SUPPORTING STATEMENT
ENVIRONMENTAL PROTECTION AGENCY

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

1. Identification of the Information Collection

1(a) Title of the Information Collection

NESHAP for Pharmaceuticals Production (40 CFR Part 63, Subpart GGG) (Renewal), EPA ICR Number 1781.08, OMB Control Number 2060-0358.

1(b) Short Characterization/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. The 2014 amendment promulgated technical correction was made to allow for EPA Method 320 as an alternative to EPA Method 18 for demonstrating that a 'vent' is not a process vent. The amendment did not impose any additional burden. 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 containing these documents, and retain the file for at least five years following the generation date of such maintenance reports and records. All reports are sent to the delegated state or local authority. In the event that there is no such delegated authority, the reports are sent directly to the U.S. Environmental Protection Agency (EPA) regional office.

Over the next three years, approximately 27 respondents per year will be subject to these standards, and no additional respondents per year will become subject to these same standards.

There are approximately 27 pharmaceuticals production facilities, which are all owned and operated by the pharmaceuticals production industry (the "Affected Public"). None of these 27 facilities in the United States are owned by either state, local, tribal entities or the Federal government. They are all owned and operated by privately-owned, for-profit businesses. The

"burden" to the Affected Public may be found below in Table 1: Annual Respondent Burden and Cost – NESHAP for Pharmaceuticals Production (40 CFR Part 63, Subpart GGG) (Renewal). The Federal government "burden" is attributed entirely to work performed by either Federal employees or government contractors and may be found below in Table 2: Average Annual EPA Burden and Cost – NESHAP for Pharmaceuticals Production (40 CFR Part 63, Subpart GGG) (Renewal). We assume that they will all respond to EPA inquiries.

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. In future collections, costs and time burden estimates should be rounded to the appropriate number of significant digits. If "reading instructions" are provided as potential time or cost burdens, then the location of the instructions or the instructions themselves should be provided. Also, the burden for refreshing on instructions should be included, as appropriate. Any detailed tables should be provided in excel format along with or in lieu of detailed tables provided within the supporting statement.

EPA has addressed each item of concern in the TOC by rounding all calculations to three significant digits, clarifying the burden with "reading instructions", is for regulated entities to read and understand the rule, and assuming all existing sources need to re-familiarize with the rule each year. EPA has also prepared a calculation spreadsheet that accompanies this supporting statement.

2. Need for and Use of the Collection

2(a) Need/Authority for the Collection

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

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

and (G) provide such other information as the Administrator may reasonably require.

In the Administrator's judgment, HAP emissions from pharmaceuticals production (predominately methanol, methylene chloride and toluene) either cause or contribute to air pollution that may reasonably be anticipated to endanger public health and/or welfare. Therefore, the NESHAP were promulgated for this source category at 40 CFR Part 63, Subpart GGG.

2(b) Practical Utility/Users of the Data

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

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

The notifications required in these standards are used to inform the Agency or delegated authority when a source becomes subject to the requirements of the regulations. The reviewing authority may then inspect the source to check if the pollution control devices are properly installed and operated, leaks are being detected and repaired, and that these standards are being met. The performance test may also be observed.

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

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 either a state or local agency has adopted its own similar standards to implement the Federal standards, a copy of the report submitted to the state or local agency can be sent to the Administrator in lieu of the report required by the Federal standards. Therefore, duplication does not exist.

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

An announcement of a public comment period for the renewal of this ICR was published in the Federal Register (82 FR 29552) on June 29, 2017. No comments were received on the 'burden' published in the Federal Register.

3(c) Consultations

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

Industry trade associations and other interested parties were provided an opportunity to comment on the burden associated with the standards as they were being developed and these same standards have previously been reviewed to determine the minimum information needed for compliance purposes. In developing this ICR, we contacted both the Pharmaceutical Research and Manufacturers of America (PhRMA), at (202) 835-3400; and 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.

3(d) Effects of Less-Frequent Collection

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

3(e) General Guidelines

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

These standards require the respondents to maintain all records, including reports and notifications for at least five years. This is consistent with the General Provisions as applied to these standards. 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.

3(f) Confidentiality

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

3(g) Sensitive Questions

The reporting or recordkeeping requirements in these standards do not include sensitive questions.

4. The Respondents and the Information Requested

4(a) Respondents/SIC Codes

The respondents to the recordkeeping and reporting requirements are 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

4(b) Information Requested

(i) Data Items

In this ICR, all the data that is 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),

Notifications	
	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)

Reports	
Reports of malfunctions	63.1260(i)
Precompliance 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 emissions averaging	63.1260(k)

A source must keep the following records:

Recordkeeping	
Recordkeeping requirements	63.10(a), 63.1259(a)

Recordkeeping	
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)

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.

