

**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 1899.10, OMB Control Number 2060-0422.

**1(b) Short Characterization/Abstract**

The Emission Guidelines (EG) (40 CFR Part 60, Subpart Ce) for Hospital/Medical/Infectious Waste Incinerators were proposed on February 27, 1995; promulgated on September 15, 1997; and revised on both October 6, 2009 and April 4, 2011. The Federal Plan Requirements for these regulations (40 CFR Part 62, Subpart HHH) were proposed on July 6, 1999; promulgated on August 15, 2000; and revised on May 13, 2013. Subpart Ce requires either states or tribes to develop plans to implement the EG. 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. The regulations in 40 CFR Part 60, Subpart Ce and 40 CFR Part 62, Subpart HHH, apply to each existing individual hospital/medical/infectious waste incinerator (HMIWI) that either commenced construction prior to December 2, 2008 or commenced modification prior to April 6, 2010. 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 that are subject to the Emission Guidelines.

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 offices.

The “Affected Public” are owners or operators of HMIWIs in the United States owned and operated by either the private sector, or the Federal government, or state and local governments. The ‘burden’ to the Affected Public 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). The ‘burden’ to the Federal Government is attributed entirely to work performed by either Federal employees or appointed 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). There are approximately 18 facilities involved in this report. One of the 18 facilities in the United States is owned by the Federal government and operated by Federal employees, one is owned by either state, local, or tribal governments, and 16 are HMIWI facilities 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 each plant site has only one respondent (i.e., the owner/operator of the plant site).

Over the next three years, approximately 28 respondents per year will be subject to these standards, and no additional respondents per year will become subject to these same standards. There are approximately 16 HMIWI, which are owned and operated by the private sector (hospitals, commercial waste disposal companies, pharmaceutical companies and private universities); one HMIWI is owned and operated by the Federal Government (Federal research facilities); and one is owned and operated by either state or local governments (state universities). In addition, there are 10 States with units subject to subpart Ce that are required to submit an annual State Plan emissions inventory for all designated facilities.

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 (SO<sub>2</sub>), nitrogen oxide (NO<sub>x</sub>), lead (Pb), cadmium (Cd), and mercury (Hg) emissions from hospital, medical, or infectious waste incinerators either cause or contribute to air pollution that may reasonably be anticipated to endanger public health and/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 these same standards at all times. During the performance test a record of the operating parameters under which compliance was achieved may be recorded and used to determine compliance in place of a continuous emission monitor.

The notifications required in these standards are used to inform the Agency or delegated authority when a source becomes subject to the requirements of 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 the standards are being met. The performance test may also be observed.

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

Additionally, on May 13, 2013, the EPA amended the rule to provide a voluntary option for electronic reporting for certain notifications or reports. The EPA allows for owners or operators of affected sources to submit electronic copies of performance test through the EPA's Central Data Exchange (CDX), using the Compliance and Emissions Data Reporting Interface (CEDRI). CEDRI includes the Electronic Reporting Tool (ERT) software, which is used by facilities to generate electronic reports of performance tests. The EPA allows for 40 CFR Part 60, Subpart Ce and 40 CFR Part 62, Subpart HHH performance test reports to be submitted through the EPA's ERT. Hard-copy paper reporting remains as an available option for HMIWI facilities.

### **3. Non-duplication, 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) Non-duplication**

For reports required to be submitted electronically, the information is sent through the EPA's CDX, using CEDRI, where the appropriate EPA regional office can review it, as well as for state and local agencies that have been delegated authority. If a state or local agency has adopted under its own authority its own standards for reporting or data collection, adherence to those non-Federal requirements does not constitute duplication.

For all other reports, 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 standards to implement the Federal standards, a copy of the report submitted to the state or local agency can be sent to the Administrator in lieu of the report required by the Federal standards. Therefore, duplication does not exist.

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

An announcement of a public comment period for the renewal of this ICR was published in the *Federal Register* (87 FR 43843) on July 22, 2022. 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 28 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 the National Waste & Recycling Association (NWRA), at (202) 244-4700, and Larson-Miller Medical Waste Disposal Service, 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 for recordkeeping are useful techniques to ensure that good operation and maintenance practices are applied and that emission limitations are met. If the information required by these standards was collected less-frequently, the proper operation and maintenance of control equipment and the possibility of detecting violations would be less likely.

