HOSPITAL/MEDICAL/INFECTIOUS WASTE INCINERATORS:

Summary of Requirements for Revised or New Section 111(d)/129 State Plans Following Amendments to the Emission Guidelines

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Hospital/Medical/Infectious Waste Incinerators: Summary of Requirements for Revised or New Section 111(d)/129 State Plans Following Amendments to the Emission Guidelines

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Disclaimer

This document does not establish any new requirements and is not binding or enforceable. It does not constitute final agency action under Clean Air Act section 307(b)(1), 42 U.S.C. 7607(b)(1). Rather, it summarizes existing regulations and provides guidance to States pertaining to State Plan development under Section 129 of the Clean Air Act as amended in 1990.

Executive Summary

Air pollution emissions from the incineration of hospital waste and medical/infectious waste are regulated by federal rules promulgated to implement the Clean Air Act (CAA) as amended in 1990. This guidance document addresses requirements established by the regulations that have been developed and amended for hospital/medical/infectious waste incinerator(s) (HMIWI) under sections 111 and 129 of the CAA. Section 111 of the CAA, 42 U.S.C. 7411, addresses Standards of Performance for Stationary Sources. Section 129, 42 U.S.C. 7429, addresses Solid Waste Combustion. The original HMIWI regulations were promulgated by EPA on September 15, 1997. Amendments to the regulations were promulgated on October 6, 2009.

Federal rules under the CAA promulgated in the Code of Federal Regulations (CFR) that affect the combustion of hospital waste and medical/infectious waste include:

1. Emission Guidelines and Compliance Times for Hospital/Medical/Infectious Waste Incinerators [40 CFR Part 60, subpart Ce, as amended October 6, 2009] (The amended Emission Guidelines [EG] apply to all HMIWI that commenced construction on or before June 20, 1996; the amended EG also apply to those HMIWI that commenced construction after June 20, 1996 but no later than December 1, 2008, except where the emission limits in the original 1997 new source performance standards [NSPS] are more stringent);

2. Rules Governing the Adoption and Submittal of State Plans for Designated Facilities [40 CFR Part 60, subpart B];

3. Standards of Performance for Hospital/Medical/Infectious Waste Incinerators for Which Construction is Commenced After June 20, 1996 [40 CFR Part 60, subpart Ec, as amended October 6, 2009] (The original NSPS promulgated in 1997 apply to those HMIWI that commenced construction after June 20, 1996 but no later than December 1, 2008, except where the emission limits in the amended EG are more stringent; the amended NSPS apply to those HMIWI that commenced construction after December 1, 2008);

4. Federal Plan Requirements for Hospital/Medical/Infectious Waste Incinerators Constructed On or Before June 20, 1996 [40 CFR Part 62, subpart HHH] (The Federal Plan Requirements apply to those HMIWI that commenced construction on or before June 20, 1996; the Federal Plan Requirements have not yet been amended to incorporate the provisions in the amended EG); and

5. Approval and Promulgation of State Plans for Designated Facilities and Pollutants; General Provisions [40 CFR Part 62, subpart A] (These General Provisions are applicable to all section 111(d)/129 plans and revisions).

Unlike the subpart Ec NSPS, which apply directly to new sources, states develop a State Plan in order to compel existing sources to meet the EG. Together, subpart B and subpart Ce specify the State Plan content and the general rules for adopting and submitting State Plans. State Plans have already been developed to implement the EG adopted on September 15, 1997, and states need to revise existing or develop new State Plans to implement the amended EG adopted on October 6, 2009. Working with EPA Regional Offices and states, EPA's Office of Air Quality Planning and Standards has produced this guidance document to assist states in ensuring that their revised or new State Plans are complete and meet all the requirements of subpart B and subpart Ce, as amended on October 6, 2009.

This document draws together relevant information from the federal regulations that affect hospital and medical/infectious waste incineration to give state regulatory agencies the information they need to revise or develop State Plans. Section 1 of this document provides an overview of regulatory and State Plan requirements; section 2 presents information on the timeline and responsibilities for revising/developing and submitting these State Plans; and section 3 discusses the required elements of a State Plan. The appendices to this document contain reference and explanatory materials, including:

1. Key elements of an acceptable State Plan;
2. A Fact Sheet on the amended EG;
3. Clarifications of the applicability of the amended EG;
4. An implementation timeline;
5. Contacts for further information;
6. Emission factors for calculating HMIWI air pollutant emissions;
7. A copy of CAA section 111(d);
8. A copy of CAA section 129;
9. A copy of 40 CFR Part 60, subpart B (rules governing adoption/submittal of State Plans);
10. A copy of 40 CFR Part 62, subpart A (General Provisions regarding approval/ promulgation of State Plans);
11. Copies of 40 CFR Part 60, subpart Ce (amended EG) and subpart Ec (amended NSPS);
12. A copy of the Federal Register (FR) notice for the amended EG; and
13. The latest (2010) inventory of HMIWI.

An appendix that was included in the original version of this document, published in November 1997 (Answers to Questions about the Emission Guidelines and State Plan Process) will be updated and provided as a separate document.

The CAA directs state regulatory agencies to implement the EG according to a State Plan developed under sections 111(d) and 129 of the CAA, and to submit the State Plan to EPA within 1 year after EPA's promulgation of the EG (i.e., by October 6, 2010 for the amended EG). To be approved by EPA, the State Plans need to contain specific information and the legal mechanisms necessary to implement the EG. The minimum requirements set forth in CAA section 129 and in 40 CFR Part 60, subparts B and Ce are listed below.

1. A demonstration of the state's legal authority to carry out the section 111(d)/129 State Plan and identification of enforceable mechanisms, including:
   - a list in the enforcement section of the State Plan indicating the consequences for sources not in compliance and the authority under which a state can shut down/close a source;
   - a reference to section 129(f)(3) ("PROHIBITION"), which prohibits a plant from operating if it does not comply with the standard; and
   - adequate authority to enforce the recordkeeping and notification requirements for co-fired combustors and incinerators burning only pathological, low-level radioactive, and chemotherapeutic waste.

   [CAA section 129(f)(3) and 40 CFR 60.26 and 60.32e(b) and (c)]

2. An inventory of sources in the state affected by the EG, including to the best of the state's knowledge, HMIWI that have shut down and are capable of restarting, and including:
   - a statement preceding the inventory which says that sources subject to the standard "include but are not limited to" the inventory in the State Plan, and
   - an additional statement that says, "should another source be discovered subsequent to this notice, there will be no need to reopen the State Plan."

   [40 CFR 60.25(a)]

3. An inventory of emissions from HMIWI operating in the state. [40 CFR 60.25(a) and (c)]

4. Emission limits for HMIWI that are at least as protective as those in the EG. [CAA section 129(b)(2) and 40 CFR 60.24(a)-(c) and 60.33e]

5. Testing and monitoring requirements at least as protective as those in the EG. [CAA section 129(b)(2) and 40 CFR 60.24(b)(2), 60.25(b), and 60.37e]

6. Reporting and recordkeeping requirements at least as protective as those in the EG. [CAA section 129(b)(2) and 40 CFR 60.25(b)(1) and 60.38e]

7. Operator training and qualification requirements at least as protective as those in the EG. [CAA section 129(b)(2) and (d) and 40 CFR 60.34e]

8. Inspection requirements at least as protective as those in the EG. [CAA section 129(b)(2) and 40 CFR 60.25(b)(2), and 60.36e]

9. Waste management plan requirements at least as protective as those in the EG. [CAA section 129(b)(2) and 40 CFR 60.35e]

10. Compliance schedules (including increments of progress for compliance schedules which extend beyond 1 year after State Plan approval). [40 CFR 60.24(a) and (e)(1) and 60.39e]

11. An expeditious final compliance date not later than 3 years after approval of the revised or new State Plan or October 6, 2014, whichever is earlier.[1] [CAA section 129(b)(2) and (f)(2) and 40 CFR 60.39e(c)]

12. A record of public hearing(s) on the State Plan. [40 CFR 60.23(f)(1) and (2)]

13. Provision for state progress reports to EPA. [40 CFR 60.25(e) and (f)]

Prior to submittal to EPA, EPA's regulations direct the state to make available to the public the State Plan and provide an opportunity for public comment. [40 CFR 60.23(c)] The deadline for the state to submit the final revised or new State Plan to EPA is October 6, 2010. [CAA section 129(b)(2) and 40 CFR 60.39e(a)(2)] EPA then has 180 days (6 months) to approve or disapprove the State Plan. [CAA section 129(b)(2)] State Plan approval or disapproval will be published in the FR. If a State Plan is disapproved, EPA will state the reasons for disapproval in the FR and give the state an opportunity to respond to EPA's concerns and submit a revised State Plan. [CAA section 129(b)(2)] Pursuant to section 129(b)(3), a Federal Plan would need to be in place by October 6, 2011 for each state that does not have an approved revised or new State Plan. [CAA section 129(b)(3) and 40 CFR 60.39e(f)]

Based on EPA's latest (2010) inventory of HMIWI subject to the EG (see Appendix M), 54 HMIWI are subject to the amended EG, with a total combustion capacity of approximately 224,000 tons per year. (Note: EPA estimated 57 HMIWI were operating when the October 6, 2009 EG were being developed, and 3 of those HMIWI have since shut down.) According to the

[1]Final compliance beyond 1 year after State Plan approval is possible only if the State Plan contains increments of progress (see section 10). [40 CFR 60.24(e) and 60.39e(c)]

2010 inventory, 96 percent of the HMIWI (which represent 99.9 percent of the U.S. HMIWI combustion capacity) employ some kind of add-on air pollution control device (APCD). An additional 4 percent of the HMIWI population (which constitute approximately 0.1 percent of the U.S. HMIWI combustion capacity) are believed to have good combustion.[2] An estimated 87 percent of the HMIWI (which represent 88 percent of the U.S. HMIWI combustion capacity) will require retrofit of an additional APCD to meet the amended EG. The table below presents the number of currently operating HMIWI by state.

Table 1. Number of Hospital/Medical/Infectious Waste Incinerators by State

EPA Region	State	Number of HMIWI[a]
I	Connecticut	1
II	New Jersey	1
III	Maryland	7
	Pennsylvania	6
	West Virginia	2
IV	Florida	10
	Georgia	1
	North Carolina	4
	Tennessee	1
V	Minnesota	1
	Illinois	3
	Indiana	3
	Ohio	4
VI	Texas	3
VII	Kansas	1
VIII	Montana	1
	North Dakota	1
	Utah	1
	Wyoming	1
IX	Hawaii	1
X	Alaska	1

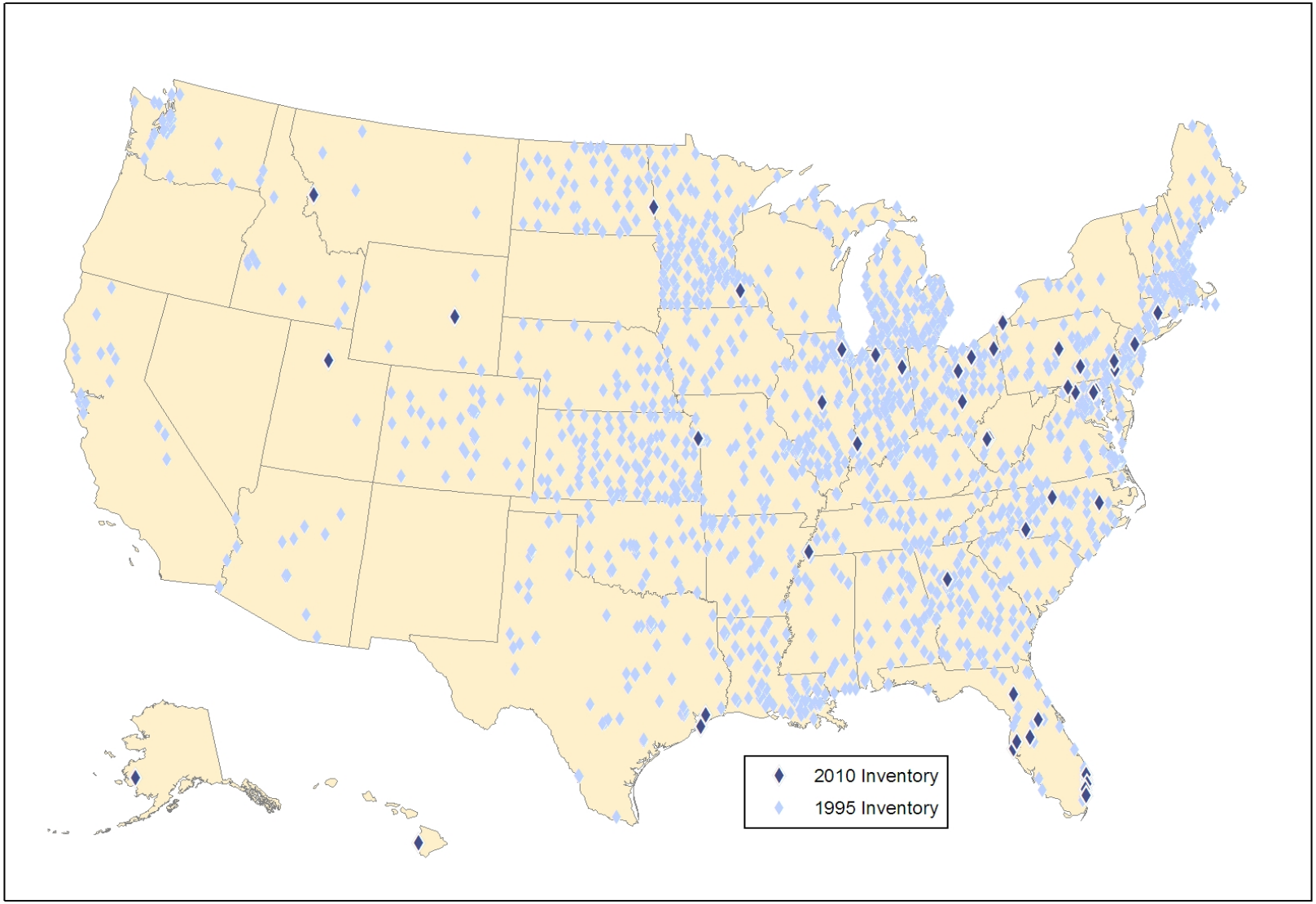
[2]To the extent that good combustion is defined, it means 2-second residence time in the secondary chamber at 1800EF. However, the Emission Guidelines do not require 2-second residence time and 1800EF. [docket no. A-91-61, document no. II-A-112, page 31]

EPA Region	State	Number of HMIWI[a]
Total		54

[a] The inventory of HMIWI is based on data gathered from contacts with EPA Regions, states, and HMIWI facilities and from review of existing HMIWI inventories, title V permits, emission test reports, and HMIWI facility websites.

The figure below shows the location of the HMIWI currently in operation (2010) (see Appendix M), compared to those HMIWI in operation in 1995—the date of the last inventory prepared prior to the 1997 HMIWI regulations (see docket no. A-91-61, document no. IV-B-45).

Figure 1. Inventory of Existing Hospital/Medical/Infectious Waste Incinerators (1995 and 2010)



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List of Acronyms and Abbreviations

AFS	Air Facility System
APCD	Air Pollution Control Device
CAA	Clean Air Act
cc	Carbon Copy
Cd	Cadmium
CEMS	Continuous Emission Monitoring System
CFR	Code of Federal Regulations
CISWI	Commercial and Industrial Solid Waste Incinerators
CO	Carbon Monoxide
DIFF	Dry Injection Fabric Filter
Dioxins/furans	Tetra- through octa- chlorinated dibenzo-p-dioxins and dibenzofurans
EPA	U.S. Environmental Protection Agency
FR	Federal Register
HMIWI	Hospital/Medical/Infectious Waste Incinerator(s)
HCl	Hydrogen Chloride
Hg	Mercury
lb/hr	Pounds per hour
MSA	Metropolitan Statistical Area
MWC	Municipal Waste Combustor
NAAQS	National Ambient Air Quality Standards
NEDS	National Emissions Data System
NESHAP	National Emission Standards for Hazardous Air Pollutants
NO_2	Nitrogen Dioxide
NO_x	Nitrogen Oxides
NSPS	New Source Performance Standard
OSWI	Other Solid Waste Incinerators
Pb	Lead
PM	Particulate Matter
PM_{10}	PM with an Aerodynamic Diameter at or below 10 μm
QA/QC	Quality Assurance/Quality Control
SIP	State Implementation Plan
SMSA	Standard Metropolitan Statistical Area, as referenced in OMB Bulletin No. 93-17, dated June 30, 1993
SNCR	Selective Noncatalytic Reduction
SO_2	Sulfur Dioxide
TCDD	Tetrachlorodibenzo-p-dioxin
TEQ	2,3,7,8-TCDD Toxic Equivalent

1.0 Introduction

The purpose of this document is to assist state air regulatory agencies in developing revised or new State Plans which will implement the amended regulations controlling air pollutant emissions from hospital/medical/infectious waste incinerator(s) (HMIWI). Under the Clean Air Act (CAA) as amended in 1990, the United States Environmental Protection Agency (EPA) is required to develop regulations to control air pollutant emissions from HMIWI. Emissions from new HMIWI are addressed by standards of performance for new sources (New Source Performance Standards [NSPS]), and emissions from existing HMIWI are addressed by guidelines for existing sources (Emission Guidelines [EG]). EPA originally promulgated the NSPS (subpart Ec) and EG (subpart Ce) for HMIWI on September 15, 1997. In a response to a suit filed by the Sierra Club and the Natural Resources Defense Council, the U.S. Court of Appeals for the District of Columbia Circuit (the Court) remanded the HMIWI regulations on March 2, 1999 for further explanation of EPA's reasoning in determining the minimum regulatory "floors" for new and existing HMIWI. The HMIWI regulations were not vacated, and states developed State Plans to implement the original EG for existing sources. For any states without an acceptable State Plan, EPA developed a Federal Plan (published in the FR on August 15, 2000 [65 FR 49868]) to implement the original EG. The original EG were fully implemented as of September 15, 2002.

On February 6, 2007, EPA published a proposed response to the Court's remand and solicited public comments. Following recent court decisions and receipt of public comments on the proposal, EPA re-assessed its response to the remand, and on December 1, 2008 published another proposed response and again solicited public comments. On October 6, 2009, EPA published its final response to the Court's remand and also satisfied the CAA section 129(a)(5) requirement to conduct a review of the standards every 5 years. EPA's response to the remand and section 129(a)(5) requirement included substantial revisions to the NSPS and EG. States are to revise, amend, or develop State Plans to implement the amended EG for existing sources and submit these revised or new State Plans to EPA by October 6, 2010. On May 14, 2010 at FR 75 FR 27249, EPA published proposed amendments to the NSPS, correcting the nitrogen oxides (NOx) and sulfur dioxide (SO_2) emissions limits for new large HMIWI, as well as errors in cross-references in the NSPS reporting and recordkeeping provisions for new HMIWI. These amendments are intended to match the final NO_X and SO_2 EG limits, which reflect EPA's intent

in the October 6, 2009 final rule; however, these revisions do not impact States' implementation of the EG. At the time of publication of this document, EPA's final action promulgating the amendments is pending the Administrator's signature.

This document provides state agencies information on the content these State Plans need to include in order to obtain EPA approval, under EPA's regulations. This document is an update to the November 1997 guidance document entitled "Hospital/Medical/Infectious Waste Incinerator Emission Guidelines: Summary of the Requirements for Section 111(d)/129 State Plans" (EPA-456/R-97-007).

1.1 Organization of this Document

This document discusses the information on the relevant parts of the various regulations that affect existing HMIWI constructed on or before December 1, 2008. These regulations were developed under section 111(d) and section 129 of the CAA. The regulations are codified in title 40 of the Code of Federal Regulations (CFR) Parts 60 and 62. The rules include (1) Adoption and Submittal of State Plans for Designated Facilities (40 CFR Part 60, subpart B); (2) the EG for existing HMIWI (40 CFR Part 60, subpart Ce), as amended October 6, 2009; and (3) Approval and Promulgation of State Plans for Designated Facilities and Pollutants; General Provisions (40 CFR Part 62, subpart A).

Section 1 of this document provides an overview of regulatory and State Plan requirements; section 2 presents information on the timeline and responsibilities for developing and submitting State Plans; and section 3 discusses the required elements of an approvable State Plan. The appendices of this document are listed in Table 1-1. The appendices include reference materials that states may find useful when revising, amending, or developing their State Plans, such as key elements of an acceptable State Plan, clarifications of the applicability of the EG, an implementation timeline, contact lists, emission factors (for estimating emissions from HMIWI), and copies of relevant regulations. An appendix from the original 1997 guidance document that provided answers to questions about the EG and State Plan process is being updated to include information about the amended EG and will be provided as a separate document.

1.2 Clean Air Act Requirements

Section 111(d) has been included in the CAA since the 1970s and requires EPA to establish procedures for the submission of State Plans for implementing EG. The first EG

adopted was for sulfuric acid plants in 1977. Other EG have been adopted since that time. The State Plans implement and provide mechanisms for enforcing the EG. Section 129 was added to

Table 1-1. Appendices to This Document

Appendix	Title
A	Key Elements of an Acceptable Section 111(d)/129 State Plan for HMIWI
B	Fact Sheet for Amended Emission Guidelines and NSPS (40 CFR Part 60 Subparts Ce and Ec)
C	Applicability of the HMIWI Emission Guidelines
D	HMIWI Implementation Timeline
E	EPA Regional and State/Local Agency Contacts
F	HMIWI Emission Factors
G	Clean Air Act Section 111(d)
H	Clean Air Act Section 129
I	40 CFR Part 60 Subpart B
J	40 CFR Part 62 Subpart A
K	40 CFR Part 60 Subparts Ce (EG) and Ec (NSPS)
L	Federal Register Notice for Amended Emission Guidelines and NSPS
M	2010 HMIWI Inventory

the CAA in 1990 and specifically addresses solid waste combustion. It requires EPA to establish EG for HMIWI and directs states to develop State Plans for implementing the EG. The subpart Ce EG for HMIWI differ from some other EG adopted in the past because the subpart Ce EG address both section 111(d) and section 129 requirements. Section 129 overrides some aspects of section 111(d). (The subpart Cb EG for Large Municipal Waste Combustors [MWCs], subpart BBBB EG for Small MWCs, subpart DDDD EG for Commercial and Industrial Solid Waste Incinerators [CISWI], and subpart FFFF EG for Other Solid Waste Incinerators [OSWI] similarly address both section 111(d) and section 129 requirements.)

Detailed procedures for submitting and approving State Plans under section 111(d) were promulgated by EPA in 1975 at 40 CFR Part 60, subpart B and amended in 1979, 1989, 1995, 2000, 2005, 2006, and 2007. The major revisions to subpart B address differences between sections 129 and 111(d) of the CAA. In particular, section 129(b)(2) directs states to submit State Plans for HMIWI to EPA within 1 year after promulgation of the EG, whereas the subpart B procedures [40 CFR 60.23(a)] developed to implement section 111(d) Plans have a

different schedule. Also, section 129(b)(2) requires section 111(d)/129 State Plans to be "at least as protective as the guidelines" in order to be approved by EPA, whereas section 111(d)(1) allows states flexibility to consider the remaining useful life of the source and other factors in developing State Plans and standards. Where section 129 conflicts with section 111(d), the December 19, 1995 revisions to subpart B supersede otherwise applicable requirements of subpart B. [60 FR 65414 and 40 CFR 60.23 and 60.24] Table 1-2 addresses the relationship between sections 111(d), section 129, and subpart B.

Table 1-2. Relationship Between Section 111(d), Section 129, and Subpart B

Statutes	Rules, Regulations, and Procedures
Clean Air Act	40 CFR Part 60
Section 111(b) (new sources)	NSPS→General Provisions→subpart A Source category NSPS→subpart D-KKKK
Section 111(d) (existing sources)	EG→→Procedures (State Plan)→subpart B - amended to allow additional directions specified in section 129 Source category EG→subpart Cb (large MWC), Ce (HMIWI), etc.
Section 129[a]	Provides more specific directions about complying with sections 111(b) and 111(d) for those solid waste combustors listed in section 129

[a] Section 129 was added with the 1990 Amendments to the CAA. Section 129 changed section 111(d) in the following ways:

- State rule needs to be at least as protective as the EG.
- Deletes opportunity for sources to have a longer compliance schedule than what the EG specify. Section 129(f)(2) of the CAA requires expeditious compliance.
- Allows states a longer time for submittal of their State Plan (i.e., 12 months instead of 9 months).

The General Provisions associated with the approval and promulgation of State Plans are codified in 40 CFR Part 62, subpart A, and each state's plan is provided in a separate subpart under Part 62. (See Appendices G, H, I, and J for the full text of section 111(d); section 129; 40 CFR Part 60, subpart B; and 40 CFR Part 62, subpart A.)

1.3 Emission Guidelines

The original EG for HMIWI were promulgated on September 15, 1997, and amendments to the EG were promulgated on October 6, 2009. [62 FR 48347 and 74 FR 51368] The EG are codified in 40 CFR Part 60, subpart Ce. An outline of the amended EG is presented in Table 1-3. The amended EG apply to all existing HMIWI that commenced construction on or before June 20, 1996, as well as to those HMIWI that commenced construction after June 20, 1996 but no later than December 1, 2008 (i.e., those HMIWI subject to the original NSPS), except where

the emission limits in the original NSPS are more stringent. [40 CFR 60.32e(a)(1) and (2) and 60.33e(a)(2), (a)(3), and (b)] The pollutants regulated by subpart Ce include metals (cadmium [Cd], lead [Pb], and mercury [Hg]); particulate matter (PM); acid gases, (sulfur dioxide [SO_2], nitrogen oxides [NO_x], and hydrogen chloride [HCl]); organic compounds (dioxins and furans); carbon monoxide (CO); and opacity. [CAA section 129(a)(4) and (b)(1), Tables 1B and 2B of subpart Ce] The amended EG are summarized in a Fact Sheet included in this document (see Appendix B). The full text of the amended EG (subpart Ce) is also provided (see Appendix K), as well as the October 6, 2009 amendments (see Appendix L).

