ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 62

[AD–FRL–6848–9]

RIN 2060–AI25

Federal Plan Requirements for Hospital/Medical/Infectious Waste Incinerators Constructed On or Before June 20, 1996

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: On September 15, 1997, EPA adopted emission guidelines for existing hospital/medical/infectious waste incinerators (HMIWI). Sections 111 and 129 of the Clean Air Act (CAA) require States with existing HMIWI subject to the emission guidelines to submit plans to EPA that implement and enforce the emission guidelines. Indian Tribes may submit, but are not required to submit, Tribal plans to implement and enforce the emission guidelines in Indian country. State plans were due from States with HMIWI subject to the emission guidelines on September 15, 1998. If a State or Tribe with existing HMIWI does not submit an approvable plan within 2 years after promulgation of the emission guidelines (September 15, 1999), sections 111(d) and 129 of the CAA require EPA to develop, implement, and enforce a Federal plan for HMIWI in that State/Tribal jurisdiction. The EPA proposed a Federal plan for HMIWI in the **Federal Register** on July 6, 1999. This action promulgates the Federal plan to implement emission guidelines for HMIWI located in States and Indian country without effective State or Tribal plans. This Federal plan is an interim action because on the effective date of an approved State/Tribal plan, the Federal plan will no longer apply to HMIWI covered by the State/Tribal plan.

EFFECTIVE DATE: The effective date of this final rule is September 14, 2000.

ADDRESSES: *Docket.* Dockets A–98–24 and A–91–61 contain the supporting information for this promulgated rule and the supporting information for EPA's promulgation of emission guidelines for existing HMIWI, respectively. Public comments on the proposed rule for this action were received in Docket A–98–24. The dockets are available for public inspection and copying between 8 a.m. and 5:30 p.m., Monday through Friday, at EPA's Air and Radiation Docket and Information Center (Mail Code 6102), 401 M Street, SW., Washington, D.C. 20460, or by calling (202) 260–7548. The docket is located in Room M–1500, Waterside Mall (ground floor, central mall). The fax number for the Center is (202) 260–4000 and the E-mail address is A-and-R-Docket@epa.gov. A reasonable fee may be charged for copying. In addition to the docket, an electronic copy of this document can be found at the EPA Unified Air Toxics Website (http://www.epa.gov/ttn/uatw/129/hmiwi/rihmiwi.html).

FOR FURTHER INFORMATION CONTACT: For procedural and implementation information regarding this Federal plan, contact Ms. Valerie Broadwell at (919) 541–3310, Program Implementation and Review Group, Information Transfer and Program Integration Division (MD–12), U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711 (broadwell.valerie@epa.gov). For technical information regarding State plans, contact Mr. Rick Copland at (919) 541–5265, Combustion Group, Emission Standards Division (MD–13), U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711 (copland.rick@epa.gov). If you have State-specific questions regarding the implementation of this Federal plan, contact your EPA Regional Office. Regional Office contacts are provided in **SUPPLEMENTARY INFORMATION.**

SUPPLEMENTARY INFORMATION: *Regulated Entities.* If you own or operate an existing HMIWI and are not already subject to an EPA-approved and effective State or Tribal plan, then you are regulated by this action. Existing HMIWI are those that commenced construction on or before June 20, 1996. Regulated categories and entities include those listed in Table 1.

TABLE 1.—REGULATED ENTITIES [a]

Category	Examples of regulated entities
Industry	Hospitals, nursing homes, research laboratories, other health care facilities, commercial waste disposal companies.
Federal Government.	Armed services, public health service, Federal hospitals, other Federal health care facilities.
State/local/Tribal Government.	State/county/city hospitals and other health care facilities.

[a] This table is not intended to be exhaustive, but rather, provides a guide for the public regarding entities likely to be regulated by this Federal plan. This table lists the types of entities that EPA is aware of that could potentially be regulated. Other types of entities not listed in the table could also be affected. To determine whether your facility is regulated by the standards or emission guidelines for HMIWI, you should carefully examine the applicability criteria in subpart HHH.

Judicial Review. This section 111(d)/129 rule for HMIWI was proposed on July 6, 1999 (64 FR 36425). This notice promulgating a rule for HMIWI constitutes final administrative action concerning that proposal. Under section 307(b)(1) of the CAA, judicial review of this final rule is available only by filing a petition for review in the U.S. Court of Appeals for the District of Columbia Circuit by October 16, 2000. Under section 307(d)(7)(B) of the CAA, only an objection to this rule that was raised with reasonable specificity during the period for public comment can be raised during judicial review. Moreover, under section 307(b)(2) of the CAA, the requirements established by today's final action may not be challenged separately in any civil or criminal proceeding brought by the EPA to enforce these requirements.

EPA Regional Office Contacts. Table 2 is a listing of EPA Regional Office contacts who can answer questions regarding implementation of this Federal plan.

TABLE 2.—EPA REGIONAL CONTACTS FOR HMIWI

Region	Regional contact	Phone/Fax	States and protectorates
I	John Courcier	617–918–1659	CT, ME, MA, NH, RI, VT.
	courcier.john@epa.gov	617–918–1505 (fax)	
II	Christine DeRosa	212–637–4022	NJ, NY, Puerto Rico, Virgin Islands.
	derosa.christine@epa.gov	212–637–3901 (fax)	
	Ted Gardella	212–637–3892	
	gardella.anthony@epa.gov	212–637–3901 (fax)	
III	James B. Topsale	215–814–2190	DE, DC, MD, PA, VA, WV.

TABLE 2.—EPA REGIONAL CONTACTS FOR HMIWI—Continued

Region	Regional contact	Phone/Fax	States and protectorates
	topsale.jim@epa.gov	215–814–2114 (fax)	
IV	Scott Davis	404–562–9127	AL, FL, GA, KY, MS, NC, SC, TN.
	davis.scottr@epa.gov	404–562–9095 (fax)	
V	Ryan Bahr	312–353–4366	IN.
	bahr.ryan@epa.gov	312–886–5824 (fax)	
	Charles Hatten	312–886–6031	WI.
	hatten.charles@epa.gov	312–886–5824 (fax)	
	Mark Palermo	312–886–6082	IL, OH.
	palermo.mark@epa.gov	312–886–5824 (fax)	
	Victoria Hayden	312–886–4023	WI.
	hayden.victoria@epa.gov	312–886–5824 (fax)	
	Doug Aburano	312–353–6960	MN.
	aburano.douglas@epa.gov	312–886–5824 (fax)	
VI	Mick Cote	214–665–7219	AR, LA, NM, OK, TX.
	cote.mick@epa.gov	214–665–7263 (fax)	
VII	Wayne Kaiser	913–551–7603	IA, KS, MO, NE.
	kaiser.wayne@epa.gov	913–551–7844 (fax)	
	Ward Burns	913–551–7960	
	burns.ward@epa.gov	913–551–7844 (fax)	
VIII	Meredith Bond	303–312–6438	CO, MT, ND, SD, UT, WY.
	bond.meredith@epa.gov	303–312–6064 (fax)	
IX	Patricia Bowlin	415–744–1188	AZ, CA, HI, NV, American Samoa, Guam.
	bowlin.patricia@epa.gov	415–744–1076 (fax)	
X	Catherine Woo	206–553–1814	AK, ID, OR, WA.
	woo.catherine@epa.gov	206–553–0110 (fax)	

Preamble Outline.

I. Background

A. HMIWI Regulations

On September 15, 1997, EPA promulgated emission guidelines for existing HMIWI under authority of sections 111 and 129 of the CAA. *See* 62 FR 48348 (to be codified at 40 CFR part 60, subpart Ce, §§ 60.30e through 60.39e). To make these emission guidelines enforceable, States with existing HMIWI were required to submit to EPA, within 1 year following promulgation of the emission guidelines, a State plan that implements and enforces the emission guidelines. States without any existing HMIWI were required to submit to the Administrator a letter of negative declaration certifying that there are no HMIWI in the State. No plan is required for States that do not have any HMIWI.

As discussed in section I.D of this preamble, Indian Tribes may, but are not required to, submit Tribal plans to cover HMIWI in Indian country. A Tribe may submit to the Administrator a letter of negative declaration certifying that no HMIWI are located in the Tribal area. No plan is required for Tribes that do not have any HMIWI.

Sections 111 and 129 of the CAA and 40 CFR 60.27(c) and (d) require EPA to develop, implement, and enforce a Federal plan to cover existing HMIWI located in States that do not have an approved plan. Hospital/medical/infectious waste incinerators located in States or Tribal areas that mistakenly submit a letter of negative declaration would be subject to the Federal plan until a State or Tribal plan that includes these HMIWI is approved and effective.

Today's action adopts a Federal plan for HMIWI that are not yet covered by an approved State or Tribal plan. The elements of the Federal plan are summarized in section II of this preamble. This HMIWI Federal plan was proposed in the **Federal Register** on July 6, 1999 (64 FR 36425). Comment letters on the proposed Federal plan were received through September 8, 1999. An opportunity for a public hearing was offered, but no requests were received and a public hearing was not held. Public comments and EPA responses are documented in ''Hospital/medical/Infectious Waste Incinerators: Background Information for Federal Plan—Summary of Public Comments and Responses,'' (EPA–456/R–00–003), Docket A–98–24, Item III–B–1. The EPA's responses to the public comments and changes to the regulation are also summarized in section III of this preamble.

B. Who This HMIWI Federal Plan Affects

This HMIWI Federal plan will affect existing HMIWI for which construction commenced on or before June 20, 1996.

The HMIWI will be subject to this Federal plan if any of the following is true on the effective date of the Federal plan:

(1) The State or Tribal plan has not become effective; [1]

(2) The State or Tribal plan was in effect but was subsequently vacated in whole or in part; or

(3) The State or Tribal plan was in effect but was subsequently revised such that it is no longer as protective as the emission guidelines.

The specific applicability of this plan is described in §§ 62.14400 through 62.14403 of subpart HHH.

Once an approved State or Tribal plan is in effect, the Federal plan will no longer apply to HMIWI covered by such plan. An approved State or Tribal plan is a plan that EPA has reviewed and approved based on the requirements in 40 CFR part 60, subpart B to implement and enforce 40 CFR part 60, subpart Ce. The State plan is effective on the date specified in the notice published in the **Federal Register** announcing EPA's approval.

Today's adoption of this HMIWI Federal plan does not preclude a State or Tribe from submitting a plan later. If a State or Tribe submits a plan after today's publication of the HMIWI Federal plan, EPA will review and approve or disapprove the State/Tribal plan. If EPA approves the plan, then the Federal plan no longer applies as of the effective date of the State/Tribal plan. (See the discussion in ''State or Tribe Submits A Plan After HMIWI Located in the Area Are Subject to the Federal Plan'' in section V.C.1 of this preamble.) If an HMIWI was overlooked by a State or Tribe and the State/Tribe submitted a negative declaration letter, the HMIWI would be subject to this Federal plan.

C. Implementing Authority

The EPA Regional Administrators have been delegated the authority for implementing the HMIWI Federal plan. All reports required by this Federal plan should be submitted to the appropriate Regional Office Administrator. Table 2 under **SUPPLEMENTARY INFORMATION** lists the names and addresses of the EPA Regional Office contacts and the States that they cover.

[1] The effective date of a State or Tribal plan from EPA's perspective (a State and Tribe may have an earlier effective date) is 30 days after the State or Tribal plan approval is published in the **Federal Register** if the approval is via the regular regulatory procedure of proposal with opportunity for comment followed by promulgation. If the approval is by direct final rule making, the effective date of the State/Tribal plan is 60 days after the approval is published in the **Federal Register** if no adverse comments are received.

D. HMIWI Federal Plan and Indian Country

The term ''Indian country,'' as used in this preamble, means (1) all land within the limits of any Indian reservation under the jurisdiction of the United States government, notwithstanding the issuance of any patent, and including rights-of-way running through the reservation; (2) all dependent Indian communities within the borders of the United States whether within the original or subsequently acquired territory thereof, and whether within or without the limits of a State; and (3) all Indian allotments, the Indian titles to which have not been extinguished, including rights-of-way running through the same.

The Tribal Authority Rule authorizes eligible Tribal governments to submit to EPA a Tribal plan for HMIWI (64 FR 7254, February 12, 1998). The Tribal Authority Rule also contains a discussion on the EPA's authority to implement Clean Air Act programs in Indian country. The Federal plan will apply throughout Indian country except where a Tribal plan has been explicitly approved by EPA to cover an area of Indian country. This approach is consistent with that in the proposed Federal Operating Permits Rule (62 FR 13747, March 21, 1997). The preamble to the proposed HMIWI Federal plan discussed and requested comments on application of the HMIWI Federal plan in Indian country. The EPA received no comments on this issue.

E. Status of State Plan Submittals

Sections 111(d) and 129(b)(2) of the CAA, as amended, 42 U.S.C. 7411(d) and 7429(b)(2), authorize EPA to develop and implement a Federal plan for HMIWI located in States with no approved and effective State plan. Table 3 summarizes the current status of State plans. The HMIWI covered in EPA-approved State plans are not subject to the HMIWI Federal plan, as of the effective date specified in the **Federal Register** notice announcing EPA's approval of the State plan. The EPA is not expecting State plans to be submitted by the States that submitted negative declarations. However, in the unlikely event that there are HMIWI located in these States, this Federal plan would automatically apply to them.

TABLE 3.—STATUS OF STATE PLANS

I. States with EPA-Approved State Plans.	Alabama, Alleghany County in Pennsylvania, Arizona, Colorado, Delaware, Georgia, Idaho, Illinois, Indiana, Iowa, Kansas, Louisiana, Mississippi, Missouri, Montana, Nebraska, New Hampshire, New York, North Dakota, South Dakota, Utah, West Virginia, and Wyoming.
II. Negative Declaration Submitted to EPA.	District of Columbia, Forsyth County in North Carolina, Huntsville in Alabama, Jefferson County in Kentucky, Nashville/Davidson County in Tennessee, Nevada, New Mexico, Oregon, and Vermont.
III. Final State Plan Submitted to EPA.	Florida, Maryland, and Pennsylvania.
IV. Draft State Plan Submitted to EPA.	Chattanooga/Hamilton County Tennessee, Knox County in Tennessee, Memphis/Shelby County in Tennessee, Michigan, Minnesota, New Jersey, Ohio, Oklahoma, Puerto Rico, Rhode Island, South Carolina, Texas, and Virginia.

The EPA is currently reviewing final and draft State plans submitted by the States listed in parts III and IV of Table 3. The Federal plan covers HMIWI in these States until these State plans are approved by EPA and become effective. Other States are making significant progress on their State plans and EPA expects many State plans to be approved in the next several months. As Regional Offices approve State plans, they will also, in the same action, amend the appropriate subpart of 40 CFR part 62 to codify their approvals. The EPA is not aware of any Indian Tribes that are developing Tribal plans.

The EPA will maintain a list of State plan submittals and approvals on the Unified Air Toxics Website at http://www.epa.gov/ttn/uatw/129/hmiwi/rihmiwi.html. The list will help HMIWI owners or operators determine whether their HMIWI is affected by a State plan, a Tribal plan, or the Federal plan. Hospital/medical/infectious waste incinerator owners and operators can also contact the EPA Regional Office for the State in which their HMIWI is located to determine whether there is an approved and effective State plan in place.

II. Required Elements of the HMIWI Federal Plan

Sections 111(d) and 129 of the CAA, as amended, 42 U.S.C. 7411(d) and

7429(b)(2), require States to develop and implement State plans for HMIWI to implement and enforce the promulgated emission guidelines. Subparts B and Ce of 40 CFR part 60 require States to submit State plans that include specified elements. Because this Federal plan is being adopted in lieu of State plans, it includes the same essential elements: (1) Identification of legal authority and mechanisms for implementation, (2) inventory of HMIWI, (3) emissions inventory, (4) emission limits, (5) compliance schedules, (6) public hearing requirements, (7) testing, monitoring, inspection, reporting, and recordkeeping requirements, (8) waste management plan requirements, (9) operator training and qualification requirements, and (10) progress reporting. Each State plan element was discussed in detail as it relates to the Federal plan in the preamble to the proposed rule (64 FR 36425). Table 4 lists each element and identifies where it is located or codified. The EPA received public comments on the mechanisms for implementation, inspection requirements, compliance schedules, and title V permitting requirements. A summary of these comments and EPA's responses is presented in section III of this preamble.

