

Table 1: Annual Respondent Burden and Cost – NESHAP for Pharmaceuticals Production (40

Burden item	(A) Person hours per occurrence	(B) No. of occurrences per respondent per year	(C) Person hours per respondent per year (AxB)
1. Applications	N/A		
2. Surveys and studies	N/A		
3. Reporting Requirements			
A. Familiarization with Regulatory Requirements	1	1	1
B. Required Activities			
i. Initial Performance Tests ^c			
New	480	1	480
Reconstructed	160	1	160
Wastewater	160	1	160
ii. Quality control plan for CMS ^c	60	1	60
iii. Repeat performance test ^d	60	1	60
C. Write reports			
i. Notification of construction/reconstruction ^c	2	1	2
ii. Notification of physical or operational changes ^{c,e}	8	3	24
iii. Notification of actual startup ^c	2	1	2
iv. Notification of initial performance test ^c	2	1	2
v. Notification of applicability ^c	2	1	2
vi. Notification of demonstration of CMS ^c	2	1	2
vii. Notification of compliance status ^c	120	1	120
viii. Pre-compliance report (with and without emission averaging implementation plan) ^c	180	1	180
ix. Malfunction report ^f	40	2	80
x. Semiannual summary report			
a. No deviations ^g	8	2	16
b. Deviations ^h	24	2	48
xi. Leak detection and repair (LDAR) report ⁱ	432	2	864
xii. Emissions averaging report ^j	20	2	40
Subtotal for Reporting Requirements			
4. Recordkeeping requirements			
A. Develop record system	40	1	40
B. Train personnel	40	1	40
C. Records for operating parameters for control devices ^k	1	365	365
D. Records of malfunctions ^l	2	26	52
E. Calibration of CMS ^m	16	1	16
F. LDAR	See 3C		
Subtotal for Recordkeeping Requirements			
TOTAL LABOR BURDEN AND COST (rounded) ⁿ			

TOTAL CAPITAL AND O&M COST (rounded) ^a			
GRAND TOTAL (rounded) ^a			

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 27 respondents.
- ^b This ICR uses the following labor rates: \$148.45 per hour for Executive, Administrative, and Managerial labor; \$121.00 per hour for other labor. These rates are from the United States Department of Labor, Bureau of Labor Statistics, March 2020, Table 2. Civilian Worker Compensation. The rates have been increased by 110 percent to account for the benefit packages available to those employees.
- ^c We have assumed that there will be no new or reconstructed facilities during the next three years of this ICR, and these 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 we have assumed that 20 percent of new respondents would have to repeat initial performance tests due to failure, we have assumed that 20 percent of new respondents would have to repeat initial performance tests due to failure.
- ^e We have assumed that each source will require an average of three processing changes each year over the next three years.
- ^f We have assumed that each respondent will take 40 hours two times per year to complete the startup, shutdown, malfunction, and start-up (SSM) report.
- ^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 report.
- ^k We have assumed that it will take each respondent 1 hour 365 times per year to record the operating parameters for combustion engines.
- ^l We have assumed that it will take each respondent 2 hours 26 times per year to record the occurrence and duration of combustion engine malfunctions. We have assumed that it will take each respondent 10 hours one time per year to record the calibration of OMS.
- ⁿ Totals have been rounded to 3 significant figures. Figures may not add exactly due to rounding.