### **3(e) General Guidelines**

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

These standards require the respondents to maintain all records, including reports and

notifications for at least five years. This is consistent with the General Provisions as applied to these same standards. The 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. The 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 either 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 operators of existing individual hospital/medical/infectious waste incinerator (HMIWI) that either commenced construction prior to December 2, 2008 or commenced modification prior to April 6, 2010. 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:

<b>40 CFR Part 60, Subpart Ce and 40 CFR Part 62, Subpart HHH</b>	<b>SIC Codes</b>	<b>NAICS Codes</b>
General Medical and Surgical Hospital	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	541713, 541714
National Security	9711	928110
Administration of Public Health Programs	9431	923120
Skilled Nursing Facilities and Continuing Care Retirement Facilities	8051, 8052, 8059	623110, 623311
Veterinary Services and Testing Laboratories	0741, 0742, 8734	541940
Medical Laboratory Testing	8071	621511

**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:

<b>Requirement</b>	
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:

<b>Notifications</b>	
Initial and repeat performance specification tests for CMS	§60.7(a)(5), §60.37e, §60.56c
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)



<b>Notifications</b>	
Waste management plan	§60.35e, §60.38e(a), §60.58c(c)(3), §62.14432
Notification of exemption claim for combustors burning pathological, low-level radioactive, and/or chemotherapeutic waste	§60.32e(b)(1), §60.14400(b)(1)
Notification of exemption claim for co-fired combustors	§60.32e(c)(1)-(2), §60.14400(b)(2)
Notification of initial performance test (PM, CO, fugitive emissions, stack opacity, dioxins/furans, HCl, Cd, Pb, Hg)	§60.8(d), §60.38e(a)

<b>Reports</b>	
Report of initial CMS demonstration	§60.7(c), §60.38e(a)
Report of initial performance test	§60.8(a), §60.38e(a), §60.58c(c)(1), §60.58c(d)(6), §62.14463(a)(1), §62.14464(a), §62.14470(b)(4)
Initial report of values for site-specific operating parameters and bag leak detection system	§60.38e(a), §60.58c(c)(2), §62.14463(a)(2), §62.14463(a)(4), §62.14464(a)
Waste management plan	§62.14432, §62.14463(a)(3), §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)
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	§60.7(c), §60.38e(a), §60.58c(d)(7), §62.14463(a)(10), §62.14464(b)
Results of previous performance tests	§60.38e(a)
Annual report of 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), §62.14464(b)
Annual report of equipment inspections, maintenance, and any repair	§60.38e(b)(2), §62.14463(a)(12), §62.14464(b)

Annual report of air pollution control device inspections, maintenance, and any repair	§60.38e(b)(2), §62.14463(a)(13), §62.14464(b)
Annual report of 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), §62.14464(b)
Petition for site-specific operating parameters for control device	§62.14463(a)(15)
Annual update of operating information	§60.34e, §§60.53c(h)-(i), §62.14464(b)
Annual review of operating information with each operator	§60.34e, §§60.53c(h)-(i)

A source must keep the following records:

<b>Recordkeeping</b>	
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)
Records of initial performance test	§60.37e, §60.56c, §§62.14460(a) and (f)
Records of CMS operation and maintenance	§60.38e(a), §60.58c, §60.7(f), §§62.14460(a) & (b)(1)-(13), §§62.14460(b)(15)-(19)
Records of annual equipment inspections, required maintenance, and repairs not completed during established timeframe	§60.38e(b), §62.14454(e)(11), §§62.14460(a) and (b)(14)
Records on a quarterly basis of periods, when only pathological, low-level radioactive, and/or chemotherapeutical waste is burned.	§60.32e(b)(2), §62.14400(b)
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)(3), §62.14400(b)
Records for which data on emissions/operating parameters were not obtained	§60.38e(a), §60.58c(b), §60.8(f), §62.14460(c)
Records related to malfunctions	§60.38e(a), §60.58c(b), §60.8(f),

<b>Recordkeeping</b>	
	§62.14460(b)(19), §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), §§62.14460(b)(2)-(13), §§62.14460(b)(15)-(17)
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. Following December 31, 2011, respondents have the voluntary option to use the EPA's Electronic Reporting Tool (ERT) to develop performance test reports and submit them through the EPA's Compliance and Emissions Data Reporting Interface (CEDRI), which can be accessed through the EPA's Central Data Exchange (CDX) (<https://cdx.epa.gov/>). The ERT is an application, rather than a form, and the requirement to use the ERT is applicable to numerous subparts. The splash screen of the ERT contains a link to the Paperwork Reduction Act (PRA) requirements, such as the OMB Control Number, expiration date, and burden estimate for this and other subparts. For purposes of this ICR, it is assumed that there is no additional burden associated with the proposed requirement for respondents to submit the notifications and reports electronically. Hard-copy paper reporting will remain as an available option for HMIWI facilities.