On April 21, 2011, 40 CFR Part 63 Subpart GGG was amended to provide for electronic reporting. 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 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
Familiarization with the regulatory requirements.
Install, calibrate, maintain, and operate monitoring devices.
Perform initial performance test, Reference Method 1, 2, 3, 4, 18, 25, 26, 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 the purpose of collecting, validating, and verifying information.
Develop, acquire, install, and utilize technology and systems for the purpose of processing and maintaining information.
Develop, acquire, install, and utilize technology and systems for the purpose of disclosing and providing information.
Train personnel to be able to respond to a collection of information.
Transmit, or otherwise disclose the information.

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

5(a) Agency Activities

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

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

5(b) Collection Methodology and Management

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

Information contained in the reports is reported by state and local governments in the ICIS Air database, which is operated and maintained by EPA's Office of Compliance. ICIS is EPA's database for the collection, maintenance, and retrieval of compliance data for industrial and government-owned facilities. 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.

5(c) Small Entity Flexibility

A 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) (Renewal).

6. Estimating the Burden and Cost of the Collection

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

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

6(a) Estimating Respondent Burden

The average annual burden to industry over the next three years from these recordkeeping and reporting requirements is estimated to be 44,300 hours (Total Labor Hours from Table 1 below). These hours are based on Agency studies and background documents from the development of these regulations, Agency knowledge and experience with the NESHAP program, the previously-approved ICR, and any comments received.

6(b) Estimating Respondent Costs

(i) Estimating Labor Costs

This ICR uses the following labor rates:

Managerial	$144.33 ($68.73+ 110%)
Technical	$108.28 ($51.56 + 110%)
Clerical	$53.34 ($25.40 + 110%)

These rates are from the United States Department of Labor, Bureau of Labor Statistics, September 2016, “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 standards are both labor costs which are addressed elsewhere in this ICR and the costs associated with continuous monitoring. The capital/startup costs are one-time costs when a

facility becomes subject to the regulations. The annual operation and maintenance costs are the ongoing costs to maintain the monitor and other costs such as photocopying and postage.

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

Capital/Startup vs. Operation and Maintenance (O&M) Costs						
(A) Continuous Monitoring Device	(B) Capital/Startup Cost for One Respondent	(C) Number of New Respondents	(D) Total Capital/Startup Cost (B x C)	(E) Annual O&M Costs for One Respondent	(F) Number of Respondents with O&M	(G) Total O&M (E x F)
Data-logger and Thermocouple	$4,400	0	$0	$4,158	27	$112,266
Total			**$0**			**$112,000**

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

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

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

6(c) Estimating Agency Burden and Cost

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

The average annual Agency cost during the three years of the ICR is estimated to be $74,400.

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

Managerial	$64.80 (GS-13, Step 5, $40.50 + 60%)
Technical	$48.08 (GS-12, Step 1, $30.05 + 60%)
Clerical	$26.02 (GS-6, Step 3, $16.26 + 60%)

These rates are from the Office of Personnel Management (OPM), 2017 General

Schedule, which excludes locality rates of pay. The rates have been increased by 60 percent to account for the benefit packages available to Federal government employees. Details upon which this estimate is based appear below in Table 2: Average Annual EPA Burden and Cost – NESHAP for Pharmaceuticals Production (40 CFR Part 63, Subpart GGG) (Renewal).

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

Based on our research for this ICR, on average over the next three years, approximately 27 existing respondents will be subject to these standards. It is estimated that no additional respondents per year will become subject to these same standards. The overall average number of respondents, as shown in the table below, is 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 [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 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	27	2	0	54
Semi-Annual Report - No deviations	24	2	0	48
Semi-Annual Report-Deviations	3	2	0	6
LDAR report	27	2	0	54
Emissions averaging report	3	2	0	6
Total Number of Annual Responses			**Total**	**249**

The number of Total Annual Responses is 249.

The total annual labor costs are $4,650,000. 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) (Renewal).

6(e) Bottom Line Burden Hours and Cost Tables

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

(i) Respondent Tally

The total annual labor hours are 44,300 hours. 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) (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.

The total annual capital/startup and O&M costs to the regulated entity are $112,000. The cost calculations are detailed in Section 6(b)(iii), Capital/Startup vs. Operation and Maintenance (O&M) Costs.

(ii) The Agency Tally

The average annual Agency burden and cost over next three years is estimated to be 1,590 labor hours at a cost of $74,400; see below in 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.

6(f) Reasons for Change in Burden

There is a reduction in the estimated number of responses, by one. The previous ICR included one response for affirmative defense. However, that item has appropriately been removed from this ICR as those provisions are outdated.

