

**SUPPORTING STATEMENT
ENVIRONMENTAL PROTECTION AGENCY**

**State and Federal Emission Guidelines for Hospital/Medical/Infectious Waste Incinerators
(40 CFR Part 60, Subpart Ce and 40 CFR Part 62, Subpart HHH) (Renewal)**

1. Identification of the Information Collection

1(a) Title of the Information Collection

State and Federal Emission Guidelines for Hospital/Medical/Infectious Waste Incinerators (40 CFR Part 60, Subpart Ce and 40 CFR Part 62, Subpart HHH) (Renewal), EPA ICR Number 1899.08, OMB Control Number 2060-0422.

1(b) Short Characterization/Abstract

The State and Federal Emission Guidelines for Hospital/Medical/Infectious Waste Incinerators (HMIWI) were proposed on February 27, 1995 (Subpart Ce) and July 6, 1999 (Subpart HHH), promulgated on September 15, 1997 (Subpart Ce) and August 15, 2000 (Subpart HHH), and revised on October 6, 2009, April 4, 2011 and May 13, 2013.

Subpart Ce requires either states or tribes to develop plans to implement the Emission Guidelines. If approvable state or tribal plans were not developed, the EPA was required to develop a Federal plan (Subpart HHH) to implement the Emission Guidelines for such states and tribes. The federal plan is an interim measure to ensure that emissions standards are implemented until states assume their role as the preferred implementers of the EG. The 2013 rule finalized amendments to the HMIWI federal plan to implement the amended EG adopted on October 6, 2009, for those states that did not have an approved revised/new state plan in place within 2 years after promulgation of the EG. These regulations apply to existing facilities constructed before December 1, 2008 or for which modification commenced prior to April 6, 2010 that own or operate Hospital/Medical/Infectious Waste Incinerators. This information is being collected to assure compliance with 40 CFR Part 60, Subpart Ce and 40 CFR Part 62, Subpart HHH.

In general, all Emission Guidelines 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 the Emission Guidelines.

Any owner/operator subject to the provisions of this part shall maintain a file of these measurements, and retain the file for at least five years following the date of such measurements, maintenance reports, and records. All reports are sent to the delegated state or local authority. In the event that there is no such delegated authority, the reports are sent directly to the United States Environmental Protection Agency (EPA) regional office.

HMIWIs in the United States are owned and operated by either the private sector, the Federal government, or state and local governments (the “Affected Public”). The burden to the “Affected Public” may be found in Table 1: Annual Respondent Burden and Cost – State and Federal Emission Guidelines for Hospital/Medical/Infectious Waste Incinerators (40 CFR Part 60, Subpart Ce and 40 CFR Part 62, Subpart HHH) (Renewal). The burden to 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 – State and Federal Emission Guidelines for Hospital/Medical/Infectious Waste Incinerators (40 CFR Part 60, Subpart Ce and 40 CFR Part 62, Subpart HHH) (Renewal).

Based on our consultations with industry representatives, there are an average of 1 affected facilities 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 58 respondents per year will be subject to the standard, and no additional respondents per year will become subject to the standard. There are approximately 31 HMIWI, which are owned and operated by the private sector (hospitals, commercial waste disposal companies, pharmaceutical companies and private universities); 5 HMIWI are owned and operated by the Federal Government (U.S. military bases, veterans’ hospitals and Federal research facilities); none are owned and operated by State or local governments (state universities). In addition, there are 22 States that require annual State Plan Inventory. We assume that they will all respond. This information is based on a 2013 inventory of HMIWIs.

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(d)(1) of the Clean Air Act (CAA), as amended, to:

... prescribe regulations which shall establish a procedure similar to that provided by section 110 under which each State shall submit to the Administrator a plan which (A) establishes standards of performance for any existing source for any air pollutant (i) for which air quality criteria have not been issued or which is not included on a list published under section 108(a) ... but (ii) to which a standard of performance under this section would apply if such existing source were a new source, and (B) provides for the implementation and enforcement of such standards of performance.

The EPA is required under section 129 of the Act, to establish guidelines for existing

stationary sources that reflect the maximum achievable control technology (MACT) for achieving continuous emission reductions:

Section 129(a)(1)(A) states:

The Administrator shall establish performance standards and other requirements pursuant to section 111 and this section for each category of solid waste incineration units. Such standards shall include emissions limitations and other requirements applicable to new units and guidelines (under section 111(d) and this section) and other requirements applicable to existing units.

Section 129(a)(2) states:

Standards applicable to solid waste incineration units promulgated under section 111 and this section shall reflect the maximum degree of reduction in emissions of air pollutants listed under section (a)(4) that the Administrator, taking into consideration the cost of achieving such emission reduction, and any non-air quality health and environmental impacts and energy requirements, determines is achievable for new or existing units in each category.

Section 129(b)(1) states:

Performance standards under this section and section 111 for solid waste incineration units shall include guidelines promulgated pursuant to section 111(d) and this section applicable to existing units. Such guidelines shall include, as provided in this section, each of the elements required by subsection (a) (emissions limitations, notwithstanding any restriction in section 111(d) regarding issuance of such limitations), subsection (c) (monitoring), subsection (d) (operator training), subsection (e) (permits), and subsection (h)(4) (residual risk).

Subpart B of 40 CFR part 60 requires State plans to include monitoring, recordkeeping, and reporting provisions consistent with the emission guidelines. In addition, section 114(a)(1) states that:

the Administrator may require any person who owns or operates any emission source, who manufactures emission control equipment or process equipment, who the Administrator believes may have information necessary for the purposes set forth in this subsection, or who is subject to any requirement of this Act (other than a manufacturer subject to the provisions of section 206(c) or 208 with respect to a provision of title II) on a one-time, periodic or continuous basis 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, particulate matter (PM), carbon monoxide (CO), dioxin/furans (D/F), hydrogen chloride (HCl), sulfur dioxide (SO₂), nitrogen oxide (NO_x), lead (Pb), cadmium (Cd), and mercury (Hg) emissions from hospital, medical, or infectious waste incinerators cause or contribute to air pollution that may reasonably be anticipated to endanger public health or welfare. Therefore, the State and Federal Emission Guidelines were promulgated for this source category at 40 CFR Part 60, Subpart Ce and 40 CFR Part 62, Subpart HHH.

2(b) Practical Utility/Users of the Data

The recordkeeping and reporting requirements in the 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 the 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 the 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 and leaks are being detected and repaired and the standard(s) 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. Nonduplication, Consultations, and Other Collection Criteria

The requested recordkeeping and reporting are required under 40 CFR Part 60, Subpart Ce and 40 CFR Part 62, Subpart HHH.

3(a) Nonduplication

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 the state or local agency can be sent to the Administrator in lieu of the report required by the Federal standards. Therefore, no duplication exists.

