

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 62**

[AD-FRL-6365-8]

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:** Proposed rule.

**SUMMARY:** On September 15, 1997, EPA adopted emission guidelines for existing hospital/medical/infectious waste incinerator(s) (HMIWI). Sections 111 and 129 of the Clean Air Act (Act or 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 Act require EPA to develop, implement, and enforce a Federal plan for HMIWI in that State/Tribal area. In this action the EPA proposes a Federal plan to implement emission guidelines for HMIWI located in States and Indian country without effective State or Tribal plans. This Federal plan will most likely be an interim action for many of these areas because when a State/Tribal plan becomes effective, the Federal plan will

no longer apply to HMIWI covered by such plan.

**DATES:** *Comments.* You must submit comments on this proposal on or before September 7, 1999.

*Public Hearings.* The EPA will hold public hearings, if requested. Requests must be received by August 5, 1999. See the ADDRESSES section of this preamble for information on requesting a public hearing. You can obtain the date and location of the public hearing(s) by calling (919) 541-5420 or by E-mailing to banker.lalit@epa.gov after August 5, 1999.

**ADDRESSES:** *Comments.* Send your comments on this proposal (in duplicate, if possible) to: Air and Radiation Docket and Information Center (MC-6102), Attention docket number A-98-24, U. S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460. You may also submit your comments electronically by following the instructions in the **SUPPLEMENTARY INFORMATION** section of this preamble.

*Docket.* Docket numbers A-98-24 and A-91-61 contain the supporting information for this proposed rule and the supporting information for EPA's promulgation of emission guidelines for existing HMIWI, respectively. These dockets are available for public inspection and copying between 8:00 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, you can find an electronic

copy of this document at the EPA/STAPPA/ALAPCO Unified Air Toxics Website (<http://www.epa.gov/ttn/uatw/129/hmiwi/rihmiwi.html>).

*Public Hearings.* The public hearing(s) will be held in the respective EPA Regional Office covering the State from which a request was received. If you wish to speak at a public hearing you should notify Mr. Lalit Banker, Program Implementation and Review Group, Information Transfer and Program Integration Division (MD-12), U. S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, telephone (919) 541-5420.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this proposal, contact Mr. Lalit Banker at (919) 541-5420, Program Implementation and Review Group, Information Transfer and Program Integration Division (MD-12), U. S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711 (banker.lalit@epa.gov). If you have technical questions, 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 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, you may be covered by this proposed action. Existing HMIWI are those that commenced construction, modification, or reconstruction on or before June 20, 1996. Regulated categories and entities include those listed in Table 1.

TABLE 1.—REGULATED ENTITIES <sup>a</sup>

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.

<sup>a</sup> This table is not intended to be exhaustive, but rather, provides a guide for the public regarding entities likely to be regulated by this proposed 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. 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.

*Electronic submittal of comments.* You may submit comments and data on this proposed rule via E-mail. Send E-mail submittals to A-and-R-Docket@epa.gov. You may file E-mail comments at most Federal Depository Libraries. Do not submit confidential business information through E-mail. You may also submit comments and data on diskettes in WordPerfect 5.1 or 6.1 file format or ASCII file format. Electronic comments must avoid the use of special characters or any form of encryption. Identify all comments and data for this proposal, whether in paper form or electronic form, by docket number A-98-24.

*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, courcier.john@epa.gov ..	617-918-1659; 617-918-1505 (fax) .....	CT, ME, MA, NH, RI, VT.
II .....	Christine DeRosa, derosa.christine@epa.gov.	212-637-4022; 212-637-3901 (fax) .....	NJ, NY, Puerto Rico, Virgin Islands.
III .....	Ted Gardella, gardella.anthony@epa.gov	212-637-3892; 212-637-3901 (fax).	
IV .....	James B. Topsale, topsale.jim@epa.gov	215-814-2190; 215-814-2114 (fax) .....	DE, DC, MD, PA, VA, WV.
V .....	Scott Davis, davis.scottr@epa.gov .....	404-562-9127; 404-562-9095 (fax) .....	AL, FL, GA, KY, MS, NC, SC, TN.
	Ryan Bahr, bahr.ryan@epa.gov .....	312-353-4366; 312-886-5824 (fax) .....	IN.
	Charles Hatten, hatten.charles@epa.gov	312-886-6031; 312-886-5824 (fax) .....	WI.
	Mark Palermo, palermo.mark@epa.gov	312-886-6082; 312-886-5824 (fax) .....	IL, OH.
	Victoria Hayden, hayden.victoria@epa.gov.	312-886-4023; 312-886-5824 (fax) .....	WI.
	Doug Aburano, aburano.douglas@epa.gov.	312-353-6960; 312-886-5824 (fax) .....	MN.
VI .....	Mick Cote, cote.mick@epa.gov .....	214-665-7219; 214-665-7263 (fax) .....	AR, LA, NM, OK, TX.
VII .....	Wayne Kaiser, kaiser.wayne@epa.gov ...	913-551-7603; 913-551-7844 (fax) .....	IA, KS, MO, NE.
	Ward Burns, burns.ward@epa.gov .....	913-551-7960; 913-551-7844 (fax) .....	
VIII .....	Meredith Bond, bond.meredith@epa.gov	303-312-6438; 303-312-6064 (fax) .....	CO, MT, ND, SD, UT, WY.
IX .....	Patricia Bowlin, bowlin.patricia@epa.gov	415-744-1188; 415-744-1076 (fax) .....	AZ, CA, HI, NV, American Samoa, Guam.
X .....	Catherine Woo, woo.catherine@epa.gov	206-553-1814; 206-553-0110 (fax) .....	AK, ID, OR, WA.

