

**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)

**1(b) Short Characterization/Abstract**

The National Emission Standards for Hazardous Air Pollutants (NESHAP) for the regulations published at 40 CFR part 63, subpart O were proposed on March 7, 1994, and promulgated on December 6, 1994. 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. This information is being collected to assure compliance with part 63, subpart O.

In general, all NESHAP standards require initial notifications, performance tests, and periodic reports. Owners or operators 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 sources subject to NESHAP.

Any owner or 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 United States Environmental Protection Agency (EPA) regional office.

Approximately 119 sources are currently subject to the regulation, and it is estimated that there will be two additional sources per year subject to the regulation over the next three years. This information was provided by the Ethylene Oxide Sterilization Association, which represents the vast majority of facilities subject to this standard, was consulted to determine these estimates.

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

There are 119 commercial ethylene oxide sterilization and fumigation facilities in the United States, which are all publicly owned and operated by the ethylene oxide sterilization and fumigation industry. None of the 119 facilities in the United States are owned by either state,

local, tribal or the Federal Government, they are all owned and operated solely by privately owned for-profit businesses, thus, the Federal Government burden does not include work performed by federal employees only work performed by contractors.

## **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 (HAP). These standards are applicable to new or existing sources of HAP and shall require the maximum degree of emission reduction. In addition, section 114(a) states that the Administrator may require any owner or 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 was promulgated for this source category at 40 CFR part 63, subpart O.

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

The control of EO emissions from sterilization facilities requires not only the installation of properly designed equipment, but also the operation and maintenance of that equipment. Emissions of EO from sterilization facilities are the result of operation of sterilization chambers. These standards are achieved by the reduction of EO emissions using acid-water scrubbers or catalytic/thermal oxidizers.

The notifications required in the applicable regulations 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, that leaks are being detected and repaired, and that the regulations are being met. The semiannual reports are used for problem identification, as a check on source operation and maintenance, and for compliance determinations.

The information generated by the monitoring, recordkeeping and reporting requirement described in this ICR is used by the Agency to ensure that facilities affected by the NESHAP continue to operate the control equipment in compliance with the regulation. Adequate monitoring, recordkeeping, and reporting are necessary to ensure compliance with the applicable regulations, as required by the Clean Air Act. The information collected from recordkeeping and reporting requirements is also used for targeting inspections, and is of sufficient quality to be used as evidence in court.

### **3. Nonduplication, Consultations, and Other Collection Criteria**

The requested recordkeeping and reporting are required under 40 CFR part 63, subpart O.

#### **3(a) Nonduplication**

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 their 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, no duplication exists.

#### **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 (71 FR 58853) on October 5, 2006. 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 also considered. The primary source of information as reported by industry, in compliance with the recordkeeping and reporting provisions in the standard, is the Air Facility System (AFS) which is operated and maintained by EPA's Office of Compliance. AFS 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. Approximately 119 respondents will be subject to the standard over the three years period covered by this ICR.

Industry trade association and other interested parties were provided an opportunity to comment on the burden associated with the standard as it was being developed and the standard has been previously reviewed to determine the minimum information needed for compliance purposes.

It is our policy to carefully review any comments received since the last ICR renewal including those submitted in response to the first federal register notice and respond

appropriately. 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 likelihood of detecting poor operation and maintenance of control equipment and noncompliance would decrease.

### **3(e) General Guidelines**

None of these reporting or recordkeeping requirements violate any of the regulations established by OMB at 5 CFR part 1320, section 1320.5.

These standards require affected facilities 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 the part 70 permit program and the five-year statute of limitations on which the permit program is based. Also, the retention of records for five years would allow EPA to establish the compliance history of a source and any pattern of compliance for purposes of determining the appropriate level of enforcement action. Historically, EPA has found that the most flagrant violators frequently have violations extending beyond the five years. EPA would be prevented from pursuing the worst violators due to the destruction or nonexistence of records if records were retained for less than five years.

### **3(f) Confidentiality**

The required information has been determined not to be confidential. However, 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 (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**

None of the reporting or recordkeeping requirements contain sensitive questions.