TABLE 4.—REQUIRED ELEMENTS AND LOCATION

Required element of the HMIWI Federal plan	Where located
Identification of legal authority and mechanisms for implementation.	Section 129(b)(3) of the CAA.
Identification of mechanisms for implementation.	Section V of this preamble.
Inventory of HMIWI ...	Docket A–98–24, Item II–B–1.
Emissions inventory ..	Docket A–98–24, Item II–B–1.
Emission limits	40 CFR 62.14410 to 62.14413 of subpart HHH.
Compliance schedules.	40 CFR 62.14470 to 62.14472 of subpart HHH.
Public hearing requirements.	Section II.I of 64 FR 36431, July 6, 1999.
Testing and monitoring requirements.	40 CFR 62.14450 to 62.14455 of subpart HHH.
Inspection requirements.	40 CFR 62.14440 to 62.14443 of subpart HHH.
Reporting and recordkeeping requirements.	40 CFR 62.14460 to 62.14465 of subpart HHH.
Waste management plan requirements.	40 CFR 62.14430 to 62.14432 of subpart HHH.
Operator training and qualification requirements.	40 CFR 62.14420 to 62.14425 of subpart HHH.
Progress reports	Section II.J of 64 FR 36431, July 6, 1999.

III. Considerations in Developing the Final Federal Plan

This section of the preamble summarizes the changes to the HMIWI Federal plan considered as a result of the public comments received on the proposed plan. There were six comments received on the proposed Federal plan. The majority of the comments addressed minor inconsistencies between the emission guidelines promulgated on September 15, 1997 and the proposed Federal plan. Three areas (the compliance schedule; title V operating permit requirements for incinerators burning only pathological waste, low-level radioactive waste, and/or chemotherapeutic waste, and co-fired combustors; and delegation of authority) are addressed in detail in the following discussion. The public comments in their entirety are summarized and addressed in the promulgation background information document (EPA–456/R–00–003, Docket A–98–24, Item III–B–1).

A. Compliance Schedule

During the public comment period one commenter expressed concern over the uncertainties associated with the March 2, 1999 U.S. Court of Appeals decision concerning the emission limits for existing HMIWI. The commenter stated that the court decision has created enough uncertainty with respect to the final emission limits and that compliance with the emission limits in the Federal plan should not be required until the Federal court is satisfied. The Sierra Club and Natural Resources Defense Council (NRDC) challenged EPA's rule establishing HMIWI standards, complaining principally that EPA failed to comply with the specifications of the maximum achievable control technology (MACT) floors for new and existing HMIWI. Although the court rejected the petitioners' statutory construction challenge, the court did conclude that there are serious doubts about the reasonableness of EPA's treatment of the floor requirements, and remanded the rule for further explanation. The court decided not to vacate the standard. Rather, the current regulation remains in place as requested by Sierra Club and NRDC. In light of the court decision, EPA is obligated to adhere to the compliance schedule set forth in the Emission Guidelines. Therefore, the EPA must promulgate the final Federal plan as scheduled.

B. Title V Permitting Requirements

One commenter objected to EPA's proposal to exempt both co-fired combustors and HMIWI that combust only pathological, low-level radioactive, and/or chemotherapeutic waste from title V permitting requirements. The commenter indicated that EPA's interpretation of title V applicability conflicts with the requirements of both section 502(a) and section 129(e) of the CAA. The commenter noted that section 502(a) requires sources subject to standards under section 111 to obtain title V permits. In addition, section 129(e) requires that ''Beginning (1) 36 months after the promulgation of a performance standard * * * each unit in the category shall operate pursuant to a permit issued under this subsection and title V.'' The commenter interpreted EPA's position as follows: If co-fired combustors (as defined in section 62.14490 of subpart HHH) and HMIWI combusting only pathological waste, low-level radioactive waste, and/or chemotherapeutic waste (also defined in section 62.14490 of subpart HHH) comply with their recordkeeping obligations, they need not obtain a title V permit. However, if they fail to keep the required records, they must obtain a title V permit. The commenter mentioned that general title V permits could be crafted to reduce the burden of title V permitting for these exempt sources.

The commenter pointed out that under EPA's proposal not to require title V permits for these sources, control agencies and the public will not be able to determine whether the sources are keeping the proper records; records which are the basis for creating and continuing the exemption from title V permitting. The commenter stated that nothing in the proposed rule requires sources to submit summaries of the required records or to certify that they are keeping the records. The commenter noted that if a title V permit were required, sources would be required to certify that they are conducting the required recordkeeping. The commenter requested that EPA either require sources to obtain title V permits or

adopt an equally enforceable and transparent mechanism to require sources to certify that they are conducting the required recordkeeping and to ensure that citizens can access information relevant to the obligation to keep such records. The commenter noted that if these records are maintained onsite at a source, then the relevant agency may take the position that the records are not subject to disclosure under ''freedom of information'' laws. Therefore, the commenter requested that this rule: (1) Require these sources to submit these records to the appropriate public authority on request; and (2) require that EPA, State and local agencies adopt rules providing that the relevant agency will request these records from sources if they are requested by the public.

A second commenter disagreed with EPA's assessment that reporting and recordkeeping requirements are not substantive elements of the HMIWI rule for purposes of title V even though pathological, low-level radioactive, and chemotherapeutic wastes are being considered under the Industrial Combustion Coordinated Rulemaking (ICCR). The commenter noted that recordkeeping and reporting supplies the agency with vital information to ensure that rules are functioning as intended and helps to supply data needed to develop new rules such as the ICCR. In addition, recordkeeping and reporting require a significant amount of employee time and facility dollars.

The second commenter stated that the CAA requires specific reasons for a decision by EPA that a source should not be required to file a title V permit. The commenter noted that section 502(a) of the CAA states that EPA may exempt a source in one or more source categories if EPA finds that ''compliance with such requirements is impracticable, infeasible, or unnecessarily burdensome on such categories. * * *'' However, the law does not state that EPA may exempt a source category when only recordkeeping and reporting are required. The commenter noted that requiring co-fired combustors and HMIWI combusting only pathological waste, low-level radioactive waste, and/or chemotherapeutic waste to file a title V permit application may not be practicable at this time because EPA may develop a rule with specific emission limits for these sources in the near future. However, the commenter stated that offering these types of sources several years of additional time to come into compliance without requiring that they take some action towards understanding their obligations under the CAA is inappropriate.

The EPA disagrees with both commenters' views concerning this Federal plan. The Federal plan requires owners or operators of HMIWI combusting only pathological waste, low-level radioactive waste, and/or chemotherapeutic waste and co-fired combustors to fulfill certain recordkeeping and reporting requirements to demonstrate that they are exempt from the emission control-related requirements of the Federal plan. These emission control-related requirements include emission limits; waste management plan requirements; operator training and qualification requirements; inspection requirements; compliance and performance testing requirements; monitoring requirements; and the emission control-related reporting and recordkeeping requirements, but not the reporting and recordkeeping requirements related to the applicability of the Federal plan and necessary for these sources to demonstrate exemption.

The reporting and recordkeeping requirements that these sources must fulfill (in section 62.14400 [Applicability] of subpart HHH) differ from the emission control-related reporting and recordkeeping requirements (in sections 62.14460 through 62.14465 [Reporting and Recordkeeping] of subpart HHH) of the Federal plan. Section 62.14400 requires owners or operators of HMIWI that combust only pathological waste, low-level radioactive waste, and/or chemotherapeutic waste and owners or operators of co-fired combustors to submit a one-time notification of an exemption claim. In addition to this exemption claim, owners or operators of HMIWI that combust only pathological waste, low-level radioactive waste, and/or chemotherapeutic waste must keep records on a calendar quarter basis of the periods of time when these types of waste are the only types of waste combusted. Owners or operators of co-fired combustors must keep records on a calendar quarter basis of the weight of hospital waste and medical/infectious waste combusted and the weight of all other fuels and wastes combusted. The emission control-related reporting and recordkeeping requirements for HMIWI include notifications, records, and reports pertaining to waste management, parameter monitoring, operator training, inspections, and performance testing.

The EPA interprets CAA section 502(a) and 40 CFR 70.3(a)(2) and 71.3(a)(2) to mean that sources subject to this exemption (HMIWI combusting only pathological waste, low-level radioactive waste, and/or chemotherapeutic waste, and co-fired combustors) are not subject to standards or regulations under section 111 for purposes of title V permitting. The Agency believes that the recordkeeping and reporting requirements with which these facilities must comply if they are to attain and maintain their exemptions are not the type of requirements that make them ''subject to'' a standard or regulation under section 111 within the meaning of the first sentence of section 502(a). In EPA's view, facilities in this unique position do not even meet the threshold criteria for sources required to obtain title V permits under section 502(a) of the CAA. Therefore, these sources are not required to apply for title V permits on the basis of the applicability of recordkeeping and reporting requirements necessary to qualify for exemption from the emission control-related requirements of the Federal plan. (Although these recordkeeping and reporting requirements do not trigger the requirement to apply for a title V permit, they must be incorporated into any title V permit these sources may be required to obtain for reasons other than subpart HHH.) However, owners and operators of these sources that do not comply with the recordkeeping and reporting requirements necessary to attain and maintain exemption from the Federal plan will become subject to the emission control-related requirements and will have to obtain title V permits. While HMIWI combusting pathological, low-level radioactive, and/or chemotherapeutic waste and co-fired combustors subject to this exemption need not obtain title V permits now as a matter of Federal law, they are not prohibited from applying for title V permits.

As the second commenter stated, section 502(a) of the CAA also provides a mechanism for the Administrator to ''promulgate regulations to exempt'' one or more source categories from title V permitting requirements, if EPA finds that compliance with such requirements is ''impracticable, infeasible, or unnecessarily burdensome on such categories, except that the Administrator may not exempt any major source from such requirements.'' The EPA is not invoking this mechanism to justify its conclusion that facilities subject to exemptions from emissions-control related requirements are not required to obtain title V permits. These facilities have not been ''exempted'' from title V within the meaning of the last sentence of section 502(a), and the Agency has not made or does not purport to have

made the statutory showing of impracticability, infeasibility or unnecessary burden for these sources. Rather, as stated earlier, the Agency believes that the recordkeeping and reporting requirements with which these facilities must comply are not the type that would make them ''subject to'' a standard under section 111 or 502(a) of the CAA. These reporting and recordkeeping requirements are simply conditions for exemption from the emission control-related requirements of the Federal plan.

Under the Federal plan sources are not required to routinely submit to EPA the records they are required to maintain onsite to support their exemption from the section 129 standard. However, we are adding two provisions to the regulation to facilitate public access to those records. First, the regulation requires in §§ 62.14400(b)(1) and (b)(2) that these sources must submit these records to EPA upon request. Second, the regulation requires in § 62.14400(c) that EPA request these records from these sources if requested by a citizen under the Freedom of Information Act, consistent with EPA regulations set forth at 40 CFR part 2. Should a State take delegation of the Federal plan rather than submitting an approvable State plan, the State would have the obligation to obtain these records from sources following receipt of a citizen request under applicable freedom of information laws (comparable to the Freedom of Information Act) and make such information available to the requestor.

Additionally, to clarify what the records maintained by co-fired combustors must contain in order for an exemption from the emission control-related requirements of subpart HHH and title V permitting to be allowed, we have added language to § 62.14400(b)(2). Language in this section states that the records maintained by the owner or operator of a co-fired combustor must reflect that the source continues to meet the definition of co-fired combustor in § 62.14490. Language has been added to § 62.14400(c) stating that the records required by paragraphs (b)(1) and (b)(2) of § 62.14400 must be maintained by the relevant sources for a period of at least 5 years. Language has also been added to § 62.14400(c) stating that the notifications of exemption claims also required by paragraphs (b)(1) and (b)(2) of § 62.14400 must be maintained by the EPA or delegated enforcement authority for a period of at least 5 years. Such notifications are to be made available upon request.

C. Transfer of Authority

One commenter raised the question of whether the authority to implement the Federal plan could be transferred to States and local agencies through the title V operating permits program. The commenter noted that part IV of the preamble to the proposed Federal plan (in section C on page 36432) describes two mechanisms for transferring authority to State and local agencies and that part V of the preamble discusses title V operating permits programs. These two mechanisms as described on page 36432 of the proposed Federal plan are (1) the approval of a State plan after the Federal plan is in effect; and (2) if a State does not submit or obtain approval of its own plan, EPA delegation to a State of the authority to implement certain portions of the HMIWI Federal plan. The commenter recommended that the preamble to the final Federal plan recognize the title V operating permits program as a third mechanism for transferring authority to State and local agencies. The commenter noted that many State and local agencies implement title V programs and that title V permits must include the requirements of the Federal plan. Thus, title V permitting authorities already have implementation responsibility for the Federal plan through the title V permits program, regardless of whether the authority to implement the Federal plan is delegated to the State or local agency. The commenter stated that the authority to implement the Federal plan would be most useful before a title V permit is issued. The commenter stated that the time required for a State to request and obtain authority to implement the Federal plan through delegation is similar to the lead time required in the Federal plan for submitting title V permit applications. The commenter requested an explanation of why delegation of the Federal plan is necessary if a title V program is in place.

There are legal and practical reasons why incorporating a standard into a permit without formal delegation is not equivalent to taking formal delegation and then issuing a part 70 permit containing the standard. The Act and part 70 require States, local agencies, or Tribes wishing to adopt a part 70 permitting program to have the legal authority to place all applicable requirements (including HMIWI standards) in permits and to implement and enforce them in that context. However, this requirement is not legally equivalent to formal delegation, nor does it take the place of formal delegation. When a State takes formal delegation, EPA allows the State to implement and enforce a standard independent of a title V permit. This is significant because a title V source may be allowed to operate without a title V permit for a number of years in some cases between the time it first triggers the requirement to apply for a permit and the issuance of the permit. Prior to the issuance of a part 70 permit and absent formal delegation, the State may not implement and enforce the requirements of a standard. Moreover, a source with a title V permit with a permit term less than 3 years is not required by part 70 to reopen the permit to include new applicable requirements, such as the HMIWI standard. See 40 CFR § 70.7(f)(1)(i). However, the source must still comply with that standard. Delegation enables a State to implement and enforce the standard outside of the permit until permit renewal.

The commenter also mentioned that the last statement in part IV of the preamble to the proposed Federal plan, which indicates that EPA would retain responsibility for enforcement after delegation, should be qualified to reflect State and local enforcement responsibility after a title V permit is issued. The commenter questioned whether EPA or the State and local title V permitting authorities would have enforcement responsibilities for the Federal plan after a title V permit is issued to a source.

The EPA first notes that the language in the proposal preamble to which the commenter refers was errant and has been deleted from the preamble to the final rule. Rather, EPA's position on this issue is accurately reflected in the same part of the proposal preamble (part IV) that the commenter references under the section titled ''Delegation of the Federal Plan and Retained Authorities'': ''The EPA will continue to hold enforcement authority along with the State or Tribe even when a State or Tribe has received delegation of the Federal plan.'' Moreover, the retained authorities discussion immediately following this sentence in the proposal preamble does not address enforcement of the Federal plan, and § 62.14495 of the proposed and final rules does not include enforcement of the Federal plan as an authority retained by the EPA Administrator. In fact, both State and Tribal permitting authorities that have taken delegation, as well as the EPA, will have responsibility for bringing enforcement actions against sources violating Federal plan requirements. Prior to delegation, only the EPA will have enforcement authority. In neither instance does the title V permit status of a source affect the enforcement

responsibility of EPA and the State or Tribal permitting authorities.

IV. Summary of Federal Plan Requirements

The HMIWI Federal rule (40 CFR part 62, subpart HHH) which implements this Federal plan includes emission limits, monitoring and performance testing requirements, inspection requirements (for small rural HMIWI only), waste management plan requirements, operator training and qualification requirements, and recordkeeping and reporting requirements. The requirements are summarized in this section.

A. Applicability

The HMIWI Federal plan applies to existing HMIWI that either are not covered by an approved and effective State or Tribal plan or are located in a State or Tribal area that has incorrectly submitted a negative declaration. An existing HMIWI is an HMIWI for which construction commenced on or before June 20, 1996. Hospital/medical/infectious waste incinerators for which construction commenced after June 20, 1996 or modification commenced after March 16, 1998 are not subject to the Federal plan; they are new sources and are subject to 40 CFR part 60 subpart Ec New Source Performance Standards (NSPS). An HMIWI is defined as any device that combusts any amount of medical/infectious waste or hospital waste. The terms ''medical/infectious waste'' and ''hospital waste'' are defined in § 62.14490 of subpart HHH.

