U.S. Environmental Protection Agency

Information Collection Request

# **TITLE:** NESHAP for Pharmaceuticals Production (40 CFR Part 63, Subpart GGG) (Renewal)

# **OMB CONTROL NUMBER:** 2060-0358

# **EPA ICR NUMBER:** 1781.10

# **ABSTRACT:**

The National Emission Standards for Hazardous Air Pollutants (NESHAP) for Pharmaceuticals Production (40 CFR Part 63, Subpart GGG) were proposed on April 2, 1997; promulgated on September 21, 1998; and amended on both April 21, 2011 and February 27, 2014. These regulations apply to existing and new pharmaceuticals manufacturing operations that are major sources of hazardous air pollutants (HAP). The affected facilities encompass all pharmaceuticals manufacturing operations that include process vents, storage tanks, equipment components, and wastewater systems. 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 GGG.

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. In the event that there is no such delegated authority, the reports are sent directly to the EPA 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” is owners and operators of pharmaceuticals production facilities. The burden to the “Affected Public” may be found in Table 1: Annual Respondent Burden and Cost – NESHAP for Pharmaceuticals Production (40 CFR Part 63, Subpart GGG) (Renewal). The burden to the “Federal Government” is attributed entirely to work performed by federal employees or government contractors and refer to Table 2: Average Annual EPA Burden and Cost – NESHAP for Pharmaceuticals Production (40 CFR Part 63, Subpart GGG) (Renewal). There are approximately 27 pharmaceuticals production facilities, which are owned and operated by the pharmaceutical production industry. None of the 27 facilities in the United States are owned by state, local, tribal or the Federal government. They are all owned and operated by privately-owned, for-profit businesses. We assume that they will all respond.

Based on our consultations with industry representatives, there are an average of one affected facilities 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 27 respondents per year will be subject to the standard, and no additional respondents per year will become subject to the standard.

The active (previous) ICR had the following Terms of Clearance (TOC):

“In accordance with 5 CFR 1320, the information collection is approved for three years. As terms of clearance, upon renewal of this collection, EPA is required to include the following in its supporting statement for this and other NESHAP ICRs: (1) a description of the regulatory text applicable to the ICR including submission specifications; (2) a clear description of the data elements being collected under the ICR; (3) screen shots of the electronic portal where the reporting requirements are submitted to EPA (with the control number and burden statement); (4) a detailed discussion of how information is submitted and the extent to which electronic reporting is available; (5) evidence of consultation with respondents (by actively reaching out to stakeholders as permitted by the PRA) to ensure the supporting statement's accuracy on availability of data, frequency of collection, clarity of instructions, accuracy of burden estimate, relevance of data elements, and similar PRA matters; and (6) discussion of how EPA addressed substantive concerns raised by respondents and other stakeholders during consultation and in response to comments received on FR notices. In addition, please convert the supporting statement to the standard 18 question SS-A format upon renewal.”

The relevant regulatory text is referenced in section 4(b) of this document. We have created a supplementary document including the regulatory text that describes the ICR requirements, which includes a description of the data elements being collected under the ICR, as identified in section 4(b)(i) of this document. All electronic collection in this information collection is submitted through EPA's 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*](https://nam04.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.epa.gov%2Felectronic-reporting-air-emissions%2Fpaperwork-reduction-act-pra-cedri-and-ert&data=05%7C01%7CLeslie.Smith%40erg.com%7C8698534f35694180db9e08dad479ac1b%7Ca17e3fab8d2346f287f33fceb7c6a000%7C1%7C0%7C638055916286015292%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=2dMaUcuw8wKlPOWmLWhASWxKGnQnAwjf2GnE0gLIKa8%3D&reserved=0)*.* We have created supplementary documents that include screenshots of the electronic portal where the reporting requirements are submitted online to EPA, including the OMB burden statement on the electronic portal. A description of the EPA’s consultation with respondents and how EPA responded to any concerns raised by respondents or other stakeholders is discussed in sections 3(b) and 3(c) of this document.

**Supporting Statement A**

# **NEED AND AUTHORITY FOR THE COLLECTION:**

*Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate 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, HAP emissions from pharmaceuticals production (predominately methanol, methylene chloride and toluene) 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 Part 63,Subpart GGG.