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## 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 Act. 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 Act 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. Furthermore, EPA plans to develop, implement, and enforce a Federal plan for Indian country until Tribes receive approval to administer their own programs. 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 proposes the HMIWI Federal plan.

### B. Who This HMIWI Federal Plan Affects

This proposed HMIWI Federal plan would affect existing HMIWI for which construction commenced on or before June 20, 1996. HMIWIs would 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;<sup>a</sup>

(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 proposed §§ 62.14400 through 62.14403 of subpart HHH.

The Federal plan would become effective 30 days after final promulgation. Once an approved State or Tribal plan is in effect, the Federal plan would no longer apply to HMIWI covered by such plan.

### C. Implementing Authority

The EPA Regional Administrators will be the delegated 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.

### 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 HMIWI Federal plan would apply throughout Indian country to ensure that there is not a regulatory gap for existing HMIWI in Indian country. However, Indian tribes now have the authority under the Act to develop Tribal plans in the same manner that States develop State plans. On February 12, 1998, EPA promulgated regulations that outline provisions of the Act for

<sup>a</sup> 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.

which EPA is authorized to treat Tribes in the same manner as States. See 63 FR 7254 (Final Rule for Indian Tribes: Air Quality Planning and Management, (Tribal Authority Rule)) (codified at 40 CFR part 49). As of March 16, 1998, the effective date of the Tribal Authority Rule, EPA has had authority under the Act to approve Tribal programs such as Tribal plans to implement and enforce HMIWI emission guidelines.

#### 1. Tribal Implementation

Section 301(d) of the Act authorizes the Administrator to treat an Indian tribe as a State under certain circumstances. The Tribal Authority Rule, which implements section 301(d) of the Act, identifies provisions of the Act for which a Tribe should be treated as a State. See 40 CFR 49.3 and 49.4. Under the Tribal Authority Rule, a Tribe is treated as a State for purposes of this Federal plan. If a Tribe meets the criteria below, EPA can delegate to an Indian tribe authority to implement the Federal plan in the same way it can delegate authority to a State:

(1) The applicant is an Indian tribe recognized by the Secretary of the Interior;

(2) The Indian tribe has a governing body carrying out substantial governmental duties and functions;

(3) The functions to be exercised by the Indian tribe pertain to the management and protection of air resources within the exterior boundaries of the reservation or other areas within the tribe's jurisdiction; and

(4) The Indian tribe is reasonably expected to be capable, in the EPA Regional Administrator's judgement, of carrying out the functions to be exercised in a manner consistent with the terms and purposes of the Act and all applicable regulations. See 40 CFR 49.6.

#### 2. EPA Implementation

The Act also provides EPA with the authority to administer Federal programs in Indian country. This authority is based in part on the general purpose of the Act, which is national in scope. Section 301(a) of the Act provides EPA broad authority to issue regulations that are necessary to carry out the functions of the Act. The EPA believes that Congress intended for EPA to have the authority to operate a Federal program when Tribes choose not to develop a program, do not adopt an approvable program, or fail to adequately implement an air program authorized under section 301(d) of the Act.

Section 301(d)(4) of the Act authorizes the Administrator to directly administer provisions of the Act to

achieve the appropriate purpose where Tribal implementation is not appropriate or administratively not feasible. The Agency's interpretation of its authority to directly implement Clean Air Act programs in Indian country is discussed in more detail in the proposed Federal Operating Permits Rule, see 62 FR 13747 (March 21, 1997), and in the Tribal Authority Rule. See 63 FR at 7262-7263.

Many Tribes may have delayed development of air quality regulations and programs pending promulgation of the Tribal Authority Rule. As mentioned previously, Tribes may, but are not required to, submit an HMIWI plan under section 111(d) of the Act.

#### 3. Applicability in Indian Country

The Federal plan would apply throughout Indian country except where a State or 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 cited above where the rationale is discussed in detail. The EPA requests comments on applying the HMIWI Federal plan in Indian country as described here.

### E. HMIWI Federal Plan and Compliance Schedules

The emission guidelines require the HMIWI owner or operator to come into compliance with the State or Tribal plan within 1 year after approval of such plan, or within 1 year after promulgation of the Federal plan (whichever applies). See 40 CFR 60.39e(b). However, if the State or Tribal plan contains measurable and enforceable increments of progress, the HMIWI may be allowed up to 3 years after approval of the plan (but in no case later than September 15, 2002) to come into compliance. See 40 CFR 60.39e(c).

This proposed Federal plan contains measurable and enforceable increments of progress that allow sources up to 3 years after promulgation of the Federal plan to comply (but in no case later than September 15, 2002.) The increments of progress are discussed in section II.E of this preamble.

#### 1. Due Within 1 Year of Promulgation

Except under the special circumstances that are discussed below, HMIWI that are planning to shut down rather than comply with the requirements of the Federal plan must do so by the date 1 year after the Federal plan is promulgated. In addition, according to § 60.39e(e) of subpart Ce, 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. This 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 pursuant to § 60.39e(d) of subpart Ce).

