SUPPORTING STATEMENT
ENVIRONMENTAL PROTECTION AGENCY

NSPS for Hospital/Medical/Infectious Waste Incinerators (40 CFR Part 60, Subpart Ec) (Renewal)

1. Identification of the Information Collection

1(a) Title of the Information Collection

NSPS for Hospital/Medical/Infectious Waste Incinerators (40 CFR Part 60, Subpart Ec) (Renewal), EPA ICR Number 1730.11, OMB Control Number 2060-0363.

1(b) Short Characterization/Abstract

The New Source Performance Standards (NSPS) for Hospital/Medical/Infectious Waste Incinerators (40 CFR Part 60, Subpart Ec) were proposed on February 27, 1995, promulgated on September 15, 1997, and amended on both October 6, 2009, and February 27, 2014. The original standards applied to either owners or operators of Hospital/Medical/Infectious Waste Incinerators (HMIWI) for which construction commenced after June 20, 1996, or for which modification commenced after March 16, 1998, but no later than April 6, 2010. Sources subject to the original standards are now covered under the revised Emission Guidelines for HMIWI at 40 CFR Part 60, Subpart Ce. This information request covers the reporting and recordkeeping requirements associated with the revised NSPS, which apply to new facilities only. New facilities include those that commenced construction after December 1, 2008 or commenced modification after April 6, 2010. This information is being collected to assure compliance with 40 CFR Part 60, Subpart Ec.

In general, all NSPS 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 NSPS.

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. If there is no such delegated authority, the reports are sent directly to the U.S. Environmental Protection Agency (EPA) regional office.

The “Affected Public” are owners and operators of HMIWI subject to the revised NSPS. The ‘burden’ to the Affected Public may be found below in Table 1: Annual Respondent Burden and Cost – NSPS for Hospital/Medical/Infectious Waste Incinerators (40 CFR Part 60, Subpart Ec) (Renewal). The Federal Government’s ‘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 NSPS for Hospital/Medical/Infectious Waste Incinerators (40 CFR Part 60, Subpart Ec) (Renewal). There are approximately 11 hospital/medical/infectious waste incinerator facilities. None of the 11 facilities in the United States are owned by either state, local, tribal or the Federal government. They are all owned and operated by privately-owned, for-profit businesses. We assume that they will all respond to EPA inquiries.

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). Over the next three years, approximately 10 respondents per year will be subject to these standards and one additional respondent per year will become subject to these same standards (for an average of 11 respondents).

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

2. Need for and Use of the Collection

2(a) Need/Authority for the Collection

The EPA is charged under Section 111 of the Clean Air Act (CAA), as amended, to establish standards of performance for new stationary sources that reflect:

> **. . .** application of the best technological system of continuous emissions reduction which (taking into consideration the cost of achieving such emissions reduction, or any non-air quality health and environmental impact and energy requirements) the Administrator determines has been adequately demonstrated. Section 111(a)(l).

The Agency refers to this charge as selecting the best demonstrated technology (BDT). Section 111 also requires that the Administrator review and, if appropriate, revise such standards every eight years. 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, dioxin/furan, particulate matter (PM), carbon monoxide

(CO), hydrogen chloride (HCl), sulfur dioxide (SO2), nitrogen oxides (NOx), lead (Pb), cadmium (Cd), and mercury (Hg) emissions from HMIWI either cause or contribute to air pollution that may reasonably be anticipated to endanger public health and/or welfare. Therefore, the NSPS were promulgated for this source category at 40 CFR Part 60, Subpart Ec.

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 these 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 either the Agency or its delegated authority when a source becomes subject to the requirements of these 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 annual and 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 60, Subpart Ec.

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 its own similar standards to implement the Federal standards, a copy of the report submitted to either 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* (83 FR 24785) on May 30, 2018. No comments were received on the burden published in the *Federal Register* for this renewal.

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. Approximately 11 respondents will be subject to these standards over the three-year period covered by this ICR.

Industry trade associations and other interested parties were provided an opportunity to comment on the burden associated with these standards as they were being developed and these same standards have been reviewed previously to determine the minimum information needed for compliance purposes. In developing this ICR, we contacted both Stericycle, Inc., at (855) 400-5172, and Larson-Miller Medical Waste Disposal, at (208) 323-7272.