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

An announcement of a public comment period for the renewal of this ICR was published in the Federal Register (80 FR 32116) on June 5, 2015. 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 the standard, is the Integrated Compliance Information System (ICIS). ICIS is EPA's database for the collection, maintenance, and retrieval of compliance data for industrial and government-owned facilities. The growth rate for the industry is based on an Agency analysis conducted in 2013.

Industry trade associations and other interested parties were provided an opportunity to comment on the burden associated with the standard as it was being developed and the standard has been previously reviewed to determine the minimum information needed for compliance purposes. In developing this ICR, we contacted: 1) the National Waste & Recycling Association (NWRA), at (202) 364-3724; and 2) the Larson-Miller Medical Waste Disposal Service, at (801) 738-6545.

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 the standards. Requirements for information gathering and

recordkeeping are useful techniques to ensure that good operation and maintenance practices are applied and emission limitations are met. If the information required by these standards was collected less frequently, the proper operation and maintenance of control equipment and the possibility of detecting violations would be less likely.

3(e) General Guidelines

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 (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 the standard 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 for which construction commenced on or before the date of the rule proposal. The United States Standard Industrial Classification (SIC) codes and the corresponding North American Industry Classification System (NAICS) codes for HMIWI units are provided in the following table.

| Standard (40 CFR Part 60, Subpart Ce and 40 CFR Part 62, Subpart HHH) | SIC Codes | NAICS Codes |
|--|------------------|--------------------|
| General Medical and Surgical Hospitals | 806228 | 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 | 541712 |
| National Security | 9711 | 928110 |
| Public Health Facility | 9431 | 923120 |
| Nursing and Personal Care Facilities | 8051, 8052, 8059 | 623110, 623311 |
| Veterinary Services | 0741, 0742, 8734 | 541940 |

4(b) Information Requested

(i) Data Items

In this ICR, all the data that is recorded or reported is required by State and Federal Emission Guidelines for Hospital/Medical/Infectious Waste Incinerators (40 CFR Part 60, Subpart Ce and 40 CFR Part 62, Subpart HHH).

State/US protectorates must perform the following requirements:

| Requirement | |
|---|---------------------|
| State Plan to implement and enforce emission guidelines | 60.39e(a), 60.23(a) |
| Notification of public hearing on State Plan | 60.23(d) |
| Certification that public hearing on State Plan conducted according to Subpart B State procedures | 60.23(f) |
| Negative Declaration, if applicable | 62.06 |

A source must make the following reports:

| Notifications | |
|----------------------|--|
| Installation of CMS | 60.37e(e), 60.56c(b)-(c), 60.57c, 62.14454 |

| Notifications | |
|--|---|
| Initial and repeat performance specification tests for CMS | 60.37e, 60.56c, 62.14460(f) |
| Increments of progress for HMIWI that will comply with regulation | 60.39e(c), 62.14470(b)(2) |
| Request for extension to shut down late | 60.39e(d), 62.14471(b) |
| Waste management plan | 60.35e, 60.38e(a), 60.55c, 60.58c(c)(3), 62.14430 |
| Notification of initial CMS demonstration | 60.38e(a), 60.7(a)(5) |
| Report of initial CMS demonstration | 60.38e(a), 60.7(c) |
| Notification of exemption claim for combustors burning pathological, low-level radioactive, and/or chemotherapeutic waste | 60.32e(b) |
| Annual report containing information from annual equipment inspection, required maintenance, and repairs not completed during established time frame | 60.38e(b)(2), 62.14463(a)(12)-(13) |
| Notification of exemption claim for co-fired combustors | 60.32e(c)(1) |
| Notification of relative weight of hospital waste, medical/infectious waste, and other fuels and/or waste to be combusted at co-fired combustor | 60.32e(c)(2) |
| Notification of initial performance test (PM, CO, fugitive emissions, stack opacity, dioxins/furans, HCl, Cd, Pb, Hg) | 60.38e(a), 60.8(d) |
| Report of initial performance test | 60.38e(a), 60.58c(c), 60.8 (a), 60.58c(d) (6), 62.14470(b)(4) 62.14463(a)(1), 62.14464(a) |
| Initial report of values for site-specific operating parameters | 60.38e(a), 60.58c(c) (2), 62.14463(a)(2), 62.14463(a)(4), 62.14464(a) |
| Annual report of values for site-specific operating parameters | 60.38e(a), 60.58c(d) (1), 62.14463(a)(7) – (8), 62.14464(b) |

| Notifications | |
|---|--|
| Annual report of the highest maximum and lowest minimum operating parameters | 60.38e(a), 60.58c(d) (2) – (3), 62.14463(a) (5) – (6), 62.14464(b) |
| Annual and semiannual reports of emissions or operating parameter exceedances, malfunctions, and periods for which data on emissions/operating parameters were not obtained | 60.38e(a), 60.58c(d) – (e), 60.7(c) – (d), 62.14463(a)(7)-(8), 62.14464(b) – (c) |
| Annual report containing results of annual performance test | 60.38e(a) – (b), 60.58c(d), 62.14463(a)(9), 62.14464(b) |
| Annual report of no excess emissions, malfunctions, or operating parameter exceedances | 60.38e(a), 60.58c(d) (7), 60.7(c), 62.14463(a)(10), 62.14464(b) |
| Results of previous performance tests | 60.38e(a) |
| Any use of the bypass stack, duration, reason for malfunction, and corrective action taken | 60.38e(a), 60.58c(d) (8), 62.14463(a)(11) |
| Concentrations of CO, PM, HCl, Pb, Cd, Hg and dioxin/furan, as applicable, as determined by the CEMS or continuous automated sampling system, as applicable | 62.14463(a)(14) |
| Petition for site-specific operating parameters for control device not listed, if applicable | 62.14463(a)(15) |
| Annual update of operating information | 60.34e, 60.53c(h) – (i), 62.14423(c) |
| Annual review of operating information with each operator | 60.34e, 60.53c(h) – (i), 62.14425(a) |