#### 2. Special Provisions of § 60.39e(d)

The Federal plan may contain provisions allowing HMIWI that are planning to shut down the opportunity to petition the State, Tribe, or EPA for an extension beyond the 1-year compliance date. See 40 CFR 60.39e(d). This proposed Federal plan contains provisions for granting and denying petitions for an extension beyond the 1-year compliance deadline (but no later than September 15, 2002). An example of a facility that might petition the enforcement authority 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 under the Federal plan, which are set forth at proposed § 62.14471 of subpart HHH, are the same as the requirements listed at § 60.39e(d) of subpart Ce, except that EPA proposes a specific date of 90 days following promulgation of the Federal plan by which petitions must be submitted to EPA under the Federal plan. This time frame, which is more than 2 years after promulgation of the emission guidelines and more than 9 months from today's proposal, should give sources sufficient time to examine their waste disposal options and to prepare the necessary documentation to justify their need for an extension. This time frame also gives EPA sufficient time to grant or deny the petition before the 1-year compliance deadline arrives.

#### F. Status of State Plan Submittals

Sections 111(d) and 129(b)(2) of the Act, 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. The EPA has received final State plans from New York, Delaware, Louisiana, Georgia, Alabama, North Dakota, Montana, and Colorado. The EPA has received draft State plans from Puerto Rico, Maryland, West Virginia, Pennsylvania, Iowa, Ohio, Indiana, Minnesota, Illinois, Michigan, South

Dakota, Utah, Washington, and Wyoming. Other States are making significant progress on their State plans and EPA expects many State plans to be approved before this Federal plan is final.

The EPA anticipates letters of negative declaration from New Mexico and Oregon. The EPA is not aware of any Indian tribes that are developing Tribal plans.

The preamble of the final Federal plan will list States and Tribes that have an EPA-approved plan in effect on the date the final Federal plan is signed by the EPA Administrator. 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 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

Because the EPA is proposing a Federal plan to cover HMIWI located in States or Tribes where plans are not in effect, this proposal includes the same elements as are required for State plans: (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; (7) testing, monitoring, inspection, reporting, and recordkeeping; (8) waste management plan; (9) operator training and qualification; and (10) progress reporting. See 40 CFR part 60 subparts B and C and sections 111 and 129 of the Act. Docket item II-B-3 in docket A-98-24 identifies each element and indicates where it is addressed. Each element is described below as it relates to the proposed HMIWI Federal plan.

##### A. Legal Authority and Enforcement Mechanism

A State or Tribal plan must demonstrate that the State or Tribe has the legal authority to adopt and implement the emission guidelines. 40 CFR 60.26. In its plan, the State or Tribe must identify the enforcement

mechanism for implementing the emission guidelines, such as a State or Tribal rule.

##### 1. EPA's Legal Authority in States

Section 301(a) of the Act provides the EPA with broad authority to write regulations that carry out the functions of the Act. Sections 111(d) and 129(b)(3) of the Act authorize the EPA to develop a Federal plan for States that do not submit approvable State plans.

##### 2. EPA's Legal Authority in Indian Country

Section 301(a) provides EPA with the authority to administer Federal programs in Indian country. Section 301(d)(4) of the Act authorizes the Administrator to directly administer provisions of the Act where Tribal implementation of those provisions is not appropriate or administratively not feasible. See section I.D. of this preamble for a more detailed discussion of EPA's authority to administer the HMIWI Federal plan in Indian country.

The EPA is proposing this Federal regulation under the legal authority of the Act to implement the emission guidelines in those States and areas of Indian country not covered by an approved plan. As discussed in section IV of this document, implementation and enforcement of the Federal plan may be delegated to Tribal, State, or local agencies when requested by a State, Tribal, or local agency, and when EPA determines that such delegation is appropriate.

##### B. Inventory of Affected HMIWI

A State or Tribal plan must include an inventory of HMIWI affected by the emission guidelines. 40 CFR 60.25(a). Consistent with this requirement, docket number A-98-24, item II-B-1 contains an inventory of all the HMIWI EPA is aware of that will be covered by this proposed Federal plan.

This inventory was initially created in 1995 in connection with development of the HMIWI emission guidelines. In late 1998, EPA gave States an opportunity to submit updates to the 1995 list. Many States responded and in most cases, EPA was able to incorporate these updates. However, EPA recognizes that this list may not be complete. Therefore, sources subject to this Federal plan would include, but would not be limited to, the HMIWI listed in docket A-98-24, item II-B-1. States, Tribes, or individuals with corrections to the Federal plan inventory are invited to submit their corrections during the comment period for this proposal.

Hospital/medical/infectious waste incinerators that are located in a State

or Tribal area with an approved and effective plan, but that are not covered by such plan (for example, because they were inadvertently omitted from the coverage of the plan and the plan fails to contain language that would include inadvertently omitted HMIWI), would automatically be covered by the Federal plan. There will be no need to reopen the Federal plan to add such HMIWI.

#### C. Inventory of Emissions

A State plan must include an emissions estimate for HMIWI subject to the emission guidelines. 40 CFR 60.25(a). The pollutants to be inventoried are dioxins/furans, cadmium (Cd), lead (Pb), mercury (Hg), particulate matter (PM), hydrogen chloride (HCl), nitrogen oxides (NO<sub>x</sub>), carbon monoxide (CO), and sulfur dioxide (SO<sub>2</sub>). For this proposal, EPA has estimated the emissions from each HMIWI that would be covered by the Federal plan for the nine pollutants regulated by the Federal plan. This emissions inventory is included in item II-B-1 in docket A-98-24.