Table 1-3. Outline of the Emission Guidelines for HMIWI (40 CFR Part 60, Subpart Ce)

Section	Contents
60.30e	Scope
60.31e	Definitions
60.32e	Designated facilities
60.33e	Emission guidelines
60.34e	Operator training and qualification guidelines
60.35e	Waste management guidelines
60.36e	Inspection guidelines
60.37e	Compliance, performance testing, and monitoring guidelines
60.38e	Reporting and recordkeeping guidelines
60.39e	Compliance times

1.4 Emission Guideline Subcategories

For the amended EG, there were no changes to the HMIWI subcategories that were developed for the original EG. The subcategories are based on (1) HMIWI pound per hour (lb/hr) capacity to burn hospital waste and medical/infectious waste [40 CFR 60.51c; see definitions for "Large HMIWI," "Medium HMIWI," and "Small HMIWI"]; and (2) distance from the nearest standard metropolitan statistical area (SMSA), as referenced in OMB Bulletin No. 93-17, dated June 30, 1993. [40 CFR 60.31e and 60.33e(b)] (Note: Such areas are currently referred to as "Metropolitan Statistical Areas (MSAs).")

The "small" subcategory consists of HMIWI that burn less than or equal to 200 lb/hr. [40 CFR 60.51c] The "small" subcategory has been further divided to include a "small rural"

subcategory, which consists of those small HMIWI located in rural areas that burns less than 2,000 pounds per week of hospital waste and medical/infectious waste. [40 CFR 60.31e and 60.33e(b)] The "rural criteria" used in determining which small HMIWI are small rural HMIWI are presented in sections 60.31e and 60.33e(b) and are further discussed in Appendix C of this document. The "medium" subcategory includes HMIWI that burn between 200 and 500 lb/hr, and the "large" subcategory consists of HMIWI which burn more than 500 lb/hr. [40 CFR 60.51c] Hospital/medical/infectious waste incinerator capacity is determined using the methods presented in section 60.51c of subpart Ec (see definition for "Maximum design waste burning capacity") and is further discussed in Appendix C of this document. The emission limits in the EG are different for each of the HMIWI subcategories.

1.5 Requirements for State Plans

States are to revise or develop section 111(d)/129 State Plans to implement the amended HMIWI EG and to submit their Plans to the appropriate EPA Regional Office for approval. The first step for revising or developing such a State Plan is to identify and prepare an updated list of sources operating in the state that are subject to the amended EG. [40 CFR 60.25(a)]

All sources, whether they are on the state's list or not, are subject to the revised or new State Plan and need to be in compliance no later than 3 years following State Plan approval or by October 6, 2014, whichever is earlier, under CAA section 129(b)(2) and (f)(2). While not required by the EG, in order to cover sources that might be discovered after submittal of the revised or new State Plan, EPA recommends that states may want to include certain language in the State Plan. Although a state could choose to revise the State Plan in order to establish a separate, but equally protective compliance schedule for the newly discovered source, it is not necessary, if states choose to include the following (or similar language) in the revised or new State Plan:

1. A statement preceding the inventory which says that sources subject to the standard "include, but are not limited to" the inventory in the State Plan; and
2. In additional statement that says, "Should another source be discovered subsequent to this notice, there will be no need to reopen the State Plan."

States may also want to include in their revised or new State Plan a generic expeditious compliance schedule with which "all other applicable sources" not listed individually in the State Plan would need to comply. Any newly discovered source would then be bound to that schedule.

It is possible that HMIWI that are not operating at the time of State Plan submittal could reopen as an existing unit in the future. Such a unit would be considered an existing HMIWI, assuming it was constructed prior to December 1, 2008.[1] [40 CFR 60.32e(a)(2)] Therefore, EPA recommends that states should make a reasonable effort to include sources in the inventory which have shut down but that have the potential to reopen. Regarding those HMIWI that reopen, EPA suggests for each state the following course of action, based on the original HMIWI Federal Plan. [40 CFR 62.14472] The state would submit a revised or new State Plan to require retrofit of the necessary air pollution controls before the HMIWI reopens. The revised Plan for the non-operating unit would contain a final compliance date and legal authority to ensure that the HMIWI would complete retrofit before reopening. As discussed above, the state would not revise the State Plan in order to require newly discovered sources to retrofit, but rather, would only refer them to the generic compliance schedule contained in the State Plan. If a source were discovered well into the compliance time and had already missed several increments of progress, it would need to shut down immediately and remain closed until it had caught up with the increments. Of course, the state always has the option of assigning a separate compliance schedule to that newly discovered source, but in order to do so, the state would need to revise the State Plan.

States which have HMIWI units are directed to submit a revised or new section 111(d)/129 State Plan. At a minimum, to be approved by EPA, the State Plan needs to include the elements listed below.

1. A demonstration of the state's legal authority to carry out the section 111(d)/129 State Plan and identification of enforceable mechanisms, including:
   - a list in the enforcement section of the State Plan indicating the consequences for sources not in compliance and the authority under which a state can shut down/close a source;
   - a reference to the section 129(f)(3) ("PROHIBITION") which prohibits a plant from operating if it does not comply with the standard; and
   - adequate authority to enforce the recordkeeping and notification requirements for co-fired combustors and incinerators burning only pathological, low-level radioactive, and chemotherapeutic waste (see section 60.32e of subpart(e)).

[1] If an HMIWI that shut down and reopened had been modified, then it would be considered a new source. Modification means any change that results in an increase in emissions to the atmosphere or the capital cost of the change is more than 50 percent of the inflation-adjusted replacement cost of the HMIWI. [CAA section 129(g)(3) and 40 CFR 60.51c]

[CAA section 129(f)(3) and 40 CFR 60.26(a) and 60.32e(b) and (c)]

2. An inventory of sources in the state affected by the EG, including to the best of the state's knowledge, HMIWI that have shut down and are capable of restarting, and including:
   - a statement preceding the inventory which says that sources subject to the standard "include but are not limited to" the inventory in the State Plan, and
   - an additional statement that says, "should another source be discovered subsequent to this notice, there will be no need to reopen the State Plan."

   [40 CFR 60.25(a)]

3. An inventory of emissions from HMIWI operating in the state. [40 CFR 60.25(a) and (c)]

4. Emission limits for HMIWI that are at least as protective as those in the EG. [CAA section 129(b)(2) and 40 CFR 60.24(a)-(c) and 60.33e]

5. Testing and monitoring requirements at least as protective as those in the EG. [CAA section 129(b)(2) and 40 CFR 60.24(b)(2), 60.25(b), and 60.37e]

6. Recordkeeping and reporting requirements at least as protective as those in the EG. [CAA section 129(b)(2) and 40 CFR 60.25(b)(1) and 60.38e]

7. Operator training and qualification requirements at least as protective as those in the EG. [CAA section 129(b)(2) and (d) and 40 CFR 60.34e]

8. Inspection requirements at least as protective as those in the EG. [CAA section 129(b)(2) and 40 CFR 60.25(b)(2), and 60.36e]

9. Waste management plan requirements at least as protective as those in the EG. [CAA section 129(b)(2) and 40 CFR 60.35e]

10. Compliance schedules (including increments of progress for compliance schedules which extend beyond 1 year after State Plan approval). [40 CFR 60.24(a) and (e)(1) and 60.39e]

11. An expeditious final compliance date not later than 3 years after approval of the revised or new State Plan or October 6, 2014, whichever is earlier.[2] [CAA section 129(b)(2) and (f)(2) and 40 CFR 60.39e(c)]

12. A record of public hearing(s) on the State Plan. [40 CFR 60.23(f)(1) and (2)]

[2] Final compliance beyond 1 year after State Plan approval is possible only if the State Plan contains increments of progress (see Section 3.6). [40 CFR 60.24(e)(1) and 60.39e(c)]

13. Provision for state progress reports to EPA. [40 CFR 60.25(e) and (f)]

The revised or new State Plans are due to EPA by October 6, 2010. Table 1-4 is a crosscheck of subpart B requirements and identifies whether or not each section applies to HMIWI. Table 1-4 also indicates where the HMIWI EG (subpart Ce) and section 129 of the CAA override specific provisions of subpart B. EPA published guidance for subpart B in 1977. That guidance applies to the HMIWI EG, except where overridden by the changes introduced in section 129 of the CAA of 1990 and the latest version of subpart Ce.

Table 1-4. Regulations for Adopting and Submitting State Plans (40 CFR Part 60 Subpart B)

Section Number and Title	General Contents	Does the Section Apply to HMIWI ?
60.20 "Applicability"	Subpart B applies when final Guidelines are promulgated (i.e., subpart Ce).	Yes, final amended HMIWI Guidelines (subpart Ce) were published October 6, 2009, so subpart B applies to HMIWI.
60.21 "Definitions"	Definitions of key terms.	Definition of "designated pollutant" in subpart B does not apply to HMIWI. Subpart Ce lists nine HMIWI pollutants that are covered. Definition of "designated facility" in subpart B is defined in subpart Ce as each HMIWI for which construction commenced on or before June 20, 1996 and for which construction commenced after June 20, 1996 but no later than December 1, 2008.
60.22 "Publication of guideline documents, Emission Guidelines, and final compliance times"	Descriptions of contents of Emission Guidelines to be developed by EPA.	Yes. Amended guidelines for HMIWI (subpart Ce) have been developed and published as required (October 6, 2009 [74 FR 51368]).
60.23 "Adoption and submittal of State Plans, public hearings"	Schedules and procedures for states to follow in developing and submitting State Plans. Requirements for public hearings on State Plans.	Yes, except for 60.23(a). Section 129 specifies that State Plans for HMIWI be submitted 1 year after publication of subpart Ce (i.e., October 6, 2010).
60.24 "Emission standards[3] and compliance schedules"	State Plans must include emission standards and compliance schedules. State Plans may be more or less stringent than the Guidelines.	Yes, except 60.24(f) does not apply. Subpart Ce and Section 129 specify that State Plans must be "at least as protective" as the Guidelines.

[3] Note that "emission standards" can include any state enforceable mechanisms including, but not limited to, state rules (see section 3.2 in this document).

Section Number and Title	General Contents	Does the Section Apply to HMIWI ?
60.25 "Emission inventories, source surveillance, reports"	Plans must include a plant inventory and an emissions inventory and provisions for monitoring compliance. States must submit progress reports to EPA.	Yes.
60.26 "Legal authority"	Plans must demonstrate that the state has legal authority to carry out the Plan as submitted.	Yes.
60.27 "Actions by the Administrator"	Procedures for EPA review and approval or disapproval of Plans. Federal Plans will be developed if states have not submitted approvable Plans.	The schedules in 60.27 do not apply. For HMIWI, section 129(b)(2) of the Clean Air Act allows 6 months for EPA to approve or disapprove State Plans. EPA will implement a Federal Plan per section 129(b) for all states (with affected sources) which do not have an EPA approved State Plan in place by October 6, 2011 (2 years after promulgation).
60.28 "Plan revisions by the state"	Procedures for revision of Plans.	Yes.
60.29 "Plan revisions by the Administrator"	Procedures for revision of Plans.	Yes.

1.6 Requirements for Negative Declarations

If no sources affected by the amended EG in the state, then the state need only submit a letter of certification, called a "negative declaration," to the appropriate EPA Regional Administrator in lieu of a revised or new State Plan.[4] [40 CFR 60.23(b) and 62.06] EPA has no formal review process for negative declaration letters. Once the negative declaration letter is received, a copy is placed in the public docket and a notice is published in the Federal Register (FR). If, at a later date, an existing HMIWI is found in the state, the Federal Plan implementing the HMIWI EG would automatically apply to that unit until the State Plan is approved. [40 CFR 62.14400 and 65 FR 49869-70, 74] If the State Plan is already approved when an existing HMIWI is found in the state, the state plan would apply.

1.7 Relationship Between the Section 111(d)/129 State Plan and SIP

The State Plans for implementing the HMIWI EG are different from State Implementation Plans (SIP) required by sections 110 or 172 of the CAA. The State Plan and the

[4] The absence of known sources does not preclude a State from submitting a State Plan. States with no known sources may still want to submit a State Plan to cover existing sources subsequently discovered.

SIP are programs for state implementation of federal requirements, and for both, the administrative procedures, particularly the public hearing process, are similar. Both programs are designed to achieve emission reductions at sources by identifying the pollutant to be controlled, establishing the emission limits for the source, and establishing procedures to ensure that emission limits are met.

However, the states and EPA fulfill different responsibilities under the two programs. The goal of section 111(d)/129 State Plans is to control the emissions of designated pollutants[5] by establishing standards of performance for existing sources. Section 111(d)/129 EG (including emission limits or performance levels) are technologically-based and are established by EPA on a national level. States are responsible for developing and implementing a program to achieve compliance with these technologically-based standards.

The goal of the SIPs, on the other hand, is to attain and maintain National Ambient Air Quality Standards (NAAQS) or ambient concentrations for certain criteria pollutants (Pb, SO_2, PM_{10}, NO_2, CO, and ozone) in a given area. Hence, in the SIP program, the state establishes emission limits or standards based on the sources' contributions to local air quality and other local factors. The emission control requirements for a regulated source category under a SIP may vary from facility to facility based on local factors. The states are responsible for implementing both section 111(d)/129 State Plans and SIP programs, and both programs complement each other.

[5] Section 111(d)/129 Plans apply to PM, SO_2, HCl, CO, NO_x, Pb, Cd, Hg, dioxins/furans, and opacity (as appropriate) [CAA section 129(a)(4) and (b)(2)].

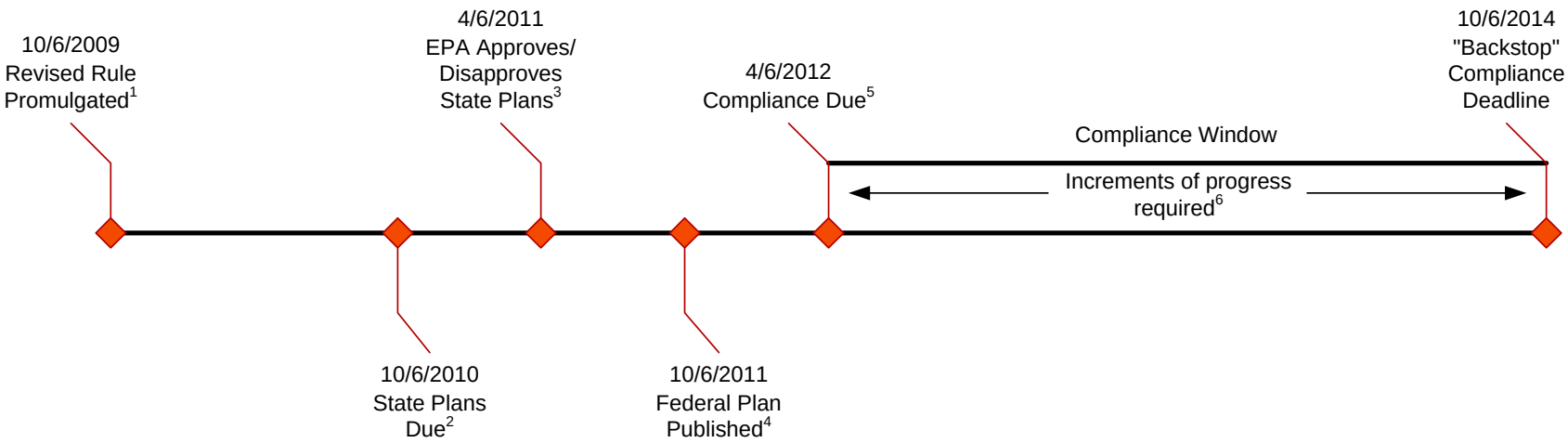
2.0 Schedule and Responsibilities

Sections 111(d) and 129 of the CAA direct each state to adopt and submit Plans that implement the HMIWI EG within 1 year after EPA publication of the final EG. [CAA sections 111(d)(1) and 129(b)(2)] Amended EG for HMIWI (40 CFR Part 60, subpart Ce) were published on October 6, 2009 [74 FR 51368], and revised or new State Plans need to be submitted to EPA on or before October 6, 2010 [CAA section 129(b)(2) and 40 CFR 60.39e(a)(2)]. Figure 2-1 is a timeline which shows how implementation of the EG might proceed if the maximum time allowed is used for each event.

2.1 State Plan Schedule

In order to submit a revised or new section 111(d)/129 State Plan by October 6, 2010, States need to revise an existing or develop a new section 111(d)/129 State Plan as soon as possible and complete the required public hearings. The steps that are necessary for states to develop and submit the State Plans are listed in Table 2-1, along with an example schedule.

After the revised or new State Plan is submitted, EPA is required to approve or disapprove the State Plan no later than 180 days (6 months) of State Plan submittal. [CAA section 129(b)(2)] EPA's decision to approve or disapprove each State Plan will be published in the FR. [40 CFR 62.02(e) and 62.04] Final decisions will be codified in 40 CFR Part 62, "Approval and Promulgation of State Plans for Designated Facilities and Pollutants." If a revised or new State Plan is not approvable, EPA will discuss its concerns about the State Plan with the state prior to official disapproval. If the State Plan is not approved, the basis for disapproval will be discussed in the FR notice, and the state would have an opportunity to submit a revised Plan addressing EPA's concerns. [CAA section 129(b)(2) and 40 CFR 62.02(e) and (f)] If the state does not have an approved Plan in place by October 6, 2011, EPA's Federal Plan will go into effect immediately and will be applicable to affected sources in that state. [CAA section 129(b)(3) and 40 CFR 62.13 and 60.39e(f)]



[1] 74 FR 51368.
[2] Section 129(b)(2) requires State Plans be submitted not later than one year after promulgation of the rule.
[3] Section 129(b)(2) requires EPA to approve or disapprove a State Plan within 180 days of submission.
[4] Section 129(b)(3) requires EPA to develop a Federal Plan within 2 years of rule promulgation (if necessary).
[5] Due 12 months after EPA approval of State Plan under section 60.39e of subpart Ce unless the State has granted an extension to a source (up to 3 years after approval of State Plan but not less than 5 years after promulgation). Note: Section 129(f)(2) requires expeditious compliance.
[6] Section 60.24(e)(1) of subpart B requires legally enforceable increments of progress for any compliance schedule extending beyond 12 months from State Plan approval. Section 60.39e(c)(1)-(9) of subpart Ce and section 60.21 of subpart B list suggested increments of progress, and section 60.21 of subpart B contains five required increments of progress.

Notes:

Subpart B	General requirements for all section 111(d) State Plans. Amended 12/19/95 to allow subsequent subparts (e.g., subpart Ce) to supersede subpart B.
Subpart Ce	Emission Guidelines for HMIWI.

Figure 2-1. HMIWI Implementation Timeline

Table 2-1. Sample State Schedule for Section 111(d)/129 State Plans

Action	Date
Begin source inventory	Immediately
Amended EG promulgated by EPA	October 6, 2009
Decide what state authority to use	November 2009
Start state rulemaking or other procedure needed to ensure state authority	December 2009
Start revising or drafting State Plan	December 2009
Notice of public hearings	February 2010 (30 days before hearing)
Complete state rulemaking or other procedure needed	June 2010
Complete public hearing on revised or new State Plan	June 2010
Revised or new State Plans due to EPA Regional Office	October 6, 2010
Respond to any clarifications requested by EPA	During the 180 day period following October 6, 2010
EPA approval/disapproval of the revised or new State Plan	No later than 6 months after State Plan submittal
If disapproved, submit revised approvable State Plan	Prior to October 6, 2011 to avoid Federal Plan
Federal Plan (if applicable)	October 6, 2011

To be approved by EPA, the revised or new section 111(d)/129 State Plans need to include a compliance schedule for all existing HMIWI located in the state. [40 CFR 60.24(a) and 60.39e] The compliance schedule should require compliance as expeditiously as practicable after EPA approval of the Plan and can allow up to 3 years from State Plan approval for HMIWI to comply, provided the State Plan includes enforceable increments of progress. [40 CFR 60.24(e)(1) and 60.39e(c)] In all cases, all applicable sources need to be in compliance no later than 3 years after State Plan approval by EPA or October 6, 2014, whichever is earlier. [CAA section 129(b)(2) and (f)(2) and 40 CFR 60.39e(c)] Compliance could be achieved by completing a retrofit of air pollution controls or by shutting down. [see 40 CFR 62.14470 and 62.14471 of the original HMIWI Federal Plan as an example] States may establish compliance schedules that are shorter than the times allowed by the EG, but they may not establish

compliance schedules that are longer than allowed by the EG. [CAA section 129(b)(2) and 40 CFR 60.24(g) and 60.39e(b)-(d)]

2.2 Responsibilities

EPA, the states, and owners and operators of HMIWI each have responsibilities for implementing the EG. The primary responsibilities for each party are outlined below.

2.2.1 EPA Responsibilities

Assisting State and Local Programs and HMIWI Owners and Operators. EPA assists state and local agencies to prepare revised or new, approvable section 111(d)/129 State Plans. EPA provides information, answers questions, and interprets federal requirements for the state and for HMIWI owners and operators. EPA conducts outreach and compliance assistance programs. EPA identifies contact persons to answer states' questions, clarify approval criteria, and address specific implementation issues as necessary. States' questions should be directed to the appropriate EPA Regional Office to ensure efficient and consistent responses. (See Appendix E for a list of Regional and state contacts.)

Review of State Plans. Section 129(b)(2) of the CAA requires EPA to approve or disapprove State Plans within 180 days (6 months) of submittal. States are to revise or develop their section 111(d)/129 State Plans pursuant to 40 CFR Part 60, subpart B (as revised December 19, 1995 to conform with section 129). EPA will inform the state if EPA has questions about the revised or new State Plan before making a decision on the approval or disapproval of the State Plan. After a state incorporates a requirement in the revised or new State Plan, and the State Plan is reviewed and approved by EPA, the state requirement becomes federally enforceable.

Federal Plan. EPA anticipates that many of the states with HMIWI will prepare revised or new, approvable section 111(d)/129 State Plans. In the event an approvable State Plan is not submitted, EPA will develop and implement a Federal Plan, which will go in effect immediately on October 6, 2011 for any state that does not have an approved State Plan.

Tribal Plans No existing HMIWI are located on tribal lands. EPA does not anticipate the need for any tribes to develop Tribal Plans.

2.2.2 State Responsibilities

Developing a State Plan. The state is to revise or develop a State Plan that meets the criteria presented in sections 111(d) and 129 and the amended EG. This document discusses how states could meet this responsibility.

Establishing Compliance Schedules. To be approved by EPA, the revised or new State Plan needs to include the amended emission limits and compliance schedules for all HMIWI. When preparing a revised or new section 111(d)/129 State Plan, states should contact HMIWI owners and operators to ensure that they understand the requirements of the amended EG. Facilities could come into compliance with the State Plan by completing a retrofit or shutting down by the 1-year compliance date (i.e., 1 year after EPA approval of the State Plan). [40 CFR 60.39e(b)] If the revised or new State Plan contains increments of progress (see section 3.6), HMIWI may be allowed to extend their retrofit schedule beyond the 1-year compliance date. [40 CFR 60.24(e)(1) and 60.39e(c)] All HMIWI planning to retrofit would need to do so within 3 years of EPA approval of the revised or new State Plan, but no later than October 6, 2014. [CAA section 129(b)(2) and (f)(2) and 40 CFR 60.39e(c)] All HMIWI planning to shut down would need to do so within 1 year after EPA approval of the revised or new State Plan, unless granted an extension by the state under the provisions of section 60.39e(d) of subpart Ce. Be aware that a state can only consider petitions per section 60.39e(d) if the State Plan includes a provision that allows such sources to request an extension to continue operating beyond 1 year after State Plan approval (see section 3.6). [40 CFR 60.24(a) and (e)(1) and 60.39e(c) and (d)]

Ensuring Compliance. Facilities could achieve compliance by completing retrofits or shutting down by the dates established in the revised or new section 111(d)/129 State Plans. [see 40 CFR 62.14470 and 62.14471 of the original HMIWI Federal Plan as an example] In order to prevent sources from continuing to operate or restarting without proper controls, the revised or new State Plans need to demonstrate the legal authority requiring HMIWI that have shut down to maintain closure. [40 CFR 60.26(a)] States are advised to include a generic compliance schedule in their revised or new State Plans to cover facilities which have shut down but may reopen in the future. Units that shut down by the date 1 year after EPA approval of the revised or new State Plan, and restart prior to the October 6, 2014 deadline would need to complete all of the missed increments of progress in the state's generic compliance schedule before restarting. [40 CFR 60.24(e)(1) and 60.39e(c); see 40 CFR 62.14472 of the original HMIWI Federal Plan as an

example] Units which restart after the October 6, 2014 compliance deadline would need to comply with the revised or new State Plan before resuming operation. [CAA section 129(f)(3) and 40 CFR 60.26(a); see 40 CFR 62.14472 of the original HMIWI Federal Plan as an example]

Hospital/medical/infectious waste incinerators that shut down can be divided into two groups. The first group is HMIWI that have shut down or will shut down and are not planning to restart. Once shut down, such sources cannot restart without a State Plan revision and retrofit of air pollution control equipment. [40 CFR 60.24(e)(1), 60.25(a), 60.28(c), and 60,39e(b) and (c); see 40 CFR 62.14471 of the original HMIWI Federal Plan as an example]

The second group is HMIWI that shut down as an element of their retrofit activities. For these HMIWI, schedules for shutdown and completion of retrofit activities would be included in the revised or new State Plan. For retrofitting facilities, the revised or new State Plan needs to include the five enforceable increments of progress for retrofit activities (discussed in section 3.6.3), along with a sixth increment, a date for shutdown. Under the State Plan, the HMIWI would shut down by the specified date and could not restart until the other increments of progress, including retrofit of controls, are complete. [40 CFR 60.24(e)(1) and 60.39e(c); see 40 CFR 62.14470 and 62.14472 of the original HMIWI Federal Plan as an example]

Submitting Progress Reports. States are to report annually to EPA on the progress of implementing the revised or new Plan, including meeting increments of progress and achieving final compliance. The States also need to include in this report (as discussed in section 3.12): (1) compliance status, (2) enforcement actions, and (3) updates on inventory. [40 CFR 60.25(e) and (f)]

2.2.3 Source Responsibilities

Developing Compliance Plans and Schedules. Hospital/medical/infectious waste incinerator owners and operators are to work with the state to develop a compliance plan and retrofit schedule under the revised or new State Plan. [40 CFR 60.39e(d)(1)(i) and (ii)] To comply, all HMIWI will need to either shut down within 1 year of EPA approval of the State Plan[1] or complete retrofits to comply with the emission limits not later than 3 years after

[1]In some cases, sources planning to shut down may be granted an extension beyond the 1-year deadline, if the State Plan contains the provisions outlined in section 60.39e(d) of subpart Ce.

approval of the revised or new section 111(d)/129 State Plan or by October 6, 2014, whichever is sooner. [CAA section 129(b)(2) and (f)(2) and 40 CFR 60.39e(b)-(d); see 40 CFR 62.14470 and 62.14471 of the original HMIWI Federal Plan as an example]

Upgrading or Retrofitting Facilities. Owners and operators will need to retrofit or upgrade their facilities to meet the amended emission limits on the compliance schedules established by the state. [CAA section 129(b)(2), (f)(2), and (f)(3) and 40 CFR 60.24(a), (c), and (e)(1) and 60.39e(b)-(d)]

Meeting Additional State Plan Requirements. In addition to completing the necessary retrofits, owners and operators are responsible for meeting other State Plan requirements (summarized in section 3.5). Facilities are required to comply with operator training and qualification requirements, inspection requirements, and waste management plan requirements. [40 CFR 60.25(b) and 60.34e-60.36e] Facilities are to report to the state their progress towards compliance, report ongoing testing and monitoring results, and keep required records to demonstrate compliance. [40 CFR 60.25(b), 60.37e, and 60.38e] Most of these requirements are to be completed at the time of full compliance, with the exception of the operator training and qualification requirements and the inspection requirements, which are to be completed within 1 year after EPA approval of the revised or new State Plan. [40 CFR 60.34e, 60.36e(a) and (c), and 60.39e(e)]

3.0 Required Elements of an Acceptable State Plan

Table 3-1 summarizes the elements of the State Plan for HMIWI, provides citations from subparts B and Ce, and identifies the sections of this chapter that discuss each element. States may find this summary helpful in preparing their revised or new section 111(d)/129 State Plans, and EPA will use it in reviewing the State Plans.