Electronic copies of records may also be maintained in order to satisfy federal recordkeeping requirements. For additional information on the Paperwork Reduction Act requirements for CEDRI and ERT for this rule, see: <https://www.epa.gov/electronic-reporting->

**(ii) Respondent Activities**

<b>Respondent Activities</b>
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 test 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.
Enter information required to be recorded above.
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 processing and maintaining information.
Develop, acquire, install, and utilize technology and systems for 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

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

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

### 5(b) Collection Methodology and Management

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

Information contained in the reports is reported by state and local governments in the ICIS Air database, which is operated and maintained by EPA's Office of Compliance. The EPA uses ICIS for tracking air pollution compliance and enforcement by local and state regulatory agencies, EPA regional offices, and EPA headquarters. The 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

The majority of the respondents in this ICR 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 these regulations. 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, these regulations include various provisions that would reduce the burden on HMIWI, including the one HMIWI within the respondent universe that is classified as a small entity. 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 at the end of this document 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. 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 19,200 hours (Total Labor Hours from Table 1 below). These hours are based on Agency studies and background documents from the development of these regulations, Agency knowledge and experience with the 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	\$157.61 (\$75.05 + 110%)
Technical	\$123.94 (\$59.02 + 110%)

Clerical            \$62.52 (\$29.77 + 110%)

These rates are from the United States Department of Labor, Bureau of Labor Statistics, September 2021, “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 varying industry wage rates and the additional overhead business costs of employing workers beyond their wages and benefits, including business expenses associated with hiring, training, and equipping their employees.

**(ii) Estimating Capital/Startup and Operation and Maintenance Costs**

The type of industry costs associated with the information collection activities in these 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 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**

<b>Capital/Startup vs. Operation and Maintenance (O&amp;M) Costs</b>						
(A) Continuous Monitoring Device	(B) Capital/Startup Cost for One Respondent <sup>1</sup>	(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)
<b>Monitoring costs</b>						
- Privately-owned HMIWI	\$3,751	0	\$0	\$11,957	16	\$191,312
- Federally owned HMIWI	\$3,700	0	\$0	\$8,317	1	\$8,317
- State/locally-owned HMIWI	\$3,700	0	\$0	\$6,275	,	\$6,275
Testing <sup>2</sup>	\$21,000	0	\$0	NA	0	\$0
File Cabinets <sup>3</sup>	\$33.50	0	\$0	NA	0	\$0
<b>Photocopying and postage</b>						
- States	N/A	0	\$0	\$16.27	10	\$163
- Privately-owned HMIWI	N/A	0	\$0	\$50.28	16	\$804
- Federally owned HMIWI	N/A	0	\$0	\$49.67	1	\$50
- State/locally-owned HMIWI	N/A	0	\$0	\$49.50	1	\$50
<b>Temperature pressure, flow rate, change rate, voltage, and pH monitors <sup>4</sup></b>						
- Privately-owned HMIWI	N/A	0	\$0	\$1,800	16	\$28,800
- Federally owned	N/A	0	\$0	\$1,800	1	\$1,800

HMIWI						
- State/locally-owned HMIWI	N/A	0	\$0	\$1,800	1	\$1,800
<b>Subtotals</b>						
- States			\$0			\$163
- Privately-owned HMIWI			\$0			\$220,916
- Federally owned HMIWI			\$0			\$10,167
- State/locally-owned HMIWI			\$0			\$8,125
<b>TOTAL</b>			\$0			<b>\$239,000</b>

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

<sup>1</sup> This ICR assumes there are no new respondents that would be required to install monitoring and testing equipment. Therefore, there are no capital/startup costs associated with this ICR.

<sup>2</sup> Average testing cost for all respondents.