A source must keep the following records:

| Recordkeeping | |
|---|---|
| Records of public hearing conducted on State Plan | 60.23(e) |
| Retention of records for 5 years | 60.38e(a), 60.58c(b), 60.58c(f), 62.14461 |
| Records of startup, shutdown, or malfunction | 60.38e(a), 60.58c, 60.7(b), 62.14460(d) |

| Recordkeeping | |
|---|--|
| Records of initial performance test | 60.37e, 60.56c, 62.14460(a) & (f) |
| Records of CMS operation and maintenance | 60.38e(a), 60.58c, 60.7(f), 62.14460(a) |
| Records of annual equipment inspections, required maintenance, and repairs not completed during established timeframe | 60.38e(b), 62.14460(a) & (b) (14) |
| Records on a quarterly basis of periods, when only pathological, low-level radioactive, and/or chemotherapeutical waste is burned. | 60.32e(b) 62.14400 |
| Records of quarterly basis of weight of hospital waste and medical/infectious waste combusted, and weight of all other fuels and waste combusted at co-fired combustors | 60.32e(c), 62.14400 |
| Records for which data on emissions/operating parameters were not obtained | 60.38e(a), 60.58c(b), 60.8(f), 62.14460(c) – (e) |
| Records related to malfunctions | 60.38e(a), 60.58c(b), 60.8(f), 62.14460(d) |
| Records of emissions or operating parameter exceedances | 60.38e(a), 60.58c(b), 60.8(f), 62.14460(e) |
| Records of initial, annual, and any subsequent performance tests | 60.38e(a), 60.58c(b), 60.8(f), 62.14460(f) |
| Records of persons completing reviews of HMIWI operating manual (initial and annual) | 60.38e(a), 60.53c(j), 60.58c(b), 62.14460(g) |
| Records of operators completing operator training course and qualification requirements | 60.38e(a), 60.53c(j), 60.58c(b), 62.14460(h) |
| Records of operators who have met the qualification requirements | 60.38e(a), 60.53c(j), 60.58c(b), 62.14460(h) – (i) |
| Records of calibration of any monitoring devices | 60.38e(a), 60.58c(b), 62.14460(j) |
| Records of emissions, process, and control device operating parameters | 60.38e(a), 60.58c(b), 60.8(f), 62.14460(a) and (b) |

| Recordkeeping | |
|--|---------------------------------|
| | (2-13) |
| Records of initial testing of fugitive ash emissions | 60.38e(a), 60.58c(b) (2)(ii) |

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. If the respondent chooses to submit an electronic copy of stack test reports to the EPA's WebFIRE database, as of December 31, 2011, they must enter the test data into the EPA's database using the Electronic Reporting Tool (ERT) located at http://www.epa.gov/ttn/chief/ert/ert_tool.html.

(ii) Respondent Activities

| Respondent Activities |
|---|
| Familiarization with the regulatory requirements. |
| Develop State Plan and inventory and update inventory annually. |
| Conduct public hearing on State Plan. |
| Install, calibrate, maintain, and operate CMS for opacity, or for pressure drop and liquid supply pressure for control device. |
| Perform CMS demonstrations and repeat CMS demonstrations if necessary. |
| Perform initial performance tests and repeat performance tests if necessary. |
| Develop, update, and review operating information. |
| Perform inspections. |
| Write the notifications and reports listed above. |
| Develop waste management plan. |
| Prepare and review reports of performance tests and CMS demonstrations. |
| 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 |

| Respondent Activities |
|--|
| maintaining information. |
| Develop, acquire, install, and utilize technology and systems for the purpose of disclosing and providing information. |
| Complete operator training and qualification. |
| Train personnel to be able to respond to a collection of information. |
| Maintain the records listed in the table above. |
| 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 |
|---|
| Observe initial performance tests and repeat performance tests if necessary. |
| 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 Online Tracking Information System (OTIS). |

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 standard. 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. However, the regulation includes various provisions that would reduce the burden on HMIWI, including the two HMIWI within the respondent universe that are classified as small entities. For example, there are provisions allowing HMIWI to skip annual tests and test reports for 2-year periods if they have demonstrated compliance for three annual tests in a row. Also, the emission guidelines allow HMIWI to submit previous emission tests to demonstrate compliance with the emission limits in the revised guidelines. 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 – State and Federal Emission Guidelines for Hospital/Medical/Infectious Waste Incinerators (40 CFR Part 60, Subpart Ce and 40 CFR Part 62, Subpart HHH) (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 each of the subparts 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 not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB Control Number.

6(a) Estimating Respondent Burden

The average annual burden to industry over the next three years from these recordkeeping and reporting requirements is estimated to be 38,800 (Total Labor Hours from Table 1). These

hours are based on Agency studies and background documents from the development of the regulation, Agency knowledge and experience with the Emission Guidelines 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 | \$129.93 (\$61.87+ 110%) |
| Technical | \$103.97 (\$49.51 + 110%) |
| Clerical | \$51.79 (\$24.66 + 110%) |

These rates are from the United States Department of Labor, Bureau of Labor Statistics, June 2014, "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 regulation. 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) 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) |
| Monitoring costs | | | | | | |
| - Privately-owned HMIWI | \$3,751 | 0 | \$0 | \$11,957 | 31 | \$370,667 |
| - Federally owned HMIWI | \$3,700 | 0 | \$0 | \$8,317 | 5 | \$41,585 |
| - State/locally-owned HMIWI | \$3,700 | 0 | \$0 | \$6,275 | 0 | \$0 |
| Testing ¹ | \$21,000 | 0 | \$0 | NA | 0 | \$0 |
| File Cabinets ² | \$33.50 | 0 | \$0 | NA | 0 | \$0 |
| Photocopying and postage | | | | | | |
| - States | N/A | 0 | \$0 | \$16.27 | 22 | \$357.94 |
| - Privately-owned HMIWI | N/A | 0 | \$0 | \$50.28 | 31 | \$1,558.68 |
| - Federally owned HMIWI | N/A | 0 | \$0 | \$49.67 | 5 | \$248.35 |
| - State/locally-owned HMIWI | N/A | 0 | \$0 | \$49.50 | 0 | \$0 |
| Temperature pressure, flow rate, change rate, voltage, and pH monitors³ | | | | | | |
| - Privately-owned HMIWI | N/A | 0 | \$0 | \$1,800 | 31 | \$55,800 |
| - Federally owned HMIWI | N/A | 0 | \$0 | \$1,800 | 5 | \$9,000 |
| - State/locally-owned HMIWI | N/A | 0 | \$0 | \$1,800 | 0 | \$0 |
| Subtotals | | | | | | |
| - States | | | \$0 | | | \$358 |
| - Privately-owned HMIWI | | | \$0 | | | \$428,025 |
| - Federally owned HMIWI | | | \$0 | | | \$50,833 |
| - State/locally-owned HMIWI | | | \$0 | | | \$0 |
| TOTAL | | | \$0 | | | \$479,000 |

Notes: Totals have been rounded to 3 significant figures. Figures may not add exactly due to rounding. This ICR assumes that all existing respondents have already installed monitoring and testing equipment to comply with the emission guidelines, including equipment for in-house testing of fugitive ash emissions required by the revised emission guidelines. Therefore, there is no capital/startup costs associated with this ICR.

¹ Average testing cost for all respondents

² Annualized cost with a capital recovery factor of 0.14238 based on a 10-year equipment life and a 7 percent interest rate, assuming each facility will purchase one standard four-drawer file cabinet (\$235 per cabinet).

