

**SUPPORTING STATEMENT
ENVIRONMENTAL PROTECTION AGENCY**

NESHAP for Pharmaceuticals Production (40 CFR Part 63, Subpart GGG) (Final Rule)

1. Identification of the Information Collection

1(a) Title of the Information Collection

NESHAP for Pharmaceuticals Production (40 CFR Part 63, Subpart GGG) . This is a revised information collection request (ICR). The EPA ICR tracking number is 1781.06, and the OMB Control Number 2060-0358.

1(b) Short Characterization/Abstract

This ICR is prepared for a U.S. Environmental Protection Agency (EPA) rulemaking developed under authority of section 112 of the Clean Air Act (CAA). The rulemaking amends title 40, chapter I, part 63, subpart GGG, National Emission Standards for Hazardous Air Pollutants from Pharmaceuticals Production, of the Code of Federal Regulations (CFR). The current Pharmaceuticals Production NESHAP were proposed on April 2, 1997, and promulgated on September 21, 1998. These standards apply to facilities in the 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 commencing construction or reconstruction after the date of that proposal. This information is being collected to assure compliance with 40 CFR part 63, subpart GGG. HAP emissions are the pollutants regulated under this subpart. The amendments to the rule eliminate the startup, shutdown, and malfunction exemption, remove the SSM plan requirement, add provisions to provide an affirmative defense against civil penalties for exceedances of emission standards caused by malfunctions, and a requirement for electronic submittal of performance test data, and correct an editorial error. The remaining portions of the NESHAP remain unchanged.

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 malfunctions 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, in general, are required of all sources subject to NESHAP. This information is used by the Agency to identify sources subject to the standards to insure that the maximum achievable control technologies are being applied. Semiannual summary reports are also required.

Any owner or operator subject to the provisions of this part will 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.

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

We have determined that there are an estimated 27 respondents currently subject to this rule. It is estimated that no additional sources will become subject to the standard over the next three years.

All of the pharmaceutical production facilities in the United States are owned and operated by the pharmaceutical industry (the “Affected Public”). None of the facilities in the United States are owned by state, local, tribal or the Federal government. They are all privately, owned for-profit businesses. The burden to the “Affected Public” is listed below in Table 1: Annual Respondent Burden and Cost - NESHAP for Pharmaceutical Production (40 CFR Part 63, Subpart GGG) (Revision). The Federal government burden associated with the review of reports submitted by the respondent is shown below in Table 2: Average Annual EPA Burden - NESHAP for Pharmaceutical Production (40 CFR Part 63, Subpart GGG) (Revision).

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 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, HAP pollutant 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 standards were promulgated for this source category at 40 CFR part 63, subpart GGG.

2(b) Practical Utility/Users of the Data

The recordkeeping and reporting requirements in the standard ensure compliance with the applicable regulations which were promulgated in accordance with the Clean Air Act. In addition, the collected information is 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 tests, 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 ensure that the pollution control devices are properly installed and operated, that leaks are being detected and repaired, and that 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.

The information generated by the monitoring, recordkeeping and reporting requirements described in this ICR is used by the Agency to ensure that facilities affected by the NESHAP continues to operate the control equipment in compliance with the regulation.

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

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

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 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

This is a rule-related ICR and comments were solicited on the proposal package and the proposed ICR, which included no revisions. This ICR contains revisions from the proposed ICR to include burden associated with the provisions for affirmative defense.

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 the EPA Office of Compliance. OTIS is the EPA 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 standard as it was being developed. During development of the original standards, we contacted the Pharmaceutical Research and Manufacturers of America (PhRMA), at (202) 835-3400, and Noramco Incorporated, at (302) 652-3840.

The number of sources was obtained by information gathered and public comments for pharmaceutical facilities subject to 40 CFR part 63, subpart GGG on the Residual Risk and Technology Review that was completed in October of 2008, by EPA's Office of Air Quality Planning and Standards

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

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 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 the five years. Without the five-year record retention, 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

None of the reporting or recordkeeping requirements contain sensitive questions.