It is our policy to respond after a thorough review of comments received since the last ICR renewal, as well as for 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 the standards. EPA believes that the five-year records retention requirement is consistent with the Part 70 permit program and the five-year statute of limitations on which the permit program is based. The retention of records for five years allows EPA to establish the compliance history of a source, any pattern of non-compliance and to determine the appropriate level of enforcement

action. EPA has found that the most flagrant violators have violations extending beyond five years. In addition, EPA would be prevented from pursuing the violators due to the destruction or nonexistence of essential records.

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 owners and operators of HMIWI. The United States Standard Industrial Classification (SIC) codes for the respondents affected by the standards and their corresponding North American Industry Classification System (NAICS) codes are listed in the table below:

40 CFR Part 60, Subpart Ec	SIC Codes	NAICS Codes
General Medical and Surgical Hospitals	8062	622110
Specialty Hospitals	8069	622310
Medicinal and Botanical Manufacturing	2833	325411
Pharmaceutical Preparation Manufacturing	2834	325412
Solid Waste Combustors and Incinerators	4953	562213
Colleges, Universities, and Professional Schools	8221	611310
Research and Development in Physical, Chemical, and Life Sciences	8731, 8733	541710
National Security	9711	928110
Public Health Facility	9431	923120

4(b) Information Requested

(i) Data Items

In this ICR, all the data that are either recorded or reported is required by the NSPS for Hospital/Medical/Infectious Waste Incinerators (40 CFR Part 60, Subpart Ec).

A source must make the following reports:

Notifications	
Notification and application of construction or modification	§60.58c(a), §60.7(a)
Notification of anticipated startup	§60.58c(a), §60.7(a)
Notification of actual startup	§60.7(a)
Notification of type(s) of waste to be combusted	§60.58c(a)(2)(i)
Notification of HMIWI capacity	§60.58c(a)(2)(ii)
Notification of initial continuous monitoring system (CMS) demonstration (including CO CEMS)	§60.7(a)
Notification of initial performance test	§60.8(d)
Notification of exemption claim for combustors burning pathological, low-level radioactive, and/or chemotherapeutic waste	§60.50c(b)(1)
Notification of exemption claim for co-fired combustors	§60.50c(c)(1)

Reports	
Statement of intent to construct/modify	§60.58c(a)(1)(i)
Documentation produced as a result of the siting requirements	§60.58c(a)(1)(iv), §60.54c(c)
Waste management plan	§60.58c(c)(3), §60.55c
Analysis and supporting documentation demonstrating conformance with EPA guidance and specifications for bag leak detection systems	§60.58c(c)(4)
Report of initial performance tests	§60.58c(d)(6), §60.8(a)
Initial report of values for site-specific operating parameters	§60.58c(c)(2), §60.7(a)
Annual report of values for site-specific operating parameters	§60.58c(d)(1)
Annual and semiannual reports of emissions or operating parameter exceedances, malfunctions, and periods for which data on emissions/operating parameters were not obtained	§60.58c(d), §60.58c(e), §60.7(c)
Annual report of no excess emissions	§60.58c(d)(7), §60.7(c)
Report of results of annual performance test	§60.58c(d)(6)

Reports	
Annual report of control equipment inspection	§60.58c(d)

A source must keep the following records:

Recordkeeping	
Retention of records for 5 years	§60.58c(b)
Records of startup, shutdown, or malfunction	§60.7(b)
Documentation produced as a result of siting requirements	§60.58c(b)(7)
Records of operators completing review of HMIWI operating manual	§60.58c(b)(8)
Records of operators completing operator training course and qualification requirements	§60.58c(b)(9)-(10)
Records of initial and annual testing of fugitive ash emissions	§60.58c(b)(2)(ii)
Records of process and control device operating parameters	§60.58c(b)(2)(iii)(xix)
Records of CMS operation and maintenance (including CO CEMS)	§60.7(f)
Records of emissions or operating parameter exceedances, malfunctions, and periods for which data on emissions/operating parameters were not obtained	§60.58c(b)(3)-(5)
Records of initial, annual, and any subsequent performance tests	§60.58c(b)(6)
Records of calibration of monitoring devices (including CO CEMS)	§60.58c(b)(11)
Records of annual control equipment inspections, required maintenance, and repairs not completed during established timeframe	§60.58c(b)(2)(xvii)
Records of bag leak detection system alarms and corrective action taken	§60.58c(b)(2)(xviii)
Records of CO concentrations from CO CEMS	§60.58c(b)(2)(xix)
Records on quarterly basis of types and amounts of materials charged for co-fired combustors and for incinerators burning only pathological, low-level radioactive, and/or chemotherapeutical waste	§60.50c(b), (c)