Some components of a section 111(d)/129 State Plan duplicate existing state requirements and, therefore, will not add additional requirements. For example, most states require public notice for rulemaking consistent with 40 CFR Part 60, subpart B. Similarly, section 112 and title V of the CAA require various demonstrations of legal authority. To the extent that earlier demonstrations of legal authority by the state meet the requirements of 40 CFR Part 60, subpart B, the state would simply need to include copies of such demonstrations in the State Plan submittal, including a copy of the state laws or regulations (if applicable).

3.1 Demonstration of Legal Authority

To be approved by EPA, the section 111(d)/129 State Plan needs to demonstrate that the state has the legal authority under current state law to adopt and implement the emission standards and compliance schedules in the State Plan. [CAA section 129(f)(3) and 40 CFR 60.26(a)] The legal authority should support the legal mechanism selected by the state to implement the emission limits for HMIWI. The legal authority needs to be available to the state at the time the state submits its section 111(d)/129 State Plan to EPA. [40 CFR 60.26(c)] States are to submit with the section 111(d)/129 State Plan copies of the laws or regulations that demonstrate the state's legal authority if a state law or regulation is the enforceable mechanism. [40 CFR 60.26(b)]1

A state could use existing demonstrations of legal authority to meet the requirements of subpart B. Which existing authorities the state uses to implement the section 111(d)/129 requirements depends on the legislative structure of the state. This implementation guidance discusses the minimum requirements of section 111(d) and 129 pertaining to HMIWI and notes

1 Only citations from the overall rule and copies of the sections pertaining to HMIWI would need to be submitted. [40 CFR 60.26(b), noting that the "provisions of law or regulations…shall be specifically identified." (emphasis added)]

that states retain flexibility to implement the requirements as long as the provisions are enforceable under state law.

Table 3-1. Summary of Requirements for Section 111(d)/129 State Plans[a]

Required Item	Reference in 40 CFR Part 60, Subpart B or Ce	Section of this Document
Demonstration that state has legal authority to carry out Plan	60.26(a) of subpart B	3.1
Enforceable mechanisms selected by the state to implement the Guidelines	60.24(a) of subpart B	3.2
Inventory of HMIWI, their emissions and information related to their emissions	60.25(a) and (c) of subpart B	3.3
Compliance with emission limits	60.24(a)-(c) of subpart B and 60.33e of subpart Ce	3.4
Provisions for determining HMIWI compliance status, including: 1. Legally enforceable procedures for requiring the maintenance of records and periodic reporting to the state for the determination of compliance; 2. Periodic inspections and testing; 3. Testing, monitoring, recordkeeping, and reporting requirements specified in subpart Ce; 4. Operator training and qualification; 5. Waste management plan; and 6. Inspections	60.24(b)(2) and 60.25(b) of subpart B and 60.34e-60.38e of subpart Ce	3.5
Compliance schedules and legally enforceable increments of progress for HMIWI to achieve compliance	60.24(a) and (e)(1) of subpart B and 60.39e of subpart Ce	3.6
Certification that a public hearing was held before the State Plan was adopted and list of the attendees at the hearing and their affiliation, with a summary of their presentations and handouts	60.23(f)(1) and (2) of subpart B	3.7
State progress reports	60.25(e) and (f) of subpart B	3.8

[a] See text of section 3 and Appendix A of this document for additional discussion of the required elements of a State Plan.

A state needs to include in its demonstration of existing legal authority a showing that it has the authority to:

1. Adopt emission standards (including stack opacity) and enforceable conditions (see section 3.2) as well as compliance schedules applicable to the designated facilities and pollutants for which the section 111(d)/129 State Plan is submitted; [40 CFR 60.26(a)(1), 60.33e, and 60.39e]

2. Enforce the relevant laws, regulations, standards and compliance schedules referenced in section 111(d) and section 129 and seek injunctive relief and prevent restart of HMIWI that have shut down; [40 CFR 60.26(a)(2)]

3. Obtain information necessary to determine compliance; [40 CFR 60.26(a)(3)]

4. Require reporting and recordkeeping, operator training and qualification, inspections, and testing; [40 CFR 60.26(a)(3), 60.34e, and 60.36e-60.38e]

5. Require the use of monitors and require emission reports of HMIWI owners/operators; [40 CFR 60.26(a)(4) and 60.37e]

6. Make emission data available to the public; [40 CFR 60.26(a)(4)] and

7. Require a waste management plan. [40 CFR 60.35e]

Demonstrations of legal authority can take several forms. States that use a legal mechanism other than rulemaking to implement the EG should submit legal documentation, preferably an opinion by the state's Attorney General, that the state possesses the adequate authority to implement and enforce the section 111(d)/129 State Plan using that legal mechanism. [CAA section 114(b)(1) and 40 CFR 60.26]

A state governmental agency other than the state air pollution control agency may be assigned responsibility for carrying out a portion of a section 111(d)/129 State Plan, provided that the state demonstrates that the state governmental agency has adequate authority. [40 CFR 60.26(d)] The state may authorize a local agency to implement a portion of the section 111(d)/129 State Plan, provided that the local agency demonstrates that it has adequate legal authority to implement that portion of the State Plan and the state is not relieved of responsibility. [40 CFR 60.26(e)]

3.2 Enforceable Mechanisms

Many states that have HMIWI covered by the amended EG will revise existing or develop new section 111(d)/129 State Plans that use state rules as the legal instrument to enforce the amended EG. An essential element of a section 111(d)/129 State Plan is the emission standards, which 40 CFR 60.21(f) defines as "a legally enforceable regulation (emphasis added) setting forth an allowable rate of emissions into the atmosphere, or prescribing equipment specifications for control of air pollution emissions."

Note that the pollutants regulated under the amended HMIWI EG are a combination of criteria and hazardous air pollutants. Generally, states have adequate authority under their air pollution statutes to regulate both criteria pollutants and hazardous air pollutants through a variety of mechanisms.

If the state relies on a mechanism that is not a state rule to implement the amended EG, the state needs to document in the State Plan how the selected mechanism ensures that the HMIWI will meet the requirements of the amended EG and attach a copy of the enforceable mechanism. [CAA section 114(b)(1), 40 CFR 60.26(b)] To ensure that the selected mechanism meets all of the requirements of the EG, the State would need to legally certify (preferably an Attorney General's Opinion) that the selected mechanism can be used to create enforceable requirements under the EG. Given that a process other than a rulemaking is being used to create federally-enforceable requirements, the State would also need to explain how the public has had an opportunity to participate in the development of the EG requirements, how the mechanism is permanent, and how the public will have access to the underlying documents which contain the limits and requirements.

The selected enforcement mechanism should not be title V permits because title V permits could not be used to create applicable federal requirements from the emission guidelines, title V permits are not permanent, and the public participation process under the EG is distinct from title V public notice requirements. Additionally, it is important to note that Attorney General Opinions submitted as part of title V program submittals would not be able to address the issues resulting from a State selecting an enforceable mechanism other than a rule to implement the EG.

3.3 Inventory

3.3.1 Source Inventory

A complete, updated source inventory of affected HMIWI in the state regulated by the EG is to be submitted as part of the state's revised or new section 111(d)/129 State Plan. [40 CFR 60.25(a)] Sources affected by the EG that will need to be included in the state's source inventory include: (1) HMIWI, (2) co-fired combustors, and (3) incinerators burning only pathological, low-level radioactive, and chemotherapeutic waste alone or in combination. [40 CFR 60.25(a) and 60.32e(a)-(c)] Each of these three types of combustors are defined in

section 60.51c of subpart Ec. The HMIWI are subject to all of the subpart Ce requirements. Co-fired combustors and incinerators burning pathological, low-level radioactive, and chemotherapeutic waste are only required to notify the Administrator of an exemption claim and to keep certain records. [40 CFR 60.32e(b) and (c)] Nevertheless, these sources are affected by the EG and thus, will need to be included in the source inventory. [40 CFR 60.25(a)] In addition, States are encouraged to make a reasonable effort to include sources which have shut down their incinerator, but which still have the capability of resuming operation.

In cases where a facility has shut down its HMIWI and does not intend to resume operation, the HMIWI may be left off of the state's source inventory if the state determines that the HMIWI is inoperable. [40 CFR 60.25(a); see also 65 FR 49876, in the preamble to the original HMIWI Federal Plan] Criteria for determining whether an incinerator is inoperable could include, but are not limited to, one or more of the following conditions:

1. Waste charge door welded shut
2. Stack/by-pass stack removed
3. Combustion air blowers removed
4. Burners or fuel supply removed

[65 FR 49876]

States should use their best judgment to ensure that a facility has taken steps to render the HMIWI inoperable before omitting the HMIWI from their source inventory.

3.3.2 Emission Inventory

An updated emission inventory, based on the updated HMIWI source inventory, for the pollutants regulated by the EG, is required by 40 CFR 60.25(a) and is to be included in the state's revised or new section 111(d)/129 State Plan. The emission inventory, as well as the source inventory, is to be made available to the public at the public hearing and presented with the applicable emission standards. [60.23(d)(2)] The inventory data should include emission data for the designated pollutants (e.g., continuous emission monitoring system [CEMS] data, actual test data, or recent estimates of emissions where practicable). [40 CFR 60.25(a) and Part 60 Appendix D] Means of estimating emissions from HMIWI are readily available and are discussed in section 3.4.1 below and in Appendix F. It may be more difficult to estimate emissions from co-fired combustors and incinerators burning only pathological, low-level radioactive, and chemotherapeutic waste due to the mixtures of wastes combusted. Unlike HMIWI, co-fired combustors and incinerators burning pathological, low-level radioactive, and

chemotherapeutic waste are not required to be subject to the emission limits in the State Plan. [40 CFR 60.32e(b) and (c)] Therefore, while states should include these sources in their source inventories, states could elect to leave these units out of the emission inventory. [40 CFR 60.25(a) and 60.32e(a)] Likewise, States could choose to leave incinerators which have shut down out of their emission inventory, since these sources would have zero emissions. [40 CFR 60.25(a); see also 65 FR 49876, in the preamble to the original HMIWI Federal Plan, as an example]

3.3.2.1 Emission Estimation Methods

Estimates of emissions for the emission inventory can be derived from a variety of methods. To the degree that a variety of types of data are available, EPA recommends the following hierarchy for estimating emissions[2]:

1st choice. Where already available, CEMS data that provide a continuous record of emissions over an extended and uninterrupted period of time.

2nd choice. Where already available, stack sampling results.

3rd choice. Emission factors:

a. AP-42/FIRE[3] emission factors rated "A" through "D"--based on source tests performed at one or more facilities within an industry ("A" is the highest rating) or EPA emission factors generated from data used in the development of the amended HMIWI EG (presented in Appendix F).
b. State emission factors--possibly more optimized to local or regional conditions.
c. Industry emission factors.
d. AP-42/FIRE emission factors rated "E" and "U" ("E" is the lowest rating on the A through E scale, and "U" is unratable).

Where emission factors are used, the AP-42 *Compilation of Air Pollutant Emission Factors* provides preferred emission estimation methods. Example calculations for estimating emissions from emission factors are provided in AP-42. However, where emissions data from

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2Chapter 4, *Introduction to Stationary Point Source Emission Inventory Development*, May 2001. http://www.epa.gov/ttn/chief/eiip/techreport/volume02/ii01_may2001.pdf

[3] AP-42 is the common name for the EPA document entitled *Compilation of Air Pollutant Emission Factors, Volume I: Stationary Point and Area Sources, Fifth Edition*, January 1995, available from GPO or from the CHIEF bulletin board. The *Factor Information Retrieval System* (FIRE) is factor retrieval software that is available from the CHIEF bulletin board or by calling Info-CHIEF hotline at (919) 541-5285.

CEMs or stack testing are already available and are thought to be representative, the data should be used in place of emission factors. Additional testing would not be needed for the inventory in the State Plan where data are not available. [40 CFR 60.25(a) and Part 60 Appendix D]

3.3.2.2 Required Emission Summary Reports

A summary of emissions should be submitted with the revised or new section 111(d)/129 State Plan. The summary should include, at a minimum, the emission rate of each of the designated pollutants for each HMIWI. These values should be provided with the corresponding emission standards to show the relationship between measured or estimated emissions and the amounts of such emissions allowed by the standard. [40 CFR 60.25(a)]

3.3.2.3 Annual Emission Reporting

In addition to the updated emission inventory required for the revised or new section 111(d)/129 State Plan, 40 CFR 60.25(e) also requires states to submit reports on progress in plan enforcement, as part of the annual report to EPA submitted under 40 CFR 51.321 through 51.323. These annual reports are to update the emission inventory for sources that achieve compliance, sources that are new or modified, sources that have shut down, and sources whose emissions have changed more than 5 percent from the most recently submitted emission data. [40 CFR 60.25(f)(4) and (5)] If none of the above events occurs, then there are no updates to report, and the only change the state would need to make to the next annual report would be to change the year (i.e., the state could still use the data from the previous year). [40 CFR 60.25(f)(5)]

3.3.2.4 Reporting to AFS

Emissions data are to be reported to the Air Facility System (AFS) as specified in paragraph (a) of Appendix D to 40 CFR Part 60. The AFS is a repository of emission information for stationary sources that supersedes the National Emissions Data System (NEDS) described in 40 CFR Part 60 Appendix D.

3.4 Compliance with Emission Limits

Hospital/medical/infectious waste incinerators will need to retrofit controls to comply with the emission limits in the revised or new State Plan or shut down their incinerator. The revised or new State Plan should include emission limits that are at least as protective as the amended EG and also should address non-operating HMIWI (unless the HMIWI is inoperable)

and HMIWI that will shut down rather than retrofit air pollution control equipment. [CAA section 129(b)(2), 60.24(c), 60.25(a), and 40 CFR 60.33e(a)] The emission limits are to apply at all times, including periods of startup, shutdown, and malfunction, as defined in subpart Ce. [40 CFR 60.37e(a) and 60.56c(a)]

Under section 129(b)(2), the revised or new section 111(d)/129 State Plans are to include emission limits that are "at least as protective as" those in the amended HMIWI EG (40 CFR Part 60, subpart Ce). The emission limits for the nine HMIWI pollutants and opacity are found in subpart Ce (presented in Appendix K of this document).

The revised or new section 111(d)/129 State Plan should include limits for all nine of the pollutants plus opacity in subpart Ce. Section 60.33e of subpart Ce specifies emission limits for PM, CO, Cd, Pb, Hg, SO_2, HCl, dioxins/furans, NO_X, and opacity. All of these pollutant limits are in units of concentration. For example, the PM and metals limits are in units of milligrams per dry standard cubic meter exhaust. The dioxins/furans limit is also a concentration limit (in units of nanograms per dry standard cubic meter) for total dioxins/furans and the toxic equivalent [TEQ] for 2,3,7,8-tetrachlorodibenzo-p-dioxin [TCDD]). The HCl, SO_2, NO_x, and CO limits are concentration limits in units of parts per million by volume. The opacity limit is in units of percent opacity.

To be approvable, the revised or new section 111(d)/129 State Plan should include emission limits in dimensions identical to the amended Guidelines, or alternative formats demonstrated to be at least as protective as the concentration limits specified for each pollutant in subpart Ce. [CAA section 129(b)(2) and 40 CFR 60.24(c) and 40 CFR 60.33e(a)] Other state programs and permits may include limits in the form of emission rates (e.g., pounds per hour) or ambient air concentrations; these types of limits are <u>not</u> required to be included in the revised or new section 111(d)/129 State Plan. If a revised or new State Plan uses any format for emission limits other than those in subpart Ce, the state needs to demonstrate to EPA that these emission limits are at least as protective as those in subpart Ce. [CAA section 129(b)(2) and 40 CFR 60.24(c) and 40 CFR 60.33e(a)]

3.5 Determining HMIWI Compliance Status

To be approved by EPA, the revised or new section 111(d)/129 State Plan needs to include requirements for the testing and monitoring, reporting and recordkeeping, operator training and qualification, waste management plans, and the inspection provisions from the EG.

These provisions are specified in the amended HMIWI EG (subpart Ce). These include, in particular:

1. The performance testing methods listed in section 60.56c of subpart Ec [40 CFR 60.37e],

2. The monitoring requirements listed in section 60.57c of subpart Ec [40 CFR 60.37e],

3. The reporting and recordkeeping provisions listed in section 60.58c of subpart Ec [40 CFR 60.38e],

4. The operator training and qualification requirements listed in section 60.53c of subpart Ec [40 CFR 60.34e],

5. The waste management guidelines listed in section 60.55c of subpart Ec [40 CFR 60.35e], and

6. The inspection guidelines listed in section 60.36e of subpart Ce.

The amended EG include periodic performance tests and monitoring of specific operating parameters. [40 CFR 60.37e(a)-(e), 60.56c(c), and 60.57c(a)-(e)] Each facility is to maintain records of the performance test and specified operating parameters for 5 years. [40 CFR 60.38e(a) and 60.58c(b)(2) and (6)] The facility is to submit annual reports if it is in compliance and semiannual reports if it exceeds emission standards or operating parameter limits. [40 CFR 60.38e(a) and (b)(2) and 60.58c(d) and (e)] Details of these requirements are contained in subpart Ce (presented in Appendix K of this document).

A revised or new State Plan that incorporates the testing, monitoring, reporting, and recordkeeping requirements specified in subpart Ce will be consistent with the State Plan requirements in subpart B. Under section 60.25(b) and (c) of subpart B, State Plan requirements for monitoring compliance are to include the following:

1. Legally enforceable requirements that require owners and operators to keep records of the nature and amount of emissions and any other information that may be necessary to enable the state to judge compliance. This information is to be

reported periodically to the state. [40 CFR 60.25(b)(1)] (Subpart Ce requires such records and reports.)

2. Legally enforceable requirements that provide for periodic inspection and testing. [40 CFR 60.25(b)(2)] (Subpart Ce requires periodic testing and monitoring of operating parameters.)

3. Provisions for making reports of emissions, correlated with the emission standards that apply available to the general public. [40 CFR 60.25(c)]

In addition, State Plan provisions for testing and monitoring are to be conducted in accordance with the quality assurance procedures in 40 CFR part 60, Appendix F, and in the underlying test methods.

3.5.1 Testing Requirements

Consistent with Section 60.37e of the amended subpart Ce EG, revised or new State Plans are to require all HMIWI, including small rural HMIWI, to demonstrate initial compliance with the 2009 amended emission limits for all nine pollutants and opacity, if the sources have not already demonstrated compliance. Revised or new State Plans may allow sources to use results of their previous emission tests to demonstrate initial compliance with the amended emissions limits as long as the sources certify that the previous test results are representative of current operations with regard to factors such as charge rate, operating parameters, etc. [40 CFR 60.37e(f)] Only those sources who could not so certify and/or whose previous emission tests do not demonstrate compliance with one or more amended emission limits would need to conduct another emission test for those pollutants. [40 CFR 60.37e(a)(2), (b)(2), and (f) and 60.56c(b)] Revised or new State Plans are also to require all HMIWI, including small rural HMIWI, to demonstrate annual compliance with the amended PM, CO, and HCl emission limits by conducting an annual performance test. [40 CFR 60.37e(a)(2) and (b)(2) and 60.56c(c)(2)] In addition, revised State Plans are to require existing HMIWI to conduct a Method 22 visible emissions test of the incinerator ash handling operations during the next performance test at the facility. State Plans for new HMIWI are to require a Method 22 visible emissions test of the incinerator ash handling operations during each compliance test. [40 CFR 60.37e(a)(2) and (b)(2) and 60.56c(b)(14)]

3.5.2 Monitoring Requirements

Revised or new State Plans are to require sources to establish site-specific operating

parameter limits during the performance tests to demonstrate initial compliance with amended emission limits, as well as to require sources to monitor those operating parameters to ensure ongoing compliance. Section 60.37e of the amended subpart Ce EG specifies the types of operating parameters to be monitored. Revised or new State Plans may also include the use of CO, PM, HCl, multi-metals, and Hg CEMS and integrated sorbent trap Hg monitoring and dioxin monitoring (i.e., continuous sampling with periodic sample analysis) as alternatives to parameter monitoring. [40 CFR 60.37e(a)(2) and (b)(2) and 60.56c(c)(4)-(7)]

3.5.3 Reporting and Recordkeeping Requirements

Revised or new State Plans are to include the reporting and recordkeeping requirements specified in section 60.38e of the subpart Ce EG, as amended on October 6, 2009. Sources covered under the State Plan would need to maintain thorough records documenting the results of their initial and annual performance tests, records of continuous monitoring of their site-specific operating parameters, records of initial and annual inspections, records of compliance with the operator training and qualification requirements, and records of compliance with the waste management plan. [40 CFR 60.35e, 60.38e(a) and (b), 60.55c, and 60.58c(b)(2), (b)(6), (b)(9), and (b)(10)] Sources would need to keep these records on file for at least 5 years. [40 CFR 60.58c(b)]

The subpart Ce EG provide for owners or operators to submit the results of the initial performance test and all subsequent performance tests or inspections. [40 CFR 60.38e(a) and (b) and 60.58c(c)(1) and (d)(6) and (d)(9)] Additionally, reports on emission rates or operating parameters that have not been obtained or that exceed applicable limits are to be submitted on a semi-annual basis. [40 CFR 60.38e(a) and 60.58c(e)] If no exceedences occur during a semi-annual period, the owner of the designated facility is to submit an annual report stating that no exceedences occurred. [40 CFR 60.38e(a) and (b)(2) and 60.58c(d)] All reports are to be signed by the facilities manager. [40 CFR 60.38e(b)(2) and 60.58c(d) and (e)]

3.5.4 Operator Training and Qualification Requirements

As specified in section 60.34e of the amended subpart Ce EG, State Plans are to require that each facility have at least one trained and qualified operator on duty or on-call. The trained and qualified HMIWI operator needs to pass an HMIWI operator training course, which is state-approved or meets the requirements specified in the amended Guidelines. [40 CFR 60.34e and

60.53c(b) and (c)] Also, State Plans are to require each facility to develop site-specific information regarding HMIWI operation. [40 CFR 60.34e and 60.53c(h)] State Plans are to require each employee involved with the operation of the HMIWI to review the operating information developed for the HMIWI each year. [40 CFR 60.34e and 60.53c(i)]

For designated facilities as defined in section 60.32e(a)(1) of the amended subpart Ce (existing sources under the September 15, 1997 HMIWI rule), the initial operator training requirements should have been met 1 year after the effective date of either the State Plan approval or Federal Plan promulgation. [40 CFR 60.34e and 60.39e(e)] For designated facilities as defined in section 60.32e(a)(2) of the amended subpart Ce (NSPS sources under the September 15, 1997 HMIWI rule), the initial operator training requirements should have been met at the time of initial facility start-up. [40 CFR 60.53c]

3.5.5 Waste Management Plan Requirements

Section 60.35e of subpart Ce directs State Plans to ensure that facilities develop a waste management plan that identifies the feasibility and the approach to separate certain components of the solid waste stream from the health care waste stream. The waste management plan requirements in State Plans are to be at least as protective as the requirements for waste management plans under section 60.55c of subpart Ec.