³ The average HMIWI operates approximately 6 continuous monitoring devices. The average cost per monitoring

device is \$300 per year. Therefore, the estimated O&M cost per respondent is estimated to be \$1,800.

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 \$479,000. 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 \$479,000. These are 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 activities such as the examination of records maintained by the respondents, periodic inspection of sources of emissions, and the publication and distribution of collected information.

The average annual Agency cost during the three years of the ICR is estimated to be \$87,000.

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

| | |
|------------|--|
| Managerial | \$62.90 (GS-13, Step 5, \$39.31 + 60%) |
| Technical | \$46.67 (GS-12, Step 1, \$29.17 + 60%) |
| Clerical | \$25.25 (GS-6, Step 3, \$15.78 + 60%) |

These rates are from the Office of Personnel Management (OPM), 2014 General Schedule, which excludes locality rates of pay. The rates have been increased by 60 percent to account for the benefit packages available to government employees. Details upon which this estimate is based appear below in Table 2: Average Annual EPA Burden and Cost – State and Federal Emission Guidelines for Hospital/Medical/Infectious Waste Incinerators (40 CFR Part 60, Subpart Ce and 40 CFR Part 62, Subpart HHH) (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 58 existing respondents (31 privately-owned, 5 Federally-owned, and no State/locally-owned, plus the 22 states requiring State Plan Inventories) will be subject to the standard. It is estimated that no additional respondents per year will become subject. The overall average number of respondents, as shown in the table below, is 58 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 | 58 | 0 | 0 | 58 |
| 2 | 0 | 58 | 0 | 0 | 58 |
| 3 | 0 | 58 | 0 | 0 | 58 |
| Average | 0 | 58 | 0 | 0 | 58 |

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 58.

The total number of annual responses per year is calculated using the following table:

| (A) Information Collection Activity | States | Privately-Owned HMIWI | Federally-Owned HMIWI | State/Locally Owned HMIWI | Total |
|--|-----------|--------------------------|--------------------------|------------------------------|------------|
| State Plan/inventory ¹ | 0 | 0 | 0 | 0 | 0 |
| Annual update of State Plan inventory | 22 | 0 | 0 | 0 | 22 |
| Notification of initial performance test and CMS demonstration | N/A | | | | |
| Annual Reports ² | | | | | |
| CMS emissions and operating parameters | 0 | 31 | 5 | 0 | 36 |
| Exceedances, malfunctions, and periods for which data not obtained | 0 | 6.2 | 1 | 0 | 7.2 |
| Results of performance tests conducted during the year | 0 | 31 | 5 | 0 | 36 |
| Report of no exceedances | 0 | 24.8 | 4 | 0 | 28.8 |
| Report of annual equipment inspection (small rural HMIWI) | 0 | 1 | 0 | 0 | 1 |
| Semiannual report of exceedances, malfunctions, and periods for which data not obtained ³ | 0 | 6.2 | 1 | 0 | 7.2 |
| Total⁴ | 22 | 100 | 16 | 0 | 138 |

¹ This ICR assumes all 22 states have approved State Plans by the first year this ICR.

²This ICR assumes 20% of respondents report exceedances, and 80% of respondents report no exceedances.

³Because 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.

⁴Totals have been rounded to 3 significant figures. Figures may not add exactly due to rounding.

The number of Total Annual Responses is 138 (22 for States, 100 for privately owned HMIWI, 16 for federally owned HMIWI and 0 for State/locally owned HMIWI).

The total annual labor costs are \$3,890,000. Details regarding these estimates may be found below in Table 1: Annual Respondent Burden and Cost – State and Federal Emission Guidelines for Hospital/Medical/Infectious Waste Incinerators (40 CFR Part 60, Subpart Ce and 40 CFR Part 62, Subpart HHH) (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 38,800. Details regarding these estimates may be found in Table 1. Annual Respondent Burden and Cost – State and Federal Emission Guidelines for Hospital/Medical/Infectious Waste Incinerators (40 CFR Part 60, Subpart Ce and 40 CFR Part 62, Subpart HHH) (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 281 hours per response.

The total annual capital/startup and O&M costs to the regulated entity are \$479,000. 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 1,920 labor hours at a cost of \$87,000. See Table 2: Average Annual EPA Burden and Cost – State and Federal Emission Guidelines for Hospital/Medical/Infectious Waste Incinerators (40 CFR Part 60, Subpart Ce and 40 CFR Part 62, Subpart HHH) (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 decrease in the respondent and Agency burden currently identified in the OMB Inventory of Approved Burdens due to a decrease in the respondent universe since the previous ICR. Based on the 2013 Agency analysis, 21 HMIWI units (16 privately owned, 1 federally owned, and 4 state owned) have been shut down over the past several years. The revised estimate results in a decreased in respondent labor hours, number of responses, and capital/O&M costs.

However, there is a slight adjustment increase in respondent hours for States due to a change in assumption. In this ICR, we assume all respondents will take some time to re-familiarize themselves with the regulatory requirements.

6(g) Burden Statement

The annual public reporting and recordkeeping burden for this collection of information is estimated to average 281 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 not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB Control Number. The OMB Control Numbers for EPA 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-2011-0272. 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), EPA 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) 566-1927. 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-2011-0272 and OMB Control Number 2060-0422 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 – State and Federal Emission Guidelines for Hospital/Medical/Infectious Waste Incinerators (40 CFR Part 60, Subpart Ce and 40 CFR Part 62, Subpart HHH) (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) Manage ment 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 (States) | | | | | | | | |
| A. Familiarize with Regulatory Requirements ^c | 1 | 1 | 1 | 22 | 22 | 1.1 | 2.2 | \$2,537.60 |
| B. Required activities ^d | | | | | | | | |
| - Development of State Plan/Inventory | 2,080 | 1 | 2,080 | 0 | 0 | 0 | 0 | \$0 |
| - Annual update of State Plan Inventory | 20 | 1 | 20 | 22 | 440 | 22 | 44 | \$50,752.02 |
| - Public hearing on State Plan | 8 | 1 | 8 | 0 | 0 | 0 | 0 | \$0 |
| C. Create information | See 3B | | | | | | | |
| D. Gather information | See 3B | | | | | | | |
| E. Write report | | | | | | | | |
| - State Plan/Inventory | See 3B | | | | | | | |
| - Annual update of State Plan Inventory | See 3B | | | | | | | |
| - Notification of public hearing on State Plan | 8 | 1 | 8 | 0 | 0 | 0 | 0 | \$0 |
| - Certification that public hearing on State Plan conducted according to Subpart B State procedures | 2 | 1 | 2 | 0 | 0 | 0 | 0 | \$0 |
| Subtotal for Reporting Requirements (States) | | | | | 531 | | | \$53,290 |
| 4. Reporting requirements (privately-owned HMIWI) | | | | | | | | |
| A. Familiarize with Regulatory Requirements ^c | 1 | 1 | 1 | 31 | 31 | 1.55 | 3.1 | \$3,575.71 |
| B. Required activities ^e | | | | | | | | |
| Installation of CMS | 15 | 1 | 15 | 0 | 0 | 0 | 0 | \$0 |
| Performance specification tests for CMS | 8 | 1 | 8 | 0 | 0 | 0 | 0 | \$0 |
| Repeat performance specification tests/CMS | 8 | 1 | 8 | 0 | 0 | 0 | 0 | \$0 |