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. For affected facilities that choose to submit an electronic copy of stack test reports to EPA's WebFIRE data base, as of December 31, 2011, the owner or operator shall enter the test data into EPA's data base using the Electronic Reporting Tool located at h*ttp://www.epa.gov/ttn/chief/ert/ert_tool.html.*

(ii) Respondent Activities

Respondent Activities
Familiarization with the regulatory requirements.
Install, calibrate, maintain, and operate CEMS where used for demonstrating compliance with emission standards for control of PM, HCl, multi-metals, and Hg. This includes CEMS for opacity, pressure drop, and liquid supply pressure for any baghouses or wet scrubbers used.
Perform initial performance test, Reference Methods 1, 3, 3A, or 3B, 5, 6 or 6C, 7 or 7E, 9, 10, 22, 23, 26 or 26A, 29, and ASME PTC-19-10-1981-Part 10 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 processing and maintaining information.
Develop, acquire, install, and utilize technology and systems for disclosing and providing information.
Train personnel to be able to respond to a collection of information.
Transmit, or otherwise disclose the information.

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.

Agency Activities
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 annual and 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

There are no small entities (i.e., small businesses) affected by this regulation. 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 in below Table 1: Annual Respondent Burden and Cost – NSPS for Hospital/Medical/Infectious Waste Incinerators (40 CFR Part 60, Subpart Ec) (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 record-keeping and reporting requirements is estimated to be 7,410 hours (Total Labor Hours from Table 1 below). These hours are based on Agency studies and background documents from the development of the regulation, Agency knowledge and experience with the NSPS 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	$147.40 ($70.19+ 110%)
Technical	$117.92 ($56.15 + 110%)
Clerical	$57.02 ($27.15 + 110%)

These rates are from the United States Department of Labor, Bureau of Labor Statistics, June 2018, "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(s) are both labor costs which are addressed elsewhere in this ICR and the costs associated with continuous monitoring. The capital/startup costs are one-time costs when a facility becomes subject to these regulations. The annual operation and maintenance costs are the ongoing costs to maintain the monitors 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)	(B)	(C)	(D)	(E)	(F)	(G)

Capital/Startup vs. Operation and Maintenance (O&M) Costs						
Continuous Monitoring Device	Capital/Startup Cost for One Respondent	Number of New Respondents	Total Capital/Startup Cost, (B X C)	Annual O&M Costs for One Respondent	Number of Respondents with O&M	Total O&M, (E X F)
DIFF/WS [1]	$1,233	1	$1,233	$4,733	11	$52,063
DIFF [1]	$967	1	$967	$2,733	11	$30,063
WS [1]	$1,233	1	$1,233	$1,133	11	$12,463
SNCR [2]	$1,400	1	$1,400	$300	11	$3,300
CO CEMS [3]	$17,500	1	$17,500	$25,100	11	$276,100
BLD [4]	$1,033	1	$1,033	$1,267	11	$13,937
ACI [5]	$0	1	$0	$3,367	11	$37,037
Testing [6]	$67,458	1	$67,458	$0	11	$0
Filing Cabinets [7]	$100	1	$100	$0	11	$0
Photocopying[7]	$0	1	$0	$199	11	$2,189
Postage [7]	$0	1	$0	$93	11	$1,023
TOTAL [8]			**$90,900**			**$428,000**

[1] Per the October 6, 2009 final rule (74 FR 51378), assume capital/startup costs of $1,233 and annual operation and maintenance costs of $4,733 per facility for each wet scrubber or dry scrubber with fabric filter followed by wet scrubber, and capital/startup costs of $967 and $2,733 per dry scrubber with fabric filter.
[2] Per the October 6, 2009 final rule, assume capital/startup costs of $1,400 and annual operation and maintenance costs of $300 per facility using SCNR for control.
[3] Per the October 6, 2009 final rule, assume capital/startup costs of $17,500 and annual operation and maintenance costs of $25,100 per facility using CO CEMS, including daily activities, RATA, CGA, and annual QA and review.
[4] Per the October 6, 2009 final rule, assume capital/startup costs of $1,033 and annual operation and maintenance costs of $1,267 per facility using a bag leak detection system.
[5] Per the October 6, 2009 final rule, assume annual operation and maintenance costs of $3,367 per facility for lime/carbon flow monitoring.
[6] Per the October 6, 2009 final rule, assumes combined initial testing costs of $67,458 per facility.
[7] Assumes an initial purchase cost of $100 for filing cabinets, and annual facility costs of $199 for photocopying and $93 for postage.
[8] 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 $90,900. This is the total of column D in the above table.

