SUPPORTING STATEMENT
ENVIRONMENTAL PROTECTION AGENCY

NESHAP for Commercial Ethylene Oxide Sterilization and Fumigation Operations (40 CFR Part 63, Subpart O) (Renewal)

1. Identification of the Information Collection

1(a) Title of the Information Collection

NESHAP for Commercial Ethylene Oxide Sterilization and Fumigation Operations (40 CFR Part 63, Subpart O) (Renewal), EPA ICR Number 1666.12, OMB Control Number 2060-0283.

1(b) Short Characterization/Abstract

The National Emission Standards for Hazardous Air Pollutants (NESHAP) for Commercial Ethylene Oxide Sterilization and Fumigation Operations (40 CFR Part 63, Subpart O) were proposed on March 7, 1994; promulgated on December 6, 1994; and most recently amended on February 27, 2014. These regulations apply to existing facilities and new facilities ethylene oxide (EO) sterilization and fumigation facilities using one ton of EO (as defined in 40 CFR section 63.361) after December 6, 1994. New facilities include those that commenced either construction, modification, or reconstruction after the date of proposal. This information is being collected to assure compliance with 40 CFR Part 63, Subpart O.

In general, all NESHAP standards require initial notifications, performance tests, and periodic reports by the owners/operators of the affected facilities. They are also required to maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative. These notifications, reports, and records are essential in determining compliance and are required of all affected facilities subject to NESHAP.

Any owner/operator subject to the provisions of this part shall maintain a file of these measurements and retain the file for at least five years following the date of such measurements, maintenance reports, and records. All reports required to be submitted electronically are submitted through the EPA's Central Data Exchange (CDX), using the Compliance and Emissions Data Reporting Interface (CEDRI), where the delegated state or local authority can review them. In the event that there is no such delegated authority, the EPA regional office can review them. All other reports are sent to the delegated state or local authority. If there is no such delegated authority, the reports are sent directly to the EPA’s regional offices. The use of the term "Designated Administrator" throughout this document refers to the U.S. EPA or a delegated authority, such as a state agency. The term "Administrator" alone refers to the U.S. EPA Administrator.

The “Affected Public” are owners or operators of commercial ethylene oxide sterilization and fumigation operations. The “burden” to the Affected Public may be found at the end of this document in Table 1: Annual Respondent Burden and Cost – NESHAP for Commercial Ethylene Oxide Sterilization and Fumigation Operations (40 CFR Part 63, Subpart O) (Renewal). The ‘burden’ to the “Federal Government” is attributed entirely to work performed by either Federal employees or government contractors and may be found in Table 2: Average Annual EPA Burden and Cost – NESHAP for Commercial Ethylene Oxide Sterilization and Fumigation Operations (40 CFR Part 63, Subpart O) (Renewal). There are approximately 97 ethylene oxide sterilization and fumigation facilities, which are owned and operated by the ethylene oxide sterilization and fumigation facilities industry. None of the 97 facilities in the United States are owned by either state, local, or tribal entities or the Federal government. They are all owned and operated by privately-owned, for-profit businesses. We assume that they will all respond to EPA inquiries.

Based on our consultations with industry representatives, there is an average of one affected facility at each plant site and each plant site has only one respondent (i.e., the owner/operator of the plant site).

Over the next three years, approximately 97 respondents per year will be subject to these standards, and no additional respondents per year will become subject to these same standards.

The previous ICR had the following Terms of Clearance (TOC): The Office of Management and Budget (OMB) approved the currently active ICR without any “Terms of Clearance.”

Upon resubmission, the agency must update the burden estimates to accurately reflect the number of respondents in industry and verify that there are no reporting or recordkeeping requirements for States in 40 CFR part 63, subpart O. The agency must also ensure that burden is calculated for all of the requirements and that the requirements and burden tables are consistent throughout the supporting statement. The agency must provide screen shots of the electronic mode of collection that is used for this information collection. In addition, the agency must have a burden statement that aligns with the requirements under 5 CFR 1320.8(b)(3) and placement of the OMB control number for on-line submissions on the initial screen per 5 CFR 1320.3(f)(2).

In renewing the currently approved ICR, the agency has reviewed the number of respondents in industry and updated the burden estimates accordingly. In this case, we identified 97 number of sources based on consolidation within the industry. There are no reporting requirements for states. ‘Burden’ has been calculated for all requirements, which are reflected in the burden tables of the supporting statement. All electronic collection in this information collection is submitted through EPA's CEDRI or ERT, as discussed in section 4(b)(i) of this document. Additional Paperwork Reduction Act requirements for CEDRI and ERT, including the burden statement and OMB control number, are available at*: https://www.epa.gov/electronic-reporting-air-emissions/paperwork-reduction-act-pra-cedri-and-ert*.