For those HMIWI covered under the September 15, 1997 HMIWI rules (subparts Ce and Ec), the waste management plan provisions under those rules should have been met no later than 60 days after the required initial performance test. [62 FR 48381 and 48389] A revised waste management plan for those sources, under the amended October 6, 2009 subpart Ce provisions, needs to be completed. The revised plan needs to be submitted no later than 60 days after the initial performance test demonstrating compliance with the amended subpart Ce emission limits contained in an approved, revised or new State Plan. [40 CFR 60.38e(a) and 60.58c(c)(3)]

3.5.6 Inspection Requirements

Revised or new State Plans are to require facilities to conduct initial and annual HMIWI and control equipment inspections. Section 60.36e of the amended subpart Ce lists the components of the HMIWI and control equipment which revised or new State Plans are to require facilities to inspect. Revised or new State Plans are to require initial HMIWI and control equipment inspections for large, medium, and small HMIWI and initial control equipment

inspections, if applicable, for small rural HMIWI within 1 year following EPA approval of the revised or new State Plan. [40 CFR 60.36e(a) and (c)] Revised or new State Plans are also to require annual HMIWI and control equipment inspections for all existing HMIWI after that point. [40 CFR 60.36e(b) and (d)] (Note: Existing small rural HMIWI should have already conducted the initial HMIWI equipment inspection included in the 1997 EG for those sources.) According to section 60.36e(a)(2) and (c)(2) of the amended subpart Ce, State Plans are to require facilities to complete any necessary HMIWI and control equipment repairs within 10 operating days following an inspection. Revised or new State Plans may allow repairs to be completed after 10 operating days, provided that the state supplies the facility with written permission and a date by which all repairs are to be completed. [40 CFR 60.36e(a)(2) and (c)(2)]

3.6 Compliance Schedules

To comply with the emission limits contained in the revised or new section 111(d)/129 State Plan, existing HMIWI may need to retrofit emission controls. The revised or new State Plan needs to contain expeditious schedules for retrofitting these HMIWI. [CAA section 129(f)(2) and 40 CFR 60.24(a), (c), and (e)(1) and 60.39e(a)-(d)] The elements included in a compliance schedule are listed in Table 3-2.

Table 3-2. Schedule for HMIWI Compliance with the HMIWI Emission Guidelines

Activity	Date
State Plan submittal	October 6, 2010
State Plan approval	April 6, 2011
If not in compliance by this date, need enforceable increments of progress for HMIWI	April 6, 2012
Submit a final control plan	October 6, 2012[a]
Award contracts for control system	May 6, 2013[a]
Initiate construction or installation of control system	January 6, 2014[a]
Complete construction or installation of control system	August 6, 2014[a]
Final compliance date for HMIWI	No later than 3 years from approval of State Plan[b] or October 6, 2014, whichever is earlier, or

Activity	Date
	shut down by that date
Reports of periodic performance test data	Annually after compliance date, if in compliance; semiannually after compliance date, if the emission limits or operating parameters are exceeded

[a] The dates presented for increments of progress are suggested dates based on the schedule included in section 62.14470 of the original HMIWI Federal Plan. A specific State Plan could include different dates.
[b] Section 129 does not preclude a state from requiring earlier compliance dates.

The retrofit schedules for HMIWI are developed by the state air pollution control agency considering input from the public and input from the HMIWI owners and operators. The EG place certain restrictions on retrofit schedules. Retrofit schedules can extend up to 3 years after section 111(d)/129 State Plan approval, but no retrofit schedule can extend beyond October 6, 2014. [CAA section 129(b)(2) and (f)(2) and 40 CFR 60.39e(c)]

The section 111(d)/129 State Plan also needs to specify legally enforceable increments of progress toward compliance for HMIWI that have compliance or retrofit schedules that extend past 1 year beyond approval of the section 111(d)/129 State Plan. [40 CFR 60.24(e)(1) and 60.39e(c)] In some cases, for example, an HMIWI could shut down as of October 6, 2014 or 3 years after state approval, whichever is earlier, complete a retrofit, and then reopen when retrofits are completed, based on provisions in the original HMIWI Federal Plan. [40 CFR 62.14472]

3.6.1 Retrofit Required

The subpart Ce Guidelines are "performance standards," that is, the standards do not prescribe one control system over another, but, rather, the HMIWI owners and operators can choose the actual equipment selected for retrofit at a facility that they believe will achieve the emission limits.

Control systems for the regulated HMIWI pollutants can be considered as two sub-groups: (1) combustion system upgrades -- referred to as "good combustion" (defined previously as 2-second residence time in the secondary chamber at 1800°F); and (2) add-on control systems (e.g., wet scrubber, dry injection followed by a fabric filter [DIFF]). "Good combustion" controls PM, CO, and organic emissions (e.g., dioxins/furans). Wet scrubbers and

DIFF are more expensive control systems and control multiple pollutants, including dioxins/furans, Pb, Cd, Hg, PM, HCl, and SO_2. Other add-on control systems that can be used in addition to these systems include activated carbon injection systems, which control Hg and dioxins/furans, and selective noncatalytic reduction (SNCR) systems, which control NO_X.

The amended EG are based on emission data associated with the best-performing 12 percent of HMIWI in each HMIWI subcategory (i.e., large, medium, small, small rural units). [73 FR 72980] The emission data reflect both technology factors (e.g., add-on control systems) and non-technology factors (e.g., waste segregation, good combustion). [73 FR 72964, 72970] The best-performing HMIWI use good combustion in combination with various types of add-on control systems, except for small rural units, which use good combustion alone (i.e., no add-on control systems in place). [73 FR 72980] HMIWI also use waste segregation. [73 FR 72964, 72975, 72979]

3.6.2 Retrofit Schedules for HMIWI

Under section 60.39e(c) of subpart Ce, HMIWI retrofits are to be in compliance with the amended EG within 3 years after approval of the revised or new State Plan or by October 6, 2014, whichever is earlier. Note, however, that enforceable increments of progress are required for units with compliance schedules extending more than 1 year after State Plan approval. [40 CFR 60.24(e)(1) and 60.39e(c)] As noted previously, State Plans could allow units to shut down by the specified date and restart after completing the retrofit. [40 CFR 60.24(e)(1) and 60.39e(c); see also 40 CFR 62.14472 of the original HMIWI Federal Plan as an example]

3.6.3 Increments of Progress

Compliance schedules for HMIWI with compliance dates that extend more than 1 year after State Plan approval should include legally enforceable increments of progress towards compliance as required by section 60.24(e) of subpart B. Each increment of progress from section 60.21(h) of subpart B should have an enforceable compliance date in the revised or new section 111(d)/129 State Plan. The minimum five increments of progress required by section 60.21(h) of subpart B for each HMIWI within a state are as follows:

1. Submitting a final control plan. This may be a brief document or letter describing the controls that the source will use to comply with the emission limits and other requirements. In most cases, the source, public, and state will have discussed this information as part of the state process for development of the compliance schedule for the draft State Plan before the State Plan is submitted to EPA; [40 CFR 60.21(h)(1)]

2. Awarding contracts for control systems or process modifications or orders for purchase of components; [40 CFR 60.21(h)(2)]

3. Initiating on-site construction or installation of the air pollution control device(s) or process changes; [40 CFR 60.21(h)(3)]

4. Completing on-site construction or installation of control equipment or process changes; [40 CFR 60.21(h)(4)] and

5. Final compliance. [40 CFR 60.21(h)(5)]

EPA's rules allow States a variety of options in setting the dates associated with these increments of progress. For example, all five increments of progress for HMIWI could be fixed calendar dates or set as floating dates. For increments one to four, the floating dates could be tied to either the date of the approval of the revised or new State Plan or the date of a local permit issuance. Also, the date for submitting a final control plan could be set as 3 months following approval of the State Plan. If an increment of progress is tied to the date of a permit issuance, EPA recommends the State Plan should identify the specific permit.

The fifth increment of progress, the date for final compliance, could also be set as a calendar date or a floating date. As a floating date, it should be tied only to the date of the approval of the revised or new State Plan, not to the date of permit issuance and would need to include the limitation that the date in no case can be later than 3 years from State Plan approval or October 6, 2014, whichever is earlier (unless the HMIWI will shut down). [CAA section 129(b)(2) and (f)(2) and 40 CFR 60.39e(c) and (d)]

The State Plan could include additional increments of progress as may be necessary for close and effective supervision of progress toward final compliance. Additional suggested increments of progress are listed in section 60.39e(c)(1) through (9) of subpart Ce. Some of these suggested increments of progress are already required by subpart B. The remaining suggested increments of progress could be included in the revised or new section 111(d)/129 State Plan as enforceable increments of progress with compliance dates, as non-enforceable

increments of progress with reporting requirements only, or they could be left out of the revised or new section 111(d)/129 State Plan entirely.

The additional suggested increments of progress from subpart Ce are:

1. Date for submitting a petition for site-specific operating parameters; [40 CFR 60.39e(c)(1)]

2. Date for obtaining services of an architectural and engineering firm regarding the air pollution control device(s); [40 CFR 60.39e(c)(2)]

3. Date for obtaining design drawings of the air pollution control device(s); [40 CFR 60.39e(c)(3)]

4. Date for ordering the air pollution control device(s); [40 CFR 60.39e(c)(4)]

5. Date for obtaining the major components of the air pollution control device(s); [40 CFR 60.39e(c)(5)]

6. Date for initiation of site preparation for installation of the air pollution control device(s); [40 CFR 60.39e(c)(6)]

7. Date for initiation of installation of the air pollution control device(s); [40 CFR 60.39e(c)(7)]

8. Date for initial startup of the air pollution control device(s); [40 CFR 60.39e(c)(8)] and

9. Date for initial compliance test(s) of the air pollution control device(s). [40 CFR 60.39e(c)(9)]

The revised or new section 111(d)/129 State Plan may include one set of increments with compliance dates applicable to all HMIWI within the state or it may tailor compliance dates to individual HMIWI to address specific issues. In all cases, the enforceable increments of progress should be arranged chronologically, and the compliance dates should be set to ensure full compliance with the applicable requirements *as expeditiously as practicable* [40 CFR 60.24(c)] but not later than 3 years after State Plan approval, or October 6, 2014, whichever is earlier. For example, a revised or new State Plan that requires a HMIWI to "submit a final control plan and to award contracts no later than the third year of the compliance schedule" would likely be disapproved because the increments are too close to the end of the compliance window, do not appear to ensure expeditious progress, and thus jeopardize timely compliance, unless the HMIWI plans to shut down. Although there may be HMIWI-specific reasons for other schedules, EPA

would expect contracts to be awarded within the first year for HMIWI taking longer than 1 year to comply. Depending on the extent of the retrofit, EPA would expect on-site construction to be completed in the second or third year of the compliance schedule.

3.6.4 HMIWI Shutdowns

Hospital/medical/infectious waste incinerators that are planning to shut down rather than meet the amended EG should be identified in the revised or new State Plan. [40 CFR 60.25(a)] These State Plans should specify that HMIWI planning to comply by shutting down should do so by a specific calendar date which is not later than 1 year after State Plan approval. [40 CFR 60.39e(b); see also 40 CFR 62.14471 of the original HMIWI Federal Plan as an example] As discussed in section 3.3, HMIWI which shut down should be included in the state's source inventory unless the HMIWI is rendered inoperable. [40 CFR 60.25(a); see 65 FR 49876 in the preamble to the original HMIWI Federal Plan as an example] In some special cases, facilities may be allowed more than 1 year after State Plan approval to shut down, provided that the State Plan contains provisions for allowing facilities to petition the state for an extension. Section 60.39e(d) of subpart Ce outlines the specific provisions that State Plans should include in order to allow facilities more than 1 year to shut down.

The provisions of section 60.39e(d) allow states to provide temporary relief to those unique facilities which are planning to shut down and have no waste disposal options other than onsite incineration. One example of a facility planning to shut down which has special needs for an extension beyond the 1-year compliance deadline would be a facility planning to install an onsite alternative waste treatment technology (e.g., an autoclave) that will not be available for installation until after the 1-year deadline. Such a facility would need to be able to demonstrate that there are no waste disposal options (e.g., commercial disposal) other than onsite incineration in the interim while the autoclave is being installed. [40 CFR 60.39e(d)(1)(i)] A second example of a facility planning to shut down that may need an extension beyond the 1-year deadline would be a facility planning to contract with a commercial hauler that, for some unusual reason, is unable to secure a contract by the 1-year deadline. [40 CFR 60.39e(d)(1)(i)]

Under such special circumstances, states could allow facilities to petition the state after approval of a State Plan for additional time to come into compliance by shutting down their HMIWI. In order to allow facilities an extension, the State Plan would need to contain provisions for granting or denying petitions for an extension beyond the 1-year deadline.

Section 60.39e(d) of subpart Ce directs that states have sources submit the following information in time to allow the state adequate opportunity to grant or deny the extension before the 1-year compliance deadline:

1. Documentation of the analysis undertaken to support the need for an extension, including an explanation of why up to 3 years after EPA approval of the Sate Plan is sufficient while 1 year after EPA approval the State Plan is not sufficient;

2. An evaluation of the option to transport the waste offsite to a commercial medical waste treatment and disposal facility on a temporary or permanent basis; and

3. A plan that documents measurable and enforceable incremental steps of progress[4] to be taken towards compliance with the EG.

When a petition for an extension is granted, states could allow sources planning to shut down up to 3 years after EPA approval of the revised or new State Plan to come into compliance with the amended EG by shutting down. [40 CFR 60.39e(d)(3)] However, states should use their best judgment to determine if the source can shut down before the date 3 years after EPA approval of the revised or new State Plan. In cases where a source requesting an extension is able to shut down before the 3-year deadline, the state should require the source to shut down as soon after the 1-year compliance deadline as possible. [CAA section 129(f)(2) and 40 CFR 60.24(c) and 60.39e(d)(3)]

Commercial medical waste disposal services, which collect medical waste from a facility and transport it to a central disposal site (usually a commercial HMIWI), are operated in many areas of the country. In some locations commercial disposal services are not readily available at a reasonable cost because the hauler would need to travel long distances. However, in many cases, the services of a commercial medical waste disposal company are available and can be acquired in a short period of time. Sources installing an onsite alternative waste treatment technology, in most cases, could contract with a commercial disposal company in the interim period between the 1-year compliance deadline and the time when the onsite alternative is installed. Therefore, section 60.39e(d) requires State Plans including provisions for an extension

[4] The incremental steps of progress for units planning to shut down are <u>not</u> the same as the incremental steps of progress for facilities planning to retrofit their HMIWI and continue operation. The increments of progress for facilities planning to shut down are intended to demonstrate that the facility is in the process of shutting down. Specific increments are discussed later in this section.

to have the source requesting an extension document reasons why the services of a commercial disposal company cannot be reasonably obtained.

Sources planning to shut down which request an extension are also to provide the state with a plan that documents the incremental steps of progress that the facility intends to take to demonstrate that it is in the process of shutting down. [40 CFR 60.39e(d)(1)] The source plan should contain completion dates for each of the increments of progress contained in the plan. The following are some suggested increments of progress (based on the original HMIWI Federal Plan) that sources requesting extensions to install onsite alternative treatment technologies could use to demonstrate to the state that they are in the process of shutting down their HMIWI:

1. Going under contract with an alternative treatment technology vendor;
2. Initiating onsite construction or installation of the alternative treatment technology;
3. Completing onsite construction or installation of the alternative treatment technology;
4. Shutting down the existing HMIWI; and
5. Rendering the existing HMIWI inoperable.[5]

[40 CFR 62.14471(b)(1)(ii); 65 FR 49876]

The following are some suggested increments of progress (based on the original HMIWI Federal Plan) that sources requesting extensions to contract with a commercial disposal company on a permanent basis could use to demonstrate to the state that they are in the process of shutting down their HMIWI:

1. Obtaining price quotes from commercial disposal services;
2. Going under contract with a commercial waste treatment and disposal facility;
3. Shutting down the existing HMIWI; and
4. Rendering the existing HMIWI inoperable.[3]

[40 CFR 62.14471(b)(1)(ii); 65 FR 49876]

3.7 Public Hearings

Public participation, under the provisions of the CAA, is an important right and responsibility of citizens in the state process of developing, adopting, and implementing section 111(d)/129 State Plans. As with SIPs for criteria pollutants, EPA regulations in 40 CFR Part 60, subpart B, make it clear that citizen input on section 111(d)/129 State Plans is

[5] Rendering the HMIWI inoperable is not necessary for a source to be shut down; however, any HMIWI capable of operation should be included on the state's source inventory (see section 3.3). [40 CFR 60.25(a)]

encouraged in order to help define appropriate emission standards and retrofit schedules. Under section 60.23 of subpart B, some minimum public participation requirements are as follows:

1. Reasonable notice of opportunity for one or more public hearing(s) at least 30 days before the hearing(s). [40 CFR 60.23(d)]

2. One or more public hearing(s) on the section 111(d)/129 State Plan (or revision) conducted at location(s) within the state, if requested. [40 CFR 60.23(c)(1)]

3. Date, time, and place of hearing(s) prominently advertised in each region affected. [40 CFR 60.23(d)(1)]

4. Availability of draft section 111(d)/129 State Plan for public inspection in at least one location in each region to which it will apply. [40CFR 60.23(d)(2)]

5. Notice of hearing provided to:
   a. EPA Regional Administrator
   b. Local affected agencies
   c. Other states affected
   [40 CFR 60.23(d)(3)-(5)]

6. Certification that the public hearing was conducted in accordance with subpart B and state procedures. [40 CFR 60.23(f)] Upon written application by the state agency, EPA may (for limited special cases) approve different procedures, provided that they ensure adequate public participation. [40 CFR 60.23(g)]

7. Retention of hearing records (e.g., list of commenters, their affiliation, and a summary of each presentation and/or comments submitted) for a minimum of 2 years. [40 CFR 60.23(e)]

3.8 State Progress Reports to EPA

In their revised or new section 111(d)/129 State Plans, states are to commit to send EPA annual reports on progress in the implementation of the amended EG. [40 CFR 60.25(e)] These reports can be incorporated into the annual source emissions and State action report required by 40 CFR section 51.321. Inclusion in this SIP report is intended to avoid duplicative reports. Each progress report should include compliance status, enforcement actions, increments of progress, identification of sources that have shut down or started operation, emission inventory information for sources that have started operation, updated emission inventory and compliance information, and copies of technical reports on all performance testing and monitoring, including concurrent process data. [40 CFR 60.25(f)(1)-(6)]

States may want to include additional information in their progress reports, such as periodic inspection and testing activities, emission and parameter exceedances, quality assurance/quality control (QA/QC), outreach activities, title V or other permit condition compliance status, and compliance assistance activities.

Some states and EPA Regional Offices have developed more specific or tailored reporting and recordkeeping procedures via Memoranda of Agreements, Program Specific Guidance for section 105 Grants, and the Timely and Appropriateness Guidance. For example, some EPA Regional Offices prefer that the states retain the performance test reports until EPA requests review as part of a compliance determination or other action. The state and EPA will continue to have discretion on the format of the annual reports.

4.0 Requirements for Co-fired Combustors and Incinerators Burning Only Pathological, Low-level Radioactive, and Chemotherapeutic Waste

Co-fired combustors are defined as units combusting 10 percent by weight or less hospital waste and/or medical/infectious waste with other fuels or wastes (e.g., coal, municipal solid waste). [40 CFR 60.51c] The original 1997 EG exempted co-fired combustors and incinerators burning only pathological, low-level radioactive, and chemotherapeutic waste from most of the requirements under the EG. [62 FR 48380, 40 CFR 60.32e(b) and (c)] These exemptions were not changed in the 2009 amended EG. All revised/updated or new State Plans are to require these units to notify the Administrator of an exemption claim and to keep certain records, per section 60.32e(b)(1) and (2) (pathological, low-level radioactive, and chemotherapeutic) and section 60.32e(c)(1)-(3) (co-fired) of the HMIWI rule, if not already done so in response to the 1997 guidelines.

Assuming an approved State Plan is in effect, exemption claims are to be sent to the head of the state air pollution control agency responsible for implementing the EG through the State Plan, with a courtesy copy of the exemption claim sent to the appropriate EPA Regional Office. [40 CFR 60.26(a), 60.32e(b)(1) and (c)(1), and 62.10] A list of state and Regional Office contacts is provided in Appendix E. Exemption claims are to be received by the state agency and EPA Regional Office within 1 year following State Plan approval, providing adequate time for the state to determine if an exemption is in order. [40 CFR 60.39e(b)]

Facilities operating co-fired combustors are to provide the state with an estimate of (1) the amount of hospital and medical/infectious waste combusted, and (2) the amount of other fuels and wastes being combusted. [40 CFR 60.32e(c)(2)] This information could be submitted to the state as part of the exemption claim. In addition to submitting an exemption claim, facilities operating co-fired combustors are to keep records on a calendar quarter basis on the weight of hospital waste and medical/infectious waste combusted and the weight of all other fuels and/or wastes combusted. [40 CFR 60.32e(c)(3)] The EG do <u>not</u> direct states to have facilities operating co-fired combustors maintain records of each individual type of waste burned. Rather, the EG should be interpreted, as in the original HMIWI Federal Plan, to mean that facilities are to keep records of two categories of wastes: (1) the combined weight of hospital waste and medical/infectious waste, and (2) the combined weight of all other wastes and fuels

burned at the co-fired incinerator. [40 CFR 62.14400(b) and 65 FR 49872, 49882]

Incinerators are not subject to the emission standards of subpart Ce during periods when only pathological, low-level radioactive, and/or chemotherapeutic waste are being incinerated, provided the facility submits an exemption claim and keeps records on a calendar quarter basis of periods of time when only such waste is burned. [40 CFR 60.32e(b)(1) and 2)]

As discussed in section 3.3, under the section 111(d)/129 State Plan requirements, states are to include co-fired combustors and incinerators burning only pathological, low-level radioactive and/or chemotherapeutic waste in their source inventory. [40 CFR 60.25(a) and 60.32e(b) and (c)]

5.0 Title V Requirements for HMIWI

Title V of the CAA provides for a nationwide operating permit program which applies to all major sources and to certain other sources. The title V permit brings together in one document all of the CAA requirements that apply to a source. Title V permits clarify which requirements apply to each source and describe how compliance with those requirements is to be maintained and demonstrated. All of the regulations applicable to each HMIWI are ultimately incorporated into the title V permit for the affected source.

State air quality agencies implement the operating permit program pursuant to criteria in 40 CFR Part 70. EPA implements the title V program under 40 CFR Part 71 in Indian country until Tribes gain approval of their permitting program.

5.1 Existing HMIWI

Owners and operators of all existing HMIWI should have already submitted permit applications and been issued a title V permit as a result of the original EG issued in 1997. With the 2009 revision of the EG, states are to develop and seek EPA approval for revised or new State Plans, and EPA is to promulgate a new Federal Plan for states that do not have an approved State Plan. If 3 or more years are remaining on the permit term for an HMIWI when the applicable State Plan is approved and becomes effective or the Federal Plan is promulgated and becomes effective, then the HMIWI owner and/or operator will receive from its permitting authority a notice of intent to reopen the title V permit to include the new requirements of the applicable State/Federal Plan. [40 CFR 70.7(f)(1)(i) and 65 FR 49868, 49878, August 15, 2000] If less than 3 years are remaining on the permit term at the time the applicable State Plan or Federal Plan becomes effective, then the owner and/or operator need not modify its title V permit to include the applicable requirements until permit renewal--bearing in mind that the sources are subject to the applicable State/Federal Plan requirements, even though the requirements are not yet contained in the permit. [40 CFR 70.7(f)(1)(i), 71.7(f)(1)(i), and 65 FR 49868, 49878, August 15, 2000] Owners and operators are reminded that they need to wait until the revised or new State Plan has been approved and becomes effective or the new Federal Plan has been promulgated and becomes effective before they can determine how much time remains on their permit term. [65 FR 49868, 49878, August 15, 2000]

5.2 Exempt Units

Co-fired combustors and incinerators burning only pathological, low-level radioactive, and chemotherapeutic waste are exempt from the HMIWI emission limits, so the owners and operators of those sources are not required to obtain a title V permit under the HMIWI regulation.[1] [CAA section 502(a), 40 CFR 70.3(a)(2), 71.3(a)(2), and 62.14480, and 65 FR 49868, 49872] If the incinerators burn waste other than pathological, low-level radioactive, or chemotherapeutic waste, then the incinerators are subject to the EG and are also subject to the requirement to apply for a title V permit. Additionally, if the incinerators or co-fired combustors do not comply with the recordkeeping and notification requirements necessary to qualify for exemption from the other requirements of the EG, these sources then become subject to the other requirements of the EG and also to the requirement to obtain a title V permit. [40 CFR 60.32e(b)(1) and (2), 60.32e(c)(1)-(3), and 65 FR 49868, 49878, August 15, 2000]

[1] However, this does not necessarily mean they would not be required to obtain a title V permit under a different regulation (e.g., the OSWI regulation).

Appendix A

Key Elements of an Acceptable Section 111(d)/129 State Plan for HMIWI

APPENDIX A--KEY ELEMENTS FOR AN ACCEPTABLE SECTION 111(d)/129 STATE PLAN FOR HMIWI

This document is provided to facilitate preparation of the required revised/amended or new State Plans.

Section 129 of the Clean Air Act (Act) requires that states submit to the U.S. Environmental Protection Agency (EPA) State Plans to implement and enforce the Emission Guidelines (EG) promulgated for hospital/medical/infectious waste incinerator(s) (HMIWI) pursuant to sections 111(d) and 129 of the Act. Section 129 requires that the state submit the State Plans not later than one year after EPA promulgates the EG. On September 15, 1997, EPA promulgated the EG as 40 CFR Part 60, subpart Ce, and State Plans were submitted to EPA for approval no later than one year later. A court remand necessitated revisions to the 1997 rule, and on October 6, 2009, EPA promulgated amendments to the rule. Revised/amended or new State Plans implementing the amended EG are due no later than October 6, 2010.

The official procedures for adoption and submittal of State Plans are codified in 40 CFR Part 60, subpart B. The EPA promulgated the subpart B provisions on November 17, 1975. The EPA amended them on December 19, 1995, to allow the subparts developed under section 129 to include specifications that supersede the provisions in subpart B regarding the schedule for submittal of State Plans, the stringency of the emission limitations, and the compliance schedules. That is, these amendments were promulgated in order to allow conformity with section 129, which requires the State Plans for HMIWI be submitted within one year and requires the State Plans to be as protective as the EG and requires that each unit be in compliance not later than three years after the State Plan is approved by EPA and no later than five years after the EG is promulgated (rather than the case-by-case exceptions the state may demonstrate as otherwise specified in subpart B).