4. The Respondents and the Information Requested

4(a) Respondents/SIC Codes

The respondents to the recordkeeping and reporting requirements are pharmaceutical production facilities. The North American Industry Classification System (NAICS) codes are listed below for each source category description.

Standard (40 CFR, part 63, subpart GGG)	NAICS Codes
Pharmaceutical Preparation Manufacturing	325412
Medicinal and Botanical Manufacturing	325411

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

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

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)

Notifications	
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(1)
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(e)(5), 63.9(g)(1), 63.10(e)(2), 63.1260(d)
Notification of 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)
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)
Reports of malfunctions	63.1260(i)
Pre-compliance report (as applicable)	63.1260(e)
Notification of process change	63.1260(h)
Periodic reports	63.1260(g)
Reports of leak detection and repair (LDAR)	63.1260(j), 63.1255(h)
Reports of emissions averaging	63.1260(k)
Reports of malfunctions that result in an exceedances of the standard for the purpose of affirmative defense	63.1250(g)(4)

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 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)

Recordkeeping	
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)

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 not widely used. At this time, it is estimated that approximately 20 percent of the respondents are reporting electronically.

The amendments to the NESHAP require that any performance tests performed after December 31, 2011 be submitted electronically to EPA's Central Data Exchange by using the Electronic Reporting Tool (ERT) for test methods that are compatible with ERT. This new requirement to submit the data to the ERT is in addition to the other existing submission requirements for this data.

(ii) Respondent Activities

Respondent Activities
Read instructions.
Plan compliance strategy (includes preparing implementation plans)
Perform initial performance test and repeat performance tests if necessary.
Perform initial performance test, Reference Methods 1, 2, 3, 4, 18, 25, and 26 test, and repeat performance test 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.
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.

Respondent Activities
Transmit, or otherwise disclose the information.

Currently, sources are using monitoring equipment that provides 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.

EPA is including in Table 3 (located at the end of this supporting statement) an estimate of the burden associated with performing an affirmative defense. EPA is providing this as an illustrative example of the potential additional administrative burden a source may incur to assert in an Affirmative Defense in response to an action to enforce the standards set forth in the applicable subpart.

This illustrative estimate is not considered a duplicate estimate of cost under the General Duty to Minimize Emissions clause under 63.6(e)(1)(i), which states: “At all times, the owner and operator must operate and maintain any affected source, including associated air pollution control equipment and monitoring equipment, in a manner consistent with safety and good air pollution control practices for minimizing emissions. Determining whether such operation and maintenance procedures are being used will be based on information available to the Administrator which may include, but is not limited to, monitoring results, review of operation and maintenance procedures, review of operation and maintenance records, and inspection of the source.”

To provide the public with an estimate of the relative magnitude of the burden associated with an assertion of the affirmative defense position adopted by a source, EPA provides an administrative adjustment to this ICR that estimates the costs of the notification, recordkeeping and reporting requirements associated with the assertion of the affirmative defense. EPA’s estimate for the required notification, reports and records, including the root cause analysis, associated with a single incident totals approximately \$3,141 and is based on the time and effort required of a source to review relevant data, interview plant employees, and document the events surrounding a malfunction that has caused an exceedance of an emission limit. The estimate also includes time to produce and retain the records and reports for submission to EPA. EPA provides this illustrative estimate of this burden because these costs are only incurred if there has been a violation and a source chooses to take advantage of the affirmative defense.

Of the number of excess emission events reported by source operators, only a small number would be expected to result from a malfunction, and only a subset of excess emissions caused by malfunctions would result in the source choosing to assert the affirmative defense. Thus we believe the number of instances in which source operators might be expected to avail themselves of the affirmative defense will be extremely small. For this reason, we estimate no more than 2 or 3 such occurrences for all sources within a given category over the 3-year period covered by this ICR. For the purpose of this estimate, we are adding two (2) instances of affirmative defense. We expect to gather information on such events in the future and will revise this estimate as better information becomes available.