Pollutant emissions are expressed in kilograms per year (kg/yr) for most pollutants and grams per year (g/yr) for dioxins/furans. The emissions inventory is based on available information about the HMIWI and emission factors developed for purposes of calculating nationwide air impacts of the emission guidelines. Refer to the emissions estimates memorandum in docket A-98-24 (item II-B-1) for the complete emissions inventory and details on the calculations.

#### D. Emission Limits

A State plan must include emission limits. 40 CFR 60.24(a). Section 129(b)(2) of the Act requires these emission limits to be "at least as protective as" those in the emission guidelines. The emission limits in this proposed HMIWI Federal plan are the same as those contained in the emission guidelines.

The HMIWI source category is divided into three subcategories based on waste burning capacity: Small ( $\leq 200$  pounds per hour [lb/hr]), medium ( $> 200$  to 500 lb/hr), and large ( $> 500$  lb/hr). Separate emission limits apply to each subcategory of existing HMIWI. Small HMIWI that meet certain "rural criteria" are allowed to meet less stringent emission limits. The numerical emission limits and additional requirements are summarized in section VI of this preamble.

#### E. Increments of Progress

Increments of progress are required for HMIWI that need more than 1 year

from State plan approval to comply, or in the case of the Federal plan, more than 1 year after promulgation of the final Federal plan. 40 CFR 60.24(e)(1). 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 proposed 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.

##### 1. How EPA Determined the Compliance Schedule

The increments of progress and the time proposed for their completion are based on case studies conducted by EPA of eight HMIWI that completed retrofits of the types of controls needed to meet the subpart Ce emission limits. These case studies are documented in docket A-98-24, item II-A-1. Based on these case studies, it appears that some HMIWI may need more than 1 year to retrofit with controls. Using the schedules from the case studies as a basis, the EPA determined the proper intervals for each of the subpart B increments.

To ensure compliance, the five increments of progress proposed for the Federal plan are the minimum increments of progress allowed by subpart B, see 40 CFR 60.21(h), and are found at proposed § 62.14470(b) of subpart HHH. The following increments would apply to all HMIWI, regardless of category or size, that require longer than 1 year after the promulgation date of this Federal plan to comply:

- (1) Submit final control plan;
- (2) Award contracts for control systems or process modifications or orders for purchase of components;
- (3) Begin onsite construction or installation of the air pollution control device(s) or process changes;
- (4) Complete onsite construction or installation of the air pollution control device(s) or process changes; and
- (5) Final compliance.

Subpart Ce suggests additional increments of progress, however, the EPA is proposing not to include additional increments of progress. By not imposing additional increments of progress, EPA hopes to minimize burden on the industry that could result with more increments. EPA, however, solicits comment on whether additional increments are warranted.

##### 2. Owner/Operator Responsibilities

The HMIWI owner or operator is responsible for meeting each of the five

increments of progress for each HMIWI unit 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 proposed 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 air pollution control devices 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.

The EPA believes this compliance schedule is achievable and necessary based on the following:

(1) When determining completion dates for the increments of progress, EPA applied the maximum amount of time that most HMIWI in the case study needed in order to comply;

(2) Since September 15, 1997 when the emission guidelines were promulgated, HMIWI owners and operators have known that they would need to make process changes or install controls by September 15, 2002; and

(3) The EPA believes that a compliance schedule with enforceable increments of progress is necessary to ensure final compliance by September 15, 2002.

### 3. Failure to Comply

If an HMIWI does not achieve final compliance by September 15, 2002, this proposed Federal plan would require 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.

### F. Waste Management Plan Requirements

Under the emission guidelines, State plans must require owners and operators of HMIWI to develop waste management plans in compliance with 40 CFR 60.55c. See 40 CFR 60.35e. The proposed HMIWI Federal plan includes the same requirement (see proposed 40 CFR 62.14430 and 62.14431 of subpart HHH).

### G. Testing, Monitoring, Inspection, Recordkeeping, and Reporting Requirements

Under the emission guidelines, State plans must include the testing, monitoring, recordkeeping, and reporting requirements set forth at 40 CFR 60.37e and 60.38e of subpart Ce. The proposed HMIWI Federal plan includes virtually the same requirements (see proposed 40 CFR 62.14450 through 62.14455 and §§ 62.14460 through 62.14465 of subpart HHH).

Minor changes are proposed to the testing and monitoring requirements to clarify the meaning of those requirements and to insert some text that was inadvertently omitted from the emission guidelines. Subpart Ce specifies a 3-hour rolling average when monitoring maximum charge rate. While this is correct for continuous and intermittent HMIWI, it is not correct for batch HMIWI. For batch HMIWI, the requirement is proposed to be a daily average, consistent with the definition of maximum charge rate for batch units.

### H. Operator Training and Qualification Requirements

Under the emission guidelines, State plans must include the operator training and qualification requirements set forth at 40 CFR 60.53c. See 40 CFR 60.34e. The proposed HMIWI Federal plan includes these requirements as well (see proposed 40 CFR 62.14420 through 62.14425 of subpart HHH).