# **PRACTICAL UTILITY/USERS OF THE DATA:**

*Indicate how, by whom, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the agency has made of the information received from the current collection.*

The recordkeeping and reporting requirements in the standard 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 the emission standard. Continuous emission monitors are used to ensure compliance with the standard 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 and leaks are being detected and repaired and the standard is 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), changes of information required in 40 CFR 63.9(j), and performance test reports 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.

CEDRI includes the Electronic Reporting Tool (ERT) software, which is used by facilities to generate electronic reports of performance tests. EPA is also requiring that 40 CFR Part 63, Subpart GGG performance test reports be submitted through the EPA’s ERT.

# **USE OF TECHNOLOGY:**

*Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also describe any consideration of using information technology to reduce burden.*

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 April 21, 2011. Respondents are required to use the EPA’s Electronic Reporting Tool (ERT) to develop performance test reports and submit them through the EPA’s Compliance and Emissions Data Reporting Interface (CEDRI), which can be accessed through the EPA’s Central Data Exchange (CDX) (<https://cdx.epa.gov/>). The ERT is an application rather than a form, and the requirement to use the ERT is applicable to numerous subparts. The splash screen of the ERT contains a link to the Paperwork Reduction Act (PRA) requirements, such as the OMB Control Number, expiration date, and burden estimate for this and other subparts. 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. 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. The supplementary documents to this ICR include screenshots of the electronic portal where the reporting requirements are submitted online to EPA, including the OMB burden statement on the electronic portal.

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*](https://www.epa.gov/electronic-reporting-air-emissions/paperwork-reduction-act-pra-cedri-and-ert).

# **EFFORTS TO IDENTIFY DUPLICATION:**

*Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purposes described in Item 2 above.*

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 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.

# **MINIMIZING BURDEN ON SMALL ENTITIES:**

*If the collection of information impacts small businesses or other small entities, describe any methods used to minimize burden.*

The majority of the respondents are large entities (i.e., large businesses). 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.

# **EFFECTS OF LESS FREQUENT COLLECTION:**

*Describe the consequence to Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.*

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.

# **GENERAL GUIDELINES:**

*Explain any special circumstances that require the collection to be conducted in a manner inconsistent with PRA Guidelines at 5 CFR 1320.5(d)(2).*

With the following exception, 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 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. 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.

# **PUBLIC COMMENT AND CONSULTATIONS****:**

## **8a. Public Comment**

*If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the Agency's notice, required by 5 CFR 1320.8(d), soliciting comments on the information collection prior to submission to OMB. Summarize public comments received in response to that notice and describe actions taken by the Agency in response to these comments. Specifically address comments received on cost and hour burden.*

An announcement of a public comment period for the renewal of this ICR was published in the *Federal Register* (88 FR 31748) on May 18, 2023. No comments were received on the burden published in the *Federal Register* for this renewal.

## **8b. Consultations**

*Describe efforts to consult with persons outside the Agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting format (if any), and on the data elements to be recorded, disclosed, or reported. Consultation with representatives of those from whom information is to be obtained or those who must compile records should occur at least once every 3 years - even if the collection of information activity is the same as in prior periods. There may be circumstances that may preclude consultation in a specific situation. These circumstances should be explained.*

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 the standard, 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 27 respondents will be subject to the standard 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 the standard as it was being developed and the standard has been previously reviewed to determine the minimum information needed for compliance purposes. In developing this ICR, we contacted both the Pharmaceutical Research and Manufacturers of America at (202) 835-3400 and the Noramco Incorporated at (302) 652-3840.

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.

# **PAYMENTS OR GIFTS TO RESPONDENTS:**

*Explain any decisions to provide payments or gifts to respondents, other than remuneration of contractors or grantees.*

The Agency does not intend to provide payments or gifts to respondents as part of this collection.

# **PROVISIONS FOR PROTECTION OF INFORMATION:**

*Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or Agency policy. If the collection requires a systems of records notice (SORN) or privacy impact assessment (PIA), those should be cited and described here.*

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).