States must adopt their State Plans according to state procedures prior to official submittal to EPA. *[section 60.23 (a)]* At a minimum, the revised/amended or new State Plan must include the following elements:

- A demonstration of the state's legal authority to carry out the revised/amended or new section 111(d)/129 State Plan as submitted;
- Demonstration of approval of state's legal authority by Administrator;
- An inventory of HMIWI in the state affected by the amended Emission Guidelines;
- An inventory of emissions from HMIWI in the state;
- Emission limits at least as protective as the amended emission limits in subpart Ce;

- Testing and monitoring requirements at least as protective as the amended testing and monitoring requirements in subpart Ce;

- Recordkeeping and reporting requirements at least as protective as the amended recordkeeping and reporting requirements in subpart Ce;

- Inspection requirements at least as protective as the amended inspection requirements in subpart Ce;

- Operator training and qualification requirements at least as protective as the operator training and qualification requirements in subpart Ce;

- Waste management plan requirements at least as protective as the amended waste management plan in subpart Ce;

- Compliance schedules, extending no later than October 6, 2014;

- A final compliance date no later than October 6, 2014;

- A record of public hearing(s) on the revised/amended or new State Plan; and

- Provision for annual state progress reports to EPA on implementation of the revised/amended or new State Plan;

The following pages include information about legal authority, emission inventories, emission standards and other emission limitations, source surveillance, compliance assurance, enforcement, compliance schedules, and cross-references to the EG.

A. <u>Legal Authority</u> *[section 60.26(a)]*

1. The State Plan shall include demonstration of the state's legal authority to:

   (a) adopt emission standards (enforceable conditions) and compliance schedules applicable to the designated facilities and designated pollutants for which the State Plan is submitted;

   (b) enforce applicable laws, regulations, standards, and compliance schedules, and seek injunctive relief;

   (c) obtain information necessary to determine compliance;

   (d) require recordkeeping, make inspections, and conduct tests;

   (e) require the use of monitors and require emission reports of owners or operators; and

(f) make emission data publicly available.

2. The state must specifically identify the provisions above and include copies of the provisions of the law establishing such legal authority unless they have been approved as a portion of a previous State Implementation Plan (SIP). To facilitate its review of State Plans, EPA encourages states to submit an opinion by the state's Attorney General as part of the demonstration required above. States may use previously submitted Attorney General opinions (e.g., under title V) to the extent those documents specifically address the requirements of section 60.26 as they apply to the designated facilities and the designated pollutants. *[section 60.26(b)]*

3. The legal authority shown must be in effect at time of State Plan submission. *[section 60.26(c)]*

4. The state may authorize another state governmental agency to carry out a portion of the State Plan, provided the state demonstrates that the state governmental agency has adequate authority. *[section 60.26(e)]*

5. The state may authorize a local agency to carry out a portion of the State Plan provided that the state demonstrates that the local agency has adequate legal authority to implement that portion of the State Plan and the state is not relieved of responsibility. *[section 60.26(e)]*

B. Emission Inventories

The State Plan must include an "emission inventory" of all designated pollutants for all designated facilities. *[section 60.25(a)]*

Emission data must be included where available, but estimates can be used where data are not currently available. Emission factors and default values are described in this Summary Document.

In addition to the initial inventory, updates are required. *[section 60.25(f)(5]* The updated information is required to be submitted annually in the section 51.321 reports. *[section 60.24(e)(1)]* The emission data should be submitted to the Air Facility System (AFS) *[sections 51.321-51.323]*

C. Emission Standards and other Emission Limitations

1. The emission limitations must be at least as protective as the EG. If the limitations are not identical, the state must demonstrate that the standards are at least as protective. *[section 60.24(f), as revised December 19, 1995, to be consistent with section 129 of the Act and section 60.33e of subpart Ce]*

NOTE: Nothing in the Clean Air Act nor the CFR restricts the state from having standards and schedules more stringent than the EG. *[section 60.24(g)]*

2. The State Plan shall include the specific emission limitations, preferably cross-referenced to the specific EG requirements. *[section 60.24(a)]*

3. Test methods and procedures for determining compliance shall be specified. *[section 60.24(b)2)]*

4. If the methods and procedures are not identical to those in section 60.56c, the state must demonstrate equivalence or request EPA approval of acceptable alternatives per current EPA method review procedures. *[section 60.24(b)(2)]*

5. If emission standards are adopted by local agencies or other state agencies, they must also be included in the State Plan and if not identical to the EG, then the state must show that they are at least as protective as the emission guidelines. *[section 60.24(a)]*

D. Source Surveillance, Compliance Assurance & Enforcement

The State Plan must provide for monitoring the status of compliance. As a minimum, the State Plan shall include:

1. Provisions for legally enforceable procedures to:

   (a) require recordkeeping on nature and amount of emissions and reports to the state. *[section 60.25(b)(1)]*

   (b) require any additional information to judge compliance. *[section 60.25(b)(1)]*

2. Provisions for periodic inspection and testing, if necessary. *[section 60.25(b)(2)]*

3. Provisions for emission data and other compliance monitoring information to be correlated with applicable emission standards and be made available to the public. "Correlated" means showing the relationship between the measured or estimated amounts of emissions and the amounts of such emissions allowable. For example, the emissions should be in the same units and averaging times. *[section 60.25(a) and (c)]*

4. HMIWI requirements for testing, monitoring, recordkeeping, and reporting that are identical to those specified in sections 60.37e and 60.38e. *[subpart Ce]*

5. Specific identification of the provisions in 1 through 4 above. Copies of such provisions should be included unless they have been approved as portions of a preceding section 111(d)/129 State Plan or SIP and the state demonstrates that the provisions are applicable and the requirements of section 60.26 (legal authorities) are met. *[section 60.25(d)]*

6. Commitment to submit reports on progress in plan enforcement to the EPA Regional Administrator on an annual basis and include it in the reports required by 51.321. *[section 60.25(e) and (f)]* Each progress report shall include: enforcement actions, achievement of increments of progress, identification of sources that have ceased operation, emission inventory information for sources that were not in operation at the time of plan development, updated emission inventory and compliance information, and copies of technical reports on all performance testing, including concurrent process data. *[section 60.25(f)(1) through 60.25(f)(6)]*

Note: Some states and Regions have developed more specific or tailored reporting and recordkeeping procedures via Memoranda of Agreements, Program Specific Guidance for Section 105 Grants, and the Timely and Appropriateness Guidance that should also be followed. For example, some Regions prefer that the state retain the performance test report until the Region needs to review it as part of a compliance determination or other action.

E. Compliance Schedules

1. Compliance schedules must match the subpart Ce and B specifications. *[subpart Ce, section 60.39e]*

2. For compliance schedules extending more than 12 months beyond the date of EPA approval of the State Plan, the compliance schedule must include legally enforceable increments of progress towards compliance for that HMIWI. Each increment of progress in section 60.21(h) of subpart B must have a compliance date and must be included as an enforceable increment in the State Plan. The State Plan may include such additional increments of progress as may be necessary to permit close and effective supervision of progress towards final compliance. *[sections 60.24(e)(1), 60.21(h), & 60.39e]*

   The minimum five increments of progress are as follows:

   (a) Submitting a final control plan (This may be a brief document or letter describing the controls that the source will use to comply with the emission limitations and other requirements. In most cases, the source, public, and state will have discussed this information as part of the state process for development of the compliance schedule for the draft State Plan prior to submittal of the State Plan to EPA.); [section *60.21(h)(1)]*

   (b) Awarding contracts for control systems or process modifications or orders for purchase of components; *[section 60.21(h)(2)]*

   (c) Initiating on-site construction or installation of the air pollution control device(s) or process changes; *[section 60.21(h)(3)]*

   (d) Completing on-site construction or installation of control equipment or process changes; *[section 60.21(h)(4)]*

(e) Final compliance. *[section 60.21(h)(5)]*

The first four of these increments of progress can be set as calendar dates or floating dates tied to the date of the approval of the revised/amended or new State Plan or the issuance date of a local permit issuance. For example, the date for submitting a final control plan could be set as three months following approval of the State Plan. If an increment of progress is tied to the date of a permit issuance, the State Plan must identify the specific permit.

The fifth increment of progress, the date for final compliance, can be set as a calendar date or a floating date, but if it is floating, it can be tied only to the date of approval of the revised/amended or new State Plan, <u>not</u> the date of permit issuance, and must include the limitation that the date can in no case be later than three years from State Plan approval or October 6, 2014, whichever is earlier (unless the HMIWI will shut down).

3. Suggested measurable and enforceable activities are listed in section 60.39e(c)(1) through (9) (60 FR 48381). The state may choose to include them in the revised/amended or new State Plan as enforceable increments of progress with compliance dates, or as non-enforceable increments of progress with reporting requirements only, or choose to leave them out of the revised/amended or new State Plan.

   The suggested increments of progress activities are:

   (a) Date for submitting a petition for site-specific operating parameters;

   (b) Date for obtaining services of an architectural and engineering firm regarding the air pollution control device(s);

   (c) Date for obtaining design drawings of the air pollution control device(s);

   (d) Date for ordering the air pollution control device(s) *[already <u>required where practicable</u> by sections 60.24(e)(1) and 60.21(h)(1)]*;

   (e) Date for obtaining the major components of the air pollution control device(s);

   (f) Date for initiation of site preparation for installation of the air pollution control device(s) *[already <u>required where practicable</u> by sections 60.24(e)(1) and 60.21(h)(1)]*;

   (g) Date for initiation of installation of the air pollution control device(s);

   (h) Date for initial startup of the air pollution control device(s);

   (i) Date for initial compliance test(s) of the air pollution control device(s);

The EPA strongly recommends that activities (h) and (i) be included in the compliance schedules. Performance tests must be conducted within 180 days after the final retrofit, and the report of the test results must be submitted within 60 days after the test is conducted. The test results will demonstrate whether or not the HMIWI is in compliance with the emission standards. This performance test timing is consistent with other EPA air regulations for existing sources, such as the Part 63 General Provisions for national emission standards for hazardous air pollutants (NESHAP). The EPA also strongly encourages states and HMIWI owners or operators to conduct preliminary performance tests at least 2-3 months prior to the scheduled final compliance date, in order for the HMIWI to make any necessary shakedown changes and retest(s), as necessary, prior to the final compliance date.

4. The State Plan may include one set of increments with compliance dates applicable to all HMIWI within the state, or it may tailor compliance dates to individual HMIWI to address specific issues. In all cases, the enforceable increments of progress must be arranged chronologically, and the compliance dates must be set to ensure full compliance with the applicable requirements *as expeditiously as practicable [section 60.24(c)]*, but not later than three years after State Plan approval, or October 6, 2014, whichever is earlier. For example, a revised/amended or new State Plan that requires an HMIWI to "submit a final control plan and to award contracts no later than the third year of the compliance schedule" will likely be disapproved because the increments are too close to the end of the compliance window, do not appear to ensure expeditious progress, and thus jeopardize timely compliance, unless the HMIWI plan to shut down. Although there may be HMIWI-specific reasons for other schedules, EPA would expect contracts to be awarded within the first year for HMIWI taking longer than one year to comply. Depending on the extent of the retrofit, EPA would expect on-site construction to be completed in the second or third year of the compliance schedule.

F. Public Participation

Public participation, under the Clean Air Act, is an important right and responsibility of citizens in the state process of developing, adopting, and implementing the required section 111(d)/129 State Plans. Under 40 CFR Part 60, subpart B, the minimum requirements for the state to conduct public hearings on the adoption of State Plans and any revisions thereof are as follows:

l. Reasonable notice of one or more public hearing(s) at least 30 days prior to the hearing(s). *[section 60.23(d)]*

2. One or more public hearing(s) on the State Plan (or revisions) conducted in location(s) within the state. *[section 60.23(c)(1)]*

3. Date, time and place of hearing(s) prominently advertised in each region affected. *[section 60.23(d)(1)]* "Region" is defined as "air quality control region." *[section 60.21(i)]*

4. Availability of draft State Plan for public inspection in at least one location in each region to which it will apply. *[section 60.23(d)(2)]*

5. Notice of hearing provided to: (a) EPA Regional Administrator, (b) local affected agencies, and (c) other states affected. *[section 60.23(d)(3),(4),&(5)]*

6. Retention of hearing records (e.g., list of commenters and their affiliation and summary of each presentation and comments submitted and the state's responses to those comments) for at least 2 years. *[section 60.23(e) and (f)]*

7. Certification that public participation was conducted in accordance with subpart B and state procedures. *[section 60.23(f)]* Upon written application by the state agency, EPA may (expected only for limited special cases) approve different procedures provided that they ensure adequate public participation. *[section 60.23(g)]*

No hearing is required on a state or local emission standard in effect prior to October 6, 2009, the promulgation date of the subpart Ce amendments, if it was adopted after a public hearing and is at least as stringent as the emission guideline. *[section 60.23(c)(3)]*

Similarly, no public hearing is required for any change to an increment of progress unless the change is likely to cause the facility to be unable to comply with the final compliance date. *[section 60.23(c)(2)]*

Appendix B

Fact Sheet for Amended Emission Guidelines and NSPS (40 CFR Part 60 Subparts Ce and Ec)

APPENDIX B-- FACT SHEET FOR AMENDED EMISSION GUIDELINES AND NSPS
(40 CFR PART 60 SUBPARTS Ce AND Ec)

Note: An electronic copy of the Fact Sheet for the amended Emission Guidelines and NSPS for HMIWI is available at EPA's TTN Air Toxics Website for HMIWI: http://www.epa.gov/ttn/atw/129/hmiwi/rihmiwi.html.

FACT SHEET

FINAL AMENDMENTS TO NEW SOURCE PERFORMANCE STANDARDS AND EMISSION GUIDELINES FOR HOSPITAL, MEDICAL, AND INFECTIOUS WASTE INCINERATORS

ACTION

- On September 15, 2009, the Environmental Protection Agency (EPA) issued final revisions to the September 1997 new source performance standards (NSPS) and emission guidelines to control emissions from existing hospital, medical, and infectious waste incinerators (HMIWI).

- EPA recalculated the maximum achievable control technology (MACT) floors for existing and new HMIWI and developed new emission limits. The MACT floor level of control is the minimum level of stringency that can be considered in establishing standards under Section 129 of the Clean Air Act.

- The final emission limits will require improvements in performance for 50 of the 57 currently operating HMIWI. EPA estimates that a total of 393,000 pounds per year of the regulated pollutants will be reduced, of which acid gases (i.e., hydrogen chloride and sulfur dioxide) comprise about 62 percent, particulate matter about 0.8 percent, carbon monoxide about 0.3 percent, nitrogen oxides about 37 percent, and metals (i.e., lead, cadmium, and mercury) and dioxins/furans about 0.2 percent.

- EPA estimates that the total nationwide cost for the 57 currently operating HMIWI to comply with the final rule revisions will be approximately $15.5 million per year. EPA also estimates that the cost of an available disposal alternative would be about $10.6 million, or roughly two-thirds of the estimated compliance costs.

- Based on the stringency of revisions being promulgated for the NSPS, EPA does not anticipate any new HMIWI, and therefore, no impacts of the revised NSPS for new units.

- EPA does not expect most facilities with HMIWI to be significantly impacted, whether the compliance costs are passed on or absorbed.

- Of the 44 companies and other entities that own HMIWI, there is one small business, which owns two HMIWI impacted by the final rule.

FINAL RULE SUMMARY

- The final amendments to the HMIWI regulations include:
    - Strengthened existing emission limits for all regulated pollutants
    - Additional stack testing requirements for existing and new sources
    - Additional monitoring requirements for new sources
    - Annual inspections of emission control devices
    - One-time visible emissions test of ash handling operations
    - Procedures for test data submittal
    - Revised waste management plan provisions

BACKGROUND

- The CAA requires EPA to develop and adopt NSPS and emission guidelines for solid waste incineration units including hospital/medical/infectious waste incinerators. The Act also requires EPA to review and, if appropriate, revise the NSPS and emission guidelines every five years after the initial promulgation.

- There were approximately 2,400 HMIWI operating in the United States at the time EPA adopted the 1997 NSPS and emission guidelines.

- The NSPS and emission guidelines require new and existing HMIWI to control emissions of hydrogen chloride, carbon monoxide, lead, cadmium, mercury, particulate matter, dioxins/furans, nitrogen oxides, and sulfur dioxide to levels that reflect the degree of emission reduction based on MACT.

- On November 14, 1997, the Sierra Club and the Natural Resources Defense Council filed suit in the U.S. Court of Appeals for the District of Columbia Circuit challenging EPA's methodology for adopting the HMIWI regulations.

- On March 2, 1999, the Court issued its opinion, rejecting Sierra Club's and Natural Resources Defense Council's statutory interpretations of the Act, but remanding the rule to EPA for further explanation of the Agency's reasoning in determining the minimum regulatory emission limits or "floors" for new and existing HMIWI.

- The Court did not vacate the regulations, stating that it was possible EPA could adequately address the Court's concerns. The NSPS and emission guidelines remained in effect during the remand and were fully implemented by September 2002.

- On February 6, 2007, EPA published a notice that proposed the Agency's response to the questions raised in the Court's remand and that also proposed its response to the Clean Air Act requirement to review the NSPS and emission guidelines every five years.

- After evaluating rulings by the U.S. Court of Appeals that came after the 2007 proposal and considering issues raised in public comments on the proposal, EPA reassessed its approach to setting the proposed MACT floor.

- On December 7, 2007, EPA and the petitioner reached a settlement agreement requiring EPA to re-propose the rule in response to the remand by November 15, 2008, and issue a final rule by September 15, 2009.

- The final action responds to the Court remand of the HMIWI regulations and implements the terms of the settlement agreement on the remand reached with the Sierra Club. The final action also satisfies the CAA requirement to conduct a review of the standards every five years.

FOR MORE INFORMATION

- Interested parties can download the final notice from EPA's website at the following address: www.epa.gov/ttn/oarpg/t3pfpr.html.

- This final rule and other background information are also available either electronically at http://www.regulations.gov, EPA's electronic public docket and comment system, or in hardcopy at the EPA Docket Center's Public Reading Room.

    - The Public Reading Room is located in the EPA Headquarters Library, Room Number 3334 in the EPA West Building, located at 1301 Constitution Ave., NW, Washington, DC. Hours of operation are 8:30 a.m. to 4:30 p.m. eastern standard time, Monday through Friday, excluding Federal holidays.
    - Visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor materials will be processed through an X-ray machine as well. Visitors will be provided a badge that must be visible at all times.
    - Materials for this final action can be accessed using Docket ID No. EPA-HQ-OAR-2006-0534.

- For further information about the final action, contact Mr. Ketan Patel of EPA's Office of Air Quality Planning and Standards, Sector Policies and Programs Division, Natural Resources and Commerce Group at (919) 541-9736 or by e-mail at patel.ketan@epa.gov.

Appendix C

Applicability of the HMIWI Emission Guidelines

C1 - Applicability Flowcharts and Venn Diagrams
C2 - HMIWI Capacity Determination
C3 - Small Rural Criteria

Appendix C1

Applicability Flowcharts and Venn Diagrams

APPENDIX C1--APPLICABILITY FLOWCHARTS AND VENN DIAGRAMS

The amended HMIWI Emission Guidelines (EG) apply to individual HMIWI for which construction was commenced on or before June 20, 1996, as well as to those HMIWI for which construction was commenced after June 20, 1996 but no later than December 1, 2008, except where the emission limits in the original subpart Ec New Source Performance Standards (NSPS) are more stringent. [40 CFR 60.32e(a)(1) and (2) and 60.33e(a)(2), (a)(3), and (b)] Hospital/medical/infectious waste incinerators which commenced construction after December 1, 2008 are not subject to the amended EG, but are subject to the amended subpart Ec NSPS. [40 CFR 60.50c(a)(3)] For HMIWI modifications, applicability for the amended EG and NSPS is determined based on a different set of dates (March 16, 1998 instead of June 20, 1996; and April 6, 2010 instead of December 1, 2008). [40 CFR 60.32e(a)(1) and (2) and 60.50c(a)(4)]

An HMIWI is any device which combusts any amount of hospital waste and/or medical/infectious waste (as defined in section 60.51c of subpart Ec). There are several exemptions to the HMIWI EG as noted below.

Combustors are not subject to the EG during periods when only pathological, low-level radioactive, and/or chemotherapeutic waste (all defined in section 60.51c of subpart Ec) are being burned, provided that facilities operating such combustors notify the Administrator of an exemption claim; and keep records of the periods of time when only these wastes are burned. [40 CFR 60.32e(b)]

Similarly, co-fired combustors are not subject to the EG, provided that facilities operating such combustors notify the Administrator of an exemption claim; provide an estimate of the weight of hospital waste, medical/infectious waste, and other fuels and/or wastes combusted; and keep quarterly records of the amount of hospital waste and medical/infectious waste, and other fuels burned. [40 CFR 60.32e(c)] Co-fired combustors are defined in section 60.51c of subpart Ec as units which combust 10 percent or less by weight (of the fuel feed) hospital waste and medical/infectious waste as measured on a calendar quarter basis. Although pathological, chemotherapeutic, and low-level radioactive wastes sometimes meet the definition of hospital waste or medical/infectious waste, they are considered Aother fuels and/or wastes@ when calculating the amount of hospital waste and medical/infectious waste burned in a co-fired combustor. [40 CFR 60.51c]

Combustors required to have a permit under Section 3005 of the Solid Waste Disposal Act; combustors subject to subparts Cb, Ea, or Eb (municipal waste combustors [MWCs] larger than 250 tons/day); and cement kilns firing hospital and/or medical/infectious waste are not subject to the HMIWI EG. [40 CFR 60.32e(d), (e), and (g)] Furthermore, pyrolysis units are not subject to the EG. [40 CFR 60.32e(f)] Pyrolysis is defined in section 60.51c of subpart Ec as the endothermic gasification of hospital waste and medical/infectious waste using external energy.

The first applicability flowchart (Figure C-1) provided below summarizes the applicability of the EG to the various types of combustors which may combust items that could be considered as hospital waste and/or medical infectious waste. Generally, the HMIWI EG

apply to incinerators located at hospitals, commercial medical waste incinerators, and other incinerators used primarily for burning hospital waste and/or medical/infections waste. [40 CFR 60.51c] However, there are many types of combustion systems that may burn small amounts of waste that could be considered as hospital waste or medical/infectious waste under the promulgated definitions of these wastes in the HMIWI EG. [40 CFR 60.51c] The purpose of the HMIWI EG is not to cover every system that may burn a few items that could be considered as hospital or medical/infectious waste. Therefore, EPA has attempted to exclude most combustion systems not intended to primarily combust hospital waste or medical/infectious waste from coverage under the HMIWI EG through either an outright exemption or through the co-fired combustor provision. [40 CFR 60.32e(b)-(g)] Regulations for other types of solid waste incinerators have been or will be developed (e.g., Other Solid Waste Incinerators [OSWI] EG). Thus, burning of hospital waste or medical/infectious wastes in other solid waste incineration units will be covered by those regulations. The questions and answers in Figure C-1 attempt to clarify how certain types of combustors are either included or excluded from the HMIWI EG.

The second applicability flowchart (Figure C-2) provided below summarizes the applicability of the EG and NSPS to those combustors that would be considered HMIWI based on Figure C-1. The amended HMIWI EG apply to those HMIWI that were subject to the 1997 EG. [40 CFR 60.32e(a)(1)] The amended guidelines also apply to those HMIWI that were subject to the 1997 NSPS, except where the emission limits in the 1997 NSPS are more stringent. [40 CFR 60.32e(a)(2) and 60.33e(a)(3)] Specifically, the 1997 NSPS PM emission limit for medium HMIWI and the 1997 NSPS HCl emission limit for small HMIWI are more stringent than the corresponding PM and HCl emission limits in the amended EG, so the "old" NSPS units would be subject to the more stringent 1997 NSPS limits. [40 CFR 60.33e(a)(3), referencing Table 1B to subpart Ce; and 40 CFR 60.52c(a)(1), referencing Table 1A to subpart Ec] Those HMIWI that started construction after December 1, 2008 are subject only to the amended NSPS. [40 CFR 60.50c(a)(3) and (4)] The questions and answers in Figure C-2 attempt to clarify this applicability.

The Venn diagrams (Figure C-3) provided below summarize the overlap of the definitions for "Hospital Waste," "Medical/Infectious Waste," and "Pathological Waste" and show how the HMIWI regulations apply in different situations. Further explanation is provided with each diagram below.

Figure C-1. Applicability Flowchart for the HMIWI Emission Guidelines, Part 1.