Incinerators that burn only pathological, low-level radioactive, or chemotherapeutic waste (all defined in § 62.14490 of subpart HHH) are not subject to the emission control-related requirements of the Federal plan during periods when they burn such wastes provided that they notify EPA of an exemption claim and keep records of the periods of time when only pathological, low-level radioactive, or chemotherapeutic waste is burned. Existing incinerators, processing operations, or boilers that cofire hospital waste and/or medical/infectious waste with other fuels or wastes and combust 10 percent or less combined medical/infectious and hospital waste by weight (on a calendar quarter basis) are also not subject to the emission control-related requirements of the Federal plan provided they file an exemption claim and keep records of the amounts of each fuel and waste burned. Any unit required to have a permit under section 3005 of the Solid Waste Disposal Act is exempt from the Federal plan, as are municipal waste combustors subject to 40 CFR 60 subparts Cb, Ea, or Eb. Finally, pyrolysis units (as defined in § 62.14490 of subpart HHH) and cement kilns firing hospital waste and/or medical/infectious waste are also not subject to this Federal plan.

The HMIWI source category is divided into small (≤200 lb/hr), medium (>200 to 500 lb/hr), and large (>500 lb/hr) subcategories based on waste burning capacity. Waste burning capacity is determined either by the maximum design capacity or by the ''maximum charge rate'' established during the most recent performance test. In other words, a source may change its size designation by establishing an enforceable ''maximum charge rate'' lower than its design capacity. For example, a ''medium'' unit with a design capacity of 250 lb/hr may establish a maximum charge rate of 200 lb/hr and be considered a ''small'' unit for purposes of the Federal plan. Separate requirements apply to each subcategory of existing HMIWI.

B. Emission Limits

Table 5 provides the emission limits for existing HMIWI covered by the Federal plan. In addition to the emission limits presented in Table 5, all HMIWI are subject to a 10 percent stack opacity limitation. Stack opacity will be determined using EPA Reference Method 9.

The Federal plan contains alternative emission limits for small HMIWI that meet the following ''rural criteria': (1) The small HMIWI is located at least 50 miles from the nearest Standard Metropolitan Statistical Area (SMSA) boundary; and (2) the small HMIWI burns no more than 2,000 pounds of hospital waste and medical/infectious waste per week. For this Federal plan, the list of areas comprising each SMSA as of June 30, 1993 (defined by the Office of Management and Budget [OMB]) will be used to determine whether a small HMIWI meets the ''rural criteria.'' The list of areas comprising each SMSA is presented in OMB Bulletin No. 93–17 entitled ''Revised Statistical Definitions for Metropolitan Areas.'' This document is available for public inspection and copying at EPA's Air and Radiation Docket and Information Center (Docket A–91–61, Item IV–J–125). See the **ADDRESSES** section at the beginning of this preamble for the telephone number and location of the docket. In addition, OMB Bulletin No. 93–17 is available at: http://www.census.gov/population/estimates/ metro-city/93mfips.txt, or from National Technical Information Services, 5285 Port Royal Road, Springfield, Virginia 22161, (703) 487–4650 (document number PB 93–192–664). The emission limits for small HMIWI that meet the rural criteria are provided in Table 6.

TABLE 5.—SUMMARY OF FEDERAL PLAN EMISSION LIMITS FOR HMIWI

Pollutant	Emission limits		
	Small HMIWI	Medium HMIWI	Large HMIWI
Particulate matter	115 mg/dscm (0.05 gr/dscf)	69 mg/dscm (0.03 gr/dscf)	34 mg/dscm (0.015 gr/dscf).
Carbon monoxide	40 ppmv	40 ppmv	40 ppmv.
Dioxins/furans	125 ng/dscm total CDD/CDF (55 gr/10^9 dscf) or 2.3 ng/dscm TEQ (1.0 gr/10^9 dscf).	125 ng/dscm total CDD/CDF (55 gr/10^9 dscf) or 2.3 ng/dscm TEQ (1.0 gr/10^9 dscf).	125 ng/dscm total CDD/CDF (55 gr/10^9 dscf) or 2.3 ng/dscm TEQ (1.0 gr/10^9 dscf).
Hydrogen chloride	100 ppmv or 93% reduction	100 ppmv or 93% reduction	100 ppmv or 93% reduction.
Sulfur dioxide	55 ppmv	55 ppmv	55 ppmv.
Nitrogen oxides	250 ppmv	250 ppmv	250 ppmv.
Lead	1.2 mg/dscm (0.52 gr/10^3 dscf) or 70% reduction.	1.2 mg/dscm (0.52 gr/10^3 dscf) or 70% reduction.	1.2 mg/dscm (0.52 gr/10^3 dscf) or 70% reduction.
Cadmium	0.16 mg/dscm (0.07 gr/10^3 dscf) or 65% reduction.	0.16 mg/dscm (0.07 gr/10^3 dscf) or 65% reduction.	0.16 mg/dscm (0.07 gr/10^3 dscf) or 65% reduction.
Mercury	0.55 mg/dscm (0.24 gr/10^3 dscf) or 85% reduction.	0.55 mg/dscm (0.24 gr/10^3 dscf) or 85% reduction.	0.55 mg/dscm (0.24 gr/10^3 dscf) or 85% reduction.

TABLE 6.—SUMMARY OF EMISSION LIMITS FOR SMALL HMIWI THAT MEET THE RURAL CRITERIA

Pollutant	Emission limits
Particulate matter.	197 mg/dscm (0.086 gr/dscf).
Carbon monoxide.	40 ppmv.
Dioxins/furans	800 ng/dscm total CDD/CDF (350 gr/10^9 dscf) or 15 ng/dscm TEQ (6.6 gr/10^9 dscf).
Hydrogen chloride.	3,100 ppmv.
Sulfur dioxide	55 ppmv.
Nitrogen oxides.	250 ppmv.
Lead	10 mg/dscm (4.4 gr/10^3 dscf).
Cadmium	4 mg/dscm (1.7 gr/10^3 dscf).
Mercury	7.5 mg/dscm (3.3 gr/10^3 dscf).

C. Additional Requirements

This section presents the other major provisions of the Federal plan for HMIWI. With the exception of the emission limits referenced above and the compliance and performance testing requirements and the inspection requirements described in this section, HMIWI that meet the small rural criteria are to comply with the same additional requirements as all other existing HMIWI. This section does not attempt to show all requirements of the Federal plan. The regulatory text of subpart HHH contains a full and comprehensive statement of the requirements of the Federal plan.

The Federal plan contains operator training and qualification requirements for all HMIWI. Each facility is required to have at least one trained and qualified operator on duty or on-call. The trained and qualified operator must pass an HMIWI operator training course and meet qualification requirements. Also, each facility is required to develop site-specific HMIWI operating procedures. Employees involved with HMIWI operation must review the site-specific operating information annually.

The Federal plan requires all facilities to develop a waste management plan that identifies the feasibility and approach of separating certain components of the healthcare waste stream in order to reduce the amount of toxic emissions from incinerated waste.

The compliance and performance testing requirements in the Federal plan differ for small rural HMIWI and for all other HMIWI. Small rural HMIWI are required to conduct an initial performance test to determine compliance with the PM, CO, CDD/CDF, and Hg emission limits and opacity limit, and to establish operating parameters. In addition, small rural HMIWI are required to conduct annual tests to determine compliance with the opacity limit.

The compliance and performance testing requirements in the Federal plan require facilities with small non-rural, medium, and large HMIWI to conduct an initial performance test to determine compliance with the PM, CO, CDD/CDF, HCl, Pb, Cd, and Hg emission limits and the opacity limit, and to establish operating parameters. These HMIWI are also required to conduct annual performance tests to determine compliance with the PM, CO, and HCl emission limits and opacity limit. The Federal plan allows facilities to conduct performance tests for PM, CO, and HCl every third year if the previous three performance tests demonstrate that the facility is in compliance with the emission limits for PM, CO, and HCl.

The Federal plan contains monitoring requirements for all HMIWI. Each facility is required to install and maintain equipment to continuously monitor operating parameters including secondary chamber temperature, waste feed rate, use of the bypass stack, and Air Pollution Control Device (APCD) operating parameters as appropriate. The Federal plan requires facilities to obtain monitoring data at all times during HMIWI operation.

In addition, the Federal plan contains reporting and recordkeeping requirements for all HMIWI. Facilities are required to maintain records for 5 years of results from the initial performance test and all subsequent performance tests, monitored operating parameters, inspections (small rural HMIWI only), and operator training and qualification. Facilities are required to submit the results of the initial performance test and all subsequent performance tests, and to submit reports on emission rates or operating parameters that have not been recorded or which exceeded applicable limits.

D. Compliance Dates

1. HMIWI That Continue Operation

The Federal plan requires owners or operators of HMIWI to either: (1) Come into compliance with the plan within 1 year after the plan is promulgated (by August 15, 2001); or (2) meet increments of progress and come into compliance by September 15, 2002. Increments of progress are necessary in order to ensure that HMIWI needing more time to comply are making progress toward meeting the emission limits. This HMIWI Federal plan includes as its compliance schedule the same five increments of progress from 40 CFR 60.21(h), as required by 40 CFR 60.24(e)(1), along with defined and enforceable dates for completion of each increment.

The HMIWI owner or operator is responsible for meeting each of the five increments of progress for each HMIWI no later than the applicable compliance date. The owner or operator must notify EPA as each increment of progress is achieved, as well as when any is missed. The notification must identify the increment and the date the increment is achieved (or missed). If an owner or operator misses an increment deadline, the owner or operator must also notify EPA when the increment is finally achieved. The owner or operator must mail the notification to the applicable EPA Regional Office within 10 business days after the increment date defined in the Federal plan. (See Table 1 under the **FOR FURTHER INFORMATION CONTACT** section of this document for a list of Regional Offices.)

The definition of each increment of progress, along with its required completion date, follows.

Submit Final Control Plan. To meet this increment, the owner or operator of each HMIWI must submit a plan that describes, at a minimum, the APCD and/or process changes that will be employed so that each HMIWI complies with the emission limits and other requirements. A final control plan is not required for units that will be shut down. *Completion date*: September 15, 2000.

Award Contract. To award a contract means the HMIWI owner or operator enters into legally binding agreements or contractual obligations that cannot be canceled or modified without substantial financial loss to the owner or operator. The EPA anticipates that the owner or operator may award a number of contracts to complete the retrofit. To meet this increment of progress, the HMIWI owner or operator must award a contract or contracts to initiate onsite construction, to initiate onsite installation of air pollution control devices, and/or to incorporate process changes. The owner or operator must mail a copy of the signed contract(s) to EPA within 10 business days of entering the contract(s). *Completion date*: April 15, 2001.

Begin Onsite Construction. To begin onsite construction, installation of air pollution control devices, or process change means to begin any of the following:

(1) Installation of an air pollution control device in order to comply with the final emission limits as outlined in the final control plan;

(2) Physical preparation necessary for the installation of an air pollution control device in order to comply with the final emission limits as outlined in the final control plan;

(3) Alteration of an existing air pollution control device in order to comply with the final emission limits as outlined in the final control plan;

(4) Alteration of the waste combustion process to accommodate installation of an air pollution control device in order to comply with the final emission limits as outlined in the final control plan; or

(5) Process changes identified in the final control plan in order to meet the emission standards. *Completion date:* December 15, 2001.

Complete Onsite Construction. To complete onsite construction means that all necessary air pollution control devices or process changes identified in the final control plan are in place, onsite, and ready for operation on the HMIWI. *Completion date:* July 15, 2002.

Final Compliance. To be in final compliance means to incorporate all process changes or complete retrofit construction in accordance with the final control plan and to connect the air pollution control equipment or process changes such that, if the HMIWI is brought on line, all necessary process changes or air pollution control equipment will operate as designed. *Completion date:* September 15, 2002.

If an HMIWI does not achieve final compliance by September 15, 2002, the Federal plan requires the HMIWI to shut down by September 15, 2002, complete the retrofit while not operating, and be in compliance upon restarting. Shut down is necessary in order to avoid being out of compliance and subject to possible enforcement action.

2. HMIWI That Have or Will Shut Down

a. *Inoperable HMIWI and HMIWI That Shut Down.* In cases where an HMIWI has been shut down and there are no plans to restart, the HMIWI may be left off the source inventory for this Federal plan if it is rendered inoperable. The HMIWI owner/operator may do one or more of the following to render an HMIWI inoperable: (1) Weld the waste charge door shut, (2) remove stack (and by-pass stack, if applicable), (3) remove combustion air blowers, and/or (4) remove burners or fuel supply.

Any owner or operator that plans to shut down their HMIWI rather than comply with the Federal plan requirements must do so by August 15, 2001, the date 1 year after the Federal plan is promulgated. The Federal plan contains provisions allowing HMIWI owners or operators that are planning to shut down the opportunity to petition EPA for an extension beyond the 1-year compliance date (but no later than September 15, 2002). An example of a facility that might petition EPA for such an extension is a facility installing an onsite alternative waste treatment technology. It is possible that installation cannot be completed within 1 year, and the facility has no feasible waste disposal options other than onsite incineration while the alternative technology is being installed. The requirements for a petition for an extension to shut down under the Federal plan are set forth at section 62.14471 of subpart HHH.

All HMIWI that continue to operate 1 year after the Federal plan promulgation date must comply with the operator training and qualification requirements and the inspection requirements of the plan within 1 year after the plan is promulgated. This requirement includes HMIWI that comply within 1 year, as well as those that have been granted an extension beyond the 1-year compliance date (i.e., HMIWI with extended retrofit schedules and HMIWI granted an extension to shut down after the 1-year compliance date).

b. *HMIWI That Have Shut Down and Will Restart.*

Hospital/medical/infectious waste incinerators that are known to have already shut down (but are not known to be inoperable) are included in the source inventory for this Federal plan.

Restarting Before September 15, 2002. If the owner or operator of an inactive HMIWI plans to restart before September 15, 2002, the Federal plan requires the owner or operator to submit a control plan for the HMIWI and bring the HMIWI into compliance with the applicable compliance schedule. Final compliance is required for all pollutants and all HMIWI no later than September 15, 2002.

Restarting After September 15, 2002. Under this Federal plan, a control plan is not needed for inactive HMIWI that restart after September 15, 2002. However, before restarting, such HMIWI must complete the operator training and qualification requirements and inspection requirements (if applicable) and complete retrofit or process modifications upon restarting. Performance testing to demonstrate compliance would be required within 180 days after restarting. There is no need to show that the increments of progress have been met since these steps will have occurred before restart while the HMIWI was shut down and not generating emissions. An HMIWI that operates out of compliance after September 15, 2002 will be in violation of the Federal plan and subject to enforcement action.

3. Summary of Compliance Dates

A summary of dates for compliance with the Federal plan for HMIWI is presented in Table 7.

TABLE 7.—COMPLIANCE TIMES UNDER THE FEDERAL PLAN FOR ALL HMIWI

Requirement	Compliance time
Operator training and qualification.	Within 1 year after promulgation of the Federal plan (for HMIWI that continue to operate beyond 1 year after promulgation).
Waste management plan.	Within 60 days after initial performance test.
Final compliance with emission limits.	Within 1 year after promulgation of the Federal plan or by September 15, 2002 if the source is granted an extension.
Initial performance test.	Within 180 days after achieving final compliance.
Repeat performance test.	Within 12 months following initial performance test and annually thereafter [a].
Parameter monitoring	Continuously, upon completion of initial performance test.
Inspection (small rural HMIWI only).	Within 1 year after promulgation of the Federal plan (for HMIWI that continue to operate beyond 1 year after promulgation).
Recordkeeping	Continuously, upon completion of initial performance test.
Reporting	Within 60 days after initial performance test; annually for subsequent reporting requirements; semiannually, if noncompliance.

[a] Facilities may conduct performance tests for PM, CO, and HCl every third year if the previous three performance tests demonstrate that the facility is in compliance with the emission limits for PM, CO, and HCl.

V. Implementation of the Federal Plan and Delegation

A. Background of Authority

Under sections 111(d) and 129(b) of the CAA, EPA is required to adopt emission guidelines that are applicable to existing solid waste incineration sources. These emission guidelines are not enforceable until EPA approves a

State or Tribal plan or adopts a Federal plan that implements and enforces them, and the State, Tribal, or Federal plan has become effective. As discussed above, the Federal plan regulates HMIWI in States or Tribal areas that do not have approved plans in effect.