# **JUSTIFICATION FOR SENSITIVE QUESTIONS:**

*Provide additional justification for any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private. This justification should include the reasons why the Agency considers the questions necessary, the specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.*

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

# **RESPONDENT BURDEN HOURS AND LABOR COSTS****:**

*Provide estimates of the hour burden of the collection of information. The statement should:*

* *Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated.*
* *If this request for approval covers more than one form, provide separate hour burden estimates for each form and the aggregate the hour burdens.*
* *Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage rate categories. The cost of contracting out or paying outside parties for information collection activities should not be included here. Instead, this cost should be included as O&M costs under non-labor costs covered under question 13.*

## **12a. RESPONDENTS/NAICS CODES**

The respondents to the recordkeeping and reporting requirements are pharmaceuticals manufacturing operations. The United States Standard Industrial Classification (SIC) code for the respondents affected by the standards and the corresponding North American Industry Classification System (NAICS) codes are listed below:

|  |  |  |
| --- | --- | --- |
| **Standard (40 CFR Part 63, Subpart GGG)** | **SIC Codes** | **NAICS Codes** |
| Pharmaceutical Preparation Manufacturing | 2835, 2834 | 325412 |
| Medicinal and Botanical Manufacturing | 2833 | 325411 |

Based on our research for this ICR, on average over the next three years, approximately 27 existing respondents will be subject to the standard. It is estimated that no additional respondents per year will become subject. The overall average number of respondents, as shown in the table below, is 27 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 a | (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 | 27 | 0 | 0 | 27 |
| 2 | 0 | 27 | 0 | 0 | 27 |
| 3 | 0 | 27 | 0 | 0 | 27 |
| **Average** | **0** | **27** | **0** | **0** | **27** |

a 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 27.

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 construction/reconstruction | 0 | 1 | 0 | 0 |
| Notification of physical or operational changes | 27 | 3 | 0 | 81 |
| Notification of actual startup | 0 | 1 | 0 | 0 |
| Notification of initial performance test | 0 | 1 | 0 | 0 |
| Notification of applicability | 0 | 1 | 0 | 0 |
| Notification of demonstration of CMS | 0 | 1 | 0 | 0 |
| Notification of compliance status | 0 | 1 | 0 | 0 |
| Pre-compliance report (emission averaging) | 0 | 1 | 0 | 0 |
| Malfunction report | 27 | 2 | 0 | 54 |
| Semiannual report - No deviations | 24 | 2 | 0 | 48 |
| Semiannual report – Deviations | 3 | 2 | 0 | 6 |
| LDAR report | 27 | 2 | 0 | 54 |
| Emissions averaging report | 3 | 2 | 0 | 6 |
|  |  |  | **Total** | **249** |

The number of Total Annual Responses is 249.

The total annual labor costs are $5,580,000. Details regarding these estimates may be found at the end of this document in Table 1: Annual Respondent Burden and Cost – NESHAP for Pharmaceuticals Production (40 CFR Part 63, Subpart GGG) (Renewal).

## **12b. INFORMATION REQUESTED**

In this ICR, all the data that are recorded or reported is required by the NESHAP for Pharmaceuticals Production (40 CFR Part 63, Subpart GGG) (Renewal).

A source must make the following reports:

| **Notifications** | |
| --- | --- |
| Change in area source status (as applicable) | §63.1(c)(5) |
| Application and notification of construction/reconstruction | §63.5(b)(4), §63.5(d), §63.1260(c) |
| Notification of applicability | §63.9(a), §63.1260(b) |
| Notification of initial startup | §63.9(b), §63.9(d), §63.1260(b) |
| Notification of initial performance test, submittal of test plan, request of waiver of performance test | §§63.7(b)(1-2), §63.7(c), §63.7(f), §63.7(h), §63.9(e), §63.1257(b)(8), §63.1260(l) |
| Notification of delay (reschedule) of initial performance test | §63.7(b)(2) |
| Notification of CMS performance evaluation and results | §63.8(e)(2), §63.9(g)(1), §63.10(e)(2), §63.1260(d) |
| Notification that the criterion necessary to continue use of alternative to relative accuracy testing has been exceeded | §63.9(g)(3), §63.1260(d) |
| Notification of compliance status report (NOCSR) | §63.9(h), §63.1260(f) |
| Notification of process change | §63.1260(h) |
| Initial performance test results | §63.10(d)(2), §63.7(g) §63.1260(f) |
| Request for compliance extension and progress reports for compliance extension (as applicable) | §63.10(d)(4), §63.1250(f)(6), §63.1260(m) |
| 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** | |
| --- | --- |
| Reports of malfunctions | §63.1260(i) |
| Pre-compliance report (as applicable) | §63.1260(e) |
| Periodic reports | §63.1260(g) |
| Reports of leak detection and repair (LDAR) | §63.1260(j), §63.1255(h) |
| Reports of malfunctions and corrective actions taken | §63.1260(i) |
| Reports of emissions averaging | §63.1260(k) |
| Performance test reports (electronic submission) | §63.1260(n) |