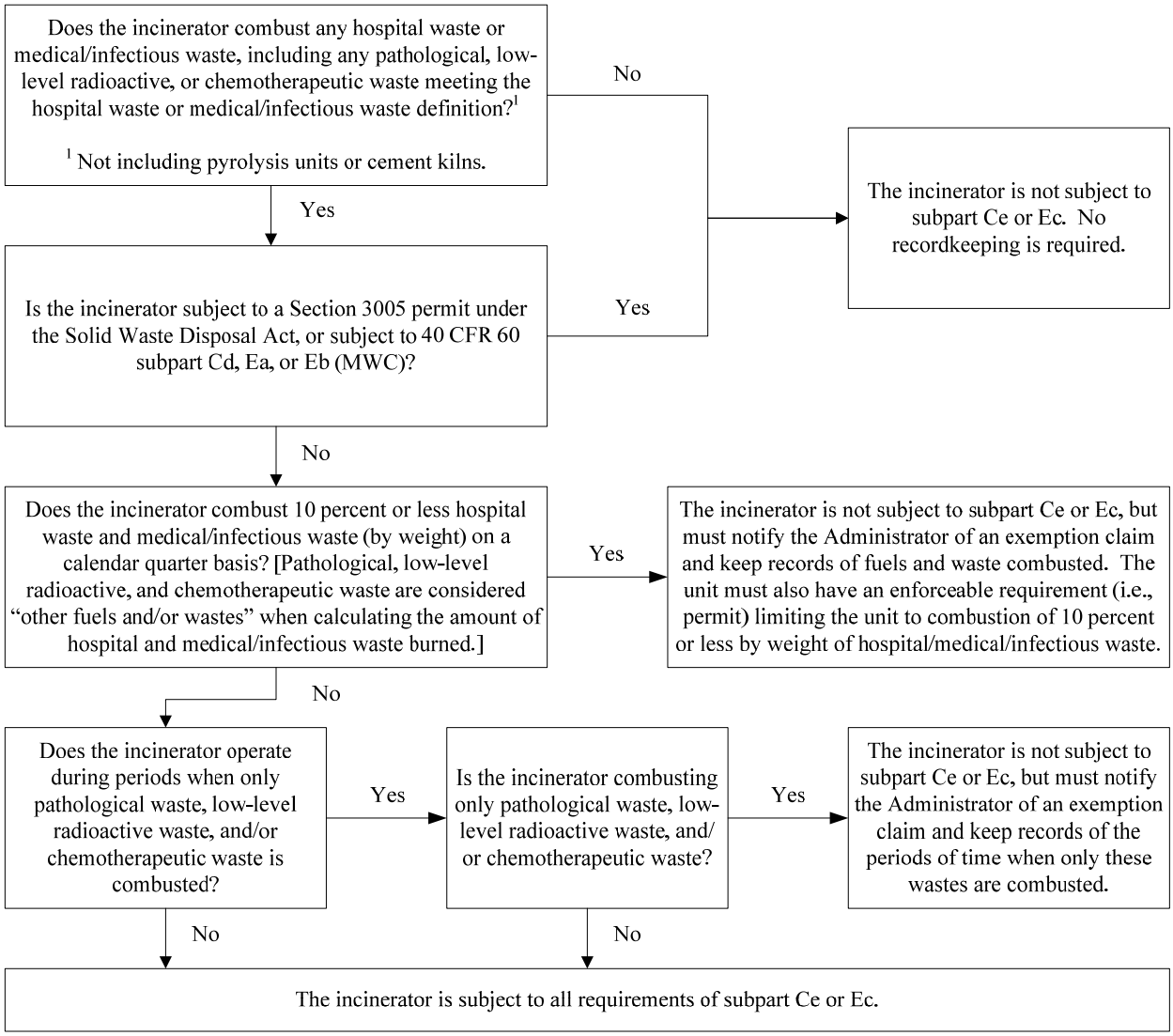


Figure C-2. Applicability Flowchart for the HMIWI Emission Guidelines, Part 2.

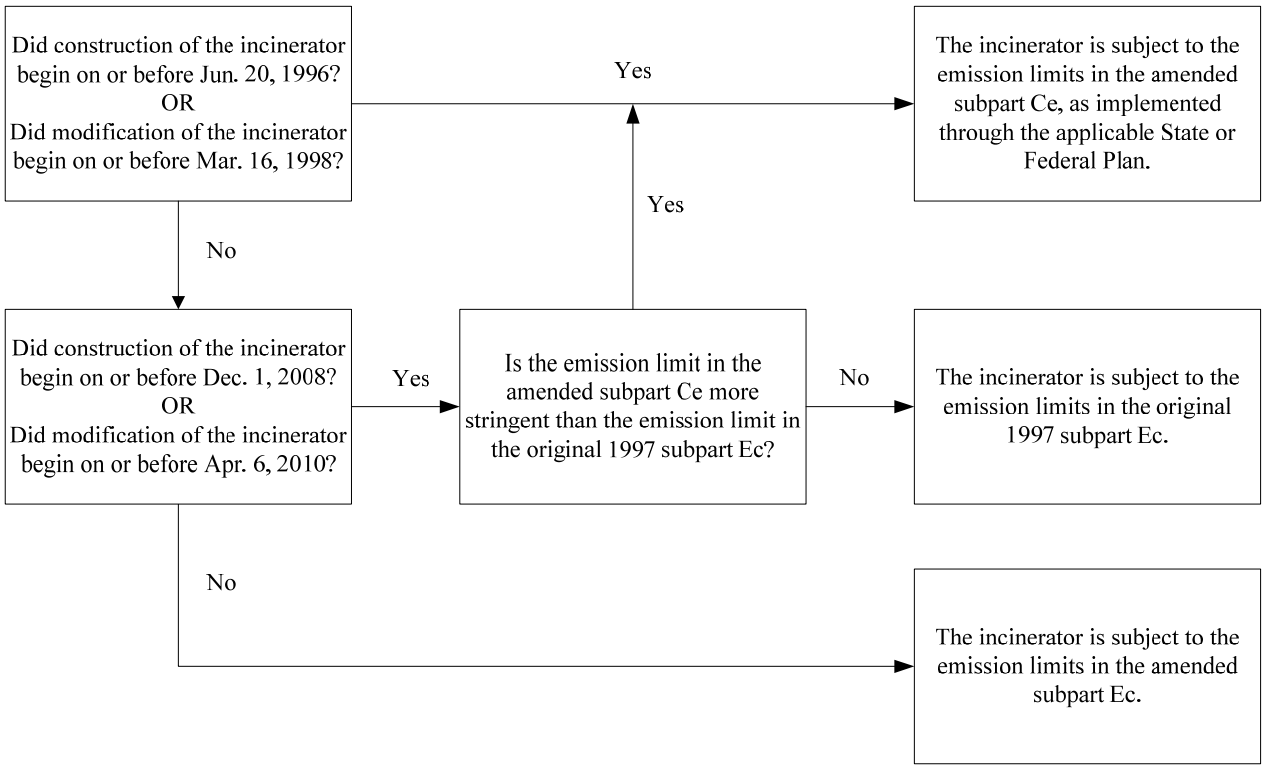
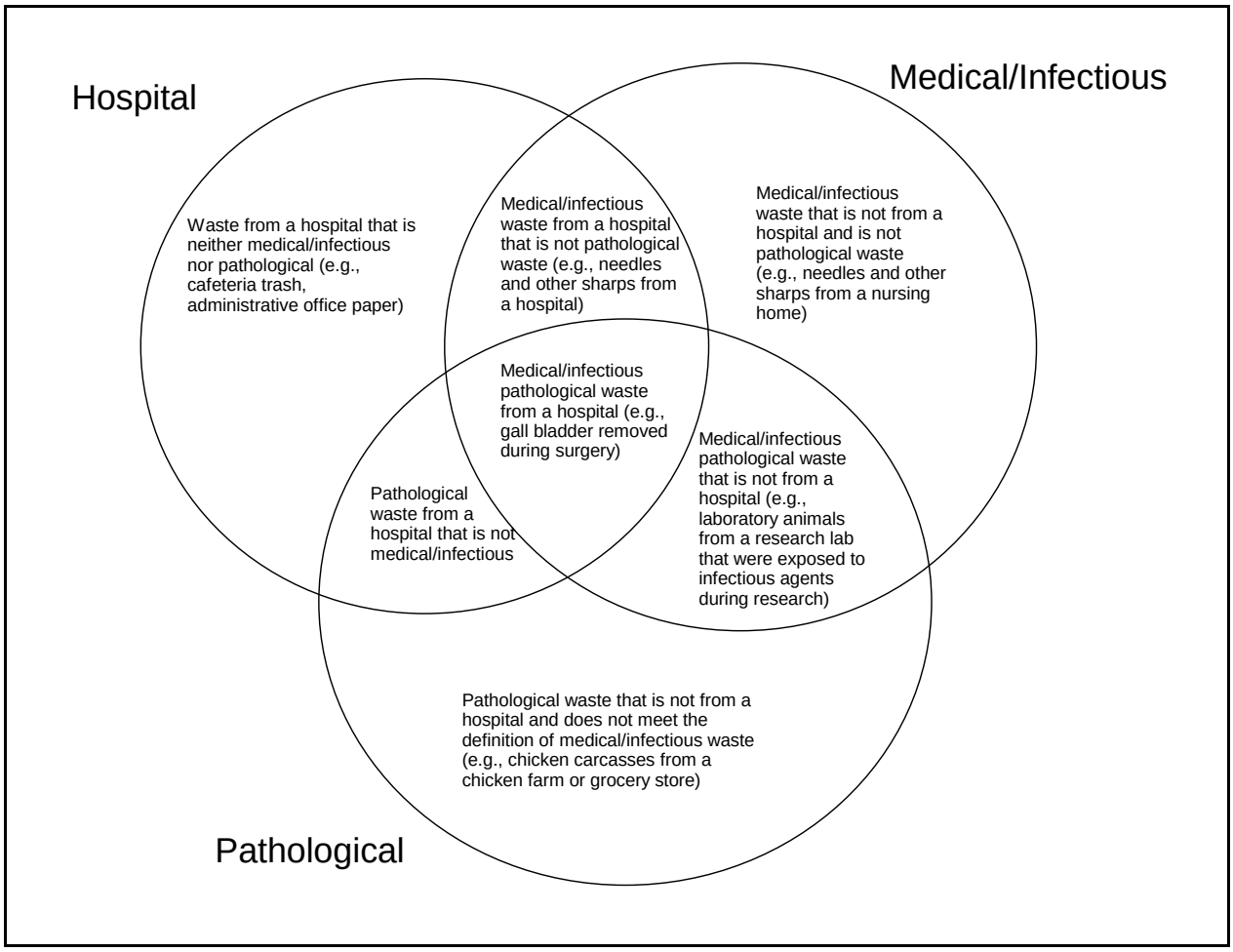


Figure C-3. Overlap of Definitions for "Hospital Waste," "Medical/Infectious Waste," and "Pathological Waste"



- Three terms are used in the hospital/medical/infectious waste incinerator (HMIWI) regulations:

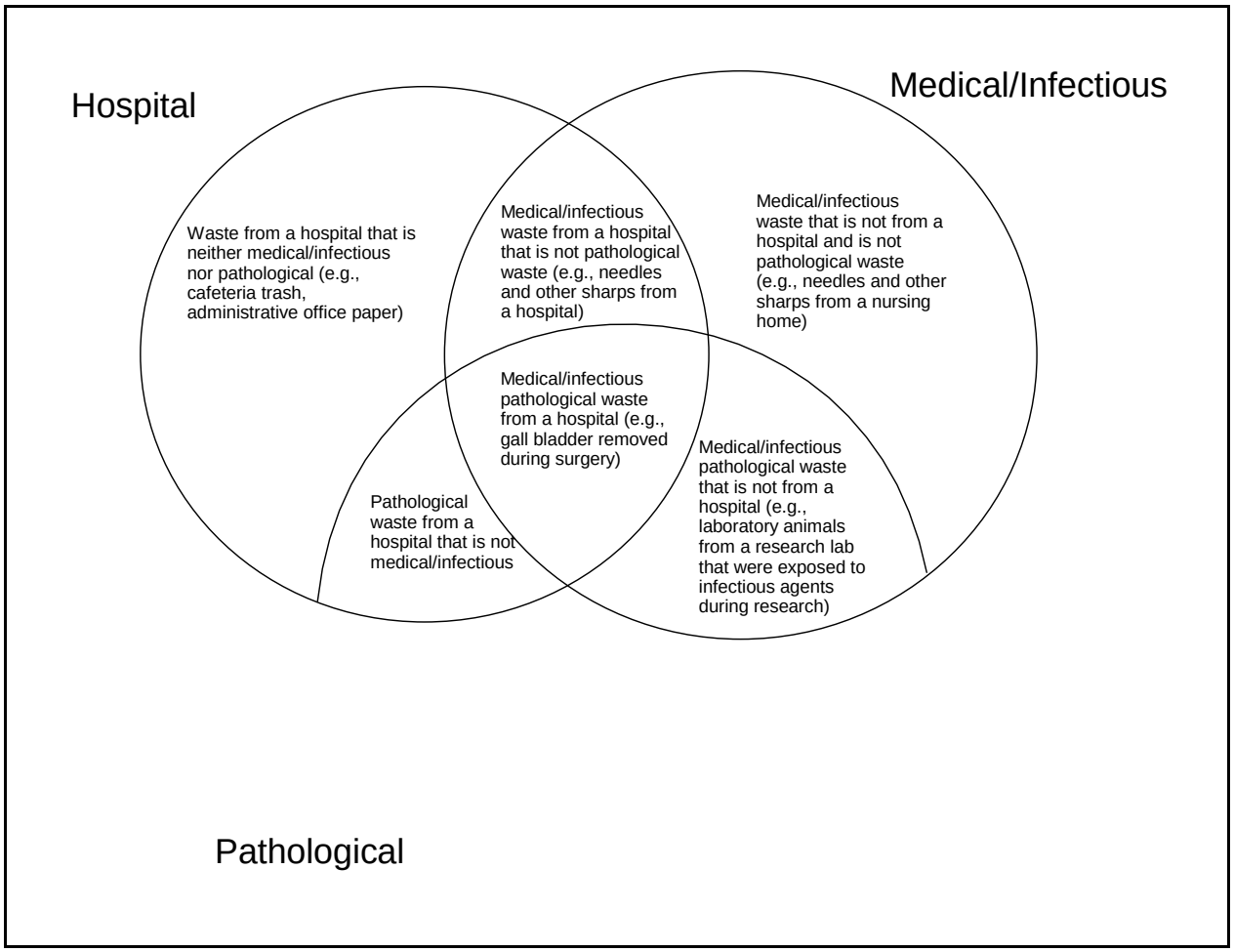
  -- Hospital Waste

  -- Medical/Infectious Waste

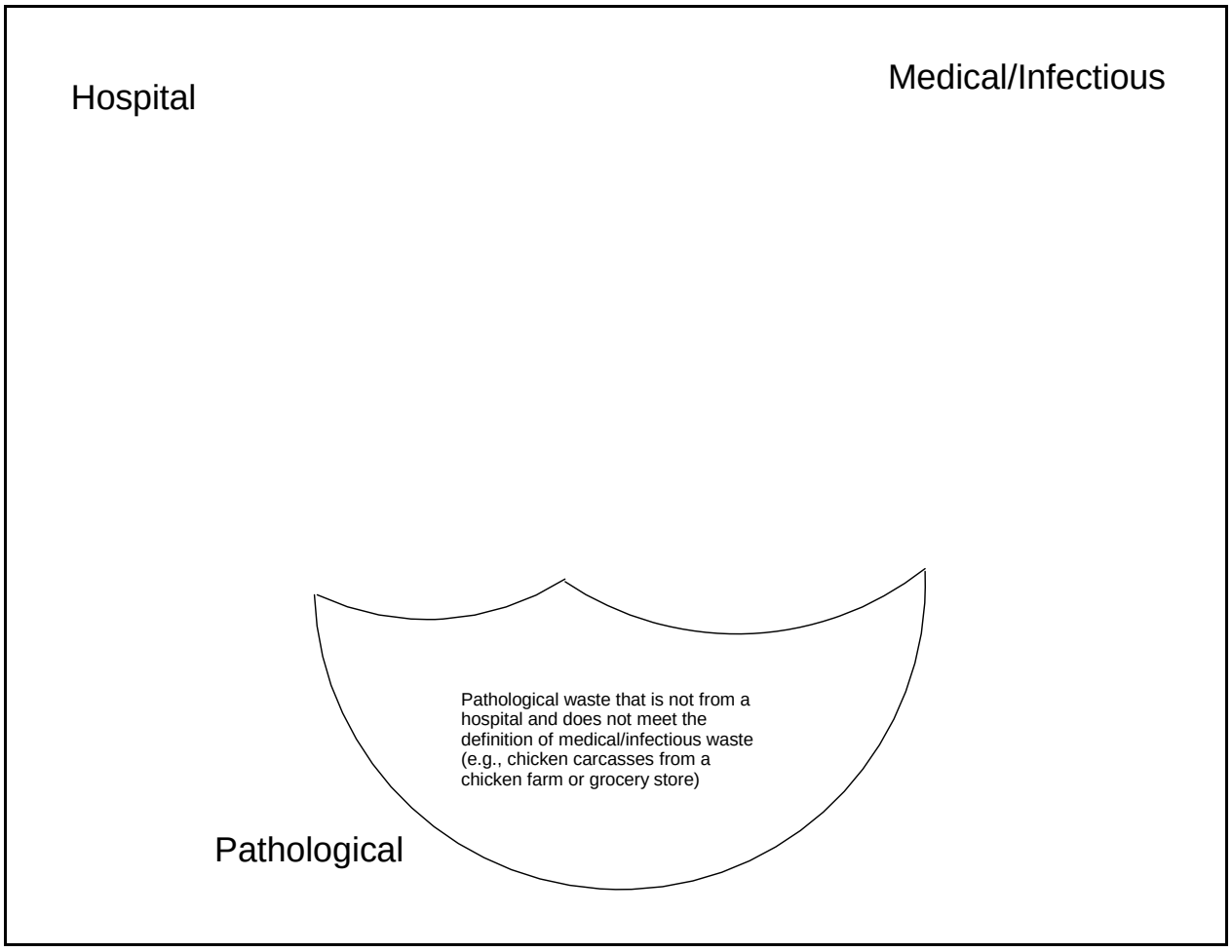
  -- Pathological Waste

  [40 CFR 60.51c]

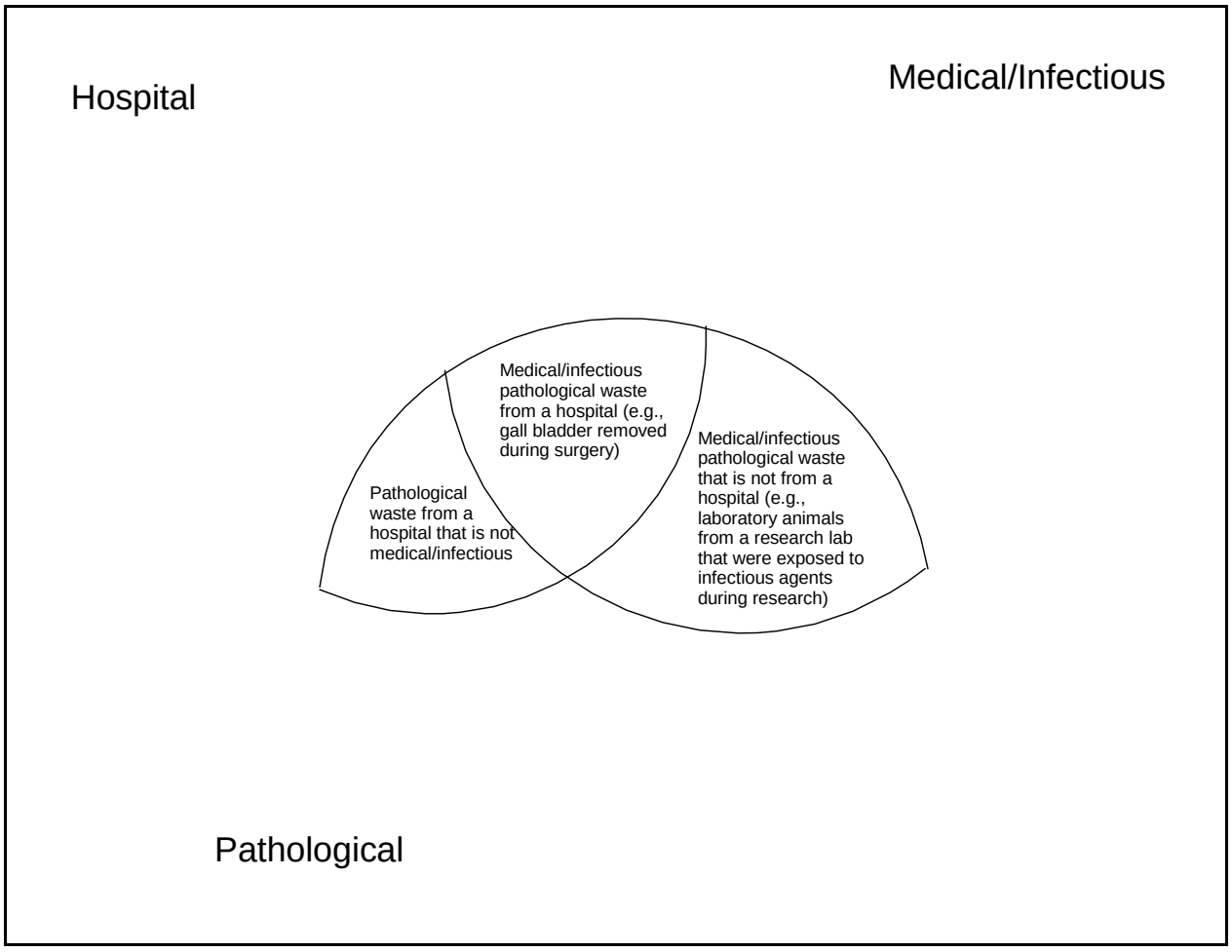
- This diagram shows how the definitions of the three types of waste overlap.
- This series of diagrams will show how the HMIWI regulations apply in different situations.



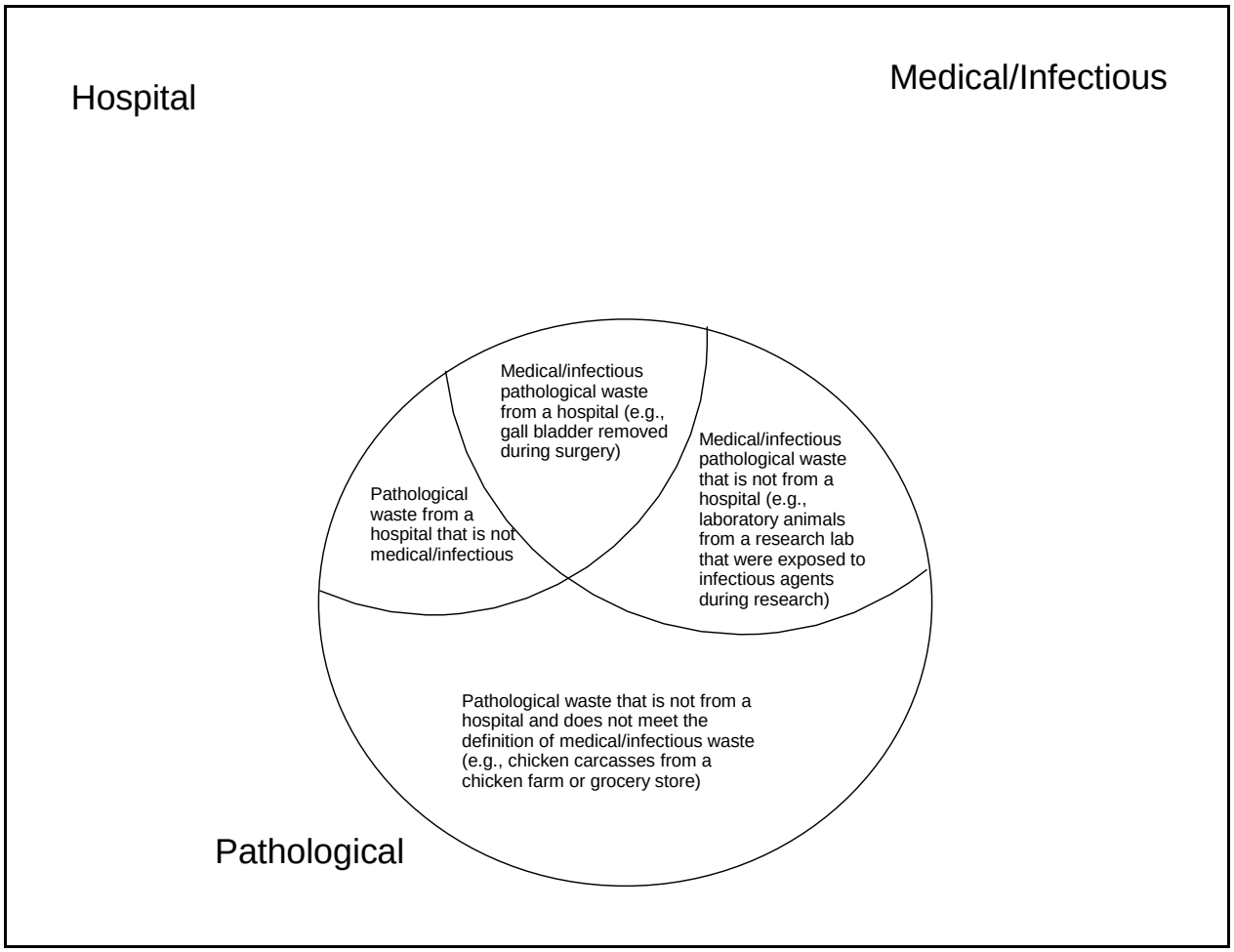
- The HMIWI regulations cover units burning these wastes. If a combustor burns any amount of these materials, it may be subject to the HMIWI regulations. [40 CFR 60.32e(a) and 60.51c]
- Conversely, if a combustor does not burn any of these materials, it is not subject to any part of the HMIWI regulations. Combustors that are not burning any of these materials need not notify EPA or keep records. They need not be included in State Plans and they need not qualify for any of the HMIWI exemptions. [40 CFR 60.32e(d)]
- If a combustor burns these materials in a hazardous waste incinerator, in a cement kiln, or in a MWC subject to the large MWC regulations, it is not subject to the HMIWI regulations (no matter how much of these materials it burns). [40 CFR 60.32e(e) and (g)]
- Pyrolysis units are not subject to the HMIWI regulations. [40 CFR 60.32e(f)]
- The pathological and co-fired combustor exemptions are described later. [40 CFR 60.32e(b) and (c)]