Congress has determined that the primary responsibility for air pollution prevention and control rests with State and local agencies. *See* section 101(a)(3) of the CAA. Consistent with that overall determination, Congress established sections 111 and 129 of the CAA with the intent that the States and local agencies take the primary responsibility for ensuring that the emission limitations and other requirements in the emission guidelines are achieved. Also, in section 111(d) of the CAA, Congress explicitly required that EPA establish procedures that are similar to those under section 110(c) for State Implementation Plans. Although Congress required EPA to propose and promulgate a Federal plan for States that fail to submit approvable State plans on time, EPA strongly encourages States to submit approvable plans. The EPA strongly encourages States that are unable to submit approvable plans to request delegation of the Federal plan so that they can have primary responsibility for implementing the emission guidelines, consistent with Congress' intent.

Approved and effective State plans or delegation of the Federal plan is EPA's preferred outcome since EPA believes that State and local agencies not only have the responsibility to carry out the emission guidelines, but also have the ''insider'' knowledge and enforcement resources critical to achieving the highest rate of compliance. For these reasons, EPA will do all that it can to expedite delegation of the Federal plan to State and local agencies, whenever possible.

The EPA also believes that Indian Tribes are the primary parties responsible for regulating air quality within Indian country. See EPA's Indian Policy (''Policy for Administration of Environmental Programs on Indian Reservations,'' signed by William D. Ruckelshaus, Administrator of EPA, dated November 4, 1984), reaffirmed in a 1994 memorandum (''EPA Indian Policy,'' signed by Carol M. Browner, Administrator of EPA, dated March 14, 1994).

B. Delegation of the Federal Plan and Retained Authorities

If a State or Indian Tribe intends to take delegation of the Federal plan, the State or Indian Tribe must submit to the appropriate EPA Regional Office a written request for delegation of authority. The State or Indian Tribe must explain how it meets the criteria for delegation. *See generally* ''Good Practices Manual for Delegation of NSPS and NESHAP'' (EPA, February 1983). In order to obtain delegation, an Indian Tribe must also establish its eligibility to be treated in the same manner as a State (see section I.D of the preamble). The letter requesting delegation of authority to implement the Federal plan must demonstrate that the State or Tribe has adequate resources, as well as the legal and enforcement authority to administer and enforce the program. As mentioned in section III.C, an MOA between the State or Tribe and the EPA would set forth the terms and conditions of the delegation, the effective date of the agreement, and would also serve as the mechanism to transfer authority. Upon signature of the agreement, the appropriate EPA Regional Office would publish an approval notice in the **Federal Register**, thereby incorporating the delegation authority into the appropriate subpart of 40 CFR part 62.

If authority is not delegated to a State or Indian Tribe, EPA will implement the Federal plan. Also, if a State or Tribe fails to properly implement a delegated portion of the Federal plan, EPA will assume direct implementation and enforcement of that portion. The EPA will continue to hold enforcement authority along with the State or Tribe even when a State or Tribe has received delegation of the Federal plan. In all cases where the Federal plan is delegated, the EPA will retain and will not transfer authority to a State or Tribe to approve the following items:

(1) Alternative site-specific operating parameters established by facilities using HMIWI controls other than a wet scrubber or dry scrubber followed by a fabric filter; and

(2) Alternative methods of demonstrating compliance.

Hospital/medical/infectious waste incinerator owners or operators who wish to establish alternative operating parameters or alternative methods of demonstrating compliance should submit a request to the Regional Office Administrator with a copy to the appropriate State or Tribe.

C. Mechanisms for Transferring Authority

There are two mechanisms for transferring implementation authority to State or Tribal agencies: (1) EPA approval of a State or Tribal plan after the Federal plan is in effect; and (2) if a State or Tribe does not submit or obtain approval of its own plan, EPA delegation to a State or Tribe of the authority to implement certain portions of this Federal plan to the extent appropriate and if allowed by State or Tribal law. Both of these options are described in more detail below.

1. State or Tribe Submits a Plan After HMIWI Located in the Area Are Subject to the Federal Plan

After HMIWI in a State or Tribal area become subject to the Federal plan, the State or Tribal agency may still adopt and submit a plan to EPA. If EPA determines that the State or Tribal plan is as protective as the emission guidelines, EPA will approve the State or Tribal plan. If EPA determines that the plan is not as protective as the emission guidelines, EPA will disapprove the plan and the HMIWI covered in the State or Tribal plan would remain subject to the Federal plan until a State or Tribal plan covering those HMIWI is approved and effective.

Upon the effective date of a State or Tribal plan, the Federal plan would no longer apply to HMIWI covered by such a plan and the State or Tribal agency would implement and enforce the State or Tribal plan in lieu of the Federal plan. When an EPA Regional Office approves a State or Tribal plan, it will amend the appropriate subpart of 40 CFR part 62 to indicate such approval.

2. State Takes Delegation of the Federal Plan

State or Tribal agencies may assume implementation of this Federal plan. As discussed above, EPA believes that it is advantageous and the best use of resources for State or Tribal agencies to agree to undertake, on EPA's behalf, administrative and substantive roles in implementing the Federal plan to the extent appropriate and where authorized by State or Tribal law. These functions could include administration and oversight of compliance reporting and recordkeeping requirements, HMIWI inspections, and preparation of notices of violation. Both States, or Tribal agencies, that have taken delegation, as well as EPA, will have responsibility for bringing enforcement actions against sources violating Federal plan provisions.

VI. Title V Operating Permits

Sources subject to this HMIWI Federal plan must obtain title V operating permits. Those title V operating permits must assure compliance with all applicable requirements for the source, including all applicable requirements of this Federal plan. *See* 40 CFR 70.6(a)(1), 70.2, 71.6(a)(1) and 71.2.

Under section 129(e) of the CAA, owners or operators of HMIWI subject to

this Federal plan must operate pursuant to a title V permit no later than 36 months after promulgation of the HMIWI emission guidelines (i.e., by September 15, 2000), or by the effective date of the State, Tribal, or Federal title V permits program that covers the area in which the unit is located, whichever is later.[2] If an owner or operator is required to obtain a title V permit for the first time by virtue of being subject to the Federal plan, the owner or operator must submit a complete title V permit application by the applicable permit deadline (i.e., by September 15, 2000) or the effective date of the State, Tribal, or Federal operating permits program, whichever is later.[3]

An earlier permit deadline may apply if an HMIWI is subject to title V for another reason. If an owner or operator is already subject to title V by virtue of some other requirement and has submitted a timely and complete permit application but the title V permit has not yet been released by the permitting authority, then the owner or operator should supplement its title V application by including the applicable requirements of the Federal plan in accordance with 40 CFR 70.5(b) or 71.5(b).

If an owner or operator of an HMIWI is already subject to title V by virtue of some other requirement on the effective date of this Federal plan and already possesses a title V permit with a remaining term of 3 or more years, then the owner or operator will receive from its permitting authority a notice of intent to reopen the title V permit to include the requirements of the Federal plan in accordance with the procedures established in 40 CFR 70.7(f) or 71.7(f). An owner or operator of an HMIWI with a title V permit having a remaining term of less than 3 years on the effective date of this Federal plan need not modify its title V permit, as a matter of Federal law, to include the Federal plan requirements until that permit is renewed.[4] However, the owner or operator remains subject to, and must act in compliance with, the Federal plan requirements.

Owners or operators of HMIWI that burn only pathological waste, low-level radioactive waste, and/or chemotherapeutic waste and co-fired combustors, as defined in § 62.14490 of subpart HHH, must comply only with certain recordkeeping and reporting requirements set forth in the Federal plan. *See* § 62.14400. These HMIWI and co-fired combustors are not subject to the emission control-related requirements of the Federal plan as long as they comply with the recordkeeping and reporting requirements set forth as conditions for their exemption. Therefore, as discussed in section III.B of this preamble and in the preamble to the proposed Federal plan (64 FR 36425, July 6, 1999), owners and operators of these sources are not required to obtain title V operating permits as a matter of Federal law if the only reason they would potentially be subject to title V is these non-emission control-related recordkeeping and reporting requirements. *See* § 62.14480. However, owners and operators of HMIWI that burn only pathological waste, low-level radioactive waste, and/or chemotherapeutic waste and co-fired combustors that do not comply with the recordkeeping and reporting requirements necessary to qualify for exemption from the other requirements of the Federal plan will become subject to those other requirements and will have to obtain title V permits. Moreover, if, in the future, EPA promulgates regulations subjecting any of these sources to requirements other than these recordkeeping and reporting requirements, these sources could become subject to title V at that time.

VII. Administrative Requirements

This section addresses the following administrative requirements: Docket, Paperwork Reduction Act, Executive Orders 12866, 13132, 13045, and 13084, Unfunded Mandates Reform Act, Regulatory Flexibility Act, Small Business Regulatory Enforcement Fairness Act, and the National Technology Transfer and Advancement Act. Since today's promulgated rule merely implements the emission guidelines promulgated on September 15, 1997 (codified at 40 part 60, subpart Ce) as they apply to HMIWI and does not impose any new requirements, much of the following discussion of administrative requirements refers to the documentation of applicable administrative requirements in the preamble to the 1997 rule promulgating the emission guidelines (62 FR 48347–48379, September 15, 1997).

A. Docket

The docket is intended to be an organized and complete file of the administrative records compiled by EPA. The docket is a dynamic file because material is added throughout the rulemaking process. The docketing system is intended to allow members of the public and industries involved to readily identify and locate documents so they can effectively participate in the rulemaking process. Along with proposed and promulgated standards and their preambles, the contents of the docket (with limited exceptions) will serve as the record in the case of judicial review. See section 307(d)(7)(A) of the CAA.

As discussed above, a docket has been prepared for this action pursuant to the procedural requirements of section 307(d) of the CAA, 42 U.S.C. 7607(d). Docket number A–91–61 contains the technical support for the September 15, 1997 emission guidelines. Public comments received on the proposal for this rulemaking and additional supporting information are included in Docket A–98–24.

B. Paperwork Reduction Act

The information collection requirements in this rule have been submitted for approval to the OMB under the *Paperwork Reduction Act,* 44 U.S.C. 3501 *et seq.* An information collection request (ICR) document has been prepared by EPA (ICR No. 1899.01) and a copy may be obtained from Ms. Sandy Farmer by mail at OP Regulatory Information Division, U. S. Environmental Protection Agency, Office of Environmental Information Collection Strategies Division (2822), 1200 Pennsylvania Avenue, NW, Washington, D.C. 20460; by E-mail at farmer.sandy@epa.gov; or by calling (202) 260–2740. A copy may also be downloaded off the Internet at http://www.epa.gov/icr.

This ICR reflects the burden estimate for the emission guidelines which were promulgated in the **Federal Register** on

[2] One area covered by title V permitting programs is the Outer Continental Shelf. *See* 40 CFR 55.6.

[3] Section 503(d) of the CAA and 40 CFR 70.7(b) and 71.7(b) allow a source to operate without being in violation of title V once the source has submitted a timely and complete permit application, even if the source has not yet received a final title V operating permit from the permitting authority. To this end, the application should be submitted early enough for the permitting authority to find the application either complete or incomplete before the application deadline. In the event the application is found incomplete by the permitting authority, the source must submit the information needed to make the application complete by the application deadline in order to obtain the application shield. *See* 40 CFR 62.14481 and 40 CFR 70.5(a)(2) and 71.5(a)(2).

[4] *See* CAA section 502(b)(6); 40 CFR 70.7(f)(1)(I) and 71.7(f)(1)(I). The CAA authorizes State, Tribal and Federal operating permits programs to require permits to be reopened and modified to incorporate the requirements of the Federal plan when fewer than 3 years remaining on a source's permit, however, so permitting authorities could reopen permits sooner than required by Federal law. Such reopenings should be completed no later than 18 months after promulgation of the applicable requirement. Any sources in this situation may wish to consult their operating permits program regulations or permitting authorities to determine whether revisions to their permits are necessary to incorporate the Federal plan requirements.

September 15, 1997. The burden estimate includes the burden associated with State/Tribal plans as well as the burden associated with the Federal plan. Consequently, the burden estimates described below overstate the information collection burden associated with the Federal plan. However, upon approval by EPA, a State/Tribal plan becomes Federally enforceable. Therefore, it is important to estimate the full burden associated with the State/Tribal plans and the Federal plan. As State/Tribal plans are approved, the Federal plan burden will decrease, but the overall burden of the State/Tribal plans and the Federal plan will remain the same.

The information collected will be used by EPA to ensure that the HMIWI regulatory requirements are implemented and are complied with on a continuous basis. Records and reports are necessary to enable EPA to identify existing HMIWI that may not be in compliance with the HMIWI regulatory requirements. Based on reported information, EPA will decide which units should be inspected and what records or processes should be inspected. The records that owners and operators of existing HMIWI maintain will indicate to EPA whether personnel are operating and maintaining control equipment properly.

Based on the inventory of HMIWI used to develop the emission guidelines, the HMIWI regulatory requirements (i.e., the State/Tribal plans and Federal plan) are projected to affect approximately 2,373 existing HMIWI in the United States or protectorates. A number of State plans are expected to be approved within the next year. When a State plan is approved, the Federal plan will no longer apply to HMIWI covered in that State plan.

The estimated average annual burden for industry for the first 3 years after the promulgation of the emission guidelines is 133,404 hours annually at a cost of $5,858,292 per year to meet the monitoring, recordkeeping, and reporting requirements. The estimated average annual burden, over the first 3 years, for the regulatory agencies (State and Federal) is 10,984 hours at a cost of $438,736 (including travel expenses) per year.

Burden means total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose, or provide information to or for a regulatory agency. This includes the time needed to do the following: Review instructions; develop, acquire, install, and use technology and systems for the purposes of collecting and validating information; process, maintain, and disclose information; amend previously applicable instructions and requirements to reflect new HMIWI State or Federal plan requirements; train personnel 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 currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR part 15.

Send comments on the Agency's need for this information, the accuracy of the burden estimates provided, and any suggested methods for minimizing respondent burden, including the use of automated collection techniques to the Director, OP Regulatory Information Division, U. S. Environmental Protection Agency (2137), 1200 Pennsylvania Ave., NW, Washington, D.C. 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, N.W., Washington, D.C. 20503, marked ''Attention: Desk Officer for EPA.'' Include the ICR number in any correspondence. Because OMB is required to make a decision on the ICR between 30 and 60 days after today's request for comment, a comment to OMB is best assured of having its full effect if OMB receives it by September 14, 2000.

C. Executive Order 12866

Under Executive Order 12866, 58 FR 51735 (October 4, 1993), EPA must determine whether the regulatory action is ''significant'' and, therefore, subject to OMB review and the requirements of the Executive Order. The EPA considered the 1997 emission guidelines to be significant and the rules were reviewed by OMB in 1997. *See* 62 FR 48374. The Federal plan promulgated today would simply implement the 1997 emission guidelines and does not result in any additional control requirements or impose any additional costs above those previously considered during promulgation of the 1997 emission guidelines. Therefore, this regulatory action is considered ''not significant'' under Executive Order 12866.

D. Executive Order 13132, Federalism

Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.''

Under section 6 of Executive Order 13132, EPA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or EPA consults with State and local officials early in the process of developing the proposed regulation. The EPA also may not issue a regulation that has federalism implications and that preempts State law, unless the Agency consults with State and local officials early in the process of developing the proposed regulation.

This proposed rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. Thus, the requirements of section 6 of the Executive Order do not apply to this proposed rule. Although section 6 of Executive Order 13132 does not apply to this final rule, EPA did consult with State and local officials to enable them to provide timely input in the development of this final rule.

E. Executive Order 13045

Executive Order 13045, ''Protection of Children from Environmental Health Risks and Safety Risks,'' 62 FR 19885 (April 23, 1997), applies to any rule that: (1) Is determined to be ''economically significant'' as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate affect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and feasible alternatives considered by the Agency.

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that are based on health or safety risks, such that the

analysis required under section 5–501 of the Order has the potential to influence the regulation. This rule is not subject to Executive Order 13045 because (1) it is not an economically significant regulatory action as defined by Executive Order 12866, and (2) it is based on technology performance and not on health or safety risks.