<sup>3</sup> 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).

<sup>4</sup> 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 \$239,000. 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 \$239,000. 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. The 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 \$48,000.

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

Managerial	\$70.56 (GS-13, Step 5, \$44.10 + 60%)
Technical	\$52.37 (GS-12, Step 1, \$32.73 + 60%)



Clerical            \$28.34 (GS-6, Step 3, \$17.71 + 60%)

These rates are from the Office of Personnel Management (OPM), 2022 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 at the end of this document 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 28 existing respondents (16 privately-owned, 1 Federally-owned, and 1 State/locally-owned, *plus* the 10 states requiring State Plan Inventories), will be subject to these standards. It is estimated that no additional respondents per year will become subject to these same standards. The overall average number of respondents, as shown in the table below, is 28 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 <sup>1</sup>	(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	28	0	0	28
2	0	28	0	0	28
3	0	28	0	0	28
Average	0	28	0	0	28

<sup>1</sup> 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 28.

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

<b>Total Annual Responses</b>					
<b>(A) Information Collection Activity</b>	<b>States</b>	<b>Privately- Owned HMIWI</b>	<b>Federally- Owned HMIWI</b>	<b>State/Locally Owned HMIWI</b>	<b>Total</b>
State Plan/inventory <sup>1</sup>	0	0	0	0	0
Annual update of State Plan inventory	10	0	0	0	0
Notification of initial performance test and CMS demonstration	N/A				
Annual Reports <sup>2</sup>					
CMS emissions and operating parameters	0	16	1	1	18
Exceedances, malfunctions, and periods for which data not obtained	0	3.2	0.2	0.2	3.6
Results of performance tests conducted during the year	0	16	1	1	18
Report of no exceedances	0	12.8	0.8	0.8	14.4
Report of annual equipment or control device inspection	0	16	1	1	18
Semiannual report of exceedances, malfunctions, and periods for which data not obtained <sup>3</sup>	0	3.2	0.2	0.2	3.6
<b>Total <sup>4</sup></b>	<b>10</b>	<b>67.2</b>	<b>4.2</b>	<b>4.2</b>	<b>76</b>

<sup>1</sup>This ICR assumes all 10 states have approved State Plans.

<sup>2</sup>This ICR assumes 20% of respondents report exceedances, and 80% of respondents report no exceedances.

<sup>3</sup>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.

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

The number of Total Annual Responses is 76.

The total annual labor costs are \$2,190,000. Details regarding these estimates may be found at the end of this document 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 at the end of this document, respectively, and summarized below.

### **(i) Respondent Tally**

The total annual labor hours are 19,200 hours. 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).

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 253 hours per response.

The total annual capital/startup and O&M costs to the regulated entity are \$239,000. 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 940 labor hours at a cost of \$48,00; see 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).

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**

The decrease in burden from the most-recently approved ICR is due to a decrease in the number of sources due to a decline in the industry. This decrease is not due to any program changes. The number of sources has declined as HMIWI units have closed. Any new units that either commence construction after December 2, 2008 or commence modification after April 6, 2010 are subject to the new source performance standards at 40 CFR Part 60, Subpart Ec. The

decrease in the operation and maintenance costs from the currently-approved ICR is also due to the decline in the number of HMIWI units. There are no changes to the capital costs because there are no new entities subject to 40 CFR Part 60, Subpart Ce or 40 CFR Part 62, Subpart HHH.

### **6(g) Burden Statement**

The annual public reporting and recordkeeping burden for this collection of information is estimated to average 253 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-OAR-2022-0022. 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. Due to COVID-19 precautions, entry to the Reading Room is available by appointment only. Please contact personnel in the Reading Room to schedule an appointment. 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-OAR-2022-0022 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 occurrence s per respondent per year	(C) Person hours per respondent per year (C=AxB)	(D) Respondent s per year <sup>a</sup>	(E) Technical person- hours per year (E=CxD)	(F) Management person hours per year (Ex0.05)	(G) Clerica l person hours per year (Ex0.1)	(H) Total Cost per year <sup>b</sup>
1. Applications	N/A							
2. Survey and Studies	N/A							
<b>3. Reporting Requirements (States)</b>								
A. Familiarize with Regulatory Requirements <sup>c</sup>	1	1	1	10	10	0.5	1	\$1,380.73
B. Required activities <sup>d</sup>								
- Development of State Plan/Inventory	2,080	1	2,080	0	0	0	0	\$0
- Annual update of State Plan Inventory	20	1	20	10	200	10	20	\$27,614.50
- 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
<b>Subtotal for Reporting Requirements (States)</b>						242		<b>\$28,995</b>
<b>4. Reporting requirements (privately-owned HMIWI)</b>								
A. Familiarize with Regulatory Requirements <sup>c</sup>	1	1	1	16	16	0.8	1.6	\$2,209.16
B. Required activities <sup>e</sup>								
Annual update of operating information <sup>f</sup>	20	1	20	16	320	16	32	\$44,183.20