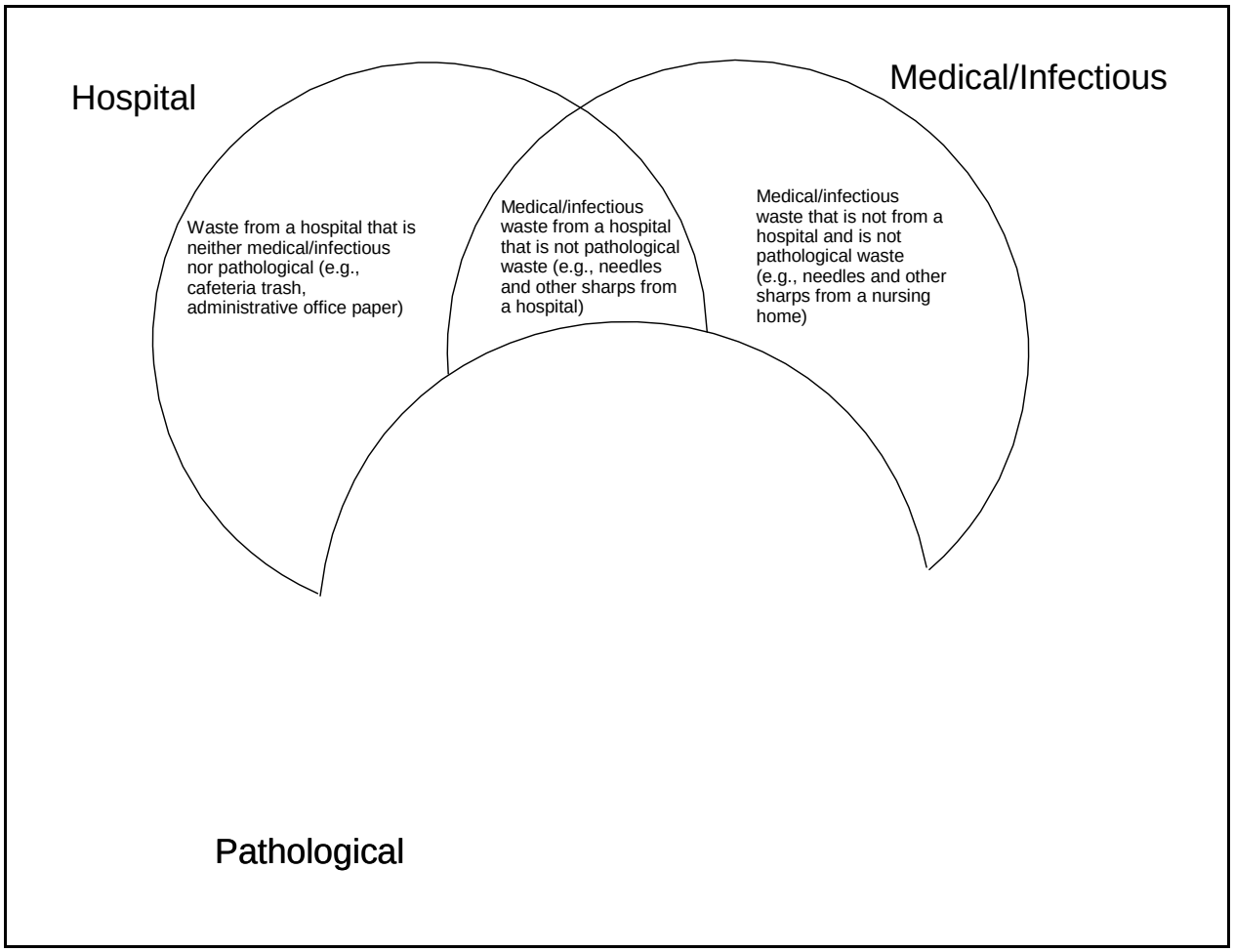
- Consequently, if a combustor is burning these materials (alone or with other materials) and is not burning any of the materials from the previous diagram, it is not subject to any part of the HMIWI regulations (i.e., it need not notify EPA, it need not keep records, it need not be included on a State Plan inventory). It need not qualify for the pathological exemption because it is not an HMIWI. [40 CFR 60.32e(d)]



- If there are time periods when a combustor burns only these materials, it is exempt from most provisions in the HMIWI regulations during those periods, but it should notify EPA and keep records. This is known as the pathological waste exemption. [40 CFR 60.32e(b)]
- This exemption applies to combustors which burn only these materials all of the time, and also applies to combustors which burn only these materials some of the time while burning other materials at other times. [40 CFR 60.32e(b)]
- If the combustor burns any other materials along with these materials (i.e., at the same time), it does not qualify for the pathological exemption (except as provided on the next diagram). [40 CFR 60.32e(b)]



- If there are time periods when a combustor burns only these materials, it is also exempt from most provisions in the HMIWI regulations, but it should notify EPA and keep records. This is part of the pathological waste exemption. [40 CFR 60.32e(b)]
- Again, these exemption applies to combustors which burn only these items all of the time, and also applies to combustors which burn only these materials some of the time while burning other materials at other times. [40 CFR 60.32e(b)]
- As stated previously, however, if the combustor burns any other materials along with these materials (i.e., at the same time), it does not qualify for the pathological exemption. [40 CFR 60.32e(b)]



- A combustor which burns 10 percent or less of these materials (in aggregate) on a calendar quarter basis is exempt from most provisions in the HMIWI regulations, but it should notify EPA and keep records. This is the co-fired combustor exemption. [40 CFR 60.32e(c)]
- Notice that pathological waste is not counted toward the 10 percent, but all other hospital and medical/infectious waste is counted toward the 10 percent. [40 CFR 60.51c]

Appendix C2

HMIWI Capacity Determination

APPENDIX C2 - HMIWI CAPACITY DETERMINATION

The HMIWI EG contain different emission limitations for the three HMIWI size subcategories: small, medium, and large. The three HMIWI size subcategories are based on waste burning capacity (pound per hour [lb/hr]). The small size subcategory consists of HMIWI that burn less than or equal to 200 pounds of waste per hour ($\leq$ 200 lb/hr). The medium size subcategory includes HMIWI that burn between 200 and 500 pounds of waste per hour (> 200 to $\leq$ 500 lb/hr). The large size subcategory includes HMIWI that burn more than 500 pounds of waste per hour (> 500 lb/hr). [40 CFR 60.51c]

Generally, there are three different HMIWI design types: batch, intermittent, and continuous. These design types differ in the methods used to charge waste and remove ash. In batch HMIWI, neither waste charging nor ash removal can occur during combustion. Intermittent HMIWI are designed to allow waste charging, but not ash removal, during combustion. Continuous HMIWI are designed to allow waste charging and ash removal during combustion. [40 CFR 60.51c]

Due to the differences in waste charging techniques, the methods for determining the maximum design waste burning capacity and maximum charge rate (defined in section 60.51c of subpart Ec) are different for batch HMIWI than for continuous and intermittent HMIWI. Either the maximum design waste burning capacity or the maximum charge rate may be used to determine the HMIWI size subcategory. [62 FR 48367]

For continuous and intermittent HMIWI, maximum charge rate is defined in subpart Ec as 110 percent of the lowest 3-hour average charge rate measured during the most recent performance test demonstrating compliance with the emission limits. Table C-1 presents an example of the maximum charge rate calculation for an intermittent HMIWI with two days of initial test data.

Maximum design waste burning capacity is defined for continuous and intermittent HMIWI with the following formula: [40 CFR 60.51c]

$$C = P_V \times (15{,}000/8{,}500)$$

where:

C = HMIWI capacity (lb/hr),
P_V = primary chamber volume (ft^3),
15,000 = primary chamber heat release rate factor ($Btu/ft^3/hr$), and
8,500 = standard waste heating value (Btu/lb).

For batch HMIWI, the maximum charge rate is defined in section 60.51c of subpart Ec as 110 percent of the lowest daily charge rate measured during the most recent performance test demonstrating compliance with the emission limits. For example, suppose a batch HMIWI was charged with 1,400 lb on day 1 and 1,700 lb on day 2 of an initial compliance test. The maximum charge rate for this HMIWI would be 110 percent of 1,400 lb/day (the lowest daily charge rate) or 1,540 lb/day.

Table C-1. Maximum Charge Rate
Example Calculation

Charge log (lb/hr)	3-hour average (lb/hr)
345	--
376	--
359	360
341	359
387	362
361	363
368	372
337	355
329	345
358	**341**
362	350
343	354
364	356
381	363
Lowest 3-hour average charge rate during initial testing = 341 lb/hr	
Maximum charge rate = 1.1 x 341 = **375 lb/hr**	

Maximum design waste burning capacity is defined for batch HMIWI with the following formula: [40 CFR 60.51c]

$$C = P_V \times (4.5/8)$$

where:

C = HMIWI capacity (lb/hr),
P_v = primary chamber volume (ft^3),
4.5 = waste density (lb/ft^3), and
8 = typical hours of operation for a batch HMIWI (hr).

Table C-2 summarizes the criteria specified in the EG for maximum design waste burning capacity and for maximum charge rate for the three HMIWI size subcategories.

Table C-2. Summary of Criteria for Determining HMIWI Size Category as Stated in the Emission Guidelines

Size Criteria	HMIWI size subcategory		
	Small	Medium	Large
Maximum design waste burning capacity (lb/hr)	≤200	>200 and ≤500	>500
Maximum charge rate for batch HMIWI (lb/day)	≤1,600	>1,600 and ≤4,000	>4,000
Maximum charge rate for intermittent and continuous HMIWI (lb/hr)	≤200	>200 and ≤500	>500

For convenience, Table C-3 presents the range of primary chamber volumes for each subcategory for batch and continuous/intermittent HMIWI. These primary chamber volumes were obtained from the above equations for maximum design waste burning capacity for each size subcategory.

Table C-3. Primary Chamber Volumes for Use in Determining Maximum Design Waste Burning Capacity

HMIWI Type	Maximum design waste burning capacity (lb/hr)		
	≤200[a]	>200 to ≤ 500[b]	>500[c]
Primary chamber volume for batch HMIWI (ft^3)	≤ 356	> 356 to ≤ 889	> 889
Primary chamber volume for intermittent or continuous HMIWI (ft^3)	≤ 113	> 113 to ≤ 283	> 283

[a]Small HMIWI size subcategory.
[b]Medium HMIWI size subcategory.
[c]Large HMIWI size subcategory.

In cases where the maximum design waste burning capacity places an HMIWI in one size subcategory and the maximum charge rate places the same HMIWI in a different size subcategory, the maximum charge rate prevails. [62 FR 48367] Most HMIWI operate at around two-thirds of their design capacity; very few HMIWI operate at their maximum design waste burning capacity. The maximum design waste burning capacity of an HMIWI is fixed and cannot be changed. The maximum charge rate, on the other hand, can be controlled by the HMIWI operator. The EG allow an HMIWI used to burn less waste than its design capacity to change its size category. For example, an HMIWI with a maximum design waste burning capacity of 300 lb/hr (e.g., a medium HMIWI by design), may only be used to burn 150 lb/hr. By virtue of the maximum charge rate, such an HMIWI could be considered as a small HMIWI for purposes of the EG, and would be allowed to meet slightly less stringent emission limits.

The HMIWI would be bound by the maximum charge rate in its state operating permit for enforcement purposes.

Larger HMIWI which derate their capacities to be considered as smaller HMIWI need to account for the 110 percent operating range specified in the EG when establishing their permitted maximum charge rate. For example, a facility operating a 300 lb/hr HMIWI needs to ensure that the lowest 3-hour average charge rate does not exceed 182 lb/hr if the HMIWI is to be considered a small HMIWI. This is because the 110 percent operation applied to the 182 lb/hr average charge rate will establish the maximum charge rate at 200 lb/hr (i.e., the cutoff for the small HMIWI size subcategory). Likewise, to fall into the medium subcategory, a facility operating a large HMIWI needs to ensure that the lowest 3-hour average charge rate does not exceed 455 lb/hr because the 110 percent operation will establish the maximum charge rate at 500 lb/hr (i.e., the cutoff for the medium HMIWI size subcategory).

Appendix C3

Small Rural Criteria

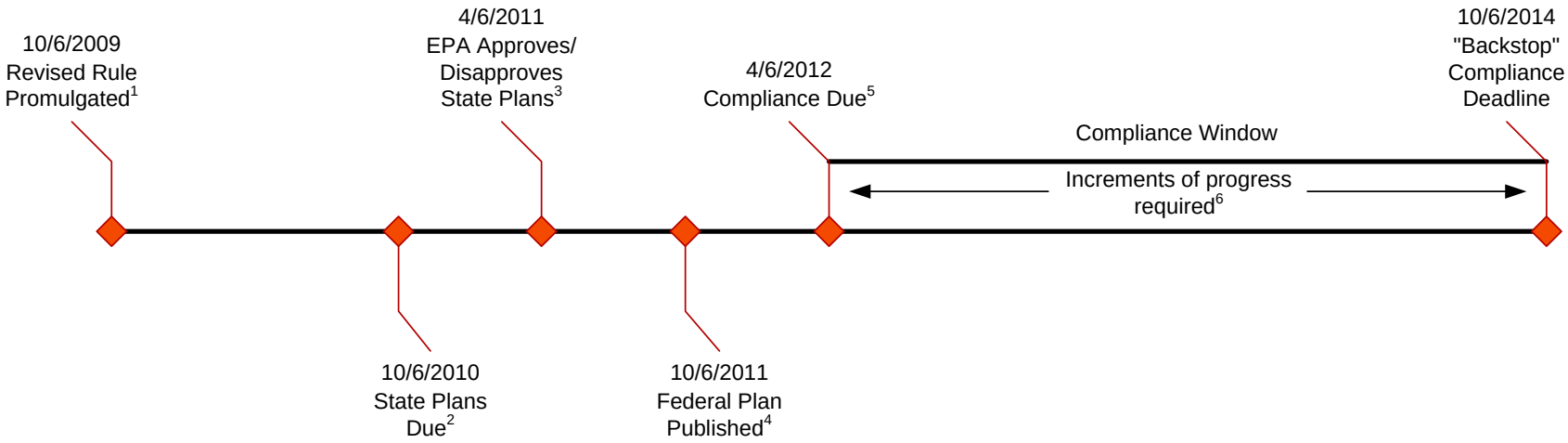
APPENDIX C3 - SMALL RURAL CRITERIA

The rural criteria in the EG state that the small HMIWI: (1) be located more than 50 miles (straight line distance) from the boundary of the nearest Standard Metropolitan Statistical Area (SMSA) and (2) burn less than 2,000 pounds per week (lb/wk)of hospital waste and medical/infectious waste. [40 CFR 60.33e(b)]

Standard Metropolitan Statistical Areas (now called simply Metropolitan Statistical Areas [MSAs]) are defined by the Office of Management and Budget (OMB). For the purposes of the EG, the SMSAs are based on the OMB June 30, 1993 listing of SMSAs [40 CFR 60.31e], which is available on the TTN Air Toxics Website for HMIWI at the following address: http://www.epa.gov/ttn/atw/129/hmiwi/rihmiwi.html.

Appendix D

HMIWI Implementation Timeline



[1] 74 FR 51368.
[2] Section 129(b)(2) requires State Plans be submitted not later than one year after promulgation of the rule.
[3] Section 129(b)(2) requires EPA to approve or disapprove a State Plan within 180 days of submission.
[4] Section 129(b)(3) requires EPA to develop a Federal Plan within 2 years of rule promulgation (if necessary).
[5] Due 12 months after EPA approval of State Plan under section 60.39e of subpart Ce unless the State has granted an extension to a source (up to 3 years after approval of State Plan but not less than 5 years after promulgation). Note: Section 129(f)(2) requires expeditious compliance.
[6] Section 60.24(e)(1) of subpart B requires legally enforceable increments of progress for any compliance schedule extending beyond 12 months from State Plan approval. Section 60.39e(c)(1)-(9) of subpart Ce and section 60.21 of subpart B list suggested increments of progress, and section 60.21 of subpart B contains five required increments of progress.

Notes:

Subpart B	General requirements for all section 111(d) State Plans. Amended 12/19/95 to allow subsequent subparts (e.g., subpart Ce) to supersede subpart B.
Subpart Ce	Emission Guidelines for HMIWI.

Figure D-1. HMIWI Implementation Timeline.

Appendix E

EPA Regional and State/Local Agency Contacts

E1 EPA Regional HMIWI Rule Contacts
E2 State Contacts

Appendix E1

EPA Regional HMIWI Rule Contacts

EPA REGIONAL HMIWI RULE CONTACTS

Regional Contact	Address	Phone #	E-mail
Region I (Connecticut, Massachusetts, Maine, New Hampshire, Rhode Island, Vermont) Contact: Ian Cohen	U.S. Environmental Protection Agency, Region I 5 Post Office Square, Suite 100 Mail Code: OEP05-2 Boston, MA 02109-3912	(617) 918-1655	cohen.ian@epa.gov
Region II (New York, New Jersey, Puerto Rico, Virgin Islands) Contact: Ted Gardella	U.S. Environmental Protection Agency, Region II 290 Broadway New York, NY 10007-1866	(212) 637-3892	gardella.anthony@epa.gov
Region III (Virginia, Delaware, District of Columbia, Maryland, Pennsylvania, West Virginia) Contact: James B. Topsale	U.S. Environmental Protection Agency, Region III 1650 Arch Street Mail Code: 3AP10 Philadelphia, PA 19103-2029	(215) 814-2190	topsale.jim@epa.gov
Region IV (Florida, Georgia, North Carolina, Alabama, Kentucky, Mississippi, South Carolina, Tennessee) Contacts: Donnette Sturdivant Daniel Garver	U.S. Environmental Protection Agency, Region IV 61 Forsyth Street, SW Mail Code: 9T25 Atlanta, GA 30303	Sturdivant: (404) 562-9431 Garver: (404) 562-9839	sturdivant.donnette@epa.gov garver.daniel@epa.gov
Region V (Minnesota, Wisconsin, Illinois, Indiana, Michigan, Ohio) Contact: Margaret Sieffert	U.S. Environmental Protection Agency, Region V 77 W. Jackson Blvd. Mail Code: AT-18J Chicago, IL 60604	(312) 353-1151	sieffert.margaret@epa.gov
Region VI (Arkansas, Louisiana, New Mexico, Oklahoma, Texas) Contact: Steve Thompson	U.S. Environmental Protection Agency, Region VI 1445 Ross Avenue, Suite 1200 Mail Code: 6EN	(214) 665-2769	thompson.steve@epa.gov

Regional Contact	Address	Phone #	E-mail
	Dallas, TX 75202-2733		
Region VII (Iowa, Kansas, Missouri, Nebraska) Contact: Lisa Hanlon	U.S. Environmental Protection Agency, Region VII 901 N. 5th St. Kansas City, KS 66101	(913) 551-7599	hanlon.lisa@epa.gov
Region VIII (Colorado, Montana, North Dakota, South Dakota, Utah, Wyoming) Contact: Christopher Razzazian	U.S. Environmental Protection Agency, Region VIII 1595 Wynkoop Street Mail Code: 8P-AR Denver, CO 80202-1129	(303) 312-6648	razzazian.christopher@epa.gov
Region IX (Arizona, California, Hawaii, Nevada) Contact: Joseph Lapka	U.S. Environmental Protection Agency, Region IX 75 Hawthorne Street Mail Code: AIR-5 San Francisco, CA 94105	(415) 947-4226	Lapka.Joseph@epa.gov
Region X (Alaska, Idaho, Oregon, Washington) Contact: Heather Valdez	U.S. Environmental Protection Agency, Region X 1200 Sixth Avenue, Suite 900 Mail Code: AWT-107 Seattle, WA 98101	(206) 553-6220	valdez.heather@epa.gov

Appendix E2

State Contacts

STATE CONTACTS

State Contact	Address	Phone #	E-mail
Alabama Contact: Geraline Handsome	Alabama Department of Environmental Management Air Division 1751 Congressman W.L. Dickenson Way Montgomery, AL 36109-2608	(334) 271-7700	gh@adem.state.al.us
City of Huntsville Contact: Danny Shea	City of Huntsville Department of Natural Resources and Environmental Management 305 Church Street Huntsville, AL 35801	(256) 427-5750	danny.shea@hsvcity.com
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Appendix F

HMIWI Emission Factors

APPENDIX F--HMIWI EMISSION FACTORS

The pollutants emitted from hospital/medical/infectious waste incinerators (HMIWI) include the following:

- metals (cadmium, lead, and mercury),
- particulate matter (PM),
- acid gases (hydrogen chloride, HCl, and sulfur dioxide, SO_2),
- organic compounds (dioxins and furans),
- carbon monoxide (CO), and
- nitrogen oxides (NO_X).

As noted in section 3 of this document, data from continuous emission monitoring systems (CEMS) and stack sampling results are preferred for estimating emissions for the emission inventories included in states' section 111(d)/129 State Plans. However, where CEMS and stack sampling results are missing, emission factors are an acceptable alternative. Emission factors for each of the pollutants listed above are included in Table F-1. The emission factors presented in Table F-1 were generated based on test data used for development of the amended Emission Guidelines for HMIWI. The test data used to develop the emission factors in Table F-1 was thoroughly reviewed for accuracy and reliability prior to use for the amended Emission Guidelines. Therefore, the emission factors presented in Table F-1 are appropriate emission factors for use in developing the updated emission inventory to be submitted in states' revised/amended or new section 111(d)/129 State Plans. The AP-42 emission factors may be used as well.

Table F-1. Emission Factors for HMIWI

Pollutant	Emission factors, lb emitted per lb waste charged			
	Combustion Control	Wet Scrubbers	Dry scrubbers	Dry/wet scrubbers
Total CDD/CDF	1.90E-06	2.66E-07	w/o carbon: 2.45E-07 w/ carbon: 9.46E-08	w/o carbon: 3.74E-07 w/ carbon: 6.84E-08
CDD/CDF TEQ	3.83E-08	4.12E-09	w/o carbon: 4.19E-09 w/ carbon: 2.96E-09	w/o carbon: 7.64E-09 w/ carbon: 7.78E-10
CO	w/ 1-sec combustion: 1.09E-04 w/ 2-sec combustion: 7.08E-05 all HMIWI (including unknown retention time): 9.47E-05			
PM	1.44E-03	6.67E-04	2.28E-04	5.46E-05
HCl	4.34E-03	6.79E-05	5.77E-04	2.96E-04
Pb	1.41E-05	4.85E-06	6.09E-07	5.27E-07
SO_2	1.03E-03	2.12E-04	2.84E-04	1.31E-04
Hg	2.85E-06	1.04E-06	w/o carbon: 1.92E-06 w/ carbon: 4.95E-07	w/o carbon: 9.11E-08 w/ carbon: 7.81E-08
Cd	2.37E-06	4.16E-07	5.54E-08	2.44E-08
NO_x	w/o NO_X control: 3.69E-03 w/ NO_X control: 1.37E-03			

Source: Memorandum from T. Holloway, RTI, to K. Patel, EPA. July 6, 2009. Revised Baseline Emissions and Emissions Reductions for Existing and New HMIWI.

When estimating emissions from emission factors, the amount of waste burned per year at a facility is simply multiplied by the pollutant emission factor. For example, to estimate the annual Pb emissions (lb/yr) for an HMIWI which burns lb of medical/infectious waste per year and is equipped with a wet scrubber, the following calculation is performed:

(424,000 lb waste/yr) x (4.85E-06 lb Pb/lb waste) = 2.06 lb Pb/yr

When using the HMIWI emission factors to estimate emissions, keep in mind that they are average values, and that emissions from HMIWI are greatly affected by the composition of the waste and may vary from facility to facility. As stated previously, actual and reliable facility-specific CEMS and stack sampling results should be used in place of emission factors where available. The preferred hierarchy for estimating emissions is as follows: (1) CEMS data, (2) stack sampling results, and (3) emission factors.

Appendix G

Clean Air Act Section 111(d)

APPENDIX G--CLEAN AIR ACT SECTION 111(d)

Note: The State Plans for HMIWI must be developed to satisfy the requirements of both Section 111(d) and Section 129. Where conflicts arise, Section 129 takes precedent. Refer to Appendix H for the text of Section 129.

(d)(1) The Administrator shall prescribe regulations which shall establish a procedure similar to that provided by Section 110 under which each State shall submit to the Administrator a plan which (A) establishes standards of performance for any existing source for any air pollutant (i) for which air quality criteria have not been issued or which is not included on a list published under Section 108(a) or 112(b)(1)(A) but (ii) to which a standard of performance under this section would apply if such existing source were a new source, and (B) provides for the implementation and enforcement of such standards of performance. Regulations of the Administrator under this paragraph shall permit the State in applying a standard of performance to any particular source under a plan submitted under this paragraph to take into consideration, among other factors, the remaining useful life of the existing source to which such standard applies.

(2) The Administrator shall have the same authority--

(A) to prescribe a plan for a State in cases where the State fails to submit a satisfactory plan as he would have under Section 110(c) in the case of failure to submit an implementation plan, and

(B) to enforce the provisions of such plan in cases where the State fails to enforce them as he would have under sections 113 and 114 with respect to an implementation plan. In promulgating a standard of performance under a plan prescribed under this paragraph, the Administrator shall take into consideration, among other factors, remaining useful lives of the sources in the category of sources to which such standard applies.

Appendix H

Clean Air Act Section 129

APPENDIX H--SECTION 129 STATUTORY LANGUAGE

Note: The State Plans for HMIWI must be developed to satisfy the requirements of both Section 111(d) and Section 129. Where conflicts arise, Section 129 takes precedent. Refer to Appendix G for the text of Section 111(d).

SEC. 129. SOLID WASTE COMBUSTION.

(a) NEW SOURCE PERFORMANCE STANDARDS.

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

(B) Standards under Section 111 and this section applicable to solid waste incineration units with capacity greater than 250 tons per day combusting municipal waste shall be promulgated not later than 12 months after the date of enactment of the Clean Air Act Amendments of 1990. Nothing in this subparagraph shall alter any schedule for the promulgation of standards applicable to such units under Section 111 pursuant to any settlement and consent decree entered by the Administrator before the date of enactment of the Clean Air Act Amendments of 1990, provided that, such standards are subsequently modified pursuant to the schedule established in this subparagraph to include each of the requirements of this section.

(C) Standards under Section 111 and this section applicable to solid waste incineration units with capacity equal to or less than 250 tons per day combusting municipal waste and units combusting hospital waste, medical waste and infectious waste shall be promulgated not later than 24 months after the date of enactment of the Clean Air Act Amendments of 1990.