The total operation and maintenance (O&M) costs for this ICR are $428,000. 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 $519,000. These are the recordkeeping costs.

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 $29,500.

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

Managerial	$65.71 (GS-13, Step 5, $41.07 + 60%)
Technical	$48.75 (GS-12, Step 1, $30.47 + 60%)
Clerical	$26.38 (GS-6, Step 3, $16.49 + 60%)

These rates are from the Office of Personnel Management (OPM), 2018 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 – NSPS for Hospital/Medical/Infectious Waste Incinerators (40 CFR Part 60, Subpart Ec) (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 10 existing respondents will be subject to these standards. It is estimated that an additional one respondent per year will become subject to these same standrads. The overall average number of respondents, as shown in the table below, is 11 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	1	9	0	0	10
2	1	10	0	0	11
3	1	11	0	0	12
Average	1	10	0	0	11

[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 11.

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 intent to construct	1	1	N/A	1
Notification of anticipated commencement of construction	1	1	N/A	1
Notification of anticipated startup	1	1	N/A	1
Notification of actual startup	1	1	N/A	1
Notification of type(s) of waste to be combusted	1	1	N/A	1
Notification of HMIWI capacity	1	1	N/A	1
Notification of initial performance test	1	1	N/A	1
Notification of initial CMS demonstration	1	1	N/A	1
Initial report for the site selection analysis	1	1	N/A	1
Waste management plan	1	1	N/A	1
Analysis and supporting documentation demonstrating conformance with EPA guidance and specifications for bag leak detection systems[1]	0.67	1	N/A	0.67
Report of initial performance test	1	1	N/A	1
Report of initial CMS demonstration	1	1	N/A	1
Annual reports				
CMS emissions and operating parameters	11	1	N/A	11
Exceedances, malfunctions, and periods for which data not obtained[2]	2.2	1	N/A	2.2
Results of performance tests conducted during the year	11	1	N/A	11
Report of no exceedances[2]	8.8	1	N/A	8.8
Report of annual control equipment inspection	11	1	N/A	11
Semiannual report of exceedances, malfunctions, and periods for which data not obtained[2]	2.2	1	N/A	2.2
			Total	59

[1] Assume the total number of sources will be evenly distributed among small, medium, and large sources and only new large and medium sources (i.e. two-thirds of the effected sources) will install baghouses.
[2] Assume 20 percent of respondents report monitoring exceedances and 80 percent report no excess emissions.

The number of Total Annual Responses is 59.

The total annual labor costs are $844,000. Details regarding these estimates may be found below in Table 1: Annual Respondent Burden and Cost – NSPS for Hospital/Medical/Infectious Waste Incinerators (40 CFR Part 60, Subpart Ec) (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 below in Tables 1 and 2, respectively, and summarized below.

(i) Respondent Tally

The total annual labor hours are 7,410 hours. Details regarding these estimates may be found below in Table 1: Annual Respondent Burden and Cost – NSPS for Hospital/Medical/Infectious Waste Incinerators (40 CFR Part 60, Subpart Ec) (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 126 hours per response.

The total annual capital/startup and O&M costs to the regulated entity are $519,000. 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 621 labor hours at a cost of $29,500; see below in Table 2: Average Annual EPA Burden and Cost – NSPS for Hospital/Medical/Infectious Waste Incinerators (40 CFR Part 60, Subpart Ec) (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 an overall increase in burden in this ICR from the most recently-approved ICR. This is due to an increase in the estimated number of sources subject to the regulation and is not caused by program changes. We estimate the industry will continue to grow at the rate of one new source per year. This results in increases in the respondent labor hours, number of responses, and capital and O&M costs.