## **4. The Respondents and the Information Requested**

### **4(a) Respondents/SIC Codes**

Respondents are owners or operators of commercial EO sterilization and fumigation facilities. The United States Standard Industrial Classification (SIC) codes and corresponding

North American Industry Classification System (NAICS) codes for EO sterilization facilities are listed in the table below.

<b>Standard</b>	<b>Description</b>	<b>SIC Codes</b>	<b>NAICS Codes</b>
40 CFR part 63, subpart O	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**

None of these reporting or recordkeeping requirements violate any of the regulations established by OMB at 5 CFR part 1320, section 1320.5.

#### **(i) Data Items**

All data in this ICR that is recorded and/or reported is required by National Emission Standards for Hazardous Air Pollutants for Commercial Ethylene Oxide Sterilization and Fumigation Operations (40 CFR Part 63, Subpart O).

A source must make the following reports:

<b>Reports for 40 CFR part 63, subpart O</b>	
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)

<b>Reports for 40 CFR part 63, subpart O</b>	
Request for extension of compliance	63.9(c)
Request for waivers	63.7(h)
Request for alternative methods/monitoring	63.8(f)

<b>Reports</b>	
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:

<b>Recordkeeping for 40 CFR part 63, subpart O</b>	
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

Currently, sources are using monitoring equipment that provides parameter data in an automated way, e.g., leaks and spills of mercury. 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. In addition, some regulatory agencies are setting up electronic reporting systems to allow sources to report electronically which is reducing the reporting burden. However, electronic reporting systems are still not widely used by the regulatory agencies. It is estimated that approximately 10 percent of the respondents use electronic reporting.

### **(ii) Respondent Activities**

<b>Respondent Activities</b>
Write the notifications and reports listed above.
Transmit, or otherwise disclose the information.
Train personnel to able to respond to a collection of information.

<b>Respondent Activities</b>
Submit the required reports developing, acquiring, installing, and utilizing technology and systems for the purpose of collecting, validating, and verifying information.
Perform initial performance test, Reference Method 2, 2A, 2C, or 2D, 18 or 25A test, and repeat performance tests if necessary.
Enter information required to be recorded above.
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.
All monitoring systems and equipment must be installed, operational, and properly calibrated before the performance test.
Adjust existing ways to comply with any previously applicable instructions and requirements.

Currently, sources are using monitoring equipment that provides parameter data in an automated way. 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.

<b>Agency Activities</b>
Observe initial performance tests and repeat performance tests if necessary.
Review notifications and reports, including performance test reports, excess emissions reports, required to be submitted by industry.
Audit facility records.
Input, analyze, and maintain data in the Air Facility System (AFS).

### **5(b) Collection Methodology and Management**

Following notification of startup, the reviewing authority might inspect the source to determine whether the pollution control devices are properly installed and operational. 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 entered into the AFS which is operated and maintained by EPA's Office of Compliance. AFS is EPA's database for the collection, maintenance, and retrieval of compliance and annual emission inventory data for more than 100,000 industrial and government-owned facilities. EPA uses the AFS 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 or operator for five years.

### **5(c) Small Entity Flexibility**

A majority of the affected facilities are primarily large entities (e.g., large businesses). However, the impact on small entities was taken into consideration during the development of the regulation. Due to technical considerations involving the process operations and the type of control equipment employed, the recordkeeping and reporting requirements are the same for both small and large entities. The Agency considers these requirements the minimum needed to ensure compliance and, therefore, cannot reduce them further for small entities.

### **5(d) Collection Schedule**

The specific frequency for each information collection activity within this request is shown in Table 1: Annual Industry Burden for NESHAP for Commercial Ethylene Oxide Sterilization and Fumigation Operations (40 CFR Part 63, Subpart O).

## **6. Estimating the Burden and Cost of the Collection**

Table 1 document 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 8,662 (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: \$93.09 per hour for Executive, Administrative and Managerial labor; \$64.13 per hour for Technical labor, and \$39.65 per hour for Clerical labor. These rates are from the United States Department of Labor, Bureau of Labor Statistics, June 2003, ATable 10. Private industry, by occupational and industry group. @ The rates are from column 1, ATotal compensation. @ The rate has been increased by 110 percent to account for the benefit packages available to those employed by private industry.