2. Need for and Use of the Collection

2(a) Need/Authority for the Collection

The EPA is charged under Section 112 of the Clean Air Act, as amended, to establish standards of performance for each category or subcategory of major sources and area sources of hazardous air pollutants. These standards are applicable to new or existing sources of hazardous air pollutants and shall require the maximum degree of emission reduction. In addition, section 114(a) states that the Administrator may require any owner/operator subject to any requirement of this Act to:

> (A) Establish and maintain such records; (B) make such reports; (C) install, use, and maintain such monitoring equipment, and use such audit procedures, or methods; (D) sample such emissions (in accordance with such procedures or methods, at such locations, at such intervals, during such periods, and in such manner as the Administrator shall prescribe); (E) keep records on control equipment parameters, production variables or other indirect data when direct monitoring of emissions is impractical; (F) submit compliance certifications in accordance with Section 114(a)(3); and (G) provide such other information as the Administrator may reasonably require.

In the Administrator's judgment, ethylene oxide emissions from commercial EO sterilization and fumigation facilities either cause or contribute to air pollution that may reasonably be anticipated to endanger public health and/or welfare. Therefore, the NESHAP were promulgated for this source category at 40 CFR Part 63, Subpart O.

2(b) Practical Utility/Users of the Data

The recordkeeping and reporting requirements in these standards ensure compliance with the applicable regulations which were promulgated in accordance with the Clean Air Act. The collected information is also used for targeting inspections and as evidence in legal proceedings.

Performance tests are required in order to determine an affected facility’s initial capability to comply with these emission standards. Continuous emission monitors are used to ensure compliance with these same standards at all times. During the performance test a record of the operating parameters under which compliance was achieved may be recorded and used to determine compliance in place of a continuous emission monitor.

The notifications required in these standards are used to inform the Agency or delegated authority when a source becomes subject to the requirements of the regulations. The reviewing authority may then inspect the source to check if the pollution control devices are properly

installed and operated, leaks are being detected and repaired, and that these standards are being met. The performance test may also be observed.

The required semiannual reports are used to determine periods of excess emissions, identify problems at the facility, verify operation/maintenance procedures, and for compliance determinations.

Additionally, the EPA is requiring electronic reporting for certain notifications or reports. The EPA is requiring that owners or operators of affected sources would submit electronic copies of initial notifications required in 40 CFR 63.9(b) and change in information already provided required by 40 CFR 63.9(j) through the EPA's Central Data Exchange (CDX), using the Compliance and Emissions Data Reporting Interface (CEDRI). For the notifications required in 40 CFR 63.9(b) and 63.9(j), owners and operators would be required to upload a PDF of the required notifications.

3. Non-duplication, Consultations, and Other Collection Criteria

The requested recordkeeping and reporting are required under 40 CFR Part 63, Subpart O.

3(a) Non-duplication

For reports required to be submitted electronically, the information is sent through the EPA's CDX, using CEDRI, where the appropriate EPA regional office can review it, as well as for state and local agencies that have been delegated authority. If a state or local agency has adopted under its own authority its own standards for reporting or data collection, adherence to those non-Federal requirements does not constitute duplication.

For all other reports, if the subject standards have not been delegated, the information is sent directly to the appropriate EPA regional office. Otherwise, the information is sent directly to the delegated state or local agency. If a state or local agency has adopted its own standards to implement the Federal standards, a copy of the report submitted to the state or local agency can be sent to the Administrator in lieu of the report required by the Federal standards. Therefore, duplication does not exist.

3(b) Public Notice Required Prior to ICR Submission to OMB

An announcement of a public comment period for the renewal of this ICR was published in the *Federal Register* (FR citation, e.g., 87 FR 20847) on April 8, 2022. No comments were received on the burden published in the *Federal Register* for this renewal.

3(c) Consultations

The Agency has consulted industry experts and internal data sources to project the number of affected facilities and industry growth over the next three years. The primary source of information as reported by industry, in compliance with the recordkeeping and reporting provisions in these standards, is the Integrated Compliance Information System (ICIS). ICIS is EPA's database for the collection, maintenance, and retrieval of compliance data for industrial and government-owned facilities. The growth rate for the industry is based on our consultations with the Agency's internal industry experts. Approximately 97 respondents will be subject to these same standards over the three-year period covered by this ICR.