| | | | | | | | | |
|--|--------|---|-----|-----|-----|------|------|--------------|
| Initial equipment inspection (small rural HMIWI) | 20 | 1 | 20 | 0 | 0 | 0 | 0 | \$0 |
| Annual update of operating information ^f | 20 | 1 | 20 | 31 | 620 | 31 | 62 | \$71,514.21 |
| Review operating information with each operator ^g | 8 | 2 | 16 | 31 | 496 | 24.8 | 49.6 | \$57,211.37 |
| Annual equipment inspection (small rural HMIWI) | 20 | 1 | 20 | 1 | 20 | 1 | 2 | \$2,306.91 |
| Annual equipment inspection (all other HMIWI) | 20 | 1 | 20 | 30 | 600 | 30 | 60 | \$69,207.30 |
| C. Create information | See 4B | | | | | | | |
| Development of operating information ^h | 160 | 1 | 160 | 0 | 0 | 0 | 0 | \$0 |
| D. Gather information | See 4B | | | | | | | |
| E. Write report ^e | | | | | | | | |
| Increments of progress for HMIWI that will Comply | | | | | | | | |
| Control plan | 24 | 1 | 24 | 0 | 0 | 0 | 0 | \$0 |
| Notification of construction contracts | 2 | 1 | 2 | 0 | 0 | 0 | 0 | \$0 |
| Notification of construction commencement | 2 | 1 | 2 | 0 | 0 | 0 | 0 | \$0 |
| Notification of construction completion | 2 | 1 | 2 | 0 | 0 | 0 | 0 | \$0 |
| Notification of control plan completion | 2 | 1 | 2 | 0 | 0 | 0 | 0 | \$0 |
| Request for extension to shut down date | 12 | 1 | 12 | 0 | 0 | 0 | 0 | \$0 |
| Notification of initial performance test | 2 | 1 | 2 | 0 | 0 | 0 | 0 | \$0 |
| Notification of initial CMS demonstration | 2 | 1 | 2 | 0 | 0 | 0 | 0 | \$0 |
| Waste management plan ⁱ | 160 | 1 | 160 | 0 | 0 | 0 | 0 | \$0 |
| Report of initial performance test for PM, CO, Hg, dioxins/furans, and stack opacity (small rural HMIWI) | 560 | 1 | 560 | 0 | 0 | 0 | 0 | \$0 |
| Report of initial performance test for PM, CO, HCl, dioxins/furans, metals, and stack opacity (small non-rural, medium, and large HMIWI) | 640 | 1 | 640 | 0 | 0 | 0 | 0 | \$0 |
| Report of initial CMS demonstration | See 4B | | | | | | | |
| Annual report | | | | | | | | |
| CMS operating parameters | 32 | 1 | 32 | 31 | 992 | 49.6 | 99.2 | \$114,422.74 |
| Emissions/parameter exceedances and periods when emission/parameter data not obtained ^j | | | | | | | | |
| - Small rural HMIWI | 16 | 1 | 16 | 0.2 | 3.2 | 0.16 | 0.32 | \$369.11 |
| - All other HMIWI | 64 | 1 | 64 | 6 | 384 | 19.2 | 38.4 | \$44,292.67 |
| Report of annual performance test | | | | | | | | |

| | | | | | | | | |
|--|--------|---|-----|-----|---------------|------|------|--------------------|
| - Small rural HMIWI | 20 | 1 | 20 | 1 | 20 | 1 | 2 | \$2,306.91 |
| - All other HMIWI | 280 | 1 | 280 | 30 | 8,400 | 420 | 840 | \$968,902.20 |
| Report of no exceedances | | | | | | | | |
| - Small rural HMIWI | 8 | 1 | 8 | 0.8 | 6.4 | 0.32 | 0.64 | \$738.21 |
| - All other HMIWI | 32 | 1 | 32 | 24 | 768 | 38.4 | 76.8 | \$88,585.34 |
| Report of annual equipment inspection | See 4B | | | | | | | |
| Semiannual report of emissions/parameter exceedances and periods when emission/parameter data not obtained (small non-rural, medium, and large HMIWI) ^j | 32 | 2 | 64 | 6 | 384 | 19.2 | 38.4 | \$44,292.67 |
| Semiannual report of emissions/parameter exceedances and periods when emission/parameter data not obtained (small rural HMIWI) ^j | 8 | 2 | 16 | 0.2 | 3.2 | 0.16 | 0.32 | \$369.11 |
| Subtotal for Reporting Requirements (Privately-owned HMIWI) | | | | | 14,637 | | | \$1,468,094 |
| 5. Reporting requirements (Federally-owned HMIWI) | | | | | | | | |
| A. Familiarize with Regulatory Requirements ^c | 1 | 1 | 1 | 5 | 5 | 0.25 | 0.5 | \$576.73 |
| B. Required activities | | | | | | | | |
| Annual update of operating information ^f | 20 | 1 | 20 | 5 | 100 | 5 | 10 | \$11,534.55 |
| Review operating information with each operator ^g | 8 | 2 | 16 | 5 | 80 | 4 | 8 | \$9,227.64 |
| Annual control equipment inspection | 20 | 1 | 20 | 5 | 100 | 5 | 10 | \$11,534.55 |
| C. Create information | NA | | | | | | | |
| D. Gather existing information | See 5B | | | | | | | |
| E. Write report | | | | | | | | |
| Annual report | | | | | | | | |
| CMS operating parameters | 32 | 1 | 32 | 5 | 160 | 8 | 16 | \$18,455.28 |
| Emissions/parameter exceedances and periods when emission/parameter data not obtained ^j | 64 | 1 | 64 | 1 | 64 | 3.2 | 6.4 | \$7,382.11 |
| Report of annual performance test | 40 | 1 | 40 | 5 | 200 | 10 | 20 | \$23,069.10 |
| Report of no exceedances | 32 | 1 | 32 | 4 | 128 | 6.4 | 12.8 | \$14,764.22 |
| Report of annual equipment inspection | See 5B | | | | | | | |
| Semiannual report of emissions/parameter exceedances and periods when emission/parameter data not obtained ^j | 32 | 2 | 64 | 1 | 64 | 3.2 | 6.4 | \$7,382.11 |
| Subtotal for Reporting Requirements (Federally-owned HMIWI) | | | | | 1,036 | | | \$103,926 |

