**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 1666.09, 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 were proposed on March 7, 1994, promulgated on December 6, 1994, and last amended on December 19, 2005. These regulations were amended on December 14, 1999 for Title V operating permit deferrals for area sources. These regulations apply to new and existing commercial ethylene oxide (EO) sterilization and fumigation facilities using 1 ton of EO (as defined in 40 CFR section 63.361) after December 6, 1994. New facilities include those that commenced construction 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 are sent to the delegated state or local authority. In the event that there is no such delegated authority, the reports are sent directly to the U. S. Environmental Protection Agency (EPA) regional office.

Over the next three years, an average of 122 respondents per year will be subject to the standard, and two additional respondents per year will become subject to the standard.

The Office of Management and Budget (OMB) approved the currently active ICR without any "Terms of Clearance."

There are 122 commercial ethylene oxide sterilization and fumigation facilities in the United States; all are commercially-owned and operated by the ethylene oxide sterilization and fumigation industry. None of the 122 facilities in the United States are owned by either state,

local, tribal or the Federal government entitites; they are all owned and operated solely by privately-owned, for-profit businesses. The burden to the "Affected Public" 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). The Federal Government "burden" is attributed entirely to work performed by either Federal employees or government contractors and may be found 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).

## 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, EO emissions from sterilization facilities cause or contribute to air pollution that may reasonably be anticipated to endanger public health or welfare. Therefore, the NESHAP were promulgated for this source category at 40 CFR part63, subpart O.

### 2(b) Practical Utility/Users of the Data

The recordkeeping and reporting requirements in the standard ensure compliance with the applicable regulations which where 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 the emission standards. Continuous emission monitors are used to

ensure compliance with the 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 the standard 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 the 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.

**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**

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 similar 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 (77 FR 63813) on October 17, 2012. No comments were received on the burden published in the Federal Register.

**3(c) Consultations**

The Agency's industry experts have been consulted, and the Agency's internal data sources and projections of industry growth over the next three years have been considered. The primary source of information as reported by industry, in compliance with the recordkeeping and reporting provisions in the standard, is the Online Tracking Information System (OTIS) which is operated and maintained by EPA's Office of Compliance. OTIS is EPA's database for the collection, maintenance, and retrieval of all compliance data. The growth rate for the industry is based on our consultations with the Agency's internal industry experts.

Industry trade associations and other interested parties were provided an opportunity to comment on the burden associated with the standards as it was being developed and the

standards have been reviewed previously to determine the minimum information needed for compliance purposes. In developing this ICR, we contacted: 1) the Ethylene Oxide Sterilization Association, Incorporated (EOSA), at (866) 235-5030; and 2) the 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 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 the 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 the standards. EPA believes that the five-year records retention requirement is consistent with 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. 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 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 owners or operators of commercial EO sterilization and fumigation facilities. The United States Standard Industrial Classification (SIC) codes for the respondents affected by the standards and the corresponding North American Industry Classification System (NAICS) codes are listed in the table below.

| Standard (40 CFR Part 63, Subpart O) | SIC Codes | NAICS Codes |
|---|---|---|
| Medical Equipment Suppliers | 3841, 3842 | 339112, 339113, |
| Pharmaceutical Suppliers | 2832, 2833, 2834, 5122 | 325411, 325412, 42221 |
| Other Health-Related Facilities | 2211, 2821, 2879, 3069, 3079, 3569, 3677, 3693, 3999, 5086 | 31321, 325211, 32532, 333999, 334416, 337127 |
| Spice Manufacturers | 2034, 2035, 2046, 2099, 5149 | 311423, 311421, 311941, 311942, 42249 |
| Contract Sterilizers | 7218, 7399, 8091 | 812332 |
| Libraries, Museums, and Archives | 8231, 8411 | 51412, 71211 |
| Laboratories | 0279, 7391, 7397, 8071, 8922 | 112519, 54199, 621512, 621511, 54169 |

### 4(b) Information Requested

#### (i) Data Items

In this ICR, all the data that is 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) |
| Notification of construction/reconstruction | 63.9(b)(3) and (4) |
| Notification of actual startup | 63.9(b)(2) and (4) |
| Notification of initial performance test | 63.9(e) |
| Notification of compliance status | 63.9(h) |

| Notifications | |
|---|---|
| | |
| Request for extension of compliance | 63.9(c) |
| Request for waivers | 63.7(h) |
| Request for alternative methods/monitoring | 63.8(f) |

| 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; performance test results; daily and monthly inspections; and documents supporting initial notifications and notification of compliance status | 63.10(c)(1) and (5), 63.10(b)(2)(ii), (iv-xii), (xiv) |
| Retain records for five years | 63.7(g)(3), 63.10(b)(1) |
| Emission testing (occurrence/duration) | 63.10(b)(2)(ii), (vi-xii), (xiv) |
| Report of EO use | 63.9(b)(2) |

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.