Industry trade association(s) and other interested parties were provided an opportunity to comment on the burden associated with these standards as they were being developed and these same standards have been reviewed previously to determine the minimum information needed for compliance purposes. In developing this ICR, we contacted both the Ethylene Oxide Sterilization Association, Inc. (EOSA), at (866) 235-5030; and Sterilization Services, at (404) 344-8423.

It is our policy to respond after a thorough review of comments received since the last ICR renewal, as well as for those submitted in response to the first *Federal Register* notice. In this case, no comments were received.

3(d) Effects of Less-Frequent Collection

Less-frequent information collection would decrease the margin of assurance that facilities are continuing to meet these standards. Requirements for information gathering and recordkeeping are useful techniques to ensure that good operation and maintenance practices are applied and emission limitations are met. If the information required by these standards was collected less-frequently, the proper operation and maintenance of control equipment and the possibility of detecting violations would be less likely.

3(e) General Guidelines

These reporting or recordkeeping requirements do not violate any of the regulations promulgated by OMB under 5 CFR Part 1320, Section 1320.5.

These standards require the respondents to maintain all records, including reports and notifications for at least five years. This is consistent with the General Provisions as applied to these standards. The EPA believes that the five-year records retention requirement is consistent with the Part 70 permit program and the five-year statute of limitations on which the permit program is based. The retention of records for five years allows EPA to establish the compliance history of a source, any pattern of non-compliance and to determine the appropriate level of enforcement action. The EPA has found that the most flagrant violators have violations

extending beyond five years. In addition, EPA would be prevented from pursuing the violators due to either the destruction or nonexistence of essential records.

3(f) Confidentiality

Any information submitted to the Agency for which a claim of confidentiality is made will be safeguarded according to the Agency policies set forth in Title 40, chapter 1, part 2, subpart B - Confidentiality of Business Information (CBI) (see 40 CFR 2; 41 FR 36902, September 1, 1976; amended by 43 FR 40000, September 8, 1978; 43 FR 42251, September 20, 1978; 44 FR 17674, March 23, 1979).

3(g) Sensitive Questions

The reporting or recordkeeping requirements in the standard do not include sensitive questions.

4. The Respondents and the Information Requested

4(a) Respondents/SIC Codes

The respondents to the recordkeeping and reporting requirements are commercial EO sterilization and fumigation facilities. The United States Standard Industrial Classification (SIC) codes and the corresponding North American Industry Classification System (NAICS) codes for the respondents affected by the standard are listed in the table below:

Standard (e.g., 40 CFR Part 63, Subpart O)	**SIC Codes**	**NAICS Codes**
Medical Equipment Suppliers	3841, 3842	339112, 339113
Pharmaceutical Suppliers	2833, 2834	325411, 325412
Other Health-Related Facilities	2211, 2821, 3569, 3677, 3693, 3999	31321, 325211, 32532, 333999, 334416, 337127
Spice Manufacturers	2034, 2035	311423, 311421, 311941, 311942
Contract Sterilizers	7218	812332
Libraries, Museums, and Archives	8412	71211
Laboratories	0279, 8071, 8999	112519, 54199, 621512, 621511, 54169

4(b) Information Requested

(i) Data Items

In this ICR, all the data that are recorded or reported is required by the NESHAP for Commercial Ethylene Oxide Sterilization and Fumigation Operations (40 CFR Part 63, Subpart O).

A source must make the following reports:

Notifications	
Notification of applicability	§63.9(a), §63.366(c)
Notification of construction/reconstruction	§§63.9(b)(4), §63.366(c)
Notification of actual startup	§§63.9(b)(2) and (4), §63.366(c)
Notification of initial performance test	§63.9(e)
Notification of compliance status	§63.9(h)
Request for extension of compliance	§63.9(c)
Request for waivers	§63.7(h)
Request for alternative methods/monitoring	§63.8(f)
Notification of changes in information (reclassification to area source status or to revert to major source status) (electronic submission)	§63.9(b), §63.9(j)

Reports	
Report of performance test results	§63.10(d)(2)
Reports of noncompliance (including excess emissions reports)	§63.10(e)(3)

A source must keep the following records:

Recordkeeping	
Records of control equipment maintenance; inspections, malfunctions; continuous monitoring systems malfunctions or in operation; calibrations and parameters; measurements to demonstrate compliance;	§§63.10(c)(1) and (5), §§63.10(b)(2) (ii), (iv-xii), (xiv),