Burden item	(A) Person hours per occurrence	(B) No. of occurrence s per respondent per year	(C) Person hours per respondent per year (C=AxB)	(D) Respondent s per year <sup>a</sup>	(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 <sup>b</sup>
Review operating information with each operator <sup>8</sup>	8	2	16	16	256	12.8	25.6	\$35,346.56
Annual equipment inspection (small rural HMIWI)	20	1	20	1	20	1	2	\$2,761.45
Annual equipment inspection (all other HMIWI)	20	1	20	15	300	15	30	\$41,421.75
C. Create information	See 4B							
D. Gather information	See 4B							
E. Write report <sup>e</sup>								
Annual report								
CMS operating parameters	32	1	32	16	512	25.6	51.2	\$70,693.12
Emissions/parameter exceedances and periods when emission/parameter data not obtained <sup>j</sup>								
- Small rural HMIWI	16	1	16	0.2	3.2	0.16	0.32	\$441.83
- All other HMIWI	64	1	64	3	192	9.6	19.2	\$26,509.92
Report of annual performance test								
- Small rural HMIWI	20	1	20	1	20	1	2	\$2,761.45
- All other HMIWI	280	1	280	15	4,200	210	420	\$579,904.50
Report of no exceedances								
- Small rural HMIWI	8	1	8	0.8	6.4	0.32	0.64	\$883.66
- All other HMIWI	32	1	32	12	384	19.2	38.4	\$53,019.84
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) <sup>j</sup>	32	2	64	3	192	9.6	19.2	\$26,509.92
Semiannual report of emissions/parameter exceedances and periods when emission/parameter data not obtained (small rural HMIWI) <sup>j</sup>	8	2	16	0.2	3.2	0.16	0.32	\$441.83

Burden item	(A) Person hours per occurrence	(B) No. of occurrence s per respondent per year	(C) Person hours per respondent per year (C=AxB)	(D) Respondent s per year <sup>a</sup>	(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 <sup>b</sup>
<b>Subtotal for Reporting Requirements (Privately-owned HMIWI)</b>					7,389			\$887,088
<b>5. Reporting requirements (Federally-owned HMIWI)</b>								
A. Familiarize with Regulatory Requirements <sup>c</sup>	1	1	1	1	1	0.05	0.1	\$58.73
B. Required activities								
Annual update of operating information <sup>f</sup>	20	1	20	1	20	1	2	\$1,174.64
Review operating information with each operator <sup>g</sup>	8	2	16	1	16	0.8	1.6	\$939.71
Annual control equipment inspection	20	1	20	1	20	1	2	\$1,174.64
C. Create information	NA							
D. Gather existing information	See 5B							
E. Write report								
Annual report								
CMS operating parameters	32	1	32	1	32	1.6	3.2	\$1,879.42
Emissions/parameter exceedances and periods when emission/parameter data not obtained <sup>j</sup>	64	1	64	0.2	12.8	0.64	1.28	\$751.77
Report of annual performance test	40	1	40	1	40	2	4	\$2,349.28
Report of no exceedances	32	1	32	0.8	25.6	1.28	2.56	\$1,503.54
Report of annual equipment inspection	See 5B							
Semiannual report of emissions/parameter exceedances and periods when emission/parameter data not obtained <sup>j</sup>	32	2	64	0.2	12.8	0.64	1.28	\$751.77
<b>Subtotal for Reporting Requirements (Federally-owned HMIWI)</b>					207			\$10,584
<b>6. Reporting requirements (State/locally-owned HMIWI)</b>								
A. Familiarize with Regulatory Requirements <sup>c</sup>	1	1	1	1	1	0.05	0.1	\$59
B. Required activities								