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
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 OTIS.

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.

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

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.

5(d) Collection Schedule

The specific frequency for each information collection activity within this request is shown below in Table 1: Annual Respondent Burden and Cost - NESHAP for Pharmaceuticals Production (40 CFR Part 63, Subpart GGG) (Revision).

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 44,266 (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

This ICR uses the following labor rates:

Managerial	\$114.49 (\$54.52 + 110%)
Technical	\$98.20 (\$46.76 + 110%)
Clerical	\$48.53 (\$23.11 + 110%)

These rates are from the United States Department of Labor, Bureau of Labor Statistics, September 2009, "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 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)
Data-logger and Thermocouple	\$4,400	0	\$0	\$4,158	27	\$112,266
Total			\$0			\$112,266

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

The total operation and maintenance (O&M) costs for this ICR are \$112,266. 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 \$112,266.

(iv) Affirmative Defense, Root Cause Analysis, and Malfunction Costs.

EPA's estimate for a affirmative defense and root cause analysis is based on general experience to calculate the time and effort required of a source to review relevant data, interview plant employees, and reconstruct the events prior to a malfunction in order to determine primary and contributing causes. The level of effort also includes time to produce and retain the report in document form so that the source will have it available should EPA or state enforcement agencies ever request to review it.

6(c) Estimating Agency Burden and Cost

The only costs to the Agency are those costs associated with analysis of the reported information. The EPA 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 \$71,518.

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), 2010 General Schedule, which excludes locality rate 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 - NESHAP for Pharmaceuticals Production (40 CFR Part 63, Subpart GGG) (Revision).

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

Based on our research for this ICR, on average over the next three years, approximately 27 respondents will be subject to the standard. It is estimated that no new 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 which 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	0	27	0	0	27
2	0	27	0	0	27
3	0	27	0	0	27
Average	0	27	0	0	27

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

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 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

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 $E=(B \times C)+D$
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	27	2	0	54
No deviations	24	2	0	48
Deviations	3	2	0	6
LDAR report	27	2	0	54
Emissions averaging report	3	2	0	6
Reports of malfunctions that result in an exceedances of the standard for the purpose of affirmative defense	27	0.025	0	0.7
Total Number of Annual Responses			Total	250

The number of Total Annual Responses is 250.

The total annual labor costs are \$4,187,309. Details regarding these estimates may be found below in Table 1: Annual Respondent Burden and Cost - NESHAP for Pharmaceuticals Production (40 CFR Part 63, Subpart GGG) (Revision).

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 below.

(i) Respondent Tally

The total annual labor hours are 44,266. Details regarding these estimates may be found below in Table 1: Annual Respondent Burden and Cost - NESHAP for Pharmaceuticals Production (40 CFR Part 63, Subpart GGG) (Revision).

Furthermore, the annual public reporting and recordkeeping burden for this collection of information is estimated to average 177 hours per response.

The total annual capital/startup and Operation and Maintenance (O&M) costs to the regulated entity are \$112,266.

(ii) The Agency Tally

The average annual Agency burden and cost over next three years is estimated to be 1,587 labor hours at a cost of \$71,518. See below Table 2: Average Annual EPA Burden and Cost – NESHAP for Pharmaceuticals Production (40 CFR Part 63, Subpart GGG) (Revision).

6(f) Reasons for Change in Burden

There is an increase in the labor hour burden in this ICR compared to the previous ICR due to the inclusion of the new requirements of the amendments to the NESHAP. EPA provides an adjustment to this ICR that estimates the costs of the notification, recordkeeping, and reporting requirements associated with the assertion of the affirmative defense. EPA's estimate for the required notification, reports and records, including the root cause analysis, associated with a single incident totals approximately \$3,141 and is based on the time and effort required of a source to review relevant data, interview plant employees, and document the events surrounding a malfunction that has caused an exceedance of an emission limit. The estimate also includes time to produce and retain the records and reports for submission to EPA. For the purpose of estimating the annual burden, EPA is attributing a total of 2 instances of affirmative defense over a three year period across all sources in the category. EPA is using this frequency of 2 events in three years because, of the number of excess emission events reported by source operators, only a small number would be expected to result from a malfunction, and only a subset of excess emissions caused by malfunctions would result in the source choosing to assert the affirmative defense. Thus we believe the number of instances in which source operators might be expected to avail themselves of the affirmative defense will be extremely small.