A source must keep the following records:

| **Recordkeeping** | |
| --- | --- |
| Recordkeeping requirements | §63.10(a), §63.1259(a) |
| All reports and notifications | §63.10(b)(1), §63.1259(a)(1) |
| Record of applicability | §63.10(b)(3), §63.1259(a)(2) |
| Records of malfunction | §63.10(b)(2), §63.1259(a)(3) |
| Records of sources with continuous monitoring systems (CMS) | §§63.10(c)(1-14), §63.1259(a)(4) |
| Application for approval of construction/reconstruction | §63.1259(a)(5) |
| Records of equipment operation | §63.1259(b) |
| Records of operating scenarios | §63.1259(c) |
| Records of LDAR programs | §63.1259(d), §63.1255(g) |
| Records of emissions averaging | §63.1259(e) |
| Records of delay of repair | §63.1259(f) |
| Records of wastewater stream or residual transfer | §63.1259(g) |
| Records of extensions | §63.1259(h) |
| Records of inspections | §63.1259(i) |
| Records should be retained for 5 years | §63.10(b)(1), §63.1259(a)(1) |

## **12c. RESPONDENT ACTIVITIES**

| **Respondent Activities** |
| --- |
| Familiarization with the regulatory requirements. |
| Install, calibrate, maintain, and operate CMS monitoring devices for established parameters for each control device. |
| Perform initial performance test, Reference Method 1, 2, 3, 4, 18, 25 or 25A, 26 or 26A, and 320 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. |

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 Pharmaceuticals Production (40 CFR Part 63, Subpart GGG) (Renewal).

## **12d. RESPONDENT BURDEN HOURS AND LABOR COSTS**

The average annual burden to industry over the next three years from these recordkeeping and reporting requirements is estimated to be 44,300 (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.

This ICR uses the following labor rates:

Managerial $163.17 ($77.70 + 110%)

Technical $130.28 ($62.04 + 110%)

Clerical $65.71 ($31.29 + 110%)

These rates are from the United States Department of Labor, Bureau of Labor Statistics, January 2023, “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.

The total annual labor hours are 44,300. Details regarding these estimates may be found in Table 1: Annual Respondent Burden and Cost – NESHAP for Pharmaceuticals Production (40 CFR Part 63, Subpart GGG) (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 178 hours per response.

# **RESPONDENT CAPITAL AND O&M COSTS:**

*Provide an estimate for the total annual cost burden to respondents or record keepers resulting from the collection of information. (Do not include the cost of any hour burden already reflected on the burden worksheet).*

*The cost estimate should be split into two components: (a) a total capital and start-up cost component (annualized over its expected useful life) and (b) a total operation and maintenance and purchase of services component. The estimates should consider costs associated with generating, maintaining, and disclosing or providing the information. Include descriptions of methods used to estimate major cost factors including system and technology acquisition, expected useful life of capital equipment, the discount rate(s), and the period over which costs will be incurred. Capital and start-up costs include, among other items, preparations for collecting information such as purchasing computers and software; monitoring, sampling, drilling, and testing equipment; and record storage facilities.*

*If cost estimates are expected to vary widely, agencies should present ranges of cost burdens and explain the reasons for the variance. The cost of purchasing or contracting out information collections services should be a part of this cost burden estimate.*

*Generally, estimates should not include purchases of equipment or services, or portions thereof, made: (1) prior to October 1, 1995, (2) to achieve regulatory compliance with requirements not associated with the information collection, (3) for reasons other than to provide information or keep records for the government, or (4) as part of customary and usual business or private practices.*

The type of industry costs associated with the information collection activities in the subject standard(s) 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.