Burden item	(A) Person hours per occurrence	(B) No. of occurrence s per respondent per year	(C) Person hours per respondent per year (C=AxB)	(D) Respondent s per year <sup>a</sup>	(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 <sup>b</sup>
Annual update of operating information	20	1	20	1	20	1	2	\$1,175
Review operating information with each operator	8	2	16	1	16	0.8	1.6	\$940
Annual control equipment inspection	20	1	20	1	20	1	2	\$1,175
C. Create information	NA							
D. Gather existing information	See 6B							
E. Write report								
Annual report								
CMS operating parameters	32	1	32	1	32	1.6	3.2	\$1,879
Emissions/parameter exceedances and periods when emission/parameter data not obtained <sup>j</sup>	64	1	64	0.2	12.8	0.64	1.28	\$752
Report of annual performance test	40	1	40	1	40	2	4	\$2,349
Report of no exceedances <sup>j</sup>	32	1	32	0.8	25.6	1.28	2.56	\$1,504
Report of annual equipment inspection	See 6B							
Semiannual report of emissions/parameter exceedances and periods when emission/parameter data not obtained <sup>j</sup>	32	2	64	0.2	12.8	0.64	1.28	\$752
<b>Subtotal for Reporting Requirements (State/locally-owned HMIWI)</b>						<b>207</b>		<b>\$10,853</b>
<b>7. Reporting requirements (co-fired combustors and pathological/low-level radioactive/chemotherapeutic waste combustors)</b>								
A. Familiarize with Regulatory Requirements <sup>c,k</sup>	1	1	1	6.9	6.92	0.346	0.692	\$955
B. Required activities	N/A							
C. Create information	N/A							
D. Gather existing information	N/A							
E. Write report								

Burden item	(A) Person hours per occurrence	(B) No. of occurrence s per respondent per year	(C) Person hours per respondent per year (C=AxB)	(D) Respondent s per year <sup>a</sup>	(E) Technical person- hours per year (E=CxD)	(F) Management person hours per year (Ex0.05)	(G) Clerica l person hours per year (Ex0.1)	(H) Total Cost per year <sup>b</sup>
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
<b>Subtotal for Reporting Requirements (Co-fired combustors and pathological/low-level radioactive/chemotherapeutic waste combustors)</b>						<b>8</b>		<b>\$955</b>
<b>8. Recordkeeping requirements (States)</b>								
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							
<b>Subtotal for Recordkeeping Requirements (States)</b>						<b>0</b>		<b>\$0</b>
<b>9. Recordkeeping requirements (privately-owned HMIWI)</b>								
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	16	1,248	62.4	124.8	\$172,314.48
Records of persons reviewing operating information	2	2	4	16	64	3.2	6.4	\$8,836.64
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

Burden item	(A) Person hours per occurrence	(B) No. of occurrence s per respondent per year	(C) Person hours per respondent per year (C=AxB)	(D) Respondent s per year <sup>a</sup>	(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 <sup>b</sup>
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	\$3,589.89
- All other HMIWI	1.5	52	78	15	1,170	58.5	117	\$161,544.83
Records of CMS operation and maintenance								
- Small rural HMIWI	0.5	250	125	1	125	6.25	12.5	\$17,259.06
- All other HMIWI	1.5	250	375	15	5,625	281.25	562.5	\$776,657.81
Records of emissions/parameter exceedances and periods when emission/parameter data not obtained <sup>1</sup>								
- Small rural HMIWI	0.5	52	26	0.2	5.2	0.26	0.52	\$717.98
- All other HMIWI	1.5	52	78	3	234	11.7	23.4	\$32,308.97
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							
<b>Subtotal for Recordkeeping Requirements (Privately-owned HMIWI)</b>						<b>9,772</b>		<b>\$1,173,230</b>
<b>10. Recordkeeping requirements (Federally-owned HMIWI)</b>								
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	1	78	3.9	7.8	\$4,581.10
Records of persons reviewing operating information	2	2	4	1	4	0.2	0.4	\$234.93