### I. Record of Public Hearings

A State must provide opportunity for public participation in adopting the State plan. See 40 CFR 60.23(c). In adopting any HMIWI Federal plan, the EPA will hold public hearing(s) at appropriate Regional Offices, if requested. A record of the public hearing(s), if any, will appear in the docket.

### J. Progress Reports

Under the emission guidelines, States or Tribes with approved and effective plans must send annual progress reports to the appropriate Regional Office to show their progress toward implementation of the emission guidelines. 40 CFR 60.25(e). Under the Federal plan, the EPA Regional Offices will prepare these progress reports. States or Tribes that have been delegated the authority to implement and enforce this Federal plan would also be required to submit annual progress reports to the appropriate EPA Regional Office.

Appendix D of 40 CFR part 60 requires reporting of emissions data to

the Aerometric Emissions Information Retrieval System Facility Subsystem (AIRS). These reports can be combined with the State implementation plan report required by 40 CFR 51.321 in order to avoid double reporting. Under the proposed Federal plan, EPA Regional Offices would report AIRS emissions data. If a State or Tribe has been delegated the authority to implement and enforce the Federal plan, the State or Tribe would report emissions data to AIRS.

Each progress report must include the following items: (1) Status of enforcement actions; (2) status of increments of progress; (3) identification of sources that have shut down or started operation; (4) emission inventory data for sources that were not in operation at the time of plan development, but that began operation during the reporting period; (5) additional data as necessary to update previously submitted source and emission information; and (6) copies of technical reports on any performance testing and monitoring.

### III. HMIWI That Have or Will Shut Down

#### A. Inoperable Units

In cases where an HMIWI has shut down and does not intend to restart, the HMIWI may be left off the source inventory in a State, Tribal, or this Federal plan if it is rendered inoperable. The HMIWI owner/operator may do 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.

#### B. HMIWI That Have Shut Down

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 of this proposed Federal plan. Such units must also be identified in any State or Tribal plan submitted to EPA.

#### 1. Restarting Before September 15, 2002

If the owner or operator of an inactive HMIWI plans to restart before September 15, 2002, the owner or operator would be required 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. (See section II.E for the discussion on compliance schedules and increments of progress.)

## 2. Restarting After September 15, 2002

Under this proposed Federal plan, a control plan would not be needed for inactive HMIWI that restart after September 15, 2002. However, before restarting, such HMIWI would have to 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 would be no need to show that the increments of progress have been met since these steps would 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 would be in violation of the Federal plan and subject to enforcement action.

## IV. Implementation of the Federal Plan and Delegation

### A. Background of Authority

Under sections 111(d) and 129(b) of the Act, 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 Act. Consistent with that overall determination, Congress established sections 111 and 129 of the Act 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 Act, 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 1994 in a memorandum entitled "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 (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. A Memorandum of Agreement (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 States, Tribes, and local 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, Tribal, or local 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 plan and the State, Tribal, or local 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, Tribal, or local 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, Tribal, or local 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 draft notices of violation. The EPA would retain responsibility for bringing enforcement actions against sources violating Federal plan provisions.

## V. Title V Operating Permits

Section 502(a) of the Act requires sources "subject to standards or regulations under section 111" to obtain title V operating permits. See also 40 CFR 70.3(a)(2) and 71.3(a)(2). Because EPA is proposing this Federal plan under sections 111 and 129 of the Act, sources subject to this Federal plan must obtain title V permits. Those title V 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 Act, 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 permit program that covers the area in which the unit is located, whichever is later. 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.<sup>b</sup>

<sup>b</sup> Section 503(d) of the Act 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

An earlier permit deadline may apply if an HMIWI is subject to title V for another reason. For example, an HMIWI might already be subject to title V as a result of being a major source under one or more of three major source definitions in title V—section 112, section 302, or part D of title I of the Act. See 40 CFR 70.3(a)(1) and 71.3(a)(1) (subjecting major sources to title V permitting) and §§ 70.2 and 71.2 (defining major source for purposes of title V). An HMIWI might also already be subject to title V if it is subject to some other earlier promulgated standard under section 111 or 112 of the Act. See 40 CFR 70.3(a)(2) and (3), 71.3(a)(2) and (3). 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.<sup>c</sup> However, the owner or operator remains subject to, and must act in compliance with, the Federal plan requirements.

Owners or operators of combustors that burn only pathological waste, low-

application deadline in order to obtain the application shield. See proposed 40 CFR 62.14481 and 40 CFR 70.5(a)(2) and 71.5(a)(2).

<sup>c</sup> 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 permit 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 permit program regulations or permitting authorities to determine whether revisions to their permits are necessary to incorporate the Federal plan requirements.

level radioactive waste, and/or chemotherapeutic waste and co-fired combustors, as defined in this proposed Federal plan, must comply only with certain recordkeeping and reporting requirements set forth in the proposed Federal plan. See proposed § 62.14400. They are not subject to the other substantive emissions 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. 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 nonemissions control-related recordkeeping and reporting requirements. See proposed § 62.14480. The EPA interprets the CAA and the regulations at parts 70 and 71 to mean that these sources are "not subject to standards or regulations under section 111" for purposes of title V permitting. See CAA section 502(a) and 40 CFR 70.3(a)(2) and 71.3(a)(2). Therefore, these sources would not be 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 substantive emissions control-related requirements of this proposed Federal plan. However, owners and operators of sources 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 would become subject to those other requirements and would have to obtain title V permits. Moreover, if, in the future, EPA promulgates regulations subjecting any of these sources to substantive requirements other than these recordkeeping and reporting requirements, these sources could become subject to title V at that time.

