)

	Capital Cost Savings	Annual O&M Cost Savings	Undiscounted Cost Savings	Discounted Cost Savings (3%)	Discounted Cost Savings (7%)
2026	\$110	\$10	\$120	\$120	\$120
2027	\$0	\$13	\$13	\$12	\$12
2028	\$140	\$24	\$160	\$150	\$140
2029	\$0	\$27	\$27	\$24	\$22
2030	\$0	\$27	\$27	\$24	\$20
2031	\$0	\$27	\$27	\$23	\$19
2032	\$0	\$27	\$27	\$22	\$18
2033	\$0	\$27	\$27	\$22	\$17
2034	\$0	\$27	\$27	\$21	\$15
2035	\$0	\$27	\$27	\$20	\$14
2036	\$16	\$27	\$43	\$32	\$22
2037	\$0	\$27	\$27	\$19	\$13
2038	\$13	\$27	\$40	\$28	\$18
2039	\$0	\$27	\$27	\$18	\$11
2040	\$0	\$27	\$27	\$18	\$10
2041	\$0	\$27	\$27	\$17	\$10
2042	\$0	\$27	\$27	\$17	\$9
2043	\$0	\$27	\$27	\$16	\$8
2044	\$0	\$27	\$27	\$16	\$8
2045	\$0	\$27	\$27	\$15	\$7
			PV	\$630	\$510
			EAV	\$43	\$48

Note: Values have been rounded to two significant figures. Values may not appear to add correctly due to rounding.

The summary of impacts of the proposed reconsideration to the subpart O NESHAP for EtO commercial sterilization and fumigation facilities is shown in Table 5. The monetized net benefits associated with the regulated pollutants are the regulatory cost savings of this proposed action presented above in Table 4. Non-monetized disbenefits associated with the regulated pollutants are expected from the health effects from estimated increases of about 7.8 tons of EtO annually.

Table 5. Present Value and Equivalent Annualized Value Estimates of Compliance Cost Savings from 2026 to 2045 (Million 2024\$)

3 Percent		7 Percent	
PV	EAV	PV	EAV
\$630	\$43	\$510	\$48

Note: Values have been rounded to two significant figures.

5 Uncertainties

The cost estimates are subject to several sources of uncertainty. This analysis includes many data sources as inputs, including source counts, equipment and labor costs, and assumptions regarding the current state of the EtO sterilization industry and how individual facilities carry out their operations, the future state of the industry, and the future state of the world (e.g., regulations, technology, economic activity, and human behavior). There is also uncertainty about the specific components of the engineering costs, such as the costs of the equipment and labor required to comply with the rule and how the costs might change over time. Facilities may comply with the requirements through alternative methods that were not accounted for in the cost memo. Each of the inputs and assumptions used is uncertain to some degree and generates uncertainty in the overall cost estimates. When the uncertainties from each stage of the analysis are compounded, even small uncertainties can have large effects on the total cost estimates.

The requirements of this proposed reconsideration may not impact all locations with EtO sterilizers equally, in part due to differences in state and local policies, such as consent orders in locations like Illinois and Georgia.²⁰ In addition, the baseline may not reflect all voluntary actions firms may take to reduce EtO emissions. By not fully accounting for state and local requirements and voluntary actions in the baseline, this analysis may overestimate the costs savings of the rule. To estimate the cost savings from this proposed reconsideration, the analysis assumes that compliance for the 2024 Final Rule would have started in 2026 and that upfront capital costs would have been incurred in 2026, and that may not be the case. Companies had two years to comply with some requirements and three years to comply with other requirements of the 2024 Final Rule upon the rule’s promulgation, but capital investment may have begun in 2024,

²⁰ For more information, see <https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/ethyleneoxide-sterilization-facility-updates>.

after promulgation of the rule, or may continue up until the later compliance date in 2027. The cost impacts were estimated out to 2045, and more uncertainty is introduced when impacts are estimated this far into the future.

The total number of facilities subject to the action could change. The EPA estimated costs for existing facilities, but other new facilities may be constructed and become subject to the requirements. Facilities may modify or upgrade in ways that affect the number of the various emissions points impacted by this rule (e.g., adding a sterilization chamber or aeration room). They may alter their EtO usage and thus become subject to different requirements. Additionally, new control technology may become available in the future at lower cost, and the EPA is unable to predict exactly how industry will comply with the rule in the future. The EPA is also unable to predict whether some firms will choose to exit the market due to the final requirements. Some firms, such as small businesses, may not be able to obtain financing at the assumed interest rate.

There may be an opportunity cost associated with the installation of environmental controls (for purposes of mitigating the emission of pollutants) that is not reflected in the compliance costs included in Section 2.1. If environmental investment displaces investment in productive capital, the difference between the rate of return on the marginal investment (which is discretionary in nature) displaced by the mandatory environmental investment is a measure of the opportunity cost of the environmental requirement to the regulated entity. To the extent that any opportunity costs are not included in the control costs, the compliance costs for this action may be underestimated.

The estimated changes in EtO emissions for affected facilities involve several uncertainties. These uncertainties, elaborated upon earlier in this section, pertain to the effectiveness of compliance methods in mitigating EtO emissions, as well as the projected production levels and operational dynamics of the impacted facilities. Additional uncertainties are from the availability and efficacy of control technologies and the potential introduction of supplementary regulations applicable to this source category. Furthermore, due to the absence of quantified health impacts associated with this proposed rule, we are unable to monetize the benefits, making the monetized net benefits associated with the regulated pollutants the regulatory cost savings. Should the impacts from increased EtO exposure be monetized, they would reduce the overall monetized benefits relative to the anticipated cost savings.