Managerial	\$93.09	(\$44.33 + 110%)
Technical	\$64.13	(\$30.54 + 110%)
Clerical	\$39.65	(\$18.88 + 110%)

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

The types 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) Cost

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 gas chromatograph used to continuously monitor EO emissions to aeration room and back chamber vents	\$32,500	2	\$65,000	\$5,500	106	\$583,000

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 \$583,000. 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 \$648,000.

### 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 \$22,800. This ICR uses the following labor rates:

Managerial	\$53.22	(GS-13, Step 5, \$33.26 x 1.6)
Technical	\$39.49	(GS-12, Step 1, \$24.68 x 1.6)
Clerical	\$21.38	(GS-6, Step 3, \$13.36 x 1.6)

These rates are from the Office of Personnel Management (OPM) A2003 General Schedule@ which excludes locality rates of pay. Details upon which this estimate is based appear in Table 2: Average Annual EPA Burden and Cost - NESHAP for Commercial Ethylene Oxide Sterilization and Fumigation Operations (40 CFR Part 63, Subpart O), attached.

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

Based on our research for this ICR, there are approximately 119 existing sources currently subject to the standard. It is estimated that two additional sources per year will become subject to the regulation in the next three years. However, we estimate that 10 percent or approximately 12 facilities will use only limited amount to EO and therefore, will not be required to submit reports.

Number of respondents is calculated using the following table which addresses the three years covered by this ICR.

Number of Respondents					
Year	(A) Number of New Respondents	(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	105	12	1	118
2	2	106	12	1	119
3	2	107	12	1	120
Average	2	106	12	1	119

To avoid double-counting respondents, column D is subtracted. As shown above, the average Number of Respondents over the three-year period of this ICR is 119.

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

<b>Respondent Universe and Number of Responses Per Year</b>						
Regulation Citation	(A) Average Number of New Respondents per Year	(B) Number of Reports for New Sources	(C) Number of Existing Respondents	(D) Number of Reports for Existing Sources	(F) Number of Respondents That Keep Records But Do Not Submit Reports	(E) Total Annual Responses = (AxB)+(CxD)+F
40 CFR part 63, subpart O	2	6.1	106	2	12	236 (rounded)

The number of total respondents is 119.

The number of Total Annual Responses is 236. This is the number in column E of the Respondent Universe and Number of Responses Per Year table above.

The total annual labor costs are \$547,959. Details regarding these estimates may be found in Table 1: Annual Industry Burden and Cost - NESHAP for Commercial Ethylene Oxide Sterilization and Fumigation Operations (40 CFR Part 63, Subpart O), attached.

#### **6(e) Bottom Line Burden Hours 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 attached.

#### **6(f) Reasons for Change in Burden**

There is no change in the labor hours or cost in this ICR compared to the previous ICR other than a fractional adjustment to account for rounding-off of the labor hour burden to the nearest whole hour in the previous ICR. This is due to two considerations. First, the regulations have not changed over the past three years and are not anticipated to change over the next three years. Secondly, the growth rate for the industry is very low, negative or non-existent, so there is no significant change in the overall burden.

Since there are no changes in the regulatory requirements and there is no significant industry growth, the labor hours and cost figures in the previous ICR are used in this ICR and there is no change in burden to industry.

**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's 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-2006-0723, which is available for online viewing at [www.regulations.gov](http://www.regulations.gov), or in person viewing at the Enforcement and Compliance Docket and Information Center in the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Ave., N.W., 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 Enforcement and Compliance Docket and Information Center Docket is (202) 566-1927. An electronic version of the public docket is available online at [www.regulations.gov](http://www.regulations.gov). This site can be used to submit or view public comments, access the index listing of the contents of the public 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 above. Also, you can send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, N.W., Washington, DC 20503, Attention: Desk Officer for EPA. Please include the EPA Docket ID Number EPA-HQ-OECA-2006-0723 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.