Section 502(a) of the Act requires title V permits of listed sources, including any source "subject to standards or regulations under section 111 \* \* \*." See also 40 CFR 70.3(a)(2) and 71.3(a)(2). The EPA reads the recordkeeping and reporting requirements of this proposed Federal plan, which are simply conditions for exemption from the other substantive emissions control-related requirements of the Federal plan, not to be requirements that would make a source "subject to" a section 111 standard (here the HMIWI Federal plan) within the



meaning of these statutory and regulatory provisions. Accordingly, HMIWI that comply with the recordkeeping and reporting requirements necessary for their exemption from the other substantive emissions control-related requirements of the Federal plan are not "subject to" the Federal plan solely for purposes of being required to obtain a title V permit. Hospital/medical/ infectious waste incinerators that are subject to Federal plan requirements other than these recordkeeping or reporting conditions as well as HMIWI that fail to comply with any of the conditions for exemption from these other substantive emissions control-related Federal plan requirements are subject to title V permitting under section 502(a).

It is worth noting that section 502(a) of the Act 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 regulations." The EPA is *not* invoking this mechanism to justify its conclusion that the HMIWI discussed above are not required to obtain title V permits. These HMIWI have not been "exempted" from title V within the meaning of the last sentence of section 502(a), and the Agency does not purport to have made the statutory showing of impracticability, infeasibility or unnecessary burden for these sources. Rather, the Agency believes that the recordkeeping and reporting requirements with which these HMIWI must comply 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, HMIWI 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 Act.

In addition to being consistent with the governing statutory provisions, EPA believes this approach is sound and environmentally protective. Where HMIWI have only recordkeeping and/or reporting obligations designed to show they are not subject to the other requirements of the Federal plan, EPA does not believe that it makes sense to compel them to obtain title V permits based upon a possible technical argument that in that minimal sense they are subject to the subpart for purposes of section 502(a) of the Act. Moreover, because these HMIWI may

well not currently be covered by applicable Federal requirements other than this Federal plan's recordkeeping and reporting requirements, a contrary approach would lead to the paradoxical and unreasonable result that these HMIWI would be obtaining title V permits whose sole requirements were conditions demonstrating their exemption from the other substantive requirements of the Federal standard that triggered the need to obtain a permit.

In addition to the likely bareness of these HMIWI title V permits, the applicability and compliance provisions these HMIWI must meet are simpler than the usual applicable requirements in a title V permit. Therefore, the multiple, sometimes complex applicability determinations so integral to the title V permit issuance process are accomplished here through simple notifications to EPA (or delegated EPA Regional Office, State, or Tribe). While title V permits are important in helping States and Tribes, EPA, sources, and the public assure compliance with a source's Clean Air Act obligations, the Agency does not believe this objective would be significantly advanced by these sources obtaining title V permits, particularly not to a degree that would outweigh the time, resources, expense and permit fees associated with the permit process in this instance. The EPA believes the approach described herein comports with the Act and Federal regulations, represents a sensible solution to these uniquely situated sources, and affords the environmental protection demanded by the law.

#### **VI. Owner/Operator Responsibilities**

The proposed HMIWI Federal rule (40 CFR part 62, subpart HHH) which will implement 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. These emission standards and requirements are the same as those in the emission guidelines (40 CFR part 60, subpart Ce). The requirements are summarized in this section.

##### **A. Applicability**

The HMIWI Federal plan would apply to existing HMIWI that 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 the 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 proposed § 62.14490 of subpart HHH.

Incinerators that burn only pathological, low-level radioactive, or chemotherapeutic waste (all defined in proposed § 62.14490 of subpart HHH) are required to 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. However, these HMIWI are not subject to the other substantive requirements of the Federal plan during periods when they burn such wastes provided that they comply with the applicable notification and recordkeeping requirements. 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 other substantive 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 part 60 subparts Cb, Ea, or Eb. Finally, pyrolysis units (as defined at 40 CFR 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 ( $\leq 200$  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 1 of subpart HHH provides the emission limits for existing HMIWI covered by the proposed Federal plan. In addition to the emission limits presented in Table 1, 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 alternative emission limits for small HMIWI that meet the rural criteria are provided in Table 1 of subpart HHH.

**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 proposed Federal plan.

The proposed Federal plan contains operator training and qualification requirements for all HMIWI. Each facility would be 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 would be required to develop site-specific HMIWI operating procedures. Employees involved with HMIWI operation must review the site-specific operating information annually.

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

The compliance and performance testing requirements in the proposed Federal plan would 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 opacity limit, and establish operating parameters. These HMIWI would also be required to conduct annual performance tests to determine compliance with the PM, CO, and HCl emission limits and opacity limit. The proposed Federal plan would allow 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 proposed Federal plan contains monitoring requirements for all HMIWI. Each facility would be required to install and maintain equipment to continuously monitor operating parameters including secondary chamber temperature, waste feed rate, bypass stack, and air pollution control device (APCD) operating parameters as appropriate. The proposed Federal plan would require facilities to obtain monitoring data at all times during HMIWI operation.