6(g) Burden Statement

The annual public reporting and recordkeeping burden for this collection of information is estimated to average 177 hours per response. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to 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; to adjust the existing ways to comply with any previously applicable instructions and requirements; to train personnel to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to 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-OAR-2010-0600. 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 content of the docket, and to access those documents in the public docket that are available electronically. When in the system, select "search" than 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 Avenue, 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) 566-1752. 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-OAR-2010-0600 and OMB Control Number 2060-0358 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 Pharmaceuticals Production (40 CFR Part 63, Subpart GGG) (Revision)

Burden item Burden item	(A)	(B)	(C)	(D)	(E)	(F)	(G)	(H)
	Person hours per occurrence	No. of occurrences per respondent per year	Person hours per respondent per year (C=AxB)	Respondents per year ^a	Technical person- hours per year (E=CxD)	Management person hours per year (Ex0.05) (Ex0.05)	Clerical person hours per year (Ex0.1) (Ex0.1)	Total Cost Per year ^b
1. Applications	N/A							
2. Surveys and studies	N/A							
42-Recordkeeping Requirements								
3. Reporting requirements	1	365	365	27	9,855	492.8	985.5	\$1,072,002
i. Records for operating parameters for control								
New sources ^c								
A. Read rule and instructions	2	26	52	27	1,404	70.2	140.4	\$152,594
ii. Records of SSCM								
B. Required activities	16	1	16	27	432	21.6	43.2	\$46,992
iii. Calibration of CMS ^m								
i. Initial performance tests								
iv. LDAR	See 3C							
New	480	1	480	0	0	0	0	\$0
Subtotal for Recordkeeping Requirements						13,444.7	0	\$0
Reconstructed	160	1	160	0	0	0	0	\$0
Wastewater	160	1	160	0	38,487	1,931.8	3,847.5	\$4,187,389
TOTAL LABOR BURDEN AND COST (rounded)						44,266	0	\$4,187,389
ii. Quality control plan for CMS	60	1	60	0	0	0	0	\$0
iii. Develop record system	40	1	40	0	0	0	0	\$0
iv. Train personnel	40	1	40	0	0	0	0	\$0
v. Repeat performance test ^d	60	1	60	0	0	0	0	\$0
C. Write reports								
i. Notification of construction/reconstruction	2	1	2	0	0	0	0	\$0
ii. Notification of physical or operational changes ^e	8	3	24	27	648	32.4	64.8	\$70,488
iii. Notification of actual startup	2	1	2	0	0	0	0	\$0
iv. Notification of initial performance test	2	1	2	0	0	0	0	\$0
v. Notification of applicability	2	1	2	0	0	0	0	\$0
vi. Notification of demonstration of CMS	2	1	2	0	0	0	0	\$0
vii. Notification of compliance status	120	1	120	0	0	0	0	\$0
viii. Pre-compliance report (emission averaging)	180	1	180	0	0	0	0	\$0
ix. Startup, shutdown, malfunction ^f	40	2	80	27	2,160	108	216	\$234,959
x. Semiannual summary report								
a. No deviations ^g	8	2	16	24	384	19.2	38.4	\$41,771
b. Deviations ^h	24	2	48	3	144	7.2	14.4	\$15,664
xi. Leak detection and repair (LDAR) report ⁱ	432	2	864	27	23,328	1,166.4	2,332.8	\$2,537,562
xii. Emissions averaging report ^j	20	2	40	3	120	6	12	\$13,053
xiii. Affirmative defense ⁿ	30	0.7	20	1	12	8	0	\$2,094
Subtotal for Reporting Requirements						30,821.6		