| | | | | | | | | |
|---|--------|---|----|------|-----------|------|------|----------------|
| 6. Reporting requirements (State/locally-owned HMIWI) | | | | | | | | |
| A. Familiarize with Regulatory Requirements ^c | 1 | 1 | 1 | 0 | 0 | 0 | 0 | \$0 |
| B. Required activities | | | | | | | | |
| Annual update of operating information | 20 | 1 | 20 | 0 | 0 | 0 | 0 | \$0 |
| Review operating information with each operator | 8 | 2 | 16 | 0 | 0 | 0 | 0 | \$0 |
| Annual control equipment inspection | 20 | 1 | 20 | 0 | 0 | 0 | 0 | \$0 |
| C. Create information | NA | | | | | | | |
| D. Gather existing information | See 6B | | | | | | | |
| E. Write report | | | | | | | | |
| Annual report | | | | | | | | |
| CMS operating parameters | 32 | 1 | 32 | 0 | 0 | 0 | 0 | \$0 |
| Emissions/parameter exceedances and periods when emission/parameter data not obtained ^j | 64 | 1 | 64 | 0 | 0 | 0 | 0 | \$0 |
| Report of annual performance test | 40 | 1 | 40 | 0 | 0 | 0 | 0 | \$0 |
| Report of no exceedances ^j | 32 | 1 | 32 | 0 | 0 | 0 | 0 | \$0 |
| Report of annual equipment inspection | See 6B | | | | | | | |
| Semiannual report of emissions/parameter exceedances and periods when emission/parameter data not obtained ^j | 32 | 2 | 64 | 0 | 0 | 0 | 0 | \$0 |
| Subtotal for Reporting Requirements (State/locally-owned HMIWI) | | | | | 0 | | | \$0 |
| 7. Reporting requirements (co-fired combustors and pathological/low-level radioactive/chemotherapeutic waste combustors) | | | | | | | | |
| A. Familiarize with Regulatory Requirements ^c | 1 | 1 | 1 | 13.4 | 13.4 | 0.67 | 1.34 | \$1,546 |
| B. Required activities | N/A | | | | | | | |
| C. Create information | N/A | | | | | | | |
| D. Gather existing information | N/A | | | | | | | |
| E. Write report | | | | | | | | |
| Notification of exemption claim | 2 | 1 | 2 | 0 | 0 | 0 | 0 | \$0 |
| Notification of relative amounts of hospital waste, medical/infectious waste, and other fuels and wastes to be combusted (co-fired combustors only) | 2 | 1 | 2 | 0 | 0 | 0 | 0 | \$0 |
| Subtotal for Reporting Requirements (Co-fired combustors and pathological/low-level radioactive/chemotherapeutic waste combustors) | | | | | 15 | | | \$1,546 |

| 8. Recordkeeping requirements (States) | | | | | | | | |
|---|--------|-----|-----|-----|----------|-------|---------|----------------|
| A. Familiarize with Regulatory Requirements | See 3A | | | | | | | |
| B. Plan activities | NA | | | | | | | |
| C. Implement activities | NA | | | | | | | |
| D. Develop record system | NA | | | | | | | |
| E. Time to enter information | NA | | | | | | | |
| F. Time to train personnel | NA | | | | | | | |
| G. Time for audits | NA | | | | | | | |
| Subtotal for Recordkeeping Requirements (States) | | | | | 0 | | | \$0 |
| 9. Recordkeeping requirements (privately-owned HMIWI) | | | | | | | | |
| A. Familiarize with Regulatory Requirements | See 4A | | | | | | | |
| B. Plan activities | N/A | | | | | | | |
| C. Implement activities | N/A | | | | | | | |
| D. Develop record system | N/A | | | | | | | |
| E. Time to enter information | | | | | | | | |
| Records of startup, shutdown, malfunction | 1.5 | 52 | 78 | 31 | 2,418 | 120.9 | 241.8 | \$278,905.42 |
| Records of persons reviewing operating information | 2 | 2 | 4 | 31 | 124 | 6.2 | 12.4 | \$14,302.84 |
| Records of operators completing training requirements | 2 | 1 | 2 | 0 | 0 | 0 | 0 | \$0 |
| Records of operators that have been qualified | 2 | 1 | 2 | 0 | 0 | 0 | 0 | \$0 |
| Records of initial performance test | See 4E | | | | | | | |
| Records of process and control device operating parameters | | | | | | | | |
| - Small rural HMIWI | 0.5 | 52 | 26 | 1 | 26 | 1.3 | 2.6 | \$2,998.98 |
| - All other HMIWI | 1.5 | 52 | 78 | 30 | 2,340 | 117.0 | 234 | \$269,908.47 |
| Records of CMS operation and maintenance | | | | | | | | |
| - Small rural HMIWI | 0.5 | 250 | 125 | 1 | 125 | 6.25 | 12.5 | \$14,418.19 |
| - All other HMIWI | 1.5 | 250 | 375 | 30 | 11,250 | 562.5 | 1,125.0 | \$1,297,636.88 |
| Records of emissions/parameter exceedances and periods when emission/parameter data not obtained ¹ | | | | | | | | |
| - Small rural HMIWI | 0.5 | 52 | 26 | 0.2 | 5.2 | 0.26 | 0.52 | \$599.80 |
| - All other HMIWI | 1.5 | 52 | 78 | 6 | 468 | 23.4 | 46.8 | \$53,981.69 |