Also, regulatory agencies in cooperation with the respondents continue to create reporting systems to transmit data electronically. However, electronic reporting systems are still not widely used. At this time, it is estimated that approximately 10 percent of the respondents use electronic reporting.

### (ii) Respondent Activities

| Respondent Activities |
|---|
| Read instructions. |
| 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 test, 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 the purpose of collecting, validating, and verifying information. |
| Develop, acquire, install, and utilize technology and systems for the purpose of processing and maintaining information. |
| Develop, acquire, install, and utilize technology and systems for the purpose of disclosing and providing information. |
| Train personnel to be able to respond to a collection of information. |
| Transmit, or otherwise disclose the information. |

Currently sources are using monitoring and reporting equipment that provide parameter data in an automated way (e.g., continuous parameter monitoring system). Although personnel at the source still need to evaluate the data, this type of monitoring equipment has significantly reduced the burden associated with monitoring and recordkeeping.

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

### 5(a) Agency Activities

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 Online Tracking Information System (OTIS). |

**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. 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 entered into OTIS which is operated and maintained by EPA's Office of Compliance. OTIS is EPA's database for the collection, maintenance, and retrieval of compliance data for approximately 125,000 industrial and government-owned facilities. EPA uses the OTIS for tracking air pollution compliance and enforcement by local and state regulatory agencies, EPA regional offices and EPA headquarters. 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**

A majority of the 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 the Ethylene Oxide Commercial Sterilization and Fumigation Operations NESHAP Implementation Document (EPA-456/R-97-004, updated March 2004). 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 in below 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. Wherever appropriate, specific tasks and major assumptions have been identified. Responses to this information collection are mandatory.

The Agency may not conduct or 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 8,887 hours (Total Labor Hours from Table 1 below). 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 | $121.44 ($57.83 + 110%) |
| Technical | $100.23 ($47.73 + 110%) |
| Clerical | $50.51 ($24.05 + 110%) |

These rates are from the United States Department of Labor, Bureau of Labor Statistics, March 2012, “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 the benefit packages available to those employed by private industry.

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

The type of industry costs associated with the information collection activities in the subject standard 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 monitor 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) |
| Computer equipment and GC [1] | $32,500 | 2 | $65,000 | $5,500 | 109 | $599,500 |

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

The total capital/startup costs for this ICR are $65,000. This is the total of column D in the above table.

The total operation and maintenance (O&M) costs for this ICR are $599,500. 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 $664,500. These are the costs of recordkeeping.

**6(c) Estimating Agency Burden and Cost**

The only costs to the Agency are those costs associated with analysis of the reported information. EPA's overall compliance and enforcement program includes activities such 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 $27,177.

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

| | |
|---|---|
| Managerial | $62.27 (GS-13, Step 5, $38.92 + 60%) |
| Technical | $46.21 (GS-12, Step 1, $28.88 + 60%) |
| Clerical | $25.01 (GS-6, Step 3, $15.63 + 60%) |

These rates are from the Office of Personnel Management (OPM), 2012 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. Details upon which this estimate is

based appear 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).

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

Based on our research for this ICR, approximately 121existing respondents will be subject to the standards on average over the next three years. However, we estimate that 10 percent or approximately 12 facilities will use only limited amounts of EO and therefore, will not be required to submit reports. It is estimated that an additional two respondents per year will become subject. The overall average number of respondents, as shown in the table below is 122 per year

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

| Number of Respondents | | | | | |
|---|---|---|---|---|---|
| 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 | 2 | 108 | 12 | 1 | 121 |
| 2 | 2 | 109 | 12 | 1 | 122 |
| 3 | 2 | 110 | 12 | 1 | 123 |
| Average | 2 | 109 | 12 | 1 | 122 |

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

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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 122.