| **Capital/Startup vs. Operation and Maintenance (O&M) Costs** | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| (A) Continuous Monitoring Device | (B) Capital/Startup Cost for One Respondent b | (C) Number of New Respondents | (D) Total Capital/Startup Cost, (B X C) | (E) Annual O&M Costs for One Respondent c | (F) Number of Respondents with O&M | (G) Total O&M,  (E X F) |
| Data-logger and Thermocouple | $6,834 | 0 | $0 | $6,458 | 27 | $174,361 |
| **Totals (rounded) a** |  |  | **$0** |  |  | **$174,000** |

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

b Assume that capital/startup costs for a new data-logger and Thermocouple is $6,240. Capital costs have been increased from 2007 to 2022 $ using the CEPCI Equipment Cost Index.

c Assume that the annual O&M costs of the sulfur CEMS and control outlet is $5,897. Costs have been increased from 2007 to 2022 $ using the CEPCI Equipment Cost Index.

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 $112,000. 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 $112,000. These are recordkeeping costs.

The total annual capital/startup and O&M costs to the regulated entity are $174,000. The cost calculations are detailed in Section 6(b)(iii), Capital/Startup vs. Operation and Maintenance (O&M) Costs.

# **AGENCY** **COSTS:**

*Provide estimates of annualized costs to the Federal government. Also, provide a description of the method used to estimate cost, which should include quantification of hours, operational expenses (such as equipment, overhead, printing, and support staff), and any other expense that would not have been incurred without this collection of information.*

## **14a. 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 Enforcement and Compliance History Online (ECHO) and ICIS. |

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 standards, and to 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. EPA uses ICIS 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.

## **14b. Agency Burden and Labor 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 $84,400.

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

Managerial $73.46 (GS-13, Step 5, $45.91 + 60%)

Technical $54.51 (GS-12, Step 1, $34.07 + 60%)

Clerical $29.50 (GS-6, Step 3, $18.44 + 60%)

These rates are from the Office of Personnel Management (OPM), 2023 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 at the end of this document in Table 2: Average Annual EPA Burden and Cost – NESHAP for Pharmaceuticals Production (40 CFR Part 63, Subpart GGG) (Renewal).

The average annual Agency burden and cost over next three years is estimated to be 1,590 labor hours at a cost of $84,400. See Table 2: Average Annual EPA Burden and Cost – NESHAP for Pharmaceuticals Production (40 CFR Part 63, Subpart GGG) (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.

## **14c. Agency Non-Labor Costs**

There are no anticipated non-labor costs for the Agency.

# **CHANGE IN BURDEN:**

*Explain the reasons for any program changes or adjustments reported in the burden or capital/O&M cost estimates.*

There is no change in burden from the most recently approved ICR as currently identified in the OMB Inventory of Approved Burdens. 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. Second, the growth rate for this industry is very low or non-existent, so there is no significant change in the overall burden. There is a slight increase in costs, which is wholly due to the use of updated labor rates. This ICR uses labor rates from the most recent Bureau of Labor Statistics report (September 2022) to calculate respondent burden costs. There is also an increase in O&M costs due to an adjustment to increase from 2007 $ to 2022 $ using the CEPCI Equipment Cost Index.

# **PUBLICATION OF DATA****:**

*For collections of information whose results will be published, outline plans for tabulation and publication. Address any complex analytical techniques that will be used. Provide the time schedule for the entire project, including beginning and ending dates of the collection of information, completion of report, publication dates, and other actions.*

# Although this rule does not require electronic reporting, respondents could choose to submit notifications or reports electronically. All non-CBI data submitted electronically to the Agency through CEDRI are available to the public for review and printing and are accessible using WebFIRE. Electronically submitted emissions data from performance testing or performance evaluations using the Electronic Reporting Tool or templates attached to CEDRI, as well as data from reports from regulations with electronic templates, are tabulated; data submitted as portable document format (PDF) files attached to CEDRI are neither tabulated nor subject to complex analytical techniques. Electronically submitted emissions data used to develop emissions factors undergo complex analytical techniques and the draft emissions factors are available on the Clearinghouse for Inventories and Emission Factors listserv at <https://www.epa.gov/chief/chief-listserv> for public review and printing. Electronically submitted emissions data, as well as other data, obtained from one-time or sporadic information collection requests often undergo complex analytical techniques; results of those activities are included in individual rulemaking dockets and are available at [https://www.regulations.gov/](https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.regulations.gov%2F&data=05%7C02%7CBruce.Teddy%40epa.gov%7Cc6cb63aa13da45fa39e608dd57392eda%7C88b378b367484867acf976aacbeca6a7%7C0%7C0%7C638762625281634715%7CUnknown%7CTWFpbGZsb3d8eyJFbXB0eU1hcGkiOnRydWUsIlYiOiIwLjAuMDAwMCIsIlAiOiJXaW4zMiIsIkFOIjoiTWFpbCIsIldUIjoyfQ%3D%3D%7C0%7C%7C%7C&sdata=3mYLTI3sN13Nsbghl6POwxyl6OxKeJ%2FupNot5BnxOOQ%3D&reserved=0) for public review and printing.