0 CFR Part 63, Subpart GGG) (Renewal)

121.46 148.45 60.23

(D) Respondents per year ^a	(E) Technical person- hours per year (Cx _D)	(F) Management person hours per year (Ex _{0.05})	(G) Clerical person hours per year (Ex _{0.1})	(H) Total Cost per year, \$ ^b
27	27	1.35	2.7	\$3,642.45
0	0	0	0	\$0
0	0	0	0	\$0
0	0	0	0	\$0
0	0	0	0	\$0
0	0	0	0	\$0
0	0	0	0	\$0
27	648	32.4	64.8	\$87,418.76
0	0	0	0	\$0
0	0	0	0	\$0
0	0	0	0	\$0
0	0	0	0	\$0
0	0	0	0	\$0
0	0	0	0	\$0
27	2,160	108	216	\$291,395.88
24	384	19.2	38.4	\$51,803.71
3	144	7.2	14.4	\$19,426.39
27	23,328	1,166.4	2,332.8	\$3,147,075.50
3	120	6	12	\$16,188.66
		30,833		\$3,616,951
0	0	0	0	\$0
0	0	0	0	\$0
27	9,855	492.75	985.5	\$1,329,493.70
27	1,404	70.2	140.4	\$189,407.32
27	432	21.6	43.2	\$58,279.18
		13,445		\$1,577,180
		44,300		\$5,190,000

1641 Hrs/Respor

				\$112,000
				\$5,300,000

178 Hrs/Respor

There will be no new additional sources during the next three years of this ICR.

at \$46 per hour for Technical labor, and \$60.23 per hour for Clerical labor. These rates are by Occupational and Industry group. The rates are from column 1, Total Wages, as reported by private industry.

Since one-time initial requirements do not apply; however, the ICR estimates that all

respondents there are no new respondents estimated, no one is assumed to conduct a repeat test.

During the next three years of this ICR.

Annual performance reports.

Annual evaluation report.

Annual report.

Annual averaging report.

Control devices.

Each malfunction.

Table 2: Average Annual EPA Burden and Cost – NESHAP for Pharmaceuticals Producti

Activity	(A) EPA person hours per occurrence	(B) No. of occurrences per plant per year	(C) EPA person hours per plant per year (AxB)
1. Required activities			
i. Initial performance tests ^c	2	1	2
ii. Repeat performance test ^d	24	1	24
2. Report review - one time ^c			
i. Notification of construction/reconstruction	2	1	2
ii. Notification of actual startup	2	1	2
iii. Notification of demonstration of CMS	2	1	2
iv. Initial notification of applicability	2	1	2
v. Notification of compliance status report	40	1	40
vi. Pre-compliance report ^e			
a. With emissions averaging ^f	20	1	20
b. Without emissions averaging	4	1	4
3. Report review - on-going			
i. Semiannual summary report			
a. No deviations ^g	2	2	4
b. Deviations ^h	8	2	16
ii. Notification of physical or operational changes ⁱ	8	3	24
iii. Malfunction ^j	2	2	4
iv. Leak detection and repair (LDAR) report ^k	8	2	16
v. Emissions averaging report ^l	8	2	16
TOTAL (rounded) ^m			

Assumptions:

^a We have assumed that the average number of respondents that will be subject to this rule will be 27. There will t

^b This cost is based on the following hourly labor rates times a 1.6 benefits multiplication factor to account for gov Technical and \$27.46 Clerical. These rates are from the Office of Personnel Management (OPM) 2020 General Sc

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

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

- ^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.

ion (40 CFR Part 63, Subpart GGG) (Renewal)

50.72 68.37 27.46

(D) Plants per year ^a	(E) Technical person- hours per year (CxD)	(F) Managem ent person hours per year (Ex0.05)	(G) Clerical person hours per year (Ex0.1)	(H) Cost, \$ ^b
0	0	0	0	\$0
0	0	0	0	\$0
0	0	0	0	\$0
0	0	0	0	\$0
0	0	0	0	\$0
0	0	0	0	\$0
0	0	0	0	\$0
0	0	0	0	\$0
0	0	0	0	\$0
24	96	4.8	9.6	\$5,460.91
3	48	2.4	4.8	\$2,730.46
27	648	32.4	64.8	\$36,861.16
27	108	5.4	10.8	\$6,143.53
27	432	21.6	43.2	\$24,574.10
3	48	2.4	4.8	\$2,730.46
		1,590		\$78,500

oe no new additional sources during the next three years of this ICR.

overnment overhead expenses: \$68.37 for Managerial, \$50.72 for
chedule which excludes locality rates of pay.

l these one-time initial requirements do not apply.

re are no new respondents estimated, no one is assumed to

; however, this is a one-time requirement; new facilities are not

r year over the next three-year period of this ICR.