Recordkeeping	
performance test results; daily and monthly inspections; and documents supporting initial notifications and notification of compliance status	§63.367(a)
Retain records for five years	§63.7(g)(3), §63.10(b)(1), §63.367(a)
Emission testing (occurrence/duration)	§§63.10(b)(2)(ii), (vi-xii), (xiv) §63.367(d)
Records of ethylene oxide usage	§63.10(b) and (c), §§63.367(b), (c)

Electronic Reporting

Some of the respondents are using monitoring equipment that automatically records parameter data. Although personnel at the affected facility must still evaluate the data, internal automation has significantly reduced the burden associated with monitoring and recordkeeping at a plant site.

The rule was amended to include electronic reporting provisions on November 19, 2020. Respondents are also required to submit electronic copies of notifications and certain reports through EPA's CEDRI. The notification is an upload of their currently required notification in portable document format (PDF) file. It reflects the reporting elements required by the rule and does not impose additional reporting elements. The OMB Control Number is displayed on the Welcome page of the template, with a link to an online repository that contains the PRA requirements. For purposes of this ICR, it is assumed that there is no additional burden associated with the proposed requirement for respondents to submit the notifications and reports electronically.

Electronic copies of records may also be maintained in order to satisfy federal recordkeeping requirements. For additional information on the Paperwork Reduction Act requirements for CEDRI and ERT for this rule, see: *https://www.epa.gov/electronic-reporting-air-emissions/paperwork-reduction-act-pra-cedri-and-ert*.

(ii) Respondent Activities

Respondent Activities
Familiarization with the regulatory requirements.

Respondent Activities
Install, calibrate, maintain, and operate CMS for opacity, or for pressure drop and liquid supply pressure for control device.
Perform initial performance test, Reference Method 2, 2A, 2C, or 2D, 18, or 25A, ASTM D 3695-88, or CARB Method 431 tests, and repeat performance tests if necessary.
Write the notifications and reports listed above.
Enter information required to be recorded above.
Submit the required reports developing, acquiring, installing, and utilizing technology and systems for collecting, validating, and verifying information.
Develop, acquire, install, and utilize technology and systems for processing and maintaining information.
Develop, acquire, install, and utilize technology and systems for disclosing and providing information.
Train personnel to be able to respond to a collection of information.
Transmit, or otherwise disclose the information.

5. The Information Collected: Agency Activities, Collection Methodology, and Information Management

5(a) Agency Activities

The EPA conducts the following activities in connection with the acquisition, analysis, storage, and distribution of the required information:

Agency Activities
Review notifications and reports, including performance test reports, and excess emissions reports, required to be submitted by industry.
Audit facility records.
Input, analyze, and maintain data in the Enforcement and Compliance History Online (ECHO) and ICIS.

5(b) Collection Methodology and Management

Following notification of startup, the reviewing authority could inspect the source to

determine whether the pollution control devices are properly installed and operated. Performance test reports are used by the Agency to discern a source's initial capability to comply with the emission standard and note the operating conditions under which compliance was achieved. Data and records maintained by the respondents are tabulated and published for use in compliance and enforcement programs. The semiannual reports are used for problem identification, as a check on source operation and maintenance, and for compliance determinations.

Information contained in the reports is reported by state and local governments in the ICIS Air database, which is operated and maintained by EPA's Office of Compliance. The EPA uses ICIS for tracking air pollution compliance and enforcement by local and state regulatory agencies, EPA regional offices, and EPA headquarters. The EPA and its delegated Authorities can edit, store, retrieve and analyze the data.

The records required by this regulation must be retained by the owner/operator for five years.

5(c) Small Entity Flexibility

The majority of respondents are large entities (i.e., large businesses). The exact number of small entities affected by this rule could not be determined based on review of available documents, including a Section 114 request for the Ethylene Oxide Commercial Sterilization and Fumigation Operations from May 2021. However, the impact on small entities (i.e., small businesses) was taken into consideration during the development of the regulation. Due to technical considerations involving the process operations and the types of control equipment employed, the recordkeeping and reporting requirements are the same for both small and large entities. The Agency considers these to be the minimum requirements needed to ensure compliance and, therefore, cannot reduce them further for small entities. To the extent that larger businesses can use economies of scale to reduce their burden, the overall burden will be reduced.