# **DISPLAY OF OMB CONTROL NUMBER AND EXPIRATION DATE ON INSTRUMENTS:**

*If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.*

The Agency plans to display the expiration date for OMB approval of the information collection on all instruments.

# **CERTIFICATION STATEMENT:**

*Explain each exception to the topics of the certification statement identified in “Certification for Paperwork Reduction Act Submissions.”*

This information collection complies with all provisions of the Certification for Paperwork Reduction Act Submissions.

# **ADDITIONAL TABLES AND APPENDICES**

**Table 1: Annual Respondent Burden and Cost – NESHAP for Pharmaceuticals Production (40 CFR Part 63, Subpart GGG) (Renewal)**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Burden Item | (A) Person hours per occurrence | (B) No. of occurrences per respondent per year | (C)  Person hours per respondent per year  (C=AxB) | (D) Respondents per year a | (E)  Technical person- hours per year (E=CxD) | (F) Management person hours per year (Ex0.05) | (G) Clerical person hours per year (Ex0.1) | (H) Cost, $ b |
| 1. Applications | N/A |  |  |  |  |  |  |  |
| 2. Surveys and studies | N/A |  |  |  |  |  |  |  |
| 3. Reporting Requirements |  |  |  |  |  |  |  |  |
| A. Familiarization with Regulatory Requirements | 1 | 1 | 1 | 27 | 27 | 1.35 | 2.7 | $3,915.26 |
| B. Required Activities |  |  |  |  |  |  |  |  |
| i. Initial Performance Tests c |  |  |  |  |  |  |  |  |
| New | 480 | 1 | 480 | 0 | 0 | 0 | 0 | $0 |
| Reconstructed | 160 | 1 | 160 | 0 | 0 | 0 | 0 | $0 |
| Wastewater | 160 | 1 | 160 | 0 | 0 | 0 | 0 | $0 |
| ii. Quality control plan for CMS c | 60 | 1 | 60 | 0 | 0 | 0 | 0 | $0 |
| iii. Repeat performance test d | 60 | 1 | 60 | 0 | 0 | 0 | 0 | $0 |
| C. Write reports |  |  |  |  |  |  |  |  |
| i. Notification of construction/reconstruction c | 2 | 1 | 2 | 0 | 0 | 0 | 0.0 | $0 |
| ii. Notification of physical or operational changes c, e | 8 | 3 | 24 | 27 | 648 | 32.4 | 64.8 | $93,966.16 |
| iii. Notification of actual startup c | 2 | 1 | 2 | 0 | 0 | 0 | 0 | $0 |
| iv. Notification of initial performance test c | 2 | 1 | 2 | 0 | 0 | 0 | 0 | $0 |
| v. Notification of applicability c | 2 | 1 | 2 | 0 | 0 | 0 | 0 | $0 |
| vi. Notification of demonstration of CMS c | 2 | 1 | 2 | 0 | 0 | 0 | 0 | $0 |
| vii. Notification of compliance status c | 120 | 1 | 120 | 0 | 0 | 0 | 0 | $0 |
| viii. Pre-compliance report (with and without emission averaging implementation plan) c | 180 | 1 | 180 | 0 | 0 | 0 | 0 | $0 |
| ix. Malfunction report f | 40 | 2 | 80 | 27 | 2,160 | 108 | 216 | $313,220.52 |
| x. Semiannual summary report |  |  |  |  |  |  |  |  |
| a. No deviations g | 8 | 2 | 16 | 24 | 384 | 19.2 | 38.4 | $55,683.65 |
| b. Deviations h | 24 | 2 | 48 | 3 | 144 | 7.2 | 14.4 | $20,881.37 |
| xi. Leak detection and repair (LDAR) report i | 432 | 2 | 864 | 27 | 23328 | 1166.4 | 2332.8 | $3,382,781.62 |
| xii. Emissions averaging report j | 20 | 2 | 40 | 3 | 120 | 6 | 12 | $17,401.14 |
| ***Subtotal for Reporting Requirements*** |  |  |  |  | ***30,833*** | | | ***$3,887,850*** |
| 4. Recordkeeping requirements |  |  |  |  |  |  |  |  |
| A. Develop record system | 40 | 1 | 40 | 0 | 0 | 0 | 0 | $0 |
| B. Train personnel | 40 | 1 | 40 | 0 | 0 | 0 | 0 | $0 |
| C. Records for operating parameters for control devices k | 1 | 365 | 365 | 27 | 9,855 | 492.75 | 985.5 | $1,429,069 |
| D. Records of malfunctions l | 2 | 26 | 52 | 27 | 1,404 | 70.2 | 140.4 | $203,593 |
| E. Calibration of CMS m | 16 | 1 | 16 | 27 | 432 | 21.6 | 43.2 | $62,644 |