There is an adjustment increase in the respondent labor hours as currently identified in the OMB Inventory of Approved Burdens. This increase is not due to any program changes. The change in the burden and cost estimates occurred due to a change in assumption. In accordance with the Terms of Clearance, this ICR assumes that all existing respondents will have to familiarize with the regulatory requirements each year.

There is also a small adjustment decrease in the total capital and O&M costs as compared the previously-approved ICR. This decrease is not due to any program changes. The change in capital and O&M costs occurred because, in accordance with the terms of clearance, this ICR rounds totals to three significant figures.

6(g) Burden Statement

The annual public reporting and recordkeeping burden for this collection of information is estimated to average 178 hours per response. “Burden” means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

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

To comment on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including the use of automated collection techniques, EPA has established a public docket for this ICR under Docket ID Number EPA-HQ-OECA-2013-0349. An electronic version of the public docket is available at http://www.regulations.gov/, which may be used to obtain a copy of the draft collection of information, submit or view public comments, access the index listing of the contents of the docket, and to access those documents in the public docket that are available electronically. When in the system, select “search,” then key in the docket ID number identified in this document. The documents are also available for public viewing at the Enforcement and Compliance Docket and Information Center in the EPA Docket Center (EPA/DC), WJC West, Room 3334, 1301 Constitution Ave., NW, Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566-1744, and the telephone number for the docket center is (202) 566-1752. Also, you can send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503, Attention: Desk Officer for EPA. Please include the EPA Docket ID Number EPA-HQ-OECA-2013-0349 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) (Renewal)

Burden item	(A) Person hours per occurrence	(B) No. of occurrences per respondent per year	(C) Person hours per respondent per year (AxB)	(D) Respondents per year [a]	(E) Technical person-hours per year (CxD)	(F) Management person hours per year (Ex0.05)	(G) Clerical person hours per year (Ex0.1)	(H) Total Cost per year, $ [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	$3,262.42
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
ii. Notification of physical or operational changes [c, e]	8	3	24	27	648	32.4	64.8	$78,298.16
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	2	1	2	0	0	0	0	$0

applicability [c]								
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	$260,993.88
x. Semiannual summary report								
a. No deviations [g]	8	2	16	24	384	19.2	38.4	$46,398.91
b. Deviations [h]	24	2	48	3	144	7.2	14.4	$17,399.59
xi. Leak detection and repair (LDAR) report [i]	432	2	864	27	23,328	1,166.4	2,332.8	$2,818,733.90
xii. Emissions averaging report [j]	20	2	40	3	120	6	12	$14,499.66
Subtotal for Reporting Requirements					***30,833***			***$3,239,587***
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	$1,190,784.58
D. Records of malfunctions [l]	2	26	52	27	1,404	70.2	140.4	$169,646.02
E. Calibration of CMS [m]	16	1	16	27	432	21.6	43.2	$52,198.78
F. LDAR	See 3C							
Subtotal for Recordkeeping Requirements					***13,445***			***$1,412,629***
TOTAL LABOR BURDEN AND COST (rounded) [n]					**44,300**			**$4,650,000**
TOTAL CAPITAL AND O&M								**$112,000**

COST (rounded) [n]								
GRAND TOTAL (rounded) [n]								**$4,760,000**

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: $144.03 per hour for Executive, Administrative, and Managerial labor; $108.28 per hour for Technical labor, and $53.34 per hour for Clerical labor. These rates are from the United States Department of Labor, Bureau of Labor Statistics, September 2016, 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 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 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)

Activity	(A) EPA person hours per occurrence	(B) No. of occurrences per plant per year	(C) EPA person hours per plant per year (AxB)	(D) Plants per year [a]	(E) Technical person-hours per year (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	$5,176.51
b. Deviations [h]	8	2	16	3	48	2.4	4.8	$2,588.26
ii. Notification of physical or	8	3	24	27	648	32.4	64.8	$34,941.46

operational changes [i]								
iii. Malfunction [j]	2	2	4	27	108	5.4	10.8	$5,823.58
iv. Leak detection and repair (LDAR) report [k]	8	2	16	27	432	21.6	43.2	$23,294.30
v. Emissions averaging report [l]	8	2	16	3	48	2.4	4.8	$2,588.26
TOTAL ANNUAL BURDEN AND COST [m]					**1,590**			**$74,400**

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 following labor rates which incorporates a 1.6 benefits multiplication factor to account for government overhead expenses: $64.80 Managerial rate (GS-13, Step 5, $40.50 x 1.6), $48.08 Technical rate (GS-12, Step 1, $30.05 x 1.6), and $26.02 Clerical rate (GS-6, Step 3, $16.26 x 1.6). These rates are from the Office of Personnel Management (OPM) 2017 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, 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.