F. Executive Order 13084

Under Executive Order 13084, 63 FR 27655 (May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian Tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the Tribal governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 13084 requires EPA to provide to the OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected Tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian Tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

The Federal plan promulgated today does not significantly or uniquely affect communities of Indian Tribal governments. The Federal plan does not impose any enforceable duties on those governments. Moreover, this Federal plan simply implements the 1997 emission guidelines and does not result in any additional control requirements or impose any additional costs above those previously considered during promulgation of the 1997 emission guidelines. Thus, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

G. Unfunded Mandates Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and Tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures by State, local, and Tribal governments, in the aggregate, or by the private sector, of $100 million or more in any 1 year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost effective, or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted.

Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including Tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

An unfunded mandates statement was prepared and published in the preamble to the September 15, 1997 NSPS and emission guidelines. *See* 62 FR at 48374–48378. The EPA has determined that the HMIWI Federal plan does not include any new Federal mandates or additional requirements above those previously considered during promulgation of the 1997 emission guidelines. Therefore, the requirements of the UMRA do not apply to this rule.

H. Regulatory Flexibility Act and Small Business Regulatory Enforcement Fairness Act

The Regulatory Flexibility Act (RFA) of 1980, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA), 5 U.S.C. 601 *et seq.*, requires Federal agencies to give special consideration to the impacts of regulations on small entities, which are defined as small businesses, small organizations, and small governments. During the 1997 HMIWI emission guidelines rulemaking, EPA estimated that small entities would not be affected by the promulgated emission guidelines and standards, and therefore, a regulatory flexibility analysis was not required. *See* 62 FR at 48378–48379. This Federal plan would not establish any new requirements. Therefore, pursuant to the provisions of 5 U.S.C. 605 (b), EPA has determined that this Federal plan will not have a significant impact on a substantial number of small entities, and thus a regulatory flexibility analysis is not required.

I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d), 15 U.S.C. 272 note, directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

The NTTAA does not apply because the Federal plan promulgated today implements an existing rule to which NTTAA did not apply. In addition, the emission guidelines, which the Federal plan is based on, does not require new technology or impose new technical standards.

J. Submission to Congress and the General Accounting Office

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the SBREFA of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The EPA submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 62.

Environmental protection, Air pollution control, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: August 4, 2000.

Carol M. Browner,

Administrator.

1. The authority citation for part 62 continues to read as follows:

Authority: 42 U.S.A. 7401–7642.

2. Amend § 62.13 by adding paragraph (c) to read as follows:

§ 62.13 Federal Plans

* * * * *

(c) The substantive requirements of the hospital/ medical/infectious waste incinerator Federal plan are contained in subpart HHH of this part. These requirements include emission limits, compliance schedules, testing, monitoring and reporting and recordkeeping requirements.

* * * * *

3. Add subpart HHH consisting of §§ 62.14400 through 62.14495 as follows:

Subpart HHH—Federal Plan Requirements for Hospital/ Medical/Infectious Waste Incinerators Constructed on or before June 20, 1996.

Applicability

Sec.

Emission Limits

Operator Training and Qualification

Waste Management Plan

Inspection Requirements

Performance Testing, and Monitoring Requirements

Reporting and Recordkeeping Requirements

Compliance Schedule

Permitting Obligation

Definitions

Delegation of Authority

Tables

Subpart HHH—Federal Plan Requirements for Hospital/Medical/Infectious Waste Incinerators Constructed on or Before June 20, 1996

Applicability

§ 62.14400 Am I subject to this subpart?

(a) You are subject to this subpart if paragraphs (a)(1), (2), and (3) of this section are all true:

(1) You own or operate an HMIWI that is not covered by an EPA approved and effective State or Tribal plan;

(2) Construction of the HMIWI commenced on or before June 20, 1996; and

(3) You do not meet any of the exemptions in paragraph (b) of this section.

(b) The following exemptions apply:

If you . . .	And you . . .	And you . . .	Then you . . .
(1) Own or operate an HMIWI that combusts only pathological waste, low-level radioactive waste, and/or chemothera-peutic waste (all defined in 40 CFR 62.14490).	Notify the EPA Administrator (or delegated enforcement authority) of an exemption claim.	Keep records on a calendar quarter basis of the periods of time when only pathological waste, low-level radio active waste, and/or chemo therapeutic waste is combusted, and you submit such records to the EPA Administrator (or delegated enforcement authority) upon request,.	Are not subject to the other sections of this subpart during periods when only pathological, low-level radioactive, and/or chemotherapeutic wastes are combusted.

If you . . .	And you . . .	And you . . .	Then you . . .
(2) Own or operate a co-fired combustor (defined in 40 CFR 62.14490).	Notify the EPA Administrator (or delegated enforcement authority) of an exemption claim and you provide an estimate of the relative weight of hospital waste, medical/infectious waste, and other fuels and/or wastes to be combusted.	Keep records on a calendar quarter basis of the weight of hospital waste and medical/infectious waste combusted as well as the weight of all other fuels and wastes combusted at the co-fired combustor, and these records reflect that the source continues to meet the definition of co-fired combustor in 40 CFR 62.14490, and you submit such records to the EPA Administrator (or delegated enforcement authority) upon request.	Are not subject to the other sections of this subpart.
(3) Own or operate a combustor that must have a permit under Section 3005 of the Solid Waste Disposal Act.	.....	.....	Are not subject to this subpart.
(4) Own or operate a combustor which meets the applicability requirements of 40 CFR part 60 subpart Cb, Ea, or Eb (standards or guidelines for certain municipal waste combustors).	.....	.....	Are not subject to this subpart.
(5) Own or operate a pyrolysis unit (defined in 40 CFR 62.14490) processing hospital waste and/or medical/infectious waste.	.....	.....	Are not subject to this subpart.
(6) Own or operate a cement kiln firing hospital waste and/or medical/infectious waste.	.....	.....	Are not subject to this subpart.

(c) Owners or operators of sources that qualify for the exemptions in paragraphs (b)(1) or (b)(2) of this section must submit records required to support their claims of exemption to the EPA Administrator (or delegated enforcement authority) upon request. Upon request by any person under the regulation at part 2 of this chapter (or a comparable law or regulation governing a delegated enforcement authority), the EPA Administrator (or delegated enforcement authority) must request the records in (b)(1) or (b)(2) from an owner or operator and make such records available to the requestor to the extent required by part 2 of this chapter (or a comparable law governing a delegated enforcement authority). Records required under paragraphs (b)(1) and (b)(2) of this section must be maintained by the source for a period of at least 5 years. Notifications of exemption claims required under paragraphs (b)(1) and (b)(2) of this section must be maintained by the EPA or delegated enforcement authority for a period of at least 5 years. Any information obtained from an owner or operator of a source accompanied by a claim of confidentiality will be treated in accordance with the regulations in part 2 of this chapter (or a comparable law governing a delegated enforcement authority).

§ 62.14401 How do I determine if my HMIWI is covered by an approved and effective State or Tribal plan?

This part (40 CFR part 62) contains a list of all States and Tribal areas with approved Clean Air Act section 111(d)/129 plans in effect. However, this part is only updated once a year. Thus, if this part does not indicate that your State or Tribal area has an approved and effective plan, you should contact your State environmental agency's air director or your EPA Regional Office to determine if approval occurred since publication of the most recent version of this part.

§ 62.14402 If my HMIWI is not listed on the Federal plan inventory, am I exempt from this subpart?

Not necessarily. Sources subject to this subpart include, but are not limited to, the inventory of sources listed in Docket A–98–24 for the Federal plan.

§ 62.14403 What happens if I modify an existing HMIWI?

(a) If you commenced modification (defined in 40 CFR 62.14490) of an existing HMIWI after March 16, 1998, you are subject to 40 CFR part 60, subpart Ec (40 CFR 60.50c through 60.58c) and you are not subject to this subpart, except as provided in paragraph (b) of this section.

(b) If you made physical or operational changes to your existing HMIWI solely for the purpose of complying with this subpart, these changes are not considered a modification, and you are not subject to 40 CFR part 60, subpart Ec (40 CFR 60.50c through 60.58c). You remain subject to this subpart.

Emission Limits

§ 62.14410 Are there different emission limits for different locations and sizes of HMIWI?

Yes, there are different emission limits for small rural, small, medium, and large HMIWI. To determine the size category of your HMIWI, consult the definitions in 40 CFR 62.14490.

§ 62.14411 What emission limits apply to my HMIWI?

You must operate your HMIWI in compliance with the emission limit requirements for your HMIWI size category listed in Table 1 of this subpart.

§ 62.14412 What stack opacity requirements apply?

Your HMIWI (regardless of size category) must not discharge into the atmosphere from the stack any gases that exhibit greater than 10 percent opacity (6-minute block average).

§ 62.14413 When do the emission limits and stack opacity requirements apply?

The emission limits and stack opacity requirements of this subpart apply at all times except during periods of startup, shutdown, or malfunction, provided that no hospital waste or medical/infectious waste is charged to your HMIWI during periods of startup, shutdown, or malfunction.

Operator Training and Qualification

§ 62.14420 Am I required to have a trained and qualified operator?

You must have a fully trained and qualified HMIWI operator, either at your facility or able to be at your facility within 1 hour. The trained and qualified HMIWI operator may operate the HMIWI directly or be the direct supervisor of one or more HMIWI operators.

§ 62.14421 How does an operator become trained and qualified?

(a) The HMIWI operator can obtain training and qualification through a State-approved program or as provided in paragraph (b) of this section.

(b) If there are no State-approved training and qualification programs available or if your operator does not want to participate in a State-approved program, then your operator must complete a training course that includes the requirements in § 62.14422 and satisfy the qualification requirements in § 62.14423.

§ 62.14422 What are the requirements for a training course that is not part of a State-approved program?

A training course must include:

(a) Twenty-four hours of training that includes all of the following subjects:

(1) Environmental concerns, including pathogen destruction and types of emissions;

(2) Basic combustion principles, including products of combustion;

(3) Operation of the type of incinerator to be used by the operator, including proper startup, waste charging, and shutdown procedures;

(4) Combustion controls and monitoring;

(5) Operation of air pollution control equipment and factors affecting performance (if applicable);

(6) Methods to monitor pollutants (continuous emission monitoring systems and monitoring of HMIWI and air pollution control device operating parameters) and equipment calibration procedures (where applicable);

(7) Inspection and maintenance of the HMIWI, air pollution control devices, and continuous emission monitoring systems;

(8) Actions to correct malfunctions and conditions that may lead to malfunction;

(9) Bottom and fly ash characteristics and handling procedures;

(10) Applicable Federal, State, and local regulations;

(11) Work safety procedures;

(12) Prestartup inspections; and

(13) Recordkeeping requirements.

(b) An examination designed and administered by the instructor; and

(c) Reference material distributed to the attendees covering the course topics.

§ 62.14423 What are the qualification requirements for operators who do not participate in a State-approved program?

(a) Operators who do not participate in a State-approved program must satisfy paragraphs (a)(1) and (2) of this section:

(1) The operator must complete a training course that satisfies the requirements in § 62.14422; and

(2) The operator must have either 6 months experience as an HMIWI operator, 6 months experience as a direct supervisor of an HMIWI operator, or completion of at least two burn cycles under the observation and supervision of two qualified HMIWI operators.

(b) The operator's qualification is valid after paragraphs (a)(1) and (2) of this section are completed.

(c) To remain qualified, the operator must complete and pass an annual review or refresher course of at least 4 hours covering, at a minimum, the following:

(1) Update of regulations;

(2) Incinerator operation, including startup and shutdown procedures;

(3) Inspection and maintenance;

(4) Responses to malfunctions or conditions that may lead to malfunction; and

(5) Discussion of operating problems encountered by attendees.

(d) If the operator's qualification lapses, he or she must renew it by one of the following methods:

(1) For a lapse of less than 3 years, complete and pass a standard annual refresher course described in paragraph (c) of this section;

(2) For a lapse of 3 years or more, complete and pass a training course with the minimum criteria described in § 62.14422.

§ 62.14424 What documentation must I maintain onsite?

(a) You must maintain the following at the facility:

(1) Summary of the applicable standards under this subpart;

(2) Description of basic combustion theory applicable to an HMIWI;

(3) Procedures for receiving, handling, and charging waste;

(4) Procedures for startup, shutdown, and malfunction;

(5) Procedures for maintaining proper combustion air supply levels;

(6) Procedures for operating the HMIWI and associated air pollution control systems within the standards established under this subpart;

(7) Procedures for responding to malfunction or conditions that may lead to malfunction;

(8) Procedures for monitoring HMIWI emissions;

(9) Reporting and recordkeeping procedures; and

(10) Procedures for handling ash.

(b) You must keep the information listed in paragraph (a) of this section in a readily accessible location for all HMIWI operators. This information, along with records of training, must be available for inspection by the EPA or its delegated enforcement agent upon request.

§ 62.14425 When must I review the documentation?

(a) You must establish a program for reviewing the information listed in § 62.14424 annually with each HMIWI operator (defined in § 62.14490).

(b) You must conduct your initial review of the information listed in § 62.14424 by February 15, 2001, or prior to assumption of responsibilities affecting HMIWI operation, whichever is later.

(c) You must conduct subsequent reviews of the information listed in § 62.14424 annually.

Waste Management Plan

§ 62.14430 Must I prepare a waste management plan?

Yes. All HMIWI owners or operators must have a waste management plan.

§ 62.14431 What must my waste management plan include?

Your waste management plan must identify both the feasibility of, and the approach for, separating certain components of solid waste from the health care waste stream in order to reduce the amount of toxic emissions from incinerated waste. The waste management plan you develop may address, but is not limited to, paper, cardboard, plastics, glass, battery, or metal recycling, or purchasing recycled or recyclable products. Your waste management plan may include different goals or approaches for different areas or departments of the facility and need not include new waste management goals for every waste stream. When you develop your waste management plan it

should identify, where possible, reasonably available additional waste management measures, taking into account the effectiveness of waste management measures already in place, the costs of additional measures, the emission reductions expected to be achieved, and any other potential environmental or energy impacts they might have. In developing your waste management plan, you must consider the American Hospital Association publication entitled ''Ounce of Prevention: Waste Reduction Strategies for Health Care Facilities.'' This publication (AHA Catalog No. 057007) is available for purchase from the American Hospital Association (AHA) Service, Inc., Post Office Box 92683, Chicago, Illinois 60675–2683.

§ 62.14432 When must my waste management plan be completed?

As specified in §§ 62.14463 and 62.14464, you must submit your waste management plan with your initial report, which is due 60 days after your initial performance test.

Inspection Requirements

§ 62.14440 Which HMIWI are subject to inspection requirements?

Only small rural HMIWI (defined in § 62.14490) are subject to inspection requirements.

§ 62.14441 When must I inspect my small rural HMIWI?

(a) You must inspect your small rural HMIWI by August 15, 2001.

(b) You must conduct inspections as outlined in § 62.14442 annually (no more than 12 months following the previous annual equipment inspection).

§ 62.14442 What must my inspection include?

At a minimum, you must do the following during your inspection:

(a) Inspect all burners, pilot assemblies, and pilot sensing devices for proper operation, and clean pilot flame sensor as necessary;

(b) Check for proper adjustment of primary and secondary chamber combustion air, and adjust as necessary;

(c) Inspect hinges and door latches, and lubricate as necessary;

(d) Inspect dampers, fans, and blowers for proper operation;

(e) Inspect HMIWI door and door gaskets for proper sealing;

(f) Inspect motors for proper operation;

(g) Inspect primary chamber refractory lining, and clean and repair/replace lining as necessary;

(h) Inspect incinerator shell for corrosion and/or hot spots;

(i) Inspect secondary/tertiary chamber and stack, and clean as necessary;

(j) Inspect mechanical loader, including limit switches, for proper operation, if applicable;

(k) Visually inspect waste bed (grates), and repair/ seal, as necessary;

(l) For the burn cycle that follows the inspection, document that the incinerator is operating properly and make any necessary adjustments;

(m) Inspect air pollution control device(s) for proper operation, if applicable;

(n) Inspect waste heat boiler systems to ensure proper operation, if applicable;

(o) Inspect bypass stack components;

(p) Ensure proper calibration of thermocouples, sorbent feed systems and any other monitoring equipment; and

(q) Generally observe that the equipment is maintained in good operating condition.

§ 62.14443 When must I do repairs?

You must complete any necessary repairs within 10 operating days of the inspection unless you obtain written approval from the EPA Administrator (or delegated enforcement authority) establishing a different date when all necessary repairs of your HMIWI must be completed.

Performance Testing and Monitoring Requirements

§ 62.14450 What are the testing requirements for small rural HMIWI?