6(g) Burden Statement

The annual public reporting and recordkeeping burden for this collection of information is estimated to average 126 hours per response. 'Burden' means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information either 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-2012-0502. 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-2012-0502 and OMB Control Number 2060-0363 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 – NSPS for Hospital/Medical/Infectious Waste Incinerators (40 CFR Part 60, Subpart Ec) (Renewal)

Burden item	(A) Person hours per occurrence	(B) No. of occurrences per respondent per year	(C) Person hours per respondent per year (C=AxB)	(D) Respondents per year [a]	(E) Technical person-hours per year (E=CxD)	(F) Management person hours per year (Ex0.05)	(G) Clerical person hours per year (Ex0.1)	(H) Total Cost Per year [b]
1. Applications	N/A							
2. Survey and Studies	N/A							
3. Reporting requirements								
A. Familiarization with the regulatory requirement	1	1	1	11	11	0.55	1.10	$1,440.91
B. Required activities								
Perf spec tests (certif) for CMS	16	1	16	1	16	0.80	1.60	$2,095.87
Repeat perf spec tests (certif) for CMS [c, d]	16	1	16	0	0	0	0	$0
Development of operating information [e]	160	1	160	1	160	8	16	$20,958.72
Annual update of operating information [f]	20	1	20	11	220	11	22	$28,818.24
Review of operating information with each operator [g, h]	8	2	16	11	176	8.8	17.6	$23,054.59
Initial control equipment inspection [i]	20	1	20	1	20	1	2	$2,619.84
Annual control equipment inspection [i]	20	1	20	11	220	11	22	$28,818.24
C. Create information	See 3B							
D. Gather existing information	See 3B							
E. Write reports								
Notification of intent to construct [f]	2	1	2	1	2	0.10	0.20	$261.98
Notification of anticipated commencement of construction [g]	2	1	2	1	2	0.10	0.20	$261.98

Notification of anticipated startup [g]	2	1	2	1	2	0.10	0.20	$261.98
Notification of actual startup [g]	2	1	2	1	2	0.10	0.20	$261.98
Notification of type(s) of waste to be combusted	2	1	2	1	2	0.10	0.20	$261.98
Notification of HMIWI capacity	2	1	2	1	2	0.10	0.20	$261.98
Notification of initial performance test [h]	2	1	2	1	2	0.10	0.20	$261.98
Notification of initial CMS demonstration	2	1	2	1	2	0.10	0.20	$261.98
Initial report for the site selection analysis [j]	460	1	460	1	460	23	46	$60,256.32
Waste management plan [k]	160	1	160	1	160	8	16	$20,958.72
Analysis and supporting documentation demonstrating conformance with EPA guidance and specifications for bag leak detection systems [l]	40	1	40	0.67	26.67	1.33	2.67	$3,493.12
Report of initial performance test [m]	8	1	8	1	8	0.40	0.80	$1,047.94
Report of initial CMS demonstration [m]	See 3B							
Annual report								
CMS emissions/operation parameters [n]	32	1	32	11	352	17.6	35.2	$46,109.18
Exceedances/ malfunctions/periods of which data not obtained [q, p]	48	1	48	2.2	105.6	5.28	10.56	$13,832.76
Results of performance tests conducted during the year [q]	40	1	40	11	440	22	44	$57,636.48
Report of no exceedances [q, p]	24	1	24	8.8	211.2	10.56	21.12	$27,665.51
Report of annual control equipment inspection	See 3B							
Semiannual report of exceedances/ malfunctions/periods for which data not obtained [q,p,r]	48	1	48	2.2	105.6	5.28	10.56	$13,832.76

Subtotal for Reporting Requirements					***3,114***			***$354,735***
4. Recordkeeping requirements								
A. Familiarize with regulatory requirement	See 3A							
B. Plan activities	N/A							
C. Implement activities	N/A							
D. Develop record system	N/A							
E. Time to enter information								
Documentation produced as a result of sitting requirements	See 3E							
Records of operators completing operator training requirements [h]	2	2	4	1	4	0.20	0.40	$523.97
Records of operators that have been qualified as HMIWI operators [h]	2	2	4	1	4	0.20	0.40	$523.97
Records of initial performance test	See 3E							
Records of startup, shutdown, or malfunction	1.5	52	78	11	858	42.9	85.8	$112,391.14
Records of persons completing review of operating information [h]	2	2	4	11	44	2.2	4.4	$5,763.65
Records of process and control device operating parameters	1.5	52	78	11	858	42.90	85.8	$112,391.14
Records of CMS operation and maintenance [g]	0.03	365	9.13	11	100.38	5.02	10.04	$13,148.32
Records of exceedances/ malfunctions/periods for which data not obtained	1.5	52	78	11	858	42.9	85.8	$112,391.14
Records of annual and any subsequent compliance tests	See 3E							
Records of annual control equipment inspections	See 3B							
Records of bag leak detection system alarms [l]	1.5	52	78	7.33	572	28.60	57.20	$74,927.42
F. Time to train personnel [t]	40	1	40	11	440	22	44	$57,636.48