5(d) Collection Schedule

The specific frequency for each information collection activity within this request is shown at the end of this document in Table 1: Annual Respondent Burden and Cost – NESHAP for Commercial Ethylene Oxide Sterilization and Fumigation Operations (40 CFR Part 63, Subpart O) (Renewal).

6. Estimating the Burden and Cost of the Collection

Table 1 documents the computation of individual burdens for the recordkeeping and reporting requirements applicable to the industry for the subpart included in this ICR. The individual burdens are expressed under standardized headings believed to be consistent with the concept of 'Burden' under the Paperwork Reduction Act. Where appropriate, specific tasks and major assumptions have been identified. Responses to this information collection are mandatory.

The Agency may neither conduct nor sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB Control Number.

6(a) Estimating Respondent Burden

The average annual burden to industry over the next three years from these recordkeeping and reporting requirements is estimated to be 6,640 hours (Total Labor Hours from Table 1). These hours are based on Agency studies and background documents from the development of the regulation, Agency knowledge and experience with the NESHAP program, the previously-approved ICR, and any comments received.

6(b) Estimating Respondent Costs

(i) Estimating Labor Costs

This ICR uses the following labor rates:

Managerial	$157.61 ($75.05 + 110%)
Technical	$123.94 ($59.02 + 110%)
Clerical	$62.52 ($29.77 + 110%)

These rates are from the United States Department of Labor, Bureau of Labor Statistics, September 2021, "Table 2. Civilian Workers, by occupational and industry group." The rates are from column 1, "Total compensation." The rates have been increased by 110 percent to account for varying industry wage rates and the additional overhead business costs of employing workers beyond their wages and benefits, including business expenses associated with hiring, training, and equipping their employees.

(ii) Estimating Capital/Startup and Operation and Maintenance Costs

The type of industry costs associated with the information collection activities in the subject standards are both labor costs which are addressed elsewhere in this ICR and the costs associated with continuous monitoring. The capital/startup costs are one-time costs when a facility becomes subject to the regulation. The annual operation and maintenance costs are the ongoing costs to maintain the monitors and other costs such as photocopying and postage.

(iii) Capital/Startup vs. Operation and Maintenance (O&M) Costs

Capital/Startup vs. Operation and Maintenance (O&M) Costs						
(A) Continuous Monitoring Device	(B) Capital/ Startup Cost for One Respondent	(C) Number of New Respondents	(D) Total Capital/Startup Cost, (B X C)	(E) Annual O&M Costs for One Respondent	(F) Number of Respondents with O&M	(G) Total O&M, (E X F) [2]
Computer equipment and GC [1]	$32,500	0	$0	$5,500	97	$534,000

[1] Computer equipment and gas chromatograph (GC) are used to continuously monitor EO emissions to aeration room and back chamber vents

[2] Totals have been rounded to 3 significant figures. Figures may not add exactly due to rounding.

The total capital/startup costs for this ICR are $0. This is the total of column D in the above table.

The total operation and maintenance (O&M) costs for this ICR are $534,000. This is the total of column G.

The average annual cost for capital/startup and operation and maintenance costs to industry over the next three years of the ICR is estimated to be $534,000. These are recordkeeping costs.

6(c) Estimating Agency Burden and Cost

The only costs to the Agency are those costs associated with analysis of the reported information. The EPA's overall compliance and enforcement program includes such activities as the examination of records maintained by the respondents, periodic inspection of sources of emissions, and the publication and distribution of collected information.

The average annual Agency cost during the three years of the ICR is estimated to be $16,400.

This cost is based on the average hourly labor rate as follows:

Managerial	$70.56 (GS-13, Step 5, $44.10 + 60%)
Technical	$52.37 (GS-12, Step 1, $32.73 + 60%)
Clerical	$28.34 (GS-6, Step 3, $17.71 + 60%)

These rates are from the Office of Personnel Management (OPM), 2022 General

Schedule, which excludes locality rates of pay. The rates have been increased by 60 percent to account for the benefit packages available to Federal government employees. Details upon which this estimate is based appear at the end of this document in Table 2: Average Annual EPA Burden and Cost – NESHAP for Commercial Ethylene Oxide Sterilization and Fumigation Operations (40 CFR Part 63, Subpart O) (Renewal).

6(d) Estimating the Respondent Universe and Total Burden and Costs

Based on our research for this ICR, on average over the next three years, approximately 97 existing respondents will be subject to these standards. It is estimated that no additional respondents per year will become subject to these same standards. The overall average number of respondents, as shown in the table below, is 97 per year.