(a) If you operate a small rural HMIWI (defined in § 62.14490), you must conduct an initial performance test for PM, opacity, CO, dioxin/furan, and Hg using the test methods and procedures outlined in § 62.14452.

(b) After the initial performance test is completed or is required to be completed under § 62.14470, whichever date comes first, if you operate a small rural HMIWI you must determine compliance with the opacity limit by conducting an annual performance test (no more than 12 months following the previous performance test) using the applicable procedures and test methods listed in § 62.14452.

(c) The 2,000 lb/wk limitation for small rural HMIWI does not apply during performance tests.

(d) The EPA Administrator may request a repeat performance test at any time.

§ 62.14451 What are the testing requirements for HMIWI that are not small rural?

(a) If you operate an HMIWI that is not a small rural HMIWI, you must conduct an initial performance test for PM, opacity, CO, dioxin/furan, HCl, Pb, Cd, and Hg using the test methods and procedures outlined in § 62.14452.

(b) After the initial performance test is completed or is required to be completed under § 62.14470, whichever date comes first, you must:

(1) Determine compliance with the opacity limit by conducting an annual performance test (no more than 12 months following the previous performance test) using the applicable procedures and test methods listed in § 62.14452.

(2) Determine compliance with the PM, CO, and HCl emission limits by conducting an annual performance test (no more than 12 months following the previous performance test) using the applicable procedures and test methods listed in § 62.14452. If all three performance tests over a 3-year period indicate compliance with the emission limit for a pollutant (PM, CO, or HCl), you may forego a performance test for that pollutant for the next 2 years. At a minimum, you must conduct a performance test for PM, CO, and HCl every third year (no more than 36 months following the previous performance test). If a performance test conducted every third year indicates compliance with the emission limit for a pollutant (PM, CO, or HCl), you may forego a performance test for that pollutant for an additional 2 years. If any performance test indicates noncompliance with the respective emission limit, you must conduct a performance test for that pollutant annually until all annual performance tests over a 3-year period indicate compliance with the emission limit.

(c) The EPA Administrator may request a repeat performance test at any time.

§ 62.14452 What test methods and procedures must I use?

You must use the following test methods and procedures to conduct performance tests to determine compliance with the emission limits:

(a) All performance tests must consist of a minimum of three test runs conducted under representative operating conditions;

(b) The minimum sample time must be 1 hour per test run unless otherwise indicated in this section;

(c) You must use EPA Reference Method 1 of 40 CFR part 60, appendix A to select the sampling location and number of traverse points;

(d) You must use EPA Reference Method 3, 3A, or 3B of 40 CFR part 60, appendix A for gas composition analysis, including measurement of

oxygen concentration. You must use EPA Reference Method 3, 3A, or 3B of 40 CFR part 60, appendix A simultaneously with each reference method;

(e) You must adjust pollutant concentrations to 7 percent oxygen using the following equation:

$$C_{adj} = C_{meas}(20.9 - 7)/(20.9 - \%O_2) \qquad \text{(Eq. 1)}$$

Where:

C_{adj} = pollutant concentration adjusted to 7 percent oxygen;

C_{meas} = pollutant concentration measured on a dry basis at standard conditions

(20.9–7) = 20.9 percent oxygen—7 percent oxygen (defined oxygen correction basis);

20.9 = oxygen concentration in air, percent; and

$\%O_2$ = oxygen concentration measured on a dry basis at standard conditions, percent.

(f) Except as provided in paragraph (l) of this section, you must use EPA Reference Method 5 or 29 of 40 CFR part 60, appendix A to measure particulate matter emissions;

(g) Except as provided in paragraph (l) of this section, you must use EPA Reference Method 9 of 40 CFR part 60, appendix A to measure stack opacity;

(h) Except as provided in paragraph (l) of this section, you must use EPA Reference Method 10 or 10B of 40 CFR part 60, appendix A to measure the CO emissions;

(i) Except as provided in paragraph (l) of this section, you must use EPA Reference Method 23 of 40 CFR part 60, appendix A to measure total dioxin/furan emissions. The minimum sample time must be 4 hours per test run. If you have selected the toxic equivalency standards for dioxin/furans under § 62.14411, you must use the following procedures to determine compliance:

(1) Measure the concentration of each dioxin/furan tetra-through octa-congener emitted using EPA Reference Method 23;

(2) For each dioxin/furan congener measured in accordance with paragraph (i)(1) of this section, multiply the congener concentration by its corresponding toxic equivalency factor specified in Table 2 of this subpart;

(3) Sum the products calculated in accordance with paragraph (i)(2) of this section to obtain the total concentration of dioxins/furans emitted in terms of toxic equivalency.

(j) Except as provided in paragraph (l) of this section, you must use EPA Reference Method 26 of 40 CFR part 60, appendix A to measure HCl emissions. If you have selected the percentage reduction standards for HCl under § 62.14411, compute the percentage reduction in HCl emissions ($\%R_{HCl}$) using the following formula:

$$(\%R_{HCl}) = \left(\frac{E_i - E_o}{E_i}\right) \times 100 \qquad \text{(Eq. 2)}$$

Where:

$\%R_{HCl}$ = percentage reduction of HCl emissions achieved;

E_i = HCl emission concentration measured at the control device inlet, corrected to 7 percent oxygen (dry basis at standard conditions); and

E_o = HCl emission concentration measured at the control device outlet, corrected to 7 percent oxygen (dry basis at standard conditions).

(k) Except as provided in paragraph (l) of this section, you must use EPA Reference Method 29 of 40 CFR part 60, appendix A to measure Pb, Cd, and Hg emissions. If you have selected the percentage reduction standards for metals under § 62.14411, compute the percentage reduction in emissions ($\%R_{metal}$) using the following formula:

$$(\%R_{metal}) = \left(\frac{E_i - E_o}{E_i}\right) \times 100 \qquad \text{(Eq. 3)}$$

Where:

$\%R_{metal}$ = percentage reduction of metal emission (Pb, Cd, or Hg) achieved;

E_i = metal emission concentration (Pb, Cd, or Hg) measured at the control device inlet, corrected to 7 percent oxygen (dry basis at standard conditions); and

E_o = metal emission concentration (Pb, Cd, or Hg) measured at the control device outlet, corrected to 7 percent oxygen (dry basis at standard conditions).

(l) If you are using a continuous emission monitoring system (CEMS) to demonstrate compliance with any of the emission limits under §§ 62.14411 or 62.14412, you must:

(1) Determine compliance with the appropriate emission limit(s) using a 12-hour rolling average, calculated each hour as the average of the previous 12 operating hours (not including startup, shutdown, or malfunction). Performance tests using EPA Reference Methods are not required for pollutants monitored with CEMS.

(2) Operate a CEMS to measure oxygen concentration, adjusting pollutant concentrations to 7 percent oxygen as specified in paragraph (e) of this section.

(3) Operate all CEMS in accordance with the applicable procedures under appendices B and F of 40 CFR part 60.

(m) Use of the bypass stack during a performance test will invalidate the performance test.

§ 62.14453 What must I monitor?

(a) If your HMIWI is a small rural HMIWI, or your HMIWI is equipped with a dry scrubber followed by a fabric filter, a wet scrubber, or a dry scrubber followed by a fabric filter and wet scrubber:

(1) You must establish the appropriate maximum and minimum operating parameters, indicated in Table 3, as site-specific operating parameters during the initial performance test to determine compliance with the emission limits; and

(2) After the date on which the initial performance test is completed or is required to be completed under § 62.14470, whichever comes first, your HMIWI must not operate above any of the applicable maximum operating parameters or below any of the applicable minimum operating parameters listed in Table 3 and measured as 3-hour rolling averages (calculated each hour as the average of the previous 3 operating hours), at all times except during startup, shutdown, malfunction, and performance tests.

(b) If your HMIWI is not a small rural HMIWI, and you are using an air pollution control device other than a dry scrubber followed by a fabric filter, a wet scrubber, or a dry scrubber followed by a fabric filter and a wet scrubber to comply with the emission limits under § 62.14411, you must petition the EPA Administrator for site-specific operating parameters to be established during the initial performance test and you must continuously monitor those parameters thereafter. You may not conduct the initial performance test until the EPA Administrator has approved the petition.

§ 62.14454 How must I monitor the required parameters?

(a) You must install, calibrate (to manufacturers' specifications), maintain, and operate devices (or establish methods) for monitoring the applicable maximum and minimum operating parameters listed in Table 3 of this subpart such that these devices (or methods) measure and record values for the operating parameters at the frequencies indicated in Table 3 of this subpart at all times except during periods of startup and shutdown. For charge rate, the device must measure and record the date, time, and weight of each charge fed to the HMIWI. This must be done automatically, meaning that the only intervention from an operator during the process would be to load the charge onto the weighing device. For batch HMIWI, the maximum charge rate is measured on a daily basis (the amount of waste charged to the unit each day).

(b) For all HMIWI except small rural HMIWI, you must install, calibrate (to manufacturers' specifications), maintain, and operate a device or method for measuring the use of the bypass stack, including the date, time, and duration of such use.

(c) For all HMIWI except small rural HMIWI, if you are using controls other than a dry scrubber followed by a fabric filter, a wet scrubber, or a dry scrubber followed by a fabric filter and a wet scrubber to comply with the emission limits under § 62.14411, you must install, calibrate (to manufacturers' specifications), maintain, and operate the equipment necessary to monitor the site-specific operating parameters developed pursuant to § 62.14453(b).

(d) You must obtain monitoring data at all times during HMIWI operation except during periods of monitoring equipment malfunction, calibration, or repair. At a minimum, valid monitoring data must be obtained for 75 percent of the operating hours per day for 90 percent of the operating days per calendar quarter that your HMIWI is combusting hospital waste and/or medical/infectious waste.

§ 62.14455 What if my HMIWI goes outside of a parameter limit?

(a) Operation above the established maximum or below the established minimum operating parameter(s) constitutes a violation of established operating parameter(s). Operating parameter limits do not apply during startup, shutdown, malfunction, and performance tests.

(b) Except as provided in paragraph (f) or (g) of this section, if your HMIWI is a small rural HMIWI,

And your HMIWI . . .	Then you are in violation of . . .
Operates above the maximum charge rate (3-hour rolling average for continuous and intermittent HMIWI, daily average for batch HMIWI) and below the minimum secondary chamber temperature (3-hour rolling average) simultaneously.	The PM, CO, and dioxin/furan emission limits.

(c) Except as provided in paragraph (f) or (g) of this section, if your HMIWI is equipped with a dry scrubber followed by a fabric filter:

And your HMIWI . . .	Then you are in violation of . . .
(1) Operates above the maximum charge rate (3-hour rolling average for continuous and intermittent HMIWI, daily average for batch HMIWI) and below the minimum secondary chamber temperature (3-hour rolling average) simultaneously.	The CO emission limit.
(2) Operates above the maximum fabric filter inlet temperature (3-hour rolling average), above the maximum charge rate (3-hour rolling average for continuous and intermittent HMIWI, daily average for batch HMIWI), and below the minimum dioxin/furan sorbent flow rate (3-hour rolling average) simultaneously.	The dioxin/furan emission limit.
(3) Operates above the maximum charge rate (3-hour rolling average for continuous and intermittent HMIWI, daily average for batch HMIWI) and below the minimum HCl sorbent flow rate (3-hour rolling average) simultaneously.	The HCl emission limit.
(4) Operates above the maximum charge rate (3-hour rolling average for continuous and intermittent HMIWI, daily average for batch HMIWI) and below the minimum Hg sorbent flow rate (3-hour rolling average) simultaneously.	The Hg emission limit.
(5) Uses the bypass stack (except during startup, shutdown, or malfunction)	The PM, dioxin/furan, HCl, Pb, Cd, and Hg emission limits.

(d) Except as provided in paragraph (f) or (g) of this section, if your HMIWI is equipped with a wet scrubber:

And your HMIWI . . .	Then you are in violation of . . .
(1) Operates above the maximum charge rate (3-hour rolling average for continuous and intermittent HMIWI, daily average for batch HMIWI) and below the minimum secondary chamber temperature (3-hour rolling average) simultaneously.	The CO emission limit.

And your HMIWI . . .	Then you are in violation of . . .
(2) Operates above the maximum charge rate (3-hour rolling average for continuous and intermittent HMIWI, daily average for batch HMIWI) and below the minimum pressure drop across the wet scrubber (3-hour rolling average) or below the minimum horsepower or amperage to the system (3-hour rolling average) simultaneously.	The PM emission limit.
(3) Operates above the maximum charge rate (3-hour rolling average for continuous and intermittent HMIWI, daily average for batch HMIWI), below the minimum secondary chamber temperature (3-hour rolling average), and below the minimum scrubber liquor flow rate (3-hour rolling average) simultaneously.	The dioxin/furan emission limit.
(4) Operates above the maximum charge rate (3-hour rolling average for continuous and intermittent HMIWI, daily average for batch HMIWI) and below the minimum scrubber liquor pH (3-hour rolling average) simultaneously.	The HCl emission limit.
(5) Operates above the maximum flue gas temperature (3-hour rolling average) and above the maximum charge rate (3-hour rolling average for continuous and intermittent HMIWI, daily average for batch HMIWI) simultaneously.	The Hg emission limit.
(6) Uses the bypass stack (except during startup, shutdown, or malfunction)	The PM, dioxin/furan, HCl, Pb, Cd, and Hg emission limits.

(e) Except as provided in paragraph (f) or (g) of this section, if your HMIWI is equipped with a dry scrubber followed by a fabric filter and a wet scrubber:

And your HMIWI . . .	Then you are in violation of . . .
(1) Operates above the maximum charge rate (3-hour rolling average for continuous and intermittent HMIWI, daily average for batch HMIWI) and below the minimum secondary chamber temperature (3-hour rolling average) simultaneously.	The CO emission limit.
(2) Operates above the maximum fabric filter inlet temperature (3-hour rolling average), above the maximum charge rate (3-hour rolling average for continuous and intermittent HMIWI, daily average for batch HMIWI), and below the minimum dioxin/furan sorbent flow rate (3-hour rolling average) simultaneously.	The dioxin/furan emission limit.
(3) Operates above the maximum charge rate (3-hour rolling average for continuous and intermittent HMIWI, daily average for batch HMIWI) and below the minimum scrubber liquor pH (3-hour rolling average) simultaneously.	The HCl emission limit.
(4) Operates above the maximum charge rate (3-hour rolling average for continuous and intermittent HMIWI, daily average for batch HMIWI) and below the minimum Hg sorbent flow rate (3-hour rolling average) simultaneously.	The Hg emission limit.
(5) Uses the bypass stack (except during startup, shutdown, or malfunction)	The PM, dioxin/furan, HCl, Pb, Cd, and Hg emission limits.

(f) You may conduct a repeat performance test within 30 days of violation of applicable operating parameter(s) to demonstrate that your HMIWI is not in violation of the applicable emission limit(s). You must conduct repeat performance tests pursuant to this paragraph using the identical operating parameters that indicated a violation under paragraph (b), (c), (d) or (e) of this section.

(g) If you are using a CEMS to demonstrate compliance with any of the emission limits in Table 1 of this subpart or § 62.14412, and your CEMS indicates compliance with an emission limit during periods when operating parameters indicate a violation of an emission limit under paragraphs (b), (c), (d), or (e) of this section, then you are considered to be in compliance with the emission limit. You need not conduct a repeat performance test to demonstrate compliance.

(h) You may conduct a repeat performance test in accordance with § 62.14452 at any time to establish new values for the operating parameters.

Reporting and Recordkeeping Requirements

§ 62.14460 What records must I maintain?

You must maintain the following:

(a) Calendar date of each record;

(b) Records of the following data:

(1) Concentrations of any pollutant listed in Table 1 and/or measurements of opacity;

(2) The HMIWI charge dates, times, and weights and hourly charge rates;

(3) Fabric filter inlet temperatures during each minute of operation, as applicable;

(4) Amount and type of dioxin/furan sorbent used during each hour of operation, as applicable;

(5) Amount and type of Hg sorbent used during each hour of operation, as applicable;

(6) Amount and type of HCl sorbent used during each hour of operation, as applicable;

(7) Secondary chamber temperatures recorded during each minute of operation;

(8) Liquor flow rate to the wet scrubber inlet during each minute of operation, as applicable,

(9) Horsepower or amperage to the wet scrubber during each minute of operation, as applicable;

(10) Pressure drop across the wet scrubber system during each minute of operation, as applicable;

(11) Temperature at the outlet from the wet scrubber during each minute of operation, as applicable;

(12) The pH at the inlet to the wet scrubber during each minute of operation, as applicable;

(13) Records of the annual equipment inspections, any required maintenance, and any repairs not completed within 10 operating days of an inspection or the time frame established by the EPA Administrator or delegated enforcement authority, as applicable;

(14) Records indicating use of the bypass stack, including dates, times, and durations; and

(15) If you are complying by monitoring site-specific operating parameters under § 62.14453(b), you must monitor all operating data collected.