| F. LDAR | See 3C |  |  |  |  |  |  |  |
| ***Subtotal for Recordkeeping Requirements*** |  | | | | ***13,445*** | | | ***$1,695,306*** |
| **Total Labor Burden and Costs (rounded) n** |  | | | | ***44,300*** | | | ***$5,580,000*** |
| **Total Capital and O&M Cost (rounded) n** |  | | | | | | | ***$174,000*** |
| **GRAND TOTAL (rounded) n** |  | | | | | | | ***$5,750,000*** |
|  |  |  |  |  |  |  |  |  |
| **Assumptions:** |  |  |  |  |  |  |  |  |
| a We have assumed that the annual average number of respondents that will be subject to this rule will be 27. There will be no new additional sources during the next three years of this ICR. | | | | | | | | |
| b This ICR uses the following labor rates: Managerial $163.17 ($77.70 + 110%); Technical $130.28 ($62.04 + 110%); and Clerical $65.71 ($31.29 + 110%). These rates are from the United States Department of Labor, Bureau of Labor Statistics, January 2023, “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. | | | | | | | | |
| c We have assumed that there will be no new or reconstructed facilities during the next three years of this ICR, and these one-time initial requirements do not apply; however, the ICR estimates that all existing sources will have changes in their operations. | | | | | | | | |
| d We have assumed that 20 percent of new respondents would have to repeat initial performance tests due to failure. Since there are no new respondents estimated, no one is assumed to conduct a repeat test. | | | | | | | | |
| e We have assumed that each source will require an average of three processing changes each year over the next three years of this ICR. | | | | | | | | |
| f We have assumed that each respondent will take 40 hours two times per year to complete the startup, shutdown, malfunction reports. | | | | | | | | |
| g We have assumed that 90 percent of respondents will each take eight hours two times per year to complete the no deviation report. | | | | | | | | |
| h We have assumed that 10 percent of respondents will each take 24 hours two times per year to complete the deviation report. | | | | | | | | |
| i We have assumed that it will take each respondent 432 hours two times per year to complete the LDAR report. | | | | | | | | |
| j We have assumed that ten percent of respondents will each take 20 hours two times per year to complete the emissions averaging report. | | | | | | | | |
| k We have assumed that it will take each respondent 1 hour 365 times per year to record the operating parameters for control devices. | | | | | | | | |
| l We have assumed that it will take each respondent 2 hours 26 times per year to record the occurrence and duration of each malfunction. | | | | | | | | |
| m We have assumed that it will take each respondent 16 hours one time per year to record the calibration of CMS. | | | | | | | | |
| n 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 Pharmaceuticals Production (40 CFR Part 63, Subpart GGG) (Renewal)**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Burden item | (A)  Person hours per occurrence | (B)  No. of occurrences per respondent per year | (C)  Person hours per respondent per year (C=AxB) | (D)  Respondents per year a | (E)  Technical person- hours per year (E=CxD) | (F)  Management person hours per year (Ex0.05) | (G)  Clerical person hours per year (Ex0.1) | (H)  Cost, $ b |
| 1. Required activities |  |  |  |  |  |  |  |  |
| i. Initial performance tests c | 2 | 1 | 2 | 0 | 0 | 0 | 0 | $0 |