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 ICR uses the following labor rates: \$114.49 per hour for Executive, Administrative, and Managerial labor; \$98.20 per hour for Technical labor, and \$48.53 per hour for Clerical labor. These rates are from the United States Department of Labor, Bureau of Labor Statistics, September, 2009, 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.
- ^d We have assumed that 20 percent of respondents would have to repeat performance tests due to failure.
- ^e We have assumed that each source will require an average of three processing changes each year to complete this task 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 hour 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 hour 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 SSM plans.
- ^m We have assumed that it will take each respondent 16 hours one time per year to record the calibration of CMS. ⁿ Assumes 2 affirmative defense reports for entire industry during the 3-yr ICR period. Formulas are not followed for person-hours per year. For affirmative defense hours required assumes 18 hours technical, 12 hours management, 0 clerical for each instance of affirmative defense.

Table 2: Average Annual EPA Burden - NESHAP for Pharmaceuticals Production (40 CFR Part 63, Subpart GGG) (Revision)

Activity	(A) EPA person- hours per occurrence	(B) No. of occurrences per plant per year	(C) EPA person- hours per plant per year (C=AxB)	(D) Plants 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 test ^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								
i. Notification of construction/reconstruction	2	1	2	0	0	0	0	\$0

Activity	(A) EPA person- hours per occurrence	(B) No. of occurrences per plant per year	(C) EPA person- hours per plant per year (C=AxB)	(D) Plants 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
ii. Notification of actual startup	2	1	2	0	0	0	0	\$0
iii. Notification of initial CMS demonstration	2	1	2	0	0	0	0	\$0
iv. Initial notification	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	\$4,975.16
b. Deviations ^h	8	2	16	3	48	2.4	4.8	\$2,487.58
ii. Notification of physical/operational change ⁱ	8	3	24	27	648	32.4	64.8	\$33,582.28
iii. SSM report ^j	2	2	4	27	108	5.4	10.8	\$5,597.05
iv. LDAR report ^k	8	2	16	27	432	21.6	43.2	\$22,388.18
v. Emission averaging report ^l	8	2	16	3	48	2.4	4.8	\$2,487.58
Subtotals Labor Burden and cost					1,380	69	138	\$71,517.83
TOTAL ANNUAL BURDEN AND COST (rounded)						1,587		\$71,518

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 following labor rates which incorporates a 1.6 benefits multiplication factor to account for government overhead expenses: \$62.27 Managerial rate (GS-13, Step 5, \$38.92 x 1.6), \$46.21 Technical rate (GS-12, Step 1, \$28.88 x 1.6), and \$25.01 Clerical rate (GS-6, Step 3, \$15.63 x 1.6). These rates are from the Office of Personnel Management (OPM) 2010 General Schedule which excludes locality rates of pay.

^c We have assumed that there will be no new or reconstructed facilities during the next three years of this ICR.

^d We have assumed that 20 percent of respondents would have to repeat performance tests due to failure.

^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; new facilities are not allowed to use emissions averaging.

^g We have assumed that 90 percent of respondents will each take two hours two times per year to complete this report.

^h We have assumed that 10 percent of respondents will have to report deviation.

ⁱ We have assumed that each respondent will be required to review the physical/operational changes for each facility three times per year over the next three-year period of this ICR.

^j We have assumed that each respondent will report actions taken during startup, shutdown, or 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 have to review the emission averaging report.

Table 3: Single Affirmative Defense Burden Estimate

Personnel	Number of Personnel	Time Requirement (hours)	Total Hours	Hourly Rate (\$/hr)	Total
Technical Personnel	3	6	18	98.20	\$ 1,768
Managerial Personnel	2	6	12	114.49	\$ 1,374
Total	5		30		\$3,141