In addition, the proposed Federal plan contains reporting and recordkeeping requirements for all HMIWI. Facilities would be required to maintain records for 5 years of results from the initial performance test and all subsequent performance tests, operating parameters, inspections (small rural HMIWI only), and operator training and qualification. Facilities would be 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.

A summary of dates for compliance with the Federal plan for HMIWI is presented in Table 3.

TABLE 3.—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. <sup>a</sup>
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.

TABLE 3.—COMPLIANCE TIMES UNDER THE FEDERAL PLAN FOR ALL HMIWI—Continued

Requirement	Compliance time
Reporting .....	Within 60 days after initial performance test; annually for subsequent reporting requirements; semiannually, if noncompliance.

<sup>a</sup> Facilities may conduct performance tests for PM, CO, and HC1 every third year if the previous three performance tests demonstrate that the facility is in compliance with the emission limits for PM, CO, and HC1.

**VII. Administrative Requirements**

This section addresses the following administrative requirements: Docket, Paperwork Reduction Act, Executive Orders 12866, 12875, 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 proposed rule merely implements the emission guidelines promulgated on September 15, 1997 (codified at 40 CFR 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 Act.

As discussed above, a docket has been prepared for this action pursuant to the procedural requirements of section 307(d) of the Act, 42 U.S.C. 7607(d). Docket number A-91-61 contains the technical support for the September 15, 1997 emission guidelines. Docket number A-98-24 contains additional supporting information for this proposed rule.

*B. Paperwork Reduction Act*

The information collection requirements in this proposed 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 (2137), 401 M Street, SW., Washington, DC 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 September 15, 1997.<sup>d</sup> The burden estimate includes the burden associated with State/Tribal plans as well as the burden associated with today's proposed 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 would be used by EPA to ensure that the HMIWI regulatory requirements are implemented and are complied with on a continuous basis. Records and reports would be necessary to enable EPA to identify existing HMIWI that may not be in compliance with the HMIWI regulatory requirements. Based on reported information, EPA would decide which units should be inspected and what records or processes should be inspected. The records that owners and operators of existing HMIWI maintain would 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 year following Federal plan promulgation. 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 would be 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) would be 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), 401 M Street, SW., Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW.,

<sup>d</sup>In promulgating the September 15, 1997 rule setting the NSPS and emission guidelines, EPA assessed only the ICR requirements associated with the NSPS. See 62 FR at 48373-74.

Washington, DC 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 August 5, 1999. The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal.

#### 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 proposed 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 12875

Under Executive Order 12875, 58 FR 58093 (October 26, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local, or Tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments or EPA consults with those governments. If EPA complies by consulting, Executive Order 12875 requires EPA to provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and Tribal governments, the nature of their concerns, any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and Tribal governments "to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates."

Today's rule does not create a mandate on State, local, or Tribal governments. The rule does not impose any enforceable duties on these entities.

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. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this 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 proposed 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 proposed today does not significantly or uniquely affect communities of Indian Tribal governments. The proposed Federal plan would 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), Pub. L. 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 48374–78. The EPA has determined that the proposed 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 proposed 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 48378–79. This proposed Federal plan would not establish any new requirements.

Therefore, pursuant to the provisions of 5 U.S.C. 605(b), EPA certifies 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”), Pub L. 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 proposed Federal plan would implement 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.

#### **List of Subjects in 40 CFR Part 62**

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

Dated: June 17, 1999.

**Carol M. Browner,**  
*Administrator.*

40 CFR part 62 is proposed to be amended as follows:

#### **PART 62—[AMENDED]**

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. Amend part 62 by adding subpart HHH consisting of §§ 62.14400 through § 62.14499 as follows:

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

Sec.

##### **Applicability**

- 62.14400 Am I subject to this subpart?  
62.14401 How do I determine if my HMIWI is covered by an approved and effective State or Tribal plan?  
62.14402 If my HMIWI is not listed on the Federal plan inventory, am I exempt from this subpart?  
62.14403 What happens if I modify an existing HMIWI?

##### **Emission Limits**

- 62.14410 Are there different emission limits for different locations and sizes of HMIWI?  
62.14411 What emission limits apply to my HMIWI?  
62.14412 What stack opacity requirements apply?  
62.14413 When do the emission limits and stack opacity requirements apply?

#### **Operator Training and Qualification 62.14420**

- Am I required to have a trained and qualified operator?  
62.14421 How does an operator become trained and qualified?  
62.14422 What are the requirements for a training course that is not part of a State-approved program?  
62.14423 What are the qualification requirements for operators who do not participate in a State-approved program?  
62.14424 What documentation must I maintain onsite?  
62.14425 When must I review the documentation?

#### **Waste Management Plan**

- 62.14430 Must I prepare a waste management plan?  
62.14431 What must my waste management plan include?  
62.14432 When must my waste management plan be completed?

#### **Inspection Requirements**

- 62.14440 Which HMIWI are subject to inspection requirements?  
62.14441 When must I inspect my small rural HMIWI?  
62.14442 What must my inspection include?  
62.14443 When must I do repairs?

#### **Compliance, Performance Testing, and Monitoring Requirements**

##### **62.14450 What are the testing requirements for small rural HMIWI?**

- 62.14451 What are the testing requirements for HMIWI that are not small rural?  
62.14452 What test methods and procedures must I use?  
62.14453 What must I monitor?  
62.14454 How must I monitor the required parameters?  
62.14455 What if my HMIWI goes outside of a parameter limit?