Burden item	(A) Person hours per occurrence	(B) No. of occurrence s per respondent per year	(C) Person hours per respondent per year (C=AxB)	(D) Respondent s per year <sup>a</sup>	(E) Technical person- hours per year (E=CxD)	(F) Management person hours per year (Ex0.05)	(G) Clerica l person hours per year (Ex0.1)	(H) Total Cost per year <sup>b</sup>
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	1	78	3.9	7.8	\$4,581.10
Records of CMS operation and maintenance	1.5	250	375	1	375	18.75	37.5	\$22,024.50
Records of emissions/parameter exceedances and periods when emission/parameter data not obtained <sup>j</sup>	1.5	52	78	0.2	15.6	0.78	1.56	\$916.22
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							
<b>Subtotal for Recordkeeping Requirements (Federally-owned HMIWI)</b>						<b>633</b>		<b>\$32,338</b>
<b>11. Recordkeeping requirements (State/locally-owned HMIWI)</b>								
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	1	78	3.9	7.8	\$4,581
Records of persons reviewing operating information r	2	2	4	1	4	0.2	0.4	\$235
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	1	78	3.9	7.8	\$4,581

Burden item	(A) Person hours per occurrence	(B) No. of occurrence s per respondent per year	(C) Person hours per respondent per year (C=AxB)	(D) Respondent s per year <sup>a</sup>	(E) Technical person- hours per year (E=CxD)	(F) Management person hours per year (Ex0.05)	(G) Clerica l person hours per year (Ex0.1)	(H) Total Cost per year <sup>b</sup>
Records of CMS operation and maintenance	1.5	250	375	1	375	18.75	37.5	\$22,025
Records of emissions/parameter exceedances and periods when emission/parameter data not obtained <sup>j</sup>	1.5	52	78	0.2	15.6	0.78	1.56	\$916
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							
<b>Subtotal for Recordkeeping Requirements (State/Locally-owned HMIWI)</b>						<b>633</b>		<b>\$32,338</b>
<b>12. Recordkeeping requirements (co-fired and pathological/low-level radioactive/ chemotherapeutic combustors)</b>								
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 <sup>k</sup>	2	4	8	6.9	55.36	2.768	5.536	\$7,643.69
Quarterly records of weight of hospital waste and medical/infectious waste combusted, and weight of all other fuels and waste combusted (co-fired only) <sup>k</sup>	2	4	8	2.6	20.64	1.032	2.064	\$2,849.82
F. Time to train personnel	N/A							
G. Time for audits	N/A							
<b>Subtotal for Recordkeeping Requirements (Co-fired and pathological/low level radioactive / chemotherapeutic combustors)</b>						<b>87</b>		<b>\$10,494</b>
<b>TOTAL REPORTING REQUIREMENTS (FROM SUBTOTALS)</b>						<b>8,052</b>		<b>\$938,475</b>
<b>TOTAL RECORDKEEPING REQUIREMENTS (FROM SUBTOTALS)</b>						<b>11,126</b>		<b>\$1,248,399</b>

Burden item	(A) Person hours per occurrence	(B) No. of occurrence s per respondent per year	(C) Person hours per respondent per year (C=AxB)	(D) Respondent s per year <sup>a</sup>	(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 <sup>b</sup>
<b>TOTAL LABOR BURDEN AND COST (rounded)<sup>lm</sup></b>						19,200		\$2,190,000
<b>TOTAL CAPITAL AND O&amp;M COST (rounded)<sup>l</sup></b>								\$239,000
<b>GRAND TOTAL (rounded)<sup>l</sup></b>								\$2,430,000

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:**

<sup>a</sup> We have assumed that there are approximately 28 respondents, with no additional new or reconstructed sources becoming subject to the rule over the next three years. The breakdown is as follows: 16 privately-owned HMIWI (including 1 small rural HMIWI), 1 Federally-owned HMIWI, and 1 State/locally-owned HMIWI. Additionally, there are 10 States that require annual State Plan Inventory.

<sup>b</sup> This ICR uses the following labor rates: Managerial \$157.61 (\$75.05+ 110%); Technical \$123.94 (\$59.02 + 110%); and Clerical \$62.52 (\$29.77 + 110%). These rates are from the United States Department of Labor, Bureau of Labor Statistics, September 2021, “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 varying industry wage rates and the additional overhead business costs of employing workers beyond their wages and benefits, including business expenses associated with hiring, training, and equipping their employees.