| | | | | | | | | |
|---|--------|-----|-----|---|---------------|-------|-------|--------------------|
| Records of annual and subsequent compliance tests | See 4E | | | | | | | |
| Records of annual equipment inspection | See 4B | | | | | | | |
| F. Time to train personnel | 40 | 1 | 40 | 0 | 0 | 0 | 0 | \$0 |
| G. Time for audits | N/A | | | | | | | |
| Subtotal for Recordkeeping Requirements (Privately-owned HMIWI) | | | | | 19,270 | | | \$1,932,752 |
| 10. Recordkeeping requirements (Federally-owned HMIWI) | | | | | | | | |
| A. Familiarize with Regulatory Requirements | See 5A | | | | | | | |
| B. Plan activities | N/A | | | | | | | |
| C. Implement activities | N/A | | | | | | | |
| D. Develop record system | N/A | | | | | | | |
| E. Time to enter information | | | | | | | | |
| Records of startup, shutdown, malfunction | 1.5 | 52 | 78 | 5 | 390 | 19.5 | 39 | \$44,984.75 |
| Records of persons reviewing operating information | 2 | 2 | 4 | 5 | 20 | 1 | 2 | \$2,306.91 |
| Records of operators completing training requirements | 2 | 1 | 2 | 0 | 0 | 0 | 0 | \$0 |
| Records of operators that have been qualified | 2 | 1 | 2 | 0 | 0 | 0 | 0 | \$0 |
| Records of initial performance test | See 5E | | | | | | | |
| Records of process and control device operating parameters | 1.5 | 52 | 78 | 5 | 390 | 19.5 | 39 | \$44,984.75 |
| Records of CMS operation and maintenance | 1.5 | 250 | 375 | 5 | 1,875 | 93.75 | 187.5 | \$216,272.81 |
| Records of emissions/parameter exceedances and periods when emission/parameter data not obtained ^j | 1.5 | 52 | 78 | 1 | 78 | 3.9 | 7.8 | \$8,996.95 |
| Records of annual and subsequent compliance tests | See 5E | | | | | | | |
| Records of annual equipment inspection | See 5B | | | | | | | |
| F. Time to train personnel | 40 | 1 | 40 | 0 | 0 | 0 | 0 | \$0 |
| G. Time for audits | N/A | | | | | | | |
| Subtotal for Recordkeeping Requirements (Federally-owned HMIWI) | | | | | 3,166 | | | \$317,546 |
| 11. Recordkeeping requirements (State/locally-owned HMIWI) | | | | | | | | |
| A. Familiarize with Regulatory Requirements | See 6A | | | | | | | |
| B. Plan activities | N/A | | | | | | | |
| C. Implement activities | N/A | | | | | | | |

| | | | | | | | | |
|--|--------|-----|-----|------|------------|------|-------|-----------------|
| D. Develop record system | N/A | | | | | | | |
| E. Time to enter information | | | | | | | | |
| Records of startup, shutdown, malfunction | 1.5 | 52 | 78 | 0 | 0 | 0 | 0 | \$0 |
| Records of persons reviewing operating information r | 2 | 2 | 4 | 0 | 0 | 0 | 0 | \$0 |
| Records of operators completing training requirements | 2 | 1 | 2 | 0 | 0 | 0 | 0 | \$0 |
| Records of operators that have been qualified | 2 | 1 | 2 | 0 | 0 | 0 | 0 | \$0 |
| Records of initial performance test | See 6E | | | | | | | |
| Records of process and control device operating parameters | 1.5 | 52 | 78 | 0 | 0 | 0 | 0 | \$0 |
| Records of CMS operation and maintenance | 1.5 | 250 | 375 | 0 | 0 | 0 | 0 | \$0 |
| Records of emissions/parameter exceedances and periods when emission/parameter data not obtained ^j | 1.5 | 52 | 78 | 0 | 0 | 0 | 0 | \$0 |
| Records of annual and subsequent compliance tests | See 6E | | | | | | | |
| Records of annual equipment inspection | See 6B | | | | | | | |
| F. Time to train personnel | 40 | 1 | 40 | 0 | 0 | 0 | 0 | \$0 |
| G. Time for audits | N/A | | | | | | | |
| Subtotal for Recordkeeping Requirements (State/Locally-owned HMIWI) | | | | | 0 | | | \$0 |
| 12. Recordkeeping requirements (co-fired and pathological/low-level radioactive/ chemotherapeutic combustors) | | | | | | | | |
| A. Familiarize with Regulatory Requirements | See 7A | | | | | | | |
| B. Plan activities | N/A | | | | | | | |
| C. Implement activities | N/A | | | | | | | |
| D. Develop record system | N/A | | | | | | | |
| E. Time to enter information | | | | | | | | |
| Quarterly records of periods when only pathological, low-level radioactive, chemotherapeutic waste burned ^k | 2 | 4 | 8 | 13.4 | 107.2 | 5.36 | 10.72 | \$12,365.04 |
| Quarterly records of weight of hospital waste and medical/infectious waste combusted, and weight of all other fuels and waste combusted (co-fired only) ^k | 2 | 4 | 8 | 5 | 40 | 2 | 4 | \$4,613.82 |
| F. Time to train personnel | N/A | | | | | | | |
| G. Time for audits | N/A | | | | | | | |
| Subtotal for Recordkeeping Requirements (Co-fired and pathological/low level radioactive / chemotherapeutic | | | | | 169 | | | \$16,979 |

| | | | | | | | |
|--|--|--|--|--|---------------|--|--------------------|
| combustors) | | | | | | | |
| TOTAL REPORTING REQUIREMENTS (FROM SUBTOTALS) | | | | | 16,220 | | \$1,626,856 |
| TOTAL RECORDKEEPING REQUIREMENTS (FROM SUBTOTALS) | | | | | 22,605 | | \$2,267,277 |
| TOTAL LABOR BURDEN AND COST (ROUNDED) ¹ | | | | | 38,800 | | \$3,890,000 |
| TOTAL CAPITAL AND O&M COST (ROUNDED) ¹ | | | | | | | \$479,000 |
| GRAND TOTAL (ROUNDED) ¹ | | | | | | | \$4,370,000 |

Note: States and tribes may choose to impose requirements that are more stringent. However, the burden estimates provided in this ICR assume that the state and tribal plans mirror the federal Emission Guidelines.

Assumptions:

^a We have assumed that there are approximately 58 respondents, with no additional new or reconstructed sources becoming subject to the rule over the next three years. The breakdown is as follows: 31 privately-owned HMIWI (including 1 small rural HMIWI), 5 Federally-owned HMIWI, and 0 State/locally-owned HMIWI, and 22 States that require annual State Plan Inventory.

^b This ICR uses the following labor rates for industry: \$129.93 per hour for Executive, Administrative, and Managerial labor; \$103.97 per hour for Technical labor, and \$51.79 per hour for Clerical labor. These rates are from the United States Department of Labor, Bureau of Labor Statistics, June 2014 “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. In addition, this ICR uses the following labor rates for State government: \$65.41 for Managerial labor; \$52.43 for Technical labor, and \$24.88 for Clerical labor. These rates are from the United States Department of Labor, Bureau of Labor Statistics, May 2013 National Industry-Specifics Occupational Employment and Wage Estimates for State government (NAICS code 999200). The rates have been increased by 60 percent to account for the benefit packages available to State government employees.

^c We have assumed all respondents will have to familiarize with regulatory requirements

^d Assume all 22 states with HMIWI have approved State Plan by the first year of this ICR. However, the State Plan/Inventory is updated on an annual basis.

^e The zero value for number of respondents indicates that burden was incurred prior to the time period covered by this supporting statement or for new respondents.