(c) Identification of calendar days for which data on emission rates or operating parameters specified under paragraph (b)(1) through (15) of this

section were not obtained, with an identification of the emission rates or operating parameters not measured, reasons for not obtaining the data, and a description of corrective actions taken;

(d) Identification of calendar days, times and durations of malfunctions, and a description of the malfunction and the corrective action taken.

(e) Identification of calendar days for which data on emission rates or operating parameters specified under paragraphs (b)(1) through (15) of this section exceeded the applicable limits, with a description of the exceedances, reasons for such exceedances, and a description of corrective actions taken.

(f) The results of the initial, annual, and any subsequent performance tests conducted to determine compliance with the emission limits and/or to establish operating parameters, as applicable.

(g) Records showing the names of HMIWI operators who have completed review of the documentation in § 62.14424 as required by § 62.14425, including the date of the initial review and all subsequent annual reviews;

(h) Records showing the names of the HMIWI operators who have completed the operator training requirements, including documentation of training and the dates of the training;

(i) Records showing the names of the HMIWI operators who have met the criteria for qualification under § 62.14423 and the dates of their qualification; and

(j) Records of calibration of any monitoring devices as required under § 62.14454.

§ 62.14461 For how long must I maintain records?

You must maintain the records specified under § 62.14460 for a period of at least 5 years.

§ 62.14462 Where must I keep the records?

You must maintain all records specified under § 62.14460 onsite in either paper copy or computer-readable format, unless an alternative format is approved by the EPA Administrator.

§ 62.14463 What reporting requirements must I satisfy?

You must report the following to the EPA Administrator (or delegated enforcement authority):

(a) The initial performance test data as recorded under § 62.14450(a) or § 62.14451(a) (whichever applies);

(b) The values for the site-specific operating parameters established pursuant to § 62.14453, as applicable;

(c) The waste management plan as specified in § 62.14431;

(d) The highest maximum operating parameter and the lowest minimum operating parameter for each operating parameter recorded for the calendar year being reported, pursuant to § 62.14453, as applicable;

(e) The highest maximum operating parameter and the lowest minimum operating parameter, as applicable, for each operating parameter recorded pursuant to § 62.14453 for the calendar year preceding the year being reported, in order to provide a summary of the performance of the HMIWI over a 2-year period;

(f) Any information recorded under § 62.14460(c) through (e) for the calendar year being reported;

(g) Any information recorded under § 62.14460(c) through (e) for the calendar year preceding the year being reported, in order to provide a summary of the performance of the HMIWI over a 2-year period;

(h) The results of any performance test conducted during the reporting period;

(i) If no exceedances or malfunctions occurred during the calendar year being reported, a statement that no exceedances occurred during the reporting period;

(j) Any use of the bypass stack, duration of such use, reason for malfunction, and corrective action taken; and

(k) Records of the annual equipment inspections, any required maintenance, and any repairs not completed within 10 days of an inspection or the time frame established by the EPA Administrator (or delegated enforcement authority).

§ 62.14464 When must I submit reports?

(a) You must submit the information specified in § 62.14463(a) through (c) no later than 60 days following the initial performance test.

(b) You must submit an annual report to the EPA Administrator (or delegated enforcement authority) no more than 1 year following the submission of the information in paragraph (a) of this section and you must submit subsequent reports no more than 1 year following the previous report (once the unit is subject to permitting requirements under title V of the Clean Air Act, you must submit these reports semiannually). The annual report must include the information specified in § 62.14463(d) through (k), as applicable.

(c) You must submit semiannual reports containing any information recorded under § 62.14460(c) through (e) no later than 60 days following the end of the semiannual reporting period. The first semiannual reporting period ends 6 months following the submission of information in paragraph (a) of this section. Subsequent reports must be submitted no later than 6 calendar months following the previous report.

§ 62.14465 Who must sign all submitted reports?

All reports must be signed by the facilities manager (defined in § 62.14490).

Compliance Schedule

§ 62.14470 When must I comply with this subpart if I plan to continue operation of my HMIWI?

If you plan to continue operation of your HMIWI, then you must follow the requirements in paragraph (a) or (b) of this section depending on when you plan to come into compliance with the requirements of this subpart.

(a) If you plan to continue operation and come into compliance with the requirements of this subpart by August 15, 2001, then you must complete the requirements of paragraphs (a)(1) through (a)(4) of this section.

(1) You must comply with the operator training and qualification requirements and inspection requirements (if applicable) of this subpart by August 15, 2001.

(2) You must achieve final compliance by August 15, 2001. This includes incorporating all process changes and/or completing retrofit construction, connecting the air pollution control equipment or process changes such that the HMIWI is brought on line, and ensuring that all necessary process changes and air pollution control equipment are operating properly.

(3) You must conduct the initial performance test required by § 62.14450(a) (for small rural HMIWI) or § 62.14451(a) (for HMIWI that are not small rural HMIWI) within 180 days after the date when you are required to achieve final compliance under paragraph (a)(2) of this section.

(4) You must submit an initial report including the results of the initial performance test and the waste management plan no later than 60 days following the initial performance test (see §§ 62.14463 and 62.14464 for complete reporting and recordkeeping requirements).

(b) If you plan to continue operation and come into compliance with the requirements of this subpart after August 15, 2001, but before September 15, 2002, then you must complete the requirements of paragraphs (b)(1) through (b)(4) of this section.

(1) You must comply with the operator training and qualification

requirements and inspection requirements (if applicable) of this subpart by August 15, 2001.

(2) You must demonstrate that you are taking steps towards compliance with the emission limits in the subpart by completing the increments of progress in paragraphs (b)(2)(i) through (b)(2)(v) of this section. You must submit notification to the EPA Administrator (or delegated enforcement authority) within 10 business days of completing (or failing to complete by the applicable date) each of the increments of progress listed in paragraphs (b)(2)(i) through (b)(2)(v) of this section. Your notification must be signed by your facilities manager (defined in § 62.14490).

(i) You must submit a final control plan by September 15, 2000. Your final control plan must, at a minimum, include a description of the air pollution control device(s) or process changes that will be employed for each unit to comply with the emission limits and other requirements of this subpart.

(ii) You must award contract(s) for onsite construction, onsite installation of emission control equipment, or incorporation of process changes by April 15, 2001. You must submit a signed copy of the contract(s) awarded.

(iii) You must begin onsite construction, begin onsite installation of emission control equipment, or begin process changes needed to meet the emission limits as outlined in the final control plan by December 15, 2001.

(iv) You must complete onsite construction, installation of emission control equipment, or process changes by July 15, 2002.

(v) You must achieve final compliance by September 15, 2002. This includes incorporating all process changes and/or completing retrofit construction as described in the final control plan, connecting the air pollution control equipment or process changes such that the HMIWI is brought on line, and ensuring that all necessary process changes and air pollution control equipment are operating properly.

(3) You must conduct the initial performance test required by § 62.14450(a) (for small rural HMIWI) or § 62.14451(a) (for HMIWI that are not small rural HMIWI) within 180 days after the date when you are required to achieve final compliance under paragraph (b)(2)(v) of this section.

(4) You must submit an initial report including the result of the initial performance test and the waste management plan no later than 60 days following the initial performance test (see §§ 62.14463 and 62.14464 for complete reporting and recordkeeping requirements).

§ 62.14471 When must I comply with this subpart if I plan to shut down?

If you plan to shut down, then you must follow the requirements in either paragraph (a) or (b) of this section depending on when you plan to shut down.

(a) If you plan to shut down by August 15, 2001, rather that come into compliance with the requirements of this subpart, then you must shut down by August 15, 2001, to avoid coverage under any of the requirements of this subpart.

(b) If you plan to shut down rather than come into compliance with the requirements of this subpart, but are unable to shut down by August 15, 2001, then you may petition EPA for an extension by following the procedures outlined in paragraphs (b)(1) through (b)(3) of this section.

(1) You must submit your request for an extension to the EPA Administrator (or delegated enforcement authority) by November 13, 2000. Your request must include:

(i) Documentation of the analyses undertaken to support your need for an extension, including an explanation of why your requested extension date is sufficient time for you to shut down while August 15, 2001, does not provide sufficient time for shut down. Your documentation must include an evaluation of the option to transport your waste offsite to a commercial medical waste treatment and disposal facility on a temporary or permanent basis; and

(ii) Documentation of incremental steps of progress, including dates for completing the increments of progress, that you will take towards shutting down. Some suggested incremental steps of progress towards shut down are provided as follows:

If you . . .	Then your increments of progress could be . . .
Need an extension so you can install an onsite alternative waste treatment technology before you shut down your HMIWI,.	Date when you will enter into a contract with an alternative treatment technology vendor, Date for initiating onsite construction or installation of the alternative technology, and Date for completing onsite construction or installation of the alternative technology, and Date for shutting down the HMIWI.
Need an extension so you can acquire the services of a commercial medical/infectious waste disposal company before you shut down your HMIWI,.	Date when price quotes will be obtained from commercial disposal companies, Date when you will enter into a contract with a commercial disposal company, and Date for shutting down the HMIWI.

(2) You must shut down no later than September 15, 2002.

(3) You must comply with the operator training and qualification requirements and inspection requirements (if applicable) of this subpart by August 15, 2001.

§ 62.14472 When must I comply with this subpart if I plan to shut down and later restart?

If you wish to shut down and later restart, then you must follow the compliance times in paragraph (a), (b), or (c) of this section depending on when you shut down and restart.

(a) If you plan to shut down and restart prior to September 15, 2002, then you must:

(1) Meet the compliance schedule outlined in § 63.14470(a) if you restart prior to August 15, 2001; or

(2) Meet the compliance schedule outlined in § 62.14470(b) if you restart after August 15, 2001. Any missed increments of progress need to be completed prior to or upon the date of restart.

(b) If you plan to shut down by August 15, 2001, and restart after September 15, 2002, then you must complete the requirements of paragraphs (b)(1) through (b)(5) of this section.

(1) You must shut down by August 15, 2001.

(2) You must comply with the operator training and qualification requirements and inspection

requirements (if applicable) of this subpart before restarting your HMIWI.

(3) You must achieve final compliance upon restarting your HMIWI. This includes incorporating all process changes and/or completing retrofit construction, connecting the air pollution control equipment or process changes such that the HMIWI is brought on line, and ensuring that all necessary process changes and air pollution control equipment are operating properly.

(4) You must conduct the initial performance test required by § 62.14450(a) (for small rural HMIWI) or § 62.14451(a) (for HMIWI that are not small rural HMIWI) within 180 days after the date when you restart.

(5) You must submit an initial report including the results of the initial performance test and the waste management plan no later than 60 days following the initial performance test (see §§ 62.14463 and 62.14464 for complete reporting and recordkeeping requirements).

(c) If you plan to shut down after August 15, 2001, and restart after September 15, 2002, then you must complete the requirements of paragraphs (c)(1) and (c)(2) of this section.

(1) You must petition EPA for an extension by following the procedures outlined in § 63.14471 paragraphs (b)(1) through (b)(3).

(2) You must comply with the requirements of paragraphs (b)(2) through (b)(5) of this section.

Permitting Obligation

§ 62.14480 Does this subpart require me to obtain an operating permit under title V of the Clean Air Act and implementing regulations?

This subpart requires you to obtain an operating permit under title V of the Clean Air Act and implementing regulations (''title V permit'') unless you are only subject to the recordkeeping and reporting requirements listed at § 62.14400(b)(1) or (b)(2), and § 62.14400(c), of this subpart. Also, if you own or operate a unit described in § 62.14400(b)(3), (b)(4), (b)(5) or (b)(6), you are not subject to any requirements of this subpart; therefore, this subpart does not require you to obtain a title V permit.

§ 62.14481 When must I submit a title V permit application for my HMIWI?

You must submit a title V permit application in time for it to be determined or deemed complete by no later than September 15, 2000 or by the effective date of a title V permits program in the jurisdiction in which the unit is located, whichever is later. (An earlier deadline may apply if your HMIWI is also subject to title V permitting requirements because of some other triggering requirement.) A ''complete'' title V permit application is one that has been approved by the appropriate permitting authority as complete under Section 503 of the Clean Air Act and 40 CFR parts 70 and 71. It is not enough to have submitted a title V permit application by September 15, 2000 because the application must be determined or deemed complete by the permitting authority by that date for your HMIWI to operate after that date in compliance with Federal law.

Definitions

§ 62.14490 Definitions.

Batch HMIWI means an HMIWI that is designed such that neither waste charging nor ash removal can occur during combustion.

Biologicals means preparations made from living organisms and their products, including vaccines, cultures, etc., intended for use in diagnosing, immunizing, or treating humans or animals or in research pertaining thereto.

Blood products means any product derived from human blood, including but not limited to blood plasma, platelets, red or white blood corpuscles, and other derived licensed products, such as interferon, etc.

Body fluids means liquid emanating or derived from humans and limited to blood; dialysate; amniotic, cerebrospinal, synovial, pleural, peritoneal and pericardial fluids; and semen and vaginal secretions.

Bypass stack means a device used for discharging combustion gases to avoid severe damage to the air pollution control device or other equipment.

Chemotherapeutic waste means waste material resulting from the production or use of antineoplastic agents used for the purpose of stopping or reversing the growth of malignant cells.

Co-fired combustor means a unit combusting hospital waste and/or medical/infectious waste with other fuels or wastes (e.g., coal, municipal solid waste) and subject to an enforceable requirement limiting the unit to combusting a fuel feed stream, 10 percent or less of the weight of which is comprised, in aggregate, of hospital waste and medical/infectious waste as measured on a calendar quarter basis. For purposes of this definition, pathological waste, chemotherapeutic waste, and low-level radioactive waste are considered ''other'' wastes when calculating the percentage of hospital waste and medical/infectious waste combusted.

Continuous emission monitoring system or *CEMS* means a monitoring system for continuously measuring and recording the emissions of a pollutant.

Continuous HMIWI means an HMIWI that is designed to allow waste charging and ash removal during combustion.

Dioxins/furans means the combined emissions of tetra-through octa-chlorinated dibenzo-para-dioxins and dibenzofurans, as measured by EPA Reference Method 23.

Dry scrubber means an add-on air pollution control system that injects dry alkaline sorbent (dry injection) or sprays an alkaline sorbent (spray dryer) to react with and neutralize acid gases in the HMIWI exhaust stream forming a dry powder material.

Fabric filter or *baghouse* means an add-on air pollution control system that removes particulate matter (PM) and nonvaporous metals emissions by passing flue gas through filter bags.

Facilities manager means the individual in charge of purchasing, maintaining, and operating the HMIWI or the owner's or operator's representative responsible for the management of the HMIWI. Alternative titles may include director of facilities or vice president of support services.

High-air phase means the stage of the batch operating cycle when the primary chamber reaches and maintains maximum operating temperatures.

Hospital means any facility which has an organized medical staff, maintains at least six inpatient beds, and where the primary function of the institution is to provide diagnostic and therapeutic patient services and continuous nursing care primarily to human inpatients who are not related and who stay on average in excess of 24 hours per admission. This definition does not include facilities maintained for the sole purpose of providing nursing or convalescent care to human patients who generally are not acutely ill but who require continuing medical supervision.

Hospital/medical/infectious waste incinerator or HMIWI or *HMIWI unit* means any device that combusts any amount of hospital waste and/or medical/infectious waste.

Hospital/medical/infectious waste incinerator operator or *HMIWI operator* means any person who operates, controls or supervises the day-to-day operation of an HMIWI.

Hospital waste means discards generated at a hospital, except unused items returned to the manufacturer. The definition of hospital waste does not include human corpses, remains, and

anatomical parts that are intended for interment or cremation.

Infectious agent means any organism (such as a virus or bacteria) that is capable of being communicated by invasion and multiplication in body tissues and capable of causing disease or adverse health impacts in humans.

Intermittent HMIWI means an HMIWI that is designed to allow waste charging, but not ash removal, during combustion.