| ii. Repeat performance test d | 24 | 1 | 24 | 0 | 0 | 0 | 0 | $0 |
| 2. Report review - one time c |  |  |  |  |  |  |  |  |
| i. Notification of construction/reconstruction | 2 | 1 | 2 | 0 | 0 | 0 | 0 | $0 |
| ii. Notification of actual startup | 2 | 1 | 2 | 0 | 0 | 0 | 0 | $0 |
| iii. Notification of demonstration of CMS | 2 | 1 | 2 | 0 | 0 | 0 | 0 | $0 |
| iv. Initial notification of applicability | 2 | 1 | 2 | 0 | 0 | 0 | 0 | $0 |
| v. Notification of compliance status report | 40 | 1 | 40 | 0 | 0 | 0 | 0 | $0 |
| vi. Pre-compliance report e |  |  |  |  |  |  |  |  |
| a. With emissions averaging f | 20 | 1 | 20 | 0 | 0 | 0 | 0 | $0 |
| b. Without emissions averaging | 4 | 1 | 4 | 0 | 0 | 0 | 0 | $0 |
| 3. Report review - on-going |  |  |  |  |  |  |  |  |
| i. Semiannual summary report |  |  |  |  |  |  |  |  |
| a. No deviations g | 2 | 2 | 4 | 24 | 96 | 4.8 | 9.6 | $5,868.77 |
| b. Deviations h | 8 | 2 | 16 | 3 | 48 | 2.4 | 4.8 | $2,934.38 |
| ii. Notification of physical or operational changes i | 8 | 3 | 24 | 27 | 648 | 32.4 | 64.8 | $39,614.18 |
| iii. Malfunction j | 2 | 2 | 4 | 27 | 108 | 5.4 | 10.8 | $6,602.36 |
| iv. Leak detection and repair (LDAR) report k | 8 | 2 | 16 | 27 | 432 | 21.6 | 43.2 | $26,409.46 |
| v. Emissions averaging report l | 8 | 2 | 16 | 3 | 48 | 2.4 | 4.8 | $2,934.38 |
| **TOTAL (rounded) m** |  | | | | **1,590** | | | **$84,400** |
|  | | | | | | | | |
| **Assumptions:** | | | | | | | | |
| a We have assumed that the average number of respondents that will be subject to this rule will be 27. There will be no new additional sources during the next three years of this ICR. | | | | | | | | |
| b This cost is based on the average hourly labor rate as follows: Managerial $73.46 (GS-13, Step 5, $45.91 + 60%); Technical $54.51 (GS-12, Step 1, $34.07 + 60%); and Clerical $29.50 (GS-6, Step 3, $18.44 + 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), 2023 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 We have assumed that there will be no new or reconstructed facilities during the next three years of this ICR, and these one-time initial requirements do not apply. | | | | | | | | |
| d We have assumed that 20 percent of respondents would have to repeat performance tests due to failure.Since there are no new respondents estimated, no one is assumed to conduct a repeat test. | | | | | | | | |
| e We have assumed that 50 percent of new facilities will submit a pre-compliance report. | | | | | | | | |
| f We have assumed that 10 percent of existing facilities will have to comply with emission averaging requirements; however, this is a one-time requirement; new facilities are not allowed to use emissions averaging. | | | | | | | | |
| g We have assumed that 90 percent of respondents will report no deviations. | | | | | | | | |
| h We have assumed that 10 percent of respondents will have to report deviations. | | | | | | | | |
| i We have assumed that each respondent will be required to submit the physical/operational changes three times per year over the next three-year period of this ICR. | | | | | | | | |
| j We have assumed that each respondent will report actions on malfunction that are consistent. | | | | | | | | |
| k We have assumed that each respondent will have to comply with the LDAR report two times per year. | | | | | | | | |
| l We have assumed that 10 percent of respondents will submit the emission averaging report. | | | | | | | | |
| m Totals have been rounded to 3 significant figures. Figures may not add exactly due to rounding. | | | | | | | | |