F. Time for audits	N/A							
Subtotal for Recordkeeping Requirements					***4,299***			***$489,697***
Total Labor Burden and Costs (rounded) [u]					**7,410**			**$844,000**
Capital and O&M Cost (rounded) [u]								**$519,000**
GRAND TOTAL (rounded) [u]								**$1,360,000**

Assumptions:

[a] We have assumed that the average number of sources that will be subject to the standard will be 11, including 10 existing respondents and one additional new source per year that will become subject to the rule over the three-year period of this ICR.

[b] This ICR uses the following labor rates: $147.40 per hour for Executive, Administrative, and Managerial labor; $117.92 per hour for Technical labor, and $57.02 per hour for Clerical labor. These rates are from the United States Department of Labor, Bureau of Labor Statistics, June 2018, "Table 2. Civilian Workers, by Occupational and Industry group." The rates are from column 1, "Total Compensation." The rates have been increased by 110% to account for the benefit packages available to those employed by private industry.

[c] We assume that performance specification to certify CMS is expected to take approximately 16 hours.

[d] We assume no failures of the initial CMS demonstrations; includes CO CEMS.

[e] We assume it will take 160 hrs to develop the operating information.

[f] We assume that it will take 20 hours to update the operating information each year.

[g] We assume that it will take 8 hours to review the operating information with each operator.

[h] We assume that it will take 2 operators per facility to enter information. Also assume there is no operator turnover at the affected facilities.

[i] We assume that annual control equipment inspection will occur for all sources.

[j] We assume that it will take 460 hours to develop the site selection analysis.

[k] We assume that it will take 160 hours to develop the waste management plan.

[l] We assume that it will take 40 hours to develop the bag leak detection system analysis and 1.5 hours to record bag leak detection system alarms. We assume the total number of sources will be evenly distributed among small, medium, and large sources and only new large and medium sources (i.e. two-thirds of the effected sources) will install baghouses.

[m] We assume that it will take 8 hours for each facility to review the report of the initial performance test for pollutants and fugitive ash.

[n] Person-hours per occurrence are assumed to be 32 hours.

[o] We have assume that it will take 48 hours and 24 hours per report per affected facility to report monitoring exceedances and no excess emissions, respectively. Because testing and monitoring requirements focus primarily on three pollutants (PM, CO, and HCl), assume three pollutants.

[p] Assume 20 percent of respondents report monitoring exceedances and 80 percent report no excess emissions.

[q] Assume 40 hours to review report of annual compliance test.

[r] Because the semiannual report coincides once each year with the annual report and both reports include information on exceedances, malfunctions, and periods for which data were not obtained, the frequency of the semiannual report is shown in the table as only once per year to avoid double-counting.

[s] We assume that this activity will be recorded daily.

[t] We assumed that it will take 40 hours once per year to train one person to perform the Method 9 and Method 22 tests. The labor requirements to train the personnel were estimated to be 8 hr/d for 5 d/yr.

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

Table 2: Average Annual EPA Burden and Cost – NSPS for Hospital/Medical/Infectious Waste Incinerators (40 CFR Part 60, Subpart Ec) (Renewal)

Activity	(A) EPA Person hours per occurrence	(B) No. of occurrences per respondent per year	(C) Person hours per respondent per year (C=AxB)	(D) Respondents per year [a]	(E) Technical person-hours per year (E=CxD)	(F) Management person hours per year (Ex0.05)	(G) Clerical person hours per year (Ex0.1)	(H) Total Cost Per year b