#### **Reporting and Recordkeeping Requirements**

- 62.14460 What records must I maintain?  
62.14461 For how long must I maintain records?  
62.14462 Where must I keep the records?  
62.14463 What reporting requirements must I satisfy?  
62.14464 When must I submit reports?  
62.14465 Who must sign all submitted reports?

#### **Compliance Schedule**

- 62.14470 When must I comply with this subpart if I plan to continue operation of my HMIWI?  
62.14471 When must I comply with this subpart if I plan to shut down?  
62.14472 When must I comply with this subpart if I plan to shut down and later restart?

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

**Definitions**

**62.14490 Definitions.**

**Delegation of Authority**

62.14495 WHAT AUTHORITIES WILL BE RETAINED BY THE EPA ADMINISTRATOR?

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

TABLE 2 OF SUBPART HHH OF PART 62—TOXIC EQUIVALENCY FACTORS

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

**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 chemotherapeutic 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 radioactive waste, and/or chemotherapeutic waste is combusted.	Are not subject to the other requirements of this subpart during periods when only pathological, low-level radioactive, and/or chemotherapeutic wastes are combusted.
(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, and the weight of all other fuels and wastes combusted at the co-fired combustor.	Are not subject to the other requirements 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.

**§ 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 § 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 § 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 within [date 6 months after publication of the final rule] or prior to assumption of responsibilities affecting HMIWI operation, whichever date 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 "An 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 [date 1 year after publication of final rule].

(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.

**Compliance, 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:

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

Where:

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

$C_{\text{meas}}$  = 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 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 ( $\%R_{\text{HCl}}$ ) using the following formula:

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

Where:

$\%R_{\text{HCl}}$  = 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 ( $\%R_{\text{metal}}$ ) using the following formula:

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

Where:

$\%R_{\text{metal}}$  = 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.
(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 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 paragraphs (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 [date 1 year after publication of final rule], 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 [date 1 year after publication of final rule].

(2) You must achieve final compliance by [date 1 year after publication of final rule]. 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 [date 1 year after publication of final rule], 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 [date 1 year after publication of final rule].

(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 [date 1 year after publication of final rule] rather than come into compliance with the requirements of this subpart, then you must shut down by [date 1 year after publication of final rule] 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 [date 1 year after publication of final rule], 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 [date 90 days after publication of final rule]. 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 [date 1 year after publication of final rule] 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.	<ul style="list-style-type: none"> <li>—Date when you will enter into a contract with an alternative treatment technology vendor,</li> <li>—Date for initiating onsite construction or installation of the alternative technology,</li> <li>—Date for completing onsite construction or installation of the alternative technology, and</li> <li>—Date for shutting down the HMIWI.</li> </ul>
Need an extension so you can acquire the services of a commercial medical/infectious waste disposal company before you shut down your HMIWI.	<ul style="list-style-type: none"> <li>—Date when price quotes will be obtained from commercial disposal companies,</li> <li>—Date when you will enter into a contract with a commercial disposal company, and</li> <li>—Date for shutting down the HMIWI.</li> </ul>

(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 [date 1 year after publication of the final rule].

**§ 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) or (b) of this section depending on when you 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 [date 1 year after publication of the final rule]; or

(2) Meet the compliance schedule outlined in § 62.14470(b) if you restart after [date 1 year after publication of the

final rule]. Any missed increments of progress need to be completed prior to or upon the date of restart.

(b) If you plan to shut down and restart after 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 before restarting your HMIWI.

(2) 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.

(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 restart.

(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).

**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). 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 permit program in the State or Tribal area in which the unit is located, whichever is later. (An earlier deadline may apply if your HMIWI is also subject to title V's 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;

$$C = P_v \times 15,000/8,500$$

Where:

C = HMIWI capacity, lb/hr

$P_v$  = primary chamber volume, ft<sup>3</sup>

15,000 = primary chamber heat release rate factor, Btu/ft<sup>3</sup>/hr

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

(2) For batch HMIWI;

$$C = P_v \times 4.5/8$$

Where:

C = HMIWI capacity, lb/hr

$P_v$  = primary chamber volume, ft<sup>3</sup>

4.5 = waste density, lb/ft<sup>3</sup>

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 included 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 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 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 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 .....



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

Pollutant	Units (7 percent oxygen, dry basis at standard conditions)	Emission limits			
		HMIWI size			
		Small rural	Small	Medium	Large
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.—TOXIC 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
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
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 <sup>1</sup> with dry scrubber followed by fabric filter	HMIWI <sup>1</sup> with wet scrubber	HMIWI <sup>1</sup> with dry scrubber followed by fabric filter and wet scrubber
Maximum operating parameters: Maximum charge rate	Once per charge	Once per charge	✓	✓	✓	✓

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

Operating parameters to be monitored	Minimum frequency		HMIWI			
	Data measurement	Data recording	Small rural HMIWI	HMIWI <sup>1</sup> with dry scrubber followed by fabric filter	HMIWI <sup>1</sup> with wet scrubber	HMIWI <sup>1</sup> with dry scrubber followed by fabric filter and wet scrubber
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 ....			✓	✓

<sup>1</sup> Does not include small rural HMIWI.

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