The number of respondents is calculated using the following table that addresses the three years covered by this ICR:

Number of Respondents					
	Respondents That Submit Reports		Respondents That Do Not Submit Any Reports		
Year	(A) Number of New Respondents [1]	(B) Number of Existing Respondents	(C) Number of Existing Respondents that keep records but do not submit reports	(D) Number of Existing Respondents That Are Also New Respondents	(E) Number of Respondents (E=A+B+C-D)
1	0	97	0	0	97
2	0	97	0	0	97
3	0	97	0	0	97
Average	0	97	0	0	97

[1] New respondents include sources with constructed, reconstructed and modified affected facilities.

Column D is subtracted to avoid double-counting respondents. As shown above, the average Number of Respondents over the three-year period of this ICR is 97.

The total number of annual responses per year is calculated using the following table:

Total Annual Responses				
(A) Information Collection Activity	(B) Number of Respondents	(C) Number of Responses	(D) Number of Existing Respondents That Keep Records But Do Not Submit Reports	(E) Total Annual Responses E=(BxC)+D
Notification of Applicability	0	1	0	0
Notification of Construction/Reconstruction	0	1	0	0
Notification of Actual Startup	0	1	0	0
Notification of Initial Performance Test	0	1	0	0
Notification of Compliance Status	0	1	0	0
Request for Waiver	0	1	0	0
Report for Alternative Method/ Monitoring	0	1	0	0
Report for Performance Test	0	1	0	0
Reports for Periods of Noncompliance	83.7	2	0	174.6
			Total (rounded)	**175**

The number of Total Annual Responses is 175.

The total annual labor costs are $797,000. Details regarding these estimates may be found at the end of this document in Table 1: Annual Respondent Burden and Cost – NESHAP for Commercial Ethylene Oxide Sterilization and Fumigation Operations (40 CFR Part 63, Subpart O) (Renewal).

6(e) Bottom Line Burden Hours and Cost Tables

The detailed bottom line burden hours and cost calculations for the respondents and the Agency are shown in Tables 1 and 2 at the end of this document, respectively, and summarized below.

(i) Respondent Tally

The total annual labor hours are 6,640. Details regarding these estimates may be found below in Table 1: Annual Respondent Burden and Cost – NESHAP for Commercial Ethylene Oxide Sterilization and Fumigation Operations (40 CFR Part 63, Subpart O) (Renewal).

We assume that burdens for managerial tasks take 5% of the time required for technical

tasks because the typical tasks for managers are to review and approve reports. Clerical burdens are assumed to take 10% of the time required for technical tasks because the typical duties of clerical staff are to proofread the reports, make copies, and maintain records.

Furthermore, the annual public reporting and recordkeeping burden for this collection of information is estimated to average 38 hours per response.

The total annual capital/startup and O&M costs to the regulated entity are 534,000. The cost calculations are detailed in Section 6(b)(iii), Capital/Startup vs. Operation and Maintenance (O&M) Costs.

(ii) The Agency Tally

The average annual Agency burden and cost over next three years is estimated to be 321 labor hours at a cost of $16,400; see below in Table 2: Average Annual EPA Burden and Cost – NESHAP for Commercial Ethylene Oxide Sterilization and Fumigation Operations (40 CFR Part 63, Subpart O) (Renewal).

We assume that burdens for managerial tasks take 5% of the time required for technical tasks because the typical tasks for managers are to review and approve reports. Clerical burdens are assumed to take 10% of the time required for technical tasks because the typical duties of clerical staff are to proofread the reports, make copies and maintain records.

6(f) Reasons for Change in Burden

There is a decrease in the total estimated respondent burden compared with the ICR currently approved by OMB. The adjustment decrease in burden from the most recently approved ICR is due to a decrease in the number of sources. The previous ICR indicated 128 respondents. The EPA has recently identified 97 respondents over the next three years based on a Section 114 request for the Ethylene Oxide Commercial Sterilization and Fumigation Operations from May 2021. Conclusively, there has been a 25% decrease in sources. This ICR also reflects that there is overall zero growth anticipated in the industry over the next three years, and removes burden associated with new source activities. The overall result is a decrease in burden hours and operation and maintenance costs.

6(g) Burden Statement

The annual public reporting and recordkeeping burden for this collection of information is estimated to average 38 hours per response. ‘Burden’ means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information either to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing

information; adjust the existing ways to comply with any previously-applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

An agency may neither conduct nor sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB Control Number. The OMB Control Numbers for EPA regulations are listed at 40 CFR Part 9 and 48 CFR Chapter 15.