Large HMIWI means:

(1) Except as provided in paragraph (2) of this definition;

(i) An HMIWI whose maximum design waste burning capacity is more than 500 pounds per hour; or

(ii) A continuous or intermittent HMIWI whose maximum charge rate is more than 500 pounds per hour; or

(iii) A batch HMIWI whose maximum charge rate is more than 4,000 pounds per day.

(2) The following are not large HMIWI:

(i) A continuous or intermittent HMIWI whose maximum charge rate is less than or equal to 500 pounds per hour; or

(ii) A batch HMIWI whose maximum charge rate is less than or equal to 4,000 pounds per day.

Low-level radioactive waste means waste material which contains radioactive nuclides emitting primarily beta or gamma radiation, or both, in concentrations or quantities that exceed applicable federal or State standards for unrestricted release. Low-level radioactive waste is not high-level radioactive waste, spent nuclear fuel, or by-product material as defined by the Atomic Energy Act of 1954 (42 U.S.C. 2014(e)(2)).

Malfunction means any sudden, infrequent, and not reasonably preventable failure of air pollution control equipment, process equipment, or a process to operate in a normal or usual manner. Failures that are caused, in part, by poor maintenance or careless operation are not malfunctions. During periods of malfunction the operator must operate within established parameters as much as possible, and monitoring of all applicable operating parameters must continue until all waste has been combusted or until the malfunction ceases, whichever comes first.

Maximum charge rate means:

(1) For continuous and intermittent HMIWI, 110 percent of the lowest 3-hour average charge rate measured during the most recent performance test demonstrating compliance with all applicable emission limits.

(2) For batch HMIWI, 110 percent of the lowest daily charge rate measured during the most recent performance test demonstrating compliance with all applicable emission limits.

Maximum design waste burning capacity means:

(1) For intermittent and continuous HMIWI,

$$C = P_v \times 15{,}000/8{,}500 \qquad \text{(Eq. 4)}$$

Where:

C = HMIWI capacity, lb/hr

P_V = primary chamber volume, ft^3

15,000 = primary chamber heat release rate factor, $Btu/ft^3/hr$

8,500 = standard waste heating value, Btu/lb;

(2) For batch HMIWI,

$$C = P_v \times 4.5/8 \qquad \text{(Eq. 5)}$$

Where:

C = HMIWI capacity, lb/hr

P_V = primary chamber volume, ft^3

4.5 = waste density, lb/ft^3

8 = typical hours of operation of a batch HMIWI, hours.

Maximum fabric filter inlet temperature means 110 percent of the lowest 3-hour average temperature at the inlet to the fabric filter (taken, at a minimum, once every minute) measured during the most recent performance test demonstrating compliance with the dioxin/furan emission limit.

Maximum flue gas temperature means 110 percent of the lowest 3-hour average temperature at the outlet from the wet scrubber (taken, at a minimum, once every minute) measured during the most recent performance test demonstrating compliance with the mercury (Hg) emission limit.

Medical/infectious waste means any waste generated in the diagnosis, treatment, or immunization of human beings or animals, in research pertaining thereto, or in the production or testing of biologicals that is listed in paragraphs (1) through (7) of this definition. The definition of medical/infectious waste does not include hazardous waste identified or listed under the regulations in part 261 of this chapter; household waste, as defined in § 261.4(b)(1) of this chapter; ash from incineration of medical/infectious waste, once the incineration process has been completed; human corpses, remains, and anatomical parts that are intended for interment or cremation; and domestic sewage materials identified in § 261.4(a)(1) of this chapter.

(1) Cultures and stocks of infectious agents and associated biologicals, including: Cultures from medical and pathological laboratories; cultures and stocks of infectious agents from research and industrial laboratories; wastes from the production of biologicals; discarded live and attenuated vaccines; and culture dishes and devices used to transfer, inoculate, and mix cultures.

(2) Human pathological waste, including tissues, organs, and body parts and body fluids that are removed during surgery or autopsy, or other medical procedures, and specimens of body fluids and their containers.

(3) Human blood and blood products including:

(i) Liquid waste human blood;

(ii) Products of blood;

(iii) Items saturated and/or dripping with human blood; or

(iv) Items that were saturated and/or dripping with human blood that are now caked with dried human blood; including serum, plasma, and other blood components, and their containers, which were used or intended for use in either patient care, testing and laboratory analysis or the development of pharmaceuticals. Intravenous bags are also include in this category.

(4) Sharps that have been used in animal or human patient care or treatment or in medical, research, or industrial laboratories, including hypodermic needles, syringes (with or without the attached needle), Pasteur pipettes, scalpel blades, blood vials, needles with attached tubing, and culture dishes (regardless of presence of infectious agents). Also included are other types of broken or unbroken glassware that were in contact with infectious agents, such as used slides and cover slips.

(5) Animal waste including contaminated animal carcasses, body parts, and bedding of animals that were known to have been exposed to infectious agents during research (including research in veterinary hospitals), production of biologicals or testing of pharmaceuticals.

(6) Isolation wastes including biological waste and discarded materials contaminated with blood, excretions, exudates, or secretions from humans who are isolated to protect others from certain highly communicable diseases, or isolated animals known to be infected with highly communicable diseases.

(7) Unused sharps including the following unused, discarded sharps: hypodermic needles, suture needles, syringes, and scalpel blades.

Medium HMIWI means:

(1) Except as provided in paragraph (2) of this definition;

(i) An HMIWI whose maximum design waste burning capacity is more than 200 pounds per hour but less than or equal to 500 pounds per hour; or

(ii) A continuous or intermittent HMIWI whose maximum charge rate is more than 200 pounds per hour but less than or equal to 500 pounds per hour; or

(iii) A batch HMIWI whose maximum charge rate is more than 1,600 pounds per day but less than or equal to 4,000 pounds per day.

(2) The following are not medium HMIWI:

(i) A continuous or intermittent HMIWI whose maximum charge rate is less than or equal to 200 pounds per hour or more than 500 pounds per hour; or

(ii) A batch HMIWI whose maximum charge rate is more than 4,000 pounds per day or less than or equal to 1,600 pounds per day.

Minimum dioxin/furan sorbent flow rate means 90 percent of the highest 3-hour average dioxin/furan sorbent flow rate (taken, at a minimum, once every hour) measured during the most recent performance test demonstrating compliance with the dioxin/furan emission limit.

Minimum Hg sorbent flow rate means 90 percent of the highest 3-hour average Hg sorbent flow rate (taken, at a minimum, once every hour) measured during the most recent performance test demonstrating compliance with the Hg emission limit.

Minimum horsepower or amperage means 90 percent of the highest 3-hour average horsepower or amperage to the wet scrubber (taken, at a minimum, once every minute) measured during the most recent performance test demonstrating compliance with the applicable emission limits.

Minimum hydrogen chloride (HCl) sorbent flow rate means 90 percent of the highest 3-hour average HCl sorbent flow rate (taken, at a minimum, once every hour) measured during the most recent performance test demonstrating compliance with the HCl emission limit.

Minimum pressure drop across the wet scrubber means 90 percent of the highest 3-hour average pressure drop across the wet scrubber PM control device (taken, at a minimum, once every minute) measured during the most recent performance test demonstrating compliance with the PM emission limit.

Minimum scrubber liquor flow rate means 90 percent of the highest 3-hour average liquor flow rate at the inlet to the wet scrubber (taken, at a minimum, once every minute) measured during the most recent performance test demonstrating compliance with all applicable emission limits.

Minimum scrubber liquor pH means 90 percent of the highest 3-hour average liquor pH at the inlet to the wet scrubber (taken, at a minimum, once every minute) measured during the most recent performance test demonstrating compliance with the HCl emission limit.

Minimum secondary chamber temperature means 90 percent of the highest 3-hour average secondary chamber temperature (taken, at a minimum, once every minute) measured during the most recent performance test demonstrating compliance with the PM, CO, or dioxin/furan emission limits.

Modification or *Modified HMIWI* means any change to an HMIWI unit after March 16, 1998, such that:

(1) The cumulative costs of the modifications, over the life of the unit, exceed 50 per centum of the original cost of the construction and installation of the unit (not including the cost of any land purchased in connection with such construction or installation) updated to current costs, or

(2) The change involves a physical change in or change in the method of operation of the unit which increases the amount of any air pollutant emitted by the unit for which standards have been established under section 129 or section 111.

Operating day means a 24-hour period between 12:00 midnight and the following midnight during which any amount of hospital waste or medical/infectious waste is combusted at any time in the HMIWI.

Operation means the period during which waste is combusted in the incinerator excluding periods of startup or shutdown.

Particulate matter or *PM* means the total particulate matter emitted from an HMIWI as measured by EPA Reference Method 5 or EPA Reference Method 29.

Pathological waste means waste material consisting of only human or animal remains, anatomical parts, and/or tissue, the bags/containers used to collect and transport the waste material, and animal bedding (if applicable).

Primary chamber means the chamber in an HMIWI that receives waste material, in which the waste is ignited, and from which ash is removed.

Pyrolysis means the endothermic gasification of hospital waste and/or medical/infectious waste using external energy.

Secondary chamber means a component of the HMIWI that receives combustion gases from the primary chamber and in which the combustion process is completed.

Shutdown means the period of time after all waste has been combusted in the primary chamber. For continuous HMIWI, shutdown must commence no less than 2 hours after the last charge to the incinerator. For intermittent HMIWI, shutdown must commence no less than 4 hours after the last charge to the incinerator. For batch HMIWI, shutdown must commence no less than 5 hours after the high-air phase of combustion has been completed.

Small HMIWI means:

(1) Except as provided in paragraph (2) of this definition;

(i) An HMIWI whose maximum design waste burning capacity is less than or equal to 200 pounds per hour; or

(ii) A continuous or intermittent HMIWI whose maximum charge rate is less than or equal to 200 pounds per hour; or

(iii) A batch HMIWI whose maximum charge rate is less than or equal to 1,600 pounds per day.

(2) The following are not small HMIWI:

(i) A continuous or intermittent HMIWI whose maximum charge rate is more than 200 pounds per hour;

(ii) A batch HMIWI whose maximum charge rate is more than 1,600 pounds per day.

Small rural HMIWI means a small HMIWI which is located more than 50 miles from the boundary of the nearest Standard Metropolitan Statistical Area and which burns less than 2,000 pounds per week of hospital waste and medical/infectious waste.

Standard conditions means a temperature of 20°C and a pressure of 101.3 kilopascals.

Standard Metropolitan Statistical Area or *SMSA* means any areas listed in

OMB Bulletin No. 93–17 entitled ''Revised Statistical Definitions for Metropolitan Areas'' dated June 30, 1993. This information can also be obtained from the nearest Metropolitan Planning Organization.

Startup means the period of time between the activation of the system and the first charge to the unit. For batch HMIWI, startup means the period of time between activation of the system and ignition of the waste.

Wet scrubber means an add-on air pollution control device that utilizes an alkaline scrubbing liquor to collect particulate matter (including nonvaporous metals and condensed organics) and/or to absorb and neutralize acid gases.

Delegation of Authority

§ 62.14495 What authorities will be retained by the EPA Administrator?

The following authorities will be retained by the EPA Administrator and not transferred to the State or Tribe:

(a) The requirements of § 62.14453(b) establishing operating parameters when using controls other than a dry scrubber followed by a fabric filter, a wet scrubber, or a dry scrubber followed by a fabric filter and a wet scrubber.

(b) Alternative methods of demonstrating compliance under 40 CFR 60.8.

TABLE 1 OF SUBPART HHH OF PART 62.—EMISSION LIMITS FOR SMALL RURAL, SMALL, MEDIUM, AND LARGE HMIWI

Pollutant	Units (7 percent oxygen, dry basis at standard conditions)	Emission limits			
		HMIWI size			
		Small rural	Small	Medium	Large
Particulate matter	Milligrams per dry standard cubic meter (grains per dry standard cubic foot).	197 (0.086)	115 (0.05)	69 (0.03)	34 (0.015)
Carbon monoxide	Parts per million by volume	40	40	40	40
Dioxins/furans	Nanograms per dry standard cubic meter total dioxins/furans (grains per billion dry standard cubic feet) or nanograms per dry standard cubic meter TEQ (grains per billion dry standard cubic feet).	800 (350) or 15 (6.6)	125 (55) or 2.3 (1.0)	125 (55) or 2.3 (1.0)	125 (55) or 2.3 (1.0)
Hydrogen chloride	Parts per million by volume or percent reduction.	3,100	100 or 93%	100 or 93%	100 or 93%
Sulfur dioxide	Parts per million by volume	55	55	55	55
Nitrogen oxides	Parts per million by volume	250	250	250	250
Lead	Milligrams per dry standard cubic meter (grains per thousand dry standard cubic feet) or percent reduction.	10 (4.4)	1.2 (0.52) or 70%	1.2 (0.52) or 70%	1.2 (0.52) or 70%
Cadmium	Milligrams per dry standard cubic meter (grains per thousand dry standard cubic feet) or percent reduction.	4 (1.7)	0.16 (0.07) or 65%	0.16 (0.07) or 65%	0.16 (0.07) or 65%
Mercury	Milligrams per dry standard cubic meter (grains per thousand dry standard cubic feet) or percent reduction.	7.5 (3.3)	0.55 (0.24) or 85%	0.55 (0.24) or 85%	0.55 (0.24) or 85%

TABLE 2 OF SUBPART HHH OF PART 62.—TONIC EQUIVALENCY FACTORS

Dioxin/furan congener	Toxic equivalency factor
2,3,7,8-tetrachlorinated dibenzo-p-dioxin	1
1,2,3,7,8-pentachlorinated dibenzo-p-dioxin	0.5
1,2,3,4,7,8-hexachlorinated dibenzo-p-dioxin	0.1
1,2,3,7,8,9-hexachlorinated dibenzo-p-dioxin	0.1
1,2,3,6,7,8-hexachlorinated dibenzo-p-dioxin	0.1
1,2,3,4,6,7,8-heptachlorinated dibenzo-p-dioxin	0.01

TABLE 2 OF SUBPART HHH OF PART 62.—TONIC EQUIVALENCY FACTORS—Continued

Dioxin/furan congener	Toxic equivalency factor
Octachlorinated dibenzo-p-dioxin	0.001
2,3,7,8-tetrachlorinated dibenzofuran	0.1
2,3,4,7,8-pentachlorinated dibenzofuran	0.5
1,2,3,7,8-pentachlorinated dibenzofuran	0.05
1,2,3,4,7,8-hexachlorinated dibenzofuran	0.1
1,2,3,6,7,8-hexachlorinated dibenzofuran	0.1

TABLE 2 OF SUBPART HHH OF PART 62.—TONIC EQUIVALENCY FACTORS—Continued

Dioxin/furan congener	Toxic equivalency factor
1,2,3,7,8,9-hexachlorinated dibenzofuran	0.1
2,3,4,6,7,8-hexachlorinated dibenzofuran	0.1
1,2,3,4,6,7,8-heptachlorinated dibenzofuran	0.01
1,2,3,4,7,8,9-heptachlorinated dibenzofuran	0.01
Octachlorinated dibenzofuran	0.001

TABLE 3 OF SUBPART HHH OF PART 62.—OPERATING PARAMETERS TO BE MONITORED AND MINIMUM MEASUREMENT AND RECORDING FREQUENCIES

Operating parameters to be monitored	Minimum frequency		HMIWI			
	Data measurement	Data recording	Small rural HMIWI	HMIWI [a] with dry scrubber followed by fabric filter	HMIWI [a] with wet scrubber	HMIWI [a] with dry scrubber followed by fabric filter and wet scrubber
Maximum operating parameters:						
Maximum charge rate	Once per charge	Once per charge	✔	✔	✔	✔
Maximum fabric filter inlet temperature.	Continuous	Once per minute		✔		✔
Maximum flue gas temperature	Continuous	Once per minute			✔	✔
Minimum operating parameters:						
Minimum secondary chamber temperature.	Continuous	Once per minute	✔	✔	✔	✔
Minimum dioxin/furan sorbent flow rate.	Hourly	Once per hour		✔		✔
Minimum HCl sorbent flow rate	Hourly	Once per hour		✔		✔
Minimum mercury (Hg) sorbent flow rate.	Hourly	Once per hour		✔		✔
Minimum pressure drop across the wet scrubber or minimum horsepower or amperage to wet scrubber.	Continuous	Once per minute			✔	✔
Minimum scrubber liquor flow rate	Continuous	Once per minute			✔	✔
Minimum scrubber liquor pH	Continuous	Once per minute			✔	✔

[a] Does not include small rural HMIWI.

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