^f We have assumed that it would take each respondent 20 hours each to update the annual operating information.

^g We have assumed that it would take each respondent 8 hours to review the operating information with each operator.

^h We have assumed that each facility will take 160 hours to develop the operating information.

ⁱ We have assumed that each facility will take 40 hours to develop the waste management plan.

^j Assume 20 percent of respondents report exceedances, and 80 percent report no exceedances.

^k We have assumed that all co-fired and pathological/low-level radioactive/ chemotherapeutic combustors units would be owned by the private sector.

¹ Totals have been rounded to 3 significant figures. Figures may not add exactly due to rounding

Table 2: Average Annual EPA Burden and Cost – State and Federal Emission Guidelines for Hospital/Medical/Infectious Waste Incinerators (40 CFR Part 60, Subpart Ce and 40 CFR Part 62, Subpart HHH) (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. Initial performance test | 32 | 1 | 32 | 0 | 0 | 0 | 0 | \$0 |
| 2. Repeat performance test | | | | | | | | |
| A. Retesting preparation | 12 | 1 | 12 | 0 | 0 | 0 | 0 | \$0 |
| B. Attend retesting | 32 | 1 | 32 | 0 | 0 | 0 | 0 | \$0 |
| 3. Report review | | | | | | | | |
| A. Review reports for co-fired combustors | | | | | | | | |
| Review notification of exemption claim | 2 | 1 | 2 | 0 | 0 | 0 | 0 | \$0 |
| Review notification of relative amounts of hospital waste, medical/infectious waste, and other fuels and wastes to be combusted | 2 | 1 | 2 | 0 | 0 | 0 | 0 | \$0 |
| B. Review notification of exemption claim for pathological, low-level radioactive, chemotherapeutic combustors | 2 | 1 | 2 | 0 | 0 | 0 | 0 | \$0 |
| C. Review reports of increments of progress | | | | | | | | |
| Review control plan | 4 | 1 | 4 | 0 | 0 | 0 | 0 | \$0 |
| Review notification of construction contracts | 2 | 1 | 2 | 0 | 0 | 0 | 0 | \$0 |
| Review notification of construction commencement | 2 | 1 | 2 | 0 | 0 | 0 | 0 | \$0 |
| Review notification of construction completion | 2 | 1 | 2 | 0 | 0 | 0 | 0 | \$0 |
| Review notification of control plan completion | 2 | 1 | 2 | 0 | 0 | 0 | 0 | \$0 |
| D. Review request for extension for HMIWI planning to shut down late | 4 | 1 | 4 | 0 | 0 | 0 | 0 | \$0 |
| E. Review reports for small non-rural, medium and large HMIWI | | | | | | | | |
| Review waste management plan | 8 | 1 | 8 | 0 | 0 | 0 | 0 | \$0 |

| | | | | | | | | |
|---|----|---|----|-----|--------------|------|------|-----------------|
| Review notification of initial performance test | 8 | 1 | 8 | 0 | 0 | 0 | 0 | \$0 |
| Review notification of initial CMS demonstration | 5 | 1 | 5 | 0 | 0 | 0 | 0 | \$0 |
| Review report of initial performance test | 36 | 1 | 36 | 0 | 0 | 0 | 0 | \$0 |
| Review report of initial CMS demonstration | 24 | 1 | 24 | 0 | 0 | 0 | 0 | \$0 |
| Review annual report | | | | | | | | |
| CMS operating parameters | | | | | | | | |
| - Small rural HMIWI | 2 | 1 | 2 | 1 | 2 | 0.1 | 0.2 | \$104.68 |
| - All other HMIWI | 6 | 1 | 6 | 35 | 210 | 10.5 | 21 | \$10,991.40 |
| Emissions/parameter exceedances and periods when emission/parameter data not obtained ^c | | | | | | | | |
| - Small rural HMIWI | 4 | 1 | 4 | 0.2 | 0.8 | 0.04 | 0.08 | \$41.87 |
| - All other HMIWI | 16 | 1 | 16 | 7 | 112 | 5.6 | 11.2 | \$5,862.08 |
| Results of annual performance test | | | | | | | | |
| - Small rural HMIWI | 6 | 1 | 6 | 1 | 6 | 0.3 | 0.6 | \$314.04 |
| - All other HMIWI | 24 | 1 | 24 | 35 | 840 | 42 | 84 | \$43,965.60 |
| Report of no exceedances | | | | | | | | |
| - Small rural HMIWI | 2 | 1 | 2 | 0.8 | 1.6 | 0.08 | 0.16 | \$83.74 |
| - All other HMIWI | 8 | 1 | 8 | 28 | 224 | 11.2 | 22.4 | \$11,724.16 |
| Review semiannual report of emissions/ parameter exceedances and periods when emission/parameter data not obtained ^c | | | | | | | | |
| - Small rural HMIWI | 2 | 1 | 2 | 0.2 | 0.4 | 0.02 | 0.04 | \$20.94 |
| - All other HMIWI | 8 | 1 | 8 | 7 | 56 | 2.8 | 5.6 | \$2,931.04 |
| Report of annual equipment inspection (Small rural HMIWI) | 4 | 1 | 4 | 1 | 4 | 0.2 | 0.4 | \$209.36 |
| Report of annual control equipment inspection (All other HMIWI) | 4 | 1 | 4 | 0 | 0 | 0 | 0 | \$0 |
| G. Review reports for States | | | | | | | | |
| Review annual update of State Plan Inventory ^d | 8 | 1 | 8 | 22 | 176 | 8.8 | 17.6 | \$9,211.84 |
| 4. Prepare annual summary report ^e | 1 | 1 | 1 | 36 | 36 | 1.8 | 3.6 | \$1,884.24 |
| TOTAL ANNUAL BURDEN AND COST (ROUNDED) ^f | | | | | 1,920 | | | \$87,000 |

Assumptions:

^a We have assumed that there are approximately 36 respondents, with no additional new or reconstructed sources becoming subject to the rule over the next three years. The 36 respondents are located in 22 States.

^b This cost is based on the following hourly labor rates times a 1.6 benefits multiplication factor to account for government overhead expenses: \$62.90 for Managerial (GS-13, Step 5, \$39.31 x 1.6), \$46.67 for Technical (GS-12, Step 1, \$29.17 x 1.6) and \$25.25 Clerical (GS-6, Step 3, \$15.78 x 1.6). These rates are from the Office of Personnel Management (OPM) “2014 General Schedule” which excludes locality rates of pay.

^c Assume 20 percent of respondents report parameter exceedances, and 80 percent report no exceedances.

^d Assume all 22 States have approved State/Plan Inventory by the first year of this ICR. All States are expected to update State Plan/Inventory annually.

^e We have assumed that all respondents will have to prepare annual summary report.

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