To comment on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including the use of automated collection techniques, EPA has established a public docket for this ICR under Docket ID Number EPA-HQ-OAR-2022-0079. An electronic version of the public docket is available at *http://www.regulations.gov/*, which may be used to obtain a copy of the draft collection of information, submit or view public comments, access the index listing of the contents of the docket, and to access those documents in the public docket that are available electronically. When in the system, select "search," then key in the docket ID number identified in this document. The documents are also available for public viewing at the Enforcement and Compliance Docket and Information Center in the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Ave., NW, Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. Due to COVID-19 precautions, entry to the Reading Room is available by appointment only. Please contact personnel in the Reading Room to schedule an appointment. The telephone number for the Reading Room is (202) 566-1744, and the telephone number for the docket center is (202) 566-1752. Also, you can send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503, Attention: Desk Officer for EPA. Please include the EPA Docket ID Number EPA-HQ-OAR-2022-0079 and OMB Control Number 2060-0283 in any correspondence.

Part B of the Supporting Statement

This part is not applicable because no statistical methods were used in collecting this information.

Table 1: Annual Respondent Burden and Cost – NESHAP for Commercial Ethylene Oxide Sterilization and Fumigation Operations (40 CFR Part 63, Subpart O) (Renewal)

Burden Items	(A) Hours per occurrence	(B) Occurrences per year	(C) Hours per year (AxB)	(D) Respondents per year [a]	(E) Technical hours per year (CxD)	(F) Managerial hours per year (Ex0.05)	(G) Clerical hours per year (Ex0.10)	(H) Total Cost per year, $ [b]
1. Applications	N/A							
2. Survey and Studies	N/A							
3. Reporting Requirements								
A. Familiarization with the regulatory requirements	1	1	1	97	97	4.85	9.7	$13,393.03
B. Required Activities								
Initial performance test [c]	200	1	200	0	0	0	0	$0
Repeat performance test [c, d]	200	1	200	0	0	0	0	$0
Preparation of site-specific test plan	Included Above							
C. Create Information	See 3B							
D. Gather Existing Information	See 3B							
E. Write Reports								
Notification of applicability [e]	2	1	2	0	0	0	0	$0
Notification of construction/reconstruction [e]	2	1	2	0	0	0	0	$0
Notification of actual startup [e]	2	1	2	0	0	0	0	$0
Notification of initial performance test [e]	2	1	2	0	0	0	0	$0
Notification of compliance	2	1	2	0	0	0	0	$0

status [e]								
Request for extension of compliance, adjustment to time periods, and changes in information	2	1	2	0	0	0	0	$0
Request for waiver [f]	6	1	6	0	0	0	0	$0
Report for alternative method monitoring [g]	6	1	6	0	0	0	0	$0
Report for performance test [h]	24	1	24	0	0	0	0	$0
Reports for periods of noncompliance (including excess emissions) [i]	14	2	28	87.3	2,444	122.22	244.44	$337,504.42
Subtotal for Reporting						***2,923***		***$350,897.45***
4. Recordkeeping Requirements								
A. Familiarization with the regulatory requirements	See 3A							
B. Plan Activities	See 3B							
C. Implement Activities	See 3B							
D. Develop Record System	See 3B							
E. Time to Enter Information								
Record of operating parameters and emissions [j]	0.1	365	36.5	87.3	3,186	159.3225	318.645	$439,961.12
Records of EO use [k]	0.6	12	7.2	0	0	0	0	$0
F. Time to transmit or disclose information [l]	0.25	2	0.5	87.3	43.65	2.1825	4.365	$6,026.86
G. Train Personnel	N/A							
H. Time for Audits	N/A							
Subtotal for Recordkeeping						***3,715***		***$445,987.98***
Total Labor Burden and						**6,640**		**$797,000**

Costs (rounded) [m]								
Total Capital and O&M Cost (rounded) [m]								**$534,000**
Grand Total (rounded) [m]								**$1,330,000**

Assumptions:

[a] There are an average of 97 respondents subject to the rule over the three-year period of this ICR. No additional new sources per year are expected to become subject to the rule over the three-year period of this ICR.

[b] This ICR uses the following labor rates: Managerial $157.61 ($75.05+ 110%); Technical $123.94 ($59.02 + 110%); and Clerical $62.52 ($29.77 + 110%). These rates are from the United States Department of Labor, Bureau of Labor Statistics, September 2021, "Table 2. Civilian Workers, by occupational and industry group." The rates are from column 1, "Total compensation." The rates have been increased by 110 percent to account for varying industry wage rates and the additional overhead business costs of employing workers beyond their wages and benefits, including business expenses associated with hiring, training, and equipping their employees.