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

| Total Annual Responses | | | | |
|---|---|---|---|---|
| (A)<br>Information Collection Activity | (B)<br>Number of Respondents | (C)<br>Number of Responses | (D)<br>Number of Existing Respondents That Keep Records But Do Not Submit Reports | (E)<br>Total Annual Responses E=(BxC)+D |
| Notification of Applicability | 2 | 1 | 0 | 2 |
| Notification of Construction/Reconstruction | 2 | 1 | 0 | 2 |
| Notification of Actual Startup | 2 | 1 | 0 | 2 |
| Notification of Initial Performance Test | 2 | 1 | 0 | 2 |
| Notification of Compliance Status | 2 | 1 | 0 | 2 |
| Request for Waiver | 2 | 0.05 | 0 | 0.1 |
| Report for Alternative Method/ Monitoring | 2 | 0.05 | 0 | 0.1 |
| Report for Performance Test | 2 | 1 | 0 | 2 |
| Reports for Periods of Noncompliance | 109 | 2 | 12 | 230 |
| | | | **Total** | **242.2** |

The number of Total Annual Responses is 242 (rounded).

The total annual labor costs are $860,413. 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).

### 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, respectively, and summarized below.

#### (i) Respondent Tally

The total annual labor hours are 8,887 hours at a cost of $860,413. 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).

Furthermore, the annual public reporting and recordkeeping burden for this collection of information is estimated to average 37 hours per response.

The total annual capital/startup and O&M costs to the regulated entity are $664,500. 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 603 labor hours at a cost of $27,177. See below 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(f) Reasons for Change in Burden**

There is an adjustment increase in burden for both the respondents and the Agency from the most recently approved ICR. This is not due to any program changes. The increase is due to an update in labor rates and an increase of three respondents subject to the regulation since the last ICR. This results in an increase in respondent and Agency labor hours, costs, and total O&M costs.

**6(g) Burden Statement**

The annual public reporting and recordkeeping burden for this collection of information is estimated to average 37 hours per response. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information 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 not conduct or 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-OECA-2012-0664. 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. 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-OECA-2012-0664 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. Read Instructions | 1 | 1 | 1 | 2 | 2 | 0.1 | 0.2 | $222.71 |
| B. Required Activities | | | | | | | | |
| Initial performance test [c] | 200 | 1 | 200 | 2 | 400 | 20 | 40 | $44,541.20 |
| Repeat performance test [c, d] | 200 | 0.2 | 40 | 2 | 80 | 4 | 8 | $8,908.24 |
| 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 | 2 | 4 | 0.2 | 0.4 | $445.41 |
| Notification of construction/reconstruction [e] | 2 | 1 | 2 | 2 | 4 | 0.2 | 0.4 | $445.41 |
| Notification of actual startup [e] | 2 | 1 | 2 | 2 | 4 | 0.2 | 0.4 | $445.41 |
| Notification of initial performance test [e] | 2 | 1 | 2 | 2 | 4 | 0.2 | 0.4 | $445.41 |
| Notification of compliance status [e] | 2 | 1 | 2 | 2 | 4 | 0.2 | 0.4 | $445.41 |
| 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 | 0.1 | 0.6 | 0.03 | 0.06 | $66.81 |
| Report for alternative method monitoring [f] | 6 | 1 | 6 | 0.1 | 0.6 | 0.03 | 0.06 | $66.81 |
| Report for performance test [g] | 24 | 1 | 24 | 2 | 48 | 2.4 | 4.8 | $5,344.94 |
| Reports for periods of noncompliance (including excess emissions) [h] | 14 | 2 | 28 | 109 | 3,052 | 152.6 | 305.2 | $339,849.36 |

| 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] |
|---|---|---|---|---|---|---|---|---|
| **Subtotal for Reporting** | | | | | | **4,143.68** | | **$401,227.13** |
| 4. Recordkeeping Requirements | | | | | | | | |
| A. Read Instructions | 1 | 1 | 1 | 4.3 | 4.3 | 0.215 | 0.43 | $478.82 |
| 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 [i] | 0.1 | 365 | 36.5 | 109 | 3,979 | 198.95 | 397.9 | $443,017.91 |
| Records of EO use [j, k] | 0.6 | 12 | 7.2 | 12 | 86.4 | 4.32 | 8.64 | $9,620.90 |
| F. Time to transmit or disclose information [l] | 0.25 | 2 | 0.5 | 109 | 54.5 | 2.725 | 5.45 | $6,068.74 |
| G. Train Personnel | N/A | | | | | | | |
| H. Time for Audits | N/A | | | | | | | |
| **Subtotal for Recordkeeping** | | | | | | **4,742.83** | | **$459,186.37** |
| **Total Labor Burden and Cost (rounded)** | | | | | | **8,887** | | **$860,413** |

**Assumptions**:

[a] The average number of respondents that will be subject to the rule will be the 122 existing respondents. There will be two additional new sources per year that will become subject to the rule over the 3-year period of this ICR.