1. Attend initial performance test [c]	32	1	32	0.08	2.56	0.13	0.26	$139.96
2. Repeat performance test								
A. Retesting preparation [d]	12	1	12	0.2	2.4	0.12	0.24	$131.22
B. Attend retesting [e]	32	1	32	0.02	0.64	0.032	0.064	$34.99
3. Litigation [f]	N/A							
4. Excess emissions--enforcement activities [g]	32	1	32	0.02	0.64	0.032	0.064	$34.99
5. Report review								
Review notification of intent to construct	2	1	2	1	2	0.1	0.2	$109.35
Review notification of anticipated commencement of construction	2	1	2	1	2	0.1	0.2	$109.35
Review notification of anticipated startup	2	1	2	1	2	0.1	0.2	$109.35
Review notification of actual startup	2	1	2	1	2	0.1	0.2	$109.35
Review notification of type(s) of waste to be combusted	2	1	2	1	2	0.1	0.2	$109.35
Review notification of HMIWI capacity	2	1	2	1	2	0.1	0.2	$109.35
Review notification of initial performance test	2	1	2	1	2	0.1	0.2	$109.35
Review notification of initial CMS demonstration	2	1	2	1	2	0.1	0.2	$109.35
Review notification addressing sitting requirements	24	1	24	1	24	1.2	2.4	$1,312.16
Review waste management plan	8	1	8	1	8	0.4	0.8	$437.39
Review analysis for bag leak detection systems [h]	8	1	8	0.67	5.33	0.27	0.53	$291.59
Review report of initial performance test [i]	54	1	54	1	54	2.7	5.4	$2,952.37
Review report of initial CMS demonstration	N/A							
Review annual report								
CMS emissions/operating parameters [j]	6	1	6	11	66	3.3	6.6	$3,608.45
Exceedances/malfunctions/periods for which data not obtained [k]	8	1	8	2.2	17.6	0.88	1.76	$962.25

Results of performance test conducted during the year [l]								
PM, CO, HCl	18	1	18	11	198	9.9	19.8	$10,825.35
Fugitive ash emissions	6	1	6	11	66	3.3	6.6	$3,608.45
Report of no exceedances [m]	2	1	2	8.8	17.6	0.88	1.76	$962.25
Report of annual control equipment inspection [n]	4	1	4	11	44	2.2	4.4	$2,405.63
Review semiannual report of exceedances/malfunctions/periods for which data not obtained [k, o]	8	1	8	2.2	17.6	0.88	1.76	$962.25
TOTAL (rounded) [p]					**621**			**$29,500**

Assumptions:

[a] We have assumed that the average number of sources that will be subject to the standard will be 11. There will be one additional new source per year that will become subject to the rule over the three-year period 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: Managerial rate of $65.71 (GS-13, Step 5, $41.07 + 60%), Technical rate of $48.75 (GS-12, Step 1, $30.47 + 60%), and Clerical rate of $26.38 (GS-6, Step 3, $16.49 + 60%). These rates are from the Office of Personnel Management (OPM) "2018 General Schedule" which excludes locality rates of pay.

[c] We assume EPA personnel attend 8 percent of the initial performance tests.

[d] We assume that 20 percent will fail the initial performance test, and will have to repeat the performance test.

[e] We assume 10 percent of initial performance re-tests are attended by EPA personnel.

[f] This ICR does not account for litigation costs.

[g] We assume 10 percent of the affected facilities are required to re-test as a result of excess emissions, and that EPA personnel attend 10 percent of these tests.

[h] We assume only new large and medium sources (i.e. two-thirds of the effected sources) will install baghouses.

[i] We assume 6 person-hours per report per pollutant. For the three new HMIWI in the three-year period, nine pollutants are required to be tested.

[j] We assume 1 person-hour per report per CMS. For HMIWI, assume each uses six CMS (flue gas temperature, secondary chamber temperature, charge weight, scrubber liquor pH, scrubber liquor flow, and scrubber energy input).

[k] We assume 20 percent of the affected facilities with recurrent burden will report monitoring exceedances.

[l] We assume 6 person-hours per report per pollutant. For annual tests, there are three pollutants (PM, CO, and HCl) for all HMIWI.

[m] We assume 80 percent of the affected facilities with recurrent burden will report no excess emissions.

[n] We assume it will take 4 hours to review the annual control equipment inspection report.

[o] Because the semiannual report coincides once each year with the annual report and both reports include information on exceedances, malfunctions, and periods for which data were not obtained, the frequency of semiannual report is shown in the table as only once per year to avoid double-counting.

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