[c] Assumes it will take 200 hours for each respondent to perform the initial and any repeat performance testing.

[d] Assumes that 20 percent of respondents will have to repeat performance tests due to failure.

[e] Assumes that it will take new respondents two hours to write each notification report.

[f] Assumes that 10 percent of new facilities will request a waiver and that it will take 6 hours to write requests for waivers.

[g] Assumes that 5 percent of new facilities will request an alternative monitoring method.

[h] Assumes that it will take 24 hours to prepare performance test reports.

[i] Assumes that 90 percent of respondents will take 14 hours each to complete reports of periods of noncompliance, which includes excess emissions. This will occur two times per year.

[j] Assumes that 90 percent of respondents will enter information on record of operating parameters and emissions 365 times per year.

[k] Assumes that 10 percent of facilities that are existing but also new are required to record EO usage. In this ICR, there are no such affected facilities, so none will be recording EO use.

[l] Assumes that 90 percent of respondents will submit reports twice per year.

[m] Totals have been rounded to 3 significant figures. Figures may not add exactly due to rounding.

Table 2: Average Annual EPA Burden and Cost – NESHAP for Commercial Ethylene Oxide Sterilization and Fumigation Operations (40 CFR Part 63, Subpart O) (Renewal)

Activity	(A) EPA Hours per Occurrence	(B) Occurrences per Year	(C) EPA Hours per Year (AxB)	(D) Plants per Year [a]	(E) Technical Hours per Year (CxD)	(F) Managerial Hours per Year (Ex0.05)	(G) Clerical hours per year (Ex0.10)	(H) Total cost per year $ [b]
Initial performance tests								
New or modified facility [c]	40	1	40	0	0	0	0	$0
Repeat performance tests								
New or modified facility [d]	40	1	40	0	0	0	0	$0
Report Review								
New or modified facility								
Notification of applicability	2	1	2	0	0	0	0	$0
Notification of construction/reconstruction [e]	2	1	2	0	0	0	0	$0
Notification of actual startup [e]	2	1	2	0	0	0	0	$0
Notification of initial performance test [e]	2	1	2	0	0	0	0	$0
Notification of compliance status [e]	2	1	2	0	0	0	0	$0
Request for extension of compliance, adjustment to time periods, and changes in information [f]	2	1	2	0	0	0	0	$0
Request for waiver [g]	4	1	4	0	0	0	0	$0
Request for alternative method/monitoring [h]	4	1	4	0	0	0	0	$0
Report of performance test [i]	8	1	8	0	0	0	0	$0
Report of periods of noncompliance (including excess emissions) [j]	8	2	16	17.5	279	14.0	27.9	$16,407.37
Total (rounded) [k]					**321**			**$16,400**

Assumptions:

[a] There are an average of 97 respondents subject to the rule over the three-year period of this ICR. No additional new sources per year are expected to become subject to the rule over the three-year period of this ICR.

[b] This cost is based on the average hourly labor rate as follows: Managerial $70.56 (GS-13, Step 5, $44.10 + 60%); Technical $52.37 (GS-12, Step 1, $32.73 + 60%); and Clerical $28.34 (GS-6, Step 3, $17.71 + 60%). This ICR assumes that Managerial hours are 5 percent of Technical hours, and Clerical hours are 10 percent of Technical hours. These rates are from the Office of Personnel Management (OPM), 2022 General Schedule, which excludes locality, rates of pay. The rates have been increased by 60 percent to account for the benefit packages available to government employees.

[c] Assumes that the Agency will take 40 hours to observe the initial performance test.

[d] Assumes that 20 percent of new respondents will fail the performance test and will have to repeat it.

[e] Assumes that the Agency will take two hours to review each notification report.

[f] Assumes that the Agency will take two hours to review each request for extension of the compliance report.

[g] The Agency assumes that 10 percent of new facilities will request a waiver.

[h] The Agency assumes that 5 percent of new facilities will request an alternative method monitoring.

[i] Assumes that the Agency will take 8 hours to review the report of performance test results.

[j] Assumes the Agency will review 20 percent of noncompliance reports and that it will take the Agency 8 hours to review reports of periods of noncompliance.

[k] Totals have been rounded to 3 significant figures. Figures may not add exactly due to rounding.