[b] This ICR uses the following labor rates: $121.44 for Managerial, $100.23 for Technical, and $50.51 for Clerical.

[c] It is assumed that it will take 200 hours for each respondent to perform the initial performance test and also repeat testing.

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

[e] It is assumed that it will initially take each of the new respondents two hours to write each notification report.

[f] It is assumed that 10 percent of new facilities will take 5 hours to write requests for waivers.

[g] It is assumed that each respondent will take 24 hours to prepare performance test reports.

[h] It is assumed that 109 respondents will take 14 hours to complete reports of periods of noncompliance, which includes excess emissions. This will occur two time per year.

[i] It is assumed that 109 respondents will enter information on record of operating parameters and emissions 365 times per year.

[j] It is assumed that the average number of affected facilities required to record EO usage is 12.

[k] It is assumed that each of the 12 respondents will record EO use 12 times per year.
[l] It is assumed that 109 respondents will disclose information two time per year.

**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 | 2 | 80 | 4 | 8 | $4,145.96 |
| Repeat performance tests | | | | | | | | |
| New or modified facility [d] | 136 | 1 | 136 | 0.4 | 54.4 | 2.72 | 5.44 | $2,819.25 |
| Report Review | | | | | | | | |
| New or modified facility | | | | | | | | |
| Notification of applicability | 2 | 1 | 2 | 2 | 4 | 0.2 | 0.4 | $207.30 |
| Notification of construction/reconstruction [e] | 2 | 1 | 2 | 2 | 4 | 0.2 | 0.4 | $207.30 |
| Notification of actual startup [e] | 2 | 1 | 2 | 2 | 4 | 0.2 | 0.4 | $207.30 |
| Notification of initial performance test [e] | 2 | 1 | 2 | 2 | 4 | 0.2 | 0.4 | $207.30 |
| Notification of compliance status [e] | 2 | 1 | 2 | 2 | 4 | 0.2 | 0.4 | $207.30 |
| Request for extension of compliance, adjustment to time periods, and changes in information | 2 | 1 | 2 | 2 | 4 | 0.2 | 0.4 | $207.30 |
| Request for waiver [g] | 4 | 1 | 4 | 0.2 | 0.8 | 0.04 | 0.08 | $41.46 |
| Request for alternative method/monitoring [h] | 4 | 1 | 4 | 0.1 | 0.4 | 0.02 | 0.04 | $20.73 |
| Report of performance test [i] | 8 | 1 | 8 | 2 | 16 | 0.8 | 1.6 | $829.19 |
| Report of periods of noncompliance (including excess emissions) [j] | 8 | 2 | 16 | 21.8 | 348.8 | 17.44 | 34.88 | $18,076.39 |
| **Total Labor Burden and Cost (rounded)** | | | | | | **603** | | **$27,177** |

**Assumptions:**

[a] It is assumed that the average number of respondents that will be subject to the rule will be the 119 existing respondents. There will be two additional new sources per year that will become subject to the rule over the three-year period of this ICR. There are 106 facilities submitting reports.

[b] This ICR uses the following labor rates: $62.27 for Managerial, $46.21 for technical, and $25.01 for Clerical.

[c] It is assumed that it will take 40 hours for each respondent to participate with performance test. Twenty percent of respondents

will fail the performance test.

[d] It is assumed that 20 percent of respondent will fail the performance test and will have to repeat it.

[e] It is assumed that it will take two hours for each respondent to review the notification report.

[f] It is assumed that it will take two hours for each respondent to review the request for extension of the compliance report.

[g] It is assumed that 10 percent of new facilities will request a waiver.

[h] It is assumed that 5 percent of new facilities will request an alternative method monitoring.

[i] It is assumed that each new respondent will take 8 hours to review the report of performance test results.

[j] It is assumed that 20 percent of respondents submitting reports will take 8 hours to review reports of period of noncompliance.