In addition, this ICR uses the following labor rates for Federal and State government: expenses: Managerial rate of \$70.56 (GS-13, Step 5, \$44.10 + 60%), Technical rate of \$52.37 (GS-12, Step 1, \$32.73 + 60%), and Clerical rate of \$28.34 (GS-6, Step 3, \$17.71 + 60%). These rates are from the Office of Personnel Management (OPM) “2022 General Schedule” which excludes locality rates of pay. The rates have been increased by 60 percent to account for the benefit packages available to State government employees and government overhead expenses.

<sup>c</sup> We have assumed all respondents will have to familiarize with regulatory requirements.

<sup>d</sup> Assume all 10 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.

<sup>e</sup> 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.

<sup>f</sup> We have assumed that it would take each respondent 20 hours each to update the annual operating information.

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

<sup>h</sup> We have assumed that each facility will take 160 hours to develop the operating information.

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

<sup>j</sup> Assume 20 percent of respondents report exceedances, and 80 percent report no exceedances.

<sup>k</sup> We have assumed that all co-fired and pathological/low-level radioactive/ chemotherapeutic combustors units would be owned by the private sector. We assume an average of 6.9 units per year (which includes 2.6 co-fired units) will need to re-familiarize themselves with regulatory requirements over the three-year period of this ICR.

<sup>l</sup> Totals have been rounded to 3 significant figures. Figures may not add exactly due to rounding.

<sup>m</sup> Total includes 4,200 hours from Federally-owned and operated facilities.

**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 <sup>a</sup>	(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 <sup>b</sup>
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



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 <sup>a</sup>	(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 <sup>b</sup>
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	\$117.46
- All other HMIWI	6	1	6	17	102	5.1	10.2	\$5,990.66
Emissions/parameter exceedances and periods when emission/parameter data not obtained <sup>c</sup>								
- Small rural HMIWI	4	1	4	0.2	0.8	0.04	0.08	\$46.99
- All other HMIWI	16	1	16	3.4	54.4	2.72	5.44	\$3,195.02
Results of annual performance test								
- Small rural HMIWI	6	1	6	1	6	0.3	0.6	\$352.39
- All other HMIWI	24	1	24	17	408	20	40.8	\$23,962.66
Report of no exceedances								
- Small rural HMIWI	2	1	2	0.8	1.6	0.08	0.16	\$93.97
- All other HMIWI	8	1	8	13.6	109	5.4	10.9	\$6,390.04
Review semiannual report of emissions/ parameter exceedances and periods when emission/parameter data not obtained <sup>c</sup>								
- Small rural HMIWI	2	1	2	0.2	0.4	0.02	0.04	\$23.49
- All other HMIWI	8	1	8	3.4	27.2	1.36	2.72	\$1,597.51
Report of annual equipment inspection (Small rural HMIWI)	4	1	4	1	4	0.2	0.4	\$234.93

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 <sup>a</sup>	(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 <sup>b</sup>
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 <sup>d</sup>	8	1	8	10	80	4	8	\$4,698.56
4. Prepare annual summary report <sup>e</sup>	1	1	1	18	18	0.9	1.8	\$1,057.18
<b>TOTAL (rounded) <sup>f</sup></b>						<b>940</b>		<b>\$48,000</b>

**Assumptions:**

<sup>a</sup> We have assumed that there are approximately 28 respondents, with no additional new or reconstructed sources becoming subject to the rule over the next three years. The breakdown is as follows: 16 privately-owned HMIWI (including 1 small rural HMIWI), 1 Federally-owned HMIWI, and 1 State/locally-owned HMIWI. Additionally, there are 10 States that require annual State Plan Inventory.

<sup>b</sup> 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 \$70.56 (GS-13, Step 5, \$44.10 + 60%), Technical rate of \$52.37 (GS-12, Step 1, \$32.73 + 60%), and Clerical rate of \$28.34 (GS-6, Step 3, \$17.71 + 60%). These rates are from the Office of Personnel Management (OPM) “2022 General Schedule” which excludes locality rates of pay.

<sup>c</sup> Assume 20 percent of respondents report parameter exceedances, and 80 percent report no exceedances.

<sup>d</sup> Assume all 10 States have approved State/Plan Inventory. All States are expected to update State Plan/Inventory annually.

<sup>e</sup> We have assumed that all respondents will have to prepare annual summary report.

<sup>f</sup> Totals have been rounded to 3 significant figures. Figures may not add exactly due to rounding.