(D) Standards under Section 111 and this section applicable to solid waste incineration units combusting commercial or industrial waste shall be proposed not later than 36 months after the date of enactment of the Clean Air Act Amendments of 1990 and promulgated not later than 48 months after such date of enactment.

(E) Not later than 18 months after the date of enactment of the Clean Air Act Amendments of 1990, the Administrator shall publish a schedule for the promulgation of standards under Section 111 and this section applicable to other categories of solid waste incineration units.

(2) EMISSIONS STANDARD. -- Standards applicable to solid waste incineration units promulgated under Section 111 and this section shall reflect the maximum degree of reduction in emissions of air pollutants listed under section (a)(4) that the Administrator, taking into consideration the cost of achieving such emission reduction, and any non-air quality health and environmental impacts and energy requirements, determines is achievable for new or existing units in each category. The Administrator may distinguish among classes, types (including mass-burn, refuse-derived fuel, modular and other types of units), and sizes of units within a category in establishing such standards. The degree of reduction in emissions that is deemed achievable for new units in a category shall not be less stringent than the emissions control that is achieved in practice by the best controlled similar unit, as determined by the Administrator. Emissions standards for existing units in a category may be less stringent than standards for new units in the same category but shall not be less stringent than the average emissions limitation achieved by the best performing 12 percent of units in the category (excluding units which first

met lowest achievable emissions rates 18 months before the date such standards are proposed or 30 months before the date such standards are promulgated, whichever is later).

(3) CONTROL METHODS AND TECHNOLOGIES. -- Standards under Section 111 and this section applicable to solid waste incineration units shall be based on methods and technologies for removal or destruction of pollutants before, during, or after combustion, and shall incorporate for new units siting requirements that minimize, on a site specific basis, to the maximum extent practicable, potential risks to public health or the environment.

(4) NUMERICAL EMISSIONS LIMITATIONS. -- The performance standards promulgated under Section 111 and this section and applicable to solid waste incineration units shall specify numerical emission limitations for the following substances or mixtures: particulate matter (total and fine), opacity (as appropriate), sulfur dioxide, hydrogen chloride, oxides of nitrogen, carbon monoxide, lead, cadmium, mercury, and dioxins and dibenzofurans. The Administrator may promulgate numerical emissions limitations or provide for the monitoring of postcombustion concentrations of surrogate substances, parameters or periods of residence time in excess of stated temperatures with respect to pollutants other than those listed in this paragraph.

(5) REVIEW AND REVISION. -- Not later than 5 years following the initial promulgation of any performance standards and other requirements under this section and Section 111 applicable to a category of solid waste incineration units, and at 5 year intervals thereafter, the Administrator shall review, and in accordance with this section and Section 111, revise such standards and requirements.

(b) EXISTING UNITS.

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

(2) STATE PLANS. -- Not later than 1 year after the Administrator promulgates guidelines for a category of solid waste incineration units, each State in which units in the category are operating shall submit to the Administrator a plan to implement and enforce the guidelines with respect to such units. The State plan shall be at least as protective as the guidelines promulgated by the Administrator and shall provide that each unit subject to the guidelines shall be in compliance with all requirements of this section not later than 3 years after the State plan is approved by the Administrator but not later than 5 years after the guidelines were promulgated. The Administrator shall approve or disapprove any State plan within 180 days of the submission, and if a plan is disapproved, the Administrator shall state the reasons for disapproval in writing. Any State may modify and resubmit a plan which has been disapproved by the Administrator.

(3) FEDERAL PLAN. -- The Administrator shall develop, implement and enforce a plan for existing solid waste incineration units within any category located in any State which has not submitted an approvable plan under this subsection with respect to units in such category within 2 years after the date on which the Administrator promulgated the relevant guidelines. Such plan shall assure that each unit subject to the plan is in compliance with all provisions of the guidelines not later than 5 years after the date the relevant guidelines are promulgated.

(c) MONITORING. -- The Administrator shall, as part of each performance standard promulgated pursuant to subsection (a) and Section 111, promulgate regulations requiring the owner or operator of each solid waste incineration unit

(1) to monitor emissions from the unit at the point at which such emissions are emitted into the ambient air (or within the stack, combustion chamber or pollution control equipment, as appropriate) and at such other points as necessary to protect public health and the environment;

(2) to monitor such other parameters relating to the operation of the unit and its pollution control technology as the Administrator determines are appropriate; and

(3) to report the results of such monitoring. Such regulations shall contain provisions regarding the frequency of monitoring, test methods and procedures validated on solid waste incineration units, and the form and frequency of reports containing the results of monitoring and shall require that any monitoring reports or test results indicating an exceedance of any standard under this section shall be reported separately and in a manner that facilitates review for purposes of enforcement actions. Such regulations shall require that copies of the results of such monitoring be maintained on file at the facility concerned and that copies shall be made available for inspection and copying by interested members of the public during business hours.

(d) OPERATOR TRAINING. -- Not later than 24 months after the enactment of the Clean Air Act Amendments of 1990, the Administrator shall develop and promote a model State program for the training and certification of solid waste incineration unit operators and high-capacity fossil fuel fired plant operators. The Administrator may authorize any State to implement a model program for the training of solid waste incineration unit operators and high-capacity fossil fuel fired plant operators, if the State has adopted a program which is at least as effective as the model program developed by the Administrator. Beginning on the date 36 months after the date on which performance standards and guidelines are promulgated under subsection (a) and Section 111 for any category of solid waste incineration units it shall be unlawful to operate any unit in the category unless each person with control over processes affecting emissions from such unit has satisfactorily completed a training program meeting the requirements established by the Administrator under this subsection.

(e) PERMITS. -- Beginning (1) 36 months after the promulgation of a performance standard under subsection (a) and Section 111 applicable to a category of solid waste incineration units, or (2) the effective date of a permit program under title V in the State in which the unit is located, whichever is later, each unit in the category shall operate pursuant to a permit issued under this subsection and title V. Permits required by this subsection may be renewed according to the provisions of title V. Notwithstanding any other provision of this Act, each permit for a solid waste incineration unit combusting municipal waste issued under this Act shall be issued for a period of up to 12 years and shall be reviewed every 5 years after date of issuance or reissuance. Each permit shall continue in effect after the date of issuance until the date of termination, unless the Administrator or State determines that the unit is not in compliance with all standards and conditions contained in the permit. Such determination shall be made at regular intervals during the term of the permit, such intervals not to exceed 5 years, and only after public comment and public hearing. No permit for a solid waste incineration unit may be issued under this Act by an agency, instrumentality or person that is also responsible, in whole or part, for the design and construction or operation of the unit. Notwithstanding any other provision of this subsection, the Administrator or the State shall require the owner or operator of any unit to comply with emissions limitations or implement any other measures, if the Administrator or the State determines that emissions in the absence of such limitations or measures my reasonably be anticipated to endanger public health or the environment. The Administrator's determination under the preceding sentence is a discretionary decision.

(f) EFFECTIVE DATE AND ENFORCEMENT.

(1) NEW UNITS. -- Performance standards and other requirements promulgated pursuant to this section and Section 111 and applicable to new solid waste incineration units shall be effective as of the date 6 months after the date of promulgation.

(2) EXISTING UNITS. -- Performance standards and other requirements promulgated pursuant to this section and Section 111 and applicable to existing solid waste incineration units shall be effective as expeditiously as practicable after approval of a State plan under subsection (b)(2) (or promulgation of a plan by the Administrator under subsection (b)(3)) but in no event later than 3 years after the State plan is approved or 5 years after the date such standards or requirements are promulgated, whichever is earlier.

(3) PROHIBITION. -- After the effective date of any performance standard, emission limitation or other requirement promulgated pursuant to this section and Section 111, it shall be unlawful for any owner or operator of any solid waste incineration unit to which such standard, limitation or requirement applies to operate such unit in violation of such limitation, standard or requirement or for any other person to violate an applicable requirement of this section.

(4) COORDINATION WITH OTHER AUTHORITIES. -- For purposes of sections 111(e), 113, 114, 116, 120, 303, 304, 307 and other provisions for the enforcement of this Act, each performance standard, emission limitation or other requirement established pursuant to this section by the Administrator or a State or local government, shall be treated in the same manner as a standard of performance under Section 111 which is an emission limitation.

(g) DEFINITIONS. -- For purposes of Section 306 of the Clean Air Act Amendments of 1990 and this section only

(1) SOLID WASTE INCINERATION UNIT. -- The term 'solid waste incineration unit' means a distinct operating unit of any facility which combusts any solid waste material from commercial or industrial establishments or the general public (including single and multiple residences, hotels, and motels). Such term does not include incinerators or other units required to have a permit under Section 3005 of the Solid Waste Disposal Act. The term 'solid waste incineration unit' does not include (A) materials recovery facilities (including primary or secondary smelters) which combust waste for the primary purpose of recovering metals, (B) qualifying small power production facilities, as defined in Section 3(17)(C) of the Federal Power Act (16 U.S.C. 769(17)(C)), or qualifying cogeneration facilities, as defined in section 3(18)(B) of the Federal Power Act (16 U.S.C. 796(18)(B)), which burn homogeneous waste (such as units which burn tires or used oil, but not including refuse-derived fuel) for the production of electric energy or in the case of qualifying cogeneration facilities which burn homogeneous waste for the production of electric energy and steam or forms of useful energy (such as heat) which are used for industrial, commercial, heating or cooling purposes, or (C) air curtain incinerators provided that such incinerators only burn wood wastes, yard wastes and clean lumber and that such air curtain incinerators comply with opacity limitations to be established by the Administrator by rule.

(2) NEW SOLID WASTE INCINERATION UNIT. -- The term 'new solid waste incineration unit' means a solid waste incineration unit the construction of which is commenced after the Administrator proposes requirements under this section establishing emissions standards or other requirements which would be applicable to such unit or a modified solid waste incineration unit.

(3) MODIFIED SOLID WASTE INCINERATION UNIT. -- The term 'modified solid waste incineration unit' means a solid waste incineration unit at which modifications have occurred after the effective date of a standard under subsection (a) if (A) the cumulative cost of the modifications, over the life of the unit, exceed 50 per centum of the original cost of 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 (B) the modification is 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 this section or Section 111.

(4) EXISTING SOLID WASTE INCINERATION UNIT. -- The term 'existing solid waste incineration unit' means a solid waste unit which is not a new or modified solid waste incineration unit.

(5) MUNICIPAL WASTE. -- The term 'municipal waste' means refuse (and refuse-derived fuel) collected from the general public and from residential, commercial, institutional, and industrial sources consisting of paper, wood, yard wastes, food wastes, plastics, leather, rubber, and other combustible materials and non-combustible materials such as metal, glass and rock, provided that: (A) the term does not include industrial process wastes or medical wastes that are segregated from such other wastes; and (B) an incineration unit shall not be considered to be combusting municipal waste for purposes of Section 111 or this section if it combusts a fuel feed stream, 30 percent or less of the weight of which is comprised, in aggregate, of municipal waste.

(6) OTHER TERMS. -- The terms 'solid waste' and 'medical waste' shall have the meanings established by the Administrator pursuant to the Solid Waste Disposal Act.

(h) OTHER AUTHORITY.

(1) STATE AUTHORITY. -- Nothing in this section shall preclude or deny the right of any State or political subdivision thereof to adopt or enforce any regulation, requirement, limitation or standard relating to solid waste incineration units that is more stringent than a regulation, requirement, limitation or standard in effect under this section or under any other provision of this Act.

(2) OTHER AUTHORITY UNDER THIS ACT. -- Nothing in this section shall diminish the authority of the Administrator or a State to establish any other requirements applicable to solid waste incineration units under any other authority of law, including the authority to establish for any air pollutant a national ambient air quality standard, except that no solid waste incineration unit subject to performance standards under this section and Section 111 shall be subject to standards under Section 112(d) of this Act.

(3) RESIDUAL RISK. -- The Administrator shall promulgate standards under Section 112(f) for a category of solid waste incineration units, if promulgation of such standards is required under Section 112(f). For purposes of this preceding sentence only

(A) the performance standards under subsection (a) and Section 111 applicable to a category of solid waste incineration units shall be deemed standards under Section 112(d)(2), and

(B) the Administrator shall consider and regulate, if required, the pollutants listed under subsection (a)(4) and no others.

(4) ACID RAIN. -- A solid waste incineration unit shall not be utility unit as defined in title IV: provided, that, more than 80 per centum of its annual average fuel consumption measured on a Btu basis, during a period or periods to be determined by the Administrator, is from a fuel (including any waste burned as a fuel) other than a fossil fuel.

(5) REQUIREMENTS OF PARTS C AND D. -- No requirement of an applicable implementation plan under Section 165 (relating to construction of facilities in regions identified pursuant to Section 107(d)(1)(A)(ii) or (iii)) or under Section 172(c)(5) (relating to permits for construction and operation in nonattainment areas) may be used to weaken the standards in effect under this section.

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(b) CONFORMING AMENDMENT. -- Section 169(1) of the Clean Air Act is amended by striking "two hundred and" after "municipal incinerators capable of charging more than".

(c) REVIEW OF ACID GAS SCRUBBING REQUIREMENTS. -- Prior to the promulgation of any performance standard for solid waste incineration units combusting municipal waste under Section 111 or Section 129 of the Clean Air Act, the Administrator shall review the availability of acid gas scrubbers as a pollution control technology for small new units and for existing units (as defined in 54 Federal Register 52190 (December 20, 1989), taking into account the provisions of subsection (a)(2) of Section 129 of the Clean Air Act.

Appendix I

40 CFR Part 60 Subpart B

APPENDIX I--40 CFR PART 60 SUBPART B

Note: CFR text for 40 CFR Part 60 subpart B accessed Apr. 22, 2010 at e-CFR web site: http://ecfr.gpoaccess.gov.

Subpart B -- Adoption and Submittal of State Plans for Designated Facilities

Source: 40 FR 53346, Nov. 17, 1975, unless otherwise noted

§ 60.20 Applicability.

The provisions of this subpart apply to States upon publication of a final guideline document under Section 60.22(a).

§ 60.21 Definitions.

Terms used but not defined in this subpart shall have the meaning given them in the Act and in subpart A:

(a) Designated pollutant means any air pollutant, the emissions of which are subject to a standard of performance for new stationary sources, but for which air quality criteria have not been issued and that is not included on a list published under section 108(a) of the Act. Designated pollutant also means any air pollutant, the emissions of which are subject to a standard of performance for new stationary sources, that is on the section 112(b)(1) list and is emitted from a facility that is not part of a source category regulated under section 112. Designated pollutant does not include pollutants on the section 112(b)(1) list that are emitted from a facility that is part of a source category regulated under section 112.

(b) Designated facility means any existing facility (see §60.2(aa)) which emits a designated pollutant and which would be subject to a standard of performance for that pollutant if the existing facility were an affected facility (see §60.2(e)).

(c) Plan means a plan under section 111(d) of the Act which establishes emission standards for designated pollutants from designated facilities and provides for the implementation and enforcement of such emission standards.

(d) Applicable plan means the plan, or most recent revision thereof, which has been approved under §60.27(b) or promulgated under §60.27(d).

(e) Emission guideline means a guideline set forth in subpart C of this part, or in a final guideline document published under §60.22(a), which reflects the degree of emission reduction achievable through the application of the best system of emission reduction which (taking into account the cost of such reduction) the Administrator has determined has been adequately demonstrated for designated facilities.

(f) Emission standard means a legally enforceable regulation setting forth an allowable rate of emissions into the atmosphere, establishing an allowance system, or prescribing equipment specifications for control of air pollution emissions.

(g) Compliance schedule means a legally enforceable schedule specifying a date or dates by which a source or category of sources must comply with specific emission standards contained in a plan or with any increments of progress to achieve such compliance.

(h) Increments of progress means steps to achieve compliance which must be taken by an owner or operator of a designated facility, including:

(1) Submittal of a final control plan for the designated facility to the appropriate air pollution control agency;

(2) Awarding of contracts for emission control systems or for process modifications, or issuance of orders for the purchase of component parts to accomplish emission control or process modification;

(3) Initiation of on-site construction or installation of emission control equipment or process change;

(4) Completion of on-site construction or installation of emission control equipment or process change; and

(5) Final compliance.

(i) Region means an air quality control region designated under section 107 of the Act and described in part 81 of this chapter.

(j) Local agency means any local governmental agency.

(k) Allowance system means a control program under which the owner or operator of each designated facility is required to hold an authorization for each specified unit of a designated pollutant emitted from that facility during a specified period and which limits the total amount of such authorizations available to be held for a designated pollutant for a specified period and allows the transfer of such authorizations not used to meet the authorization-holding requirement.

[40 FR 53346, Nov. 17, 1975, as amended at 70 FR 28649, May 18, 2005]

§ 60.22 Publication of guideline documents, emission guidelines, and final compliance times.

(a) Concurrently upon or after proposal of standards of performance for the control of a designated pollutant from affected facilities, the Administrator will publish a draft guideline document containing information pertinent to control of the designated pollutant form designated facilities. Notice of the availability of the draft guideline document will be published in the Federal Register and public comments on its contents will be invited. After consideration of public comments and upon or after promulgation of standards of performance for control of a designated pollutant from affected facilities, a final guideline document will be published and notice of its availability will be published in the Federal Register.

(b) Guideline documents published under this section will provide information for the development of State plans, such as:

(1) Information concerning known or suspected endangerment of public health or welfare caused, or contributed to, by the designated pollutant.

(2) A description of systems of emission reduction which, in the judgment of the Administrator, have been adequately demonstrated.

(3) Information on the degree of emission reduction which is achievable with each system, together with information on the costs and environmental effects of applying each system to designated facilities.

(4) Incremental periods of time normally expected to be necessary for the design, installation, and startup of identified control systems.

(5) An emission guideline that reflects the application of the best system of emission reduction (considering the cost of such reduction) that has been adequately demonstrated for designated facilities, and the time within which compliance with emission standards of equivalent stringency can be achieved. The Administrator will specify different emission guidelines or compliance times or both for different sizes, types, and classes of designated facilities when costs of control, physical limitations, geographical location, or similar factors make subcategorization appropriate. (6) Such other available information as the Administrator determines may contribute to the formulation of State plans.

(c) Except as provided in paragraph (d)(1) of this section, the emission guidelines and compliance times referred to in paragraph (b)(5) of this section will be proposed for comment upon publication of the draft guideline document, and after consideration of comments will be promulgated in subpart C of this part with such modifications as may be appropriate.

(d)(1) If the Administrator determines that a designated pollutant may cause or contribute to endangerment of public welfare, but that adverse effects on public health have not been demonstrated, he will include the determination in the draft guideline document and in the Federal Register notice of its availability. Except as provided in paragraph (d)(2) of this section, paragraph (c) of this section shall be inapplicable in such cases.

(2) If the Administrator determines at any time on the basis of new information that a prior determination under paragraph (d)(1) of this section is incorrect or no longer correct, he will publish notice of the determination in the Federal Register, revise the guideline document as necessary under paragraph (a) of this section, and propose and promulgate emission guidelines and compliance times under paragraph (c) of this section.

[40 FR 53346, Nov. 17, 1975, as amended at 54 FR 52189, Dec. 20, 1989]

§ 60.23 Adoption and submittal of State plans; public hearings.

(a)(1) Unless otherwise specified in the applicable subpart, within 9 months after notice of the availability of a final guideline document is published under §60.22(a), each State shall adopt and submit to the Administrator, in accordance with §60.4 of subpart A of this part, a plan for the control of the designated pollutant to which the guideline document applies.

(2) Within nine months after notice of the availability of a final revised guideline document is published as provided in §60.22(d)(2), each State shall adopt and submit to the Administrator any plan revision necessary to meet the requirements of this subpart.

(b) If no designated facility is located within a State, the State shall submit a letter of certification to that effect to the Administrator within the time specified in paragraph (a) of this section. Such certification shall exempt the State from the requirements of this subpart for that designated pollutant.

(c)(1) Except as provided in paragraphs (c)(2) and (c)(3) of this section, the State shall, prior to the adoption of any plan or revision thereof, conduct one or more public hearings within the State on such plan or plan revision.

(2) No hearing shall be required for any change to an increment of progress in an approved compliance schedule unless the change is likely to cause the facility to be unable to comply with the final compliance date in the schedule.

(3) No hearing shall be required on an emission standard in effect prior to the effective date of this subpart if it was adopted after a public hearing and is at least as stringent as the corresponding emission guideline specified in the applicable guideline document published under §60.22(a).

(d) Any hearing required by paragraph (c) of this section shall be held only after reasonable notice. Notice shall be given at least 30 days prior to the date of such hearing and shall include:

(1) Notification to the public by prominently advertising the date, time, and place of such hearing in each region affected;

(2) Availability, at the time of public announcement, of each proposed plan or revision thereof for public inspection in at least one location in each region to which it will apply;

(3) Notification to the Administrator;

(4) Notification to each local air pollution control agency in each region to which the plan or revision will apply; and

(5) In the case of an interstate region, notification to any other State included in the region.

(e) The State shall prepare and retain, for a minimum of 2 years, a record of each hearing for inspection by any interested party. The record shall contain, as a minimum, a list of witnesses together with the text of each presentation.

(f) The State shall submit with the plan or revision:

(1) Certification that each hearing required by paragraph (c) of this section was held in accordance with the notice required by paragraph (d) of this section; and

(2) A list of witnesses and their organizational affiliations, if any, appearing at the hearing and a brief written summary of each presentation or written submission.

(g) Upon written application by a State agency (through the appropriate Regional Office), the Administrator may approve State procedures designed to insure public participation in the matters for which hearings are required and public notification of the opportunity to participate if, in the judgment of the Administrator, the procedures, although different from the requirements of this subpart, in fact provide for adequate notice to and participation of the public. The Administrator may impose such conditions on his approval as he deems necessary. Procedures approved under this section shall be deemed to satisfy the requirements of this subpart regarding procedures for public hearings.

[40 FR 53346, Nov. 17, 1975, as amended at 60 FR 65414, Dec. 19, 1995]

§ 60.24 Emission standards and compliance schedules.

(a) Each plan shall include emission standards and compliance schedules.

(b)(1) Emission standards shall either be based on an allowance system or prescribe allowable rates of emissions except when it is clearly impracticable.

(2) Test methods and procedures for determining compliance with the emission standards shall be specified in the plan. Methods other than those specified in appendix A to this part may be specified in the plan if shown to be equivalent or alternative methods as defined in §60.2 (t) and (u).

(3) Emission standards shall apply to all designated facilities within the State. A plan may contain emission standards adopted by local jurisdictions provided that the standards are enforceable by the State.

(c) Except as provided in paragraph (f) of this section, where the Administrator has determined that a designated pollutant may cause or contribute to endangerment of public health, emission standards shall be no less stringent than the corresponding emission guideline(s) specified in subpart C of this part, and final compliance shall be required as expeditiously as practicable but no later than the compliance times specified in subpart C of this part.

(d) Where the Administrator has determined that a designated pollutant may cause or contribute to endangerment of public welfare but that adverse effects on public health have not been demonstrated, States may balance the emission guidelines, compliance times, and other information provided in the applicable guideline document against other factors of public concern in establishing emission standards, compliance schedules, and variances. Appropriate consideration shall be given to the factors specified in §60.22(b) and to information presented at the public hearing(s) conducted under §60.23(c).

(e)(1) Any compliance schedule extending more than 12 months from the date required for submittal of the plan must include legally enforceable increments of progress to achieve

compliance for each designated facility or category of facilities. Unless otherwise specified in the applicable subpart, increments of progress must include, where practicable, each increment of progress specified in §60.21(h) and must include such additional increments of progress as may be necessary to permit close and effective supervision of progress toward final compliance.

(2) A plan may provide that compliance schedules for individual sources or categories of sources will be formulated after plan submittal. Any such schedule shall be the subject of a public hearing held according to §60.23 and shall be submitted to the Administrator within 60 days after the date of adoption of the schedule but in no case later than the date prescribed for submittal of the first semiannual report required by §60.25(e).

(f) Unless otherwise specified in the applicable subpart on a case-by-case basis for particular designated facilities or classes of facilities, States may provide for the application of less stringent emissions standards or longer compliance schedules than those otherwise required by paragraph (c) of this section, provided that the State demonstrates with respect to each such facility (or class of facilities):

(1) Unreasonable cost of control resulting from plant age, location, or basic process design;

(2) Physical impossibility of installing necessary control equipment; or

(3) Other factors specific to the facility (or class of facilities) that make application of a less stringent standard or final compliance time significantly more reasonable.

(g) Nothing in this subpart shall be construed to preclude any State or political subdivision thereof from adopting or enforcing (1) emission standards more stringent than emission guidelines specified in subpart C of this part or in applicable guideline documents or (2) compliance schedules requiring final compliance at earlier times than those specified in subpart C or in applicable guideline documents.

(h) Each of the States identified in paragraph (h)(1) of this section shall be subject to the requirements of paragraphs (h)(2) through (7) of this section.

(1) Alaska, Alabama, Arkansas, Arizona, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, Wyoming, and the District of Columbia shall each, and, if approved for treatment as a State under part 49 of this chapter, the Navajo Nation and the Ute Indian Tribe may each, submit a State plan meeting the requirements of paragraphs (h)(2) through (7) of this section and the other applicable requirements for a State plan under this subpart.

(2) The State's State plan under paragraph (h)(1) of this section must be submitted to the Administrator by no later than November 17, 2006. The State shall deliver five copies of the State plan to the appropriate Regional Office, with a letter giving notice of such action.

(3) The State's State plan under paragraph (h)(1) of this section shall contain emission standards and compliance schedules and demonstrate that they will result in compliance with the State's annual electrical generating unit (EGU) mercury (Hg) budget for the appropriate periods. The amount of the annual EGU Hg budget, in tons of Hg per year, shall be as follows, for the indicated State for the indicated period:

State	Annual EGU Hg budget (tons)	
	2010–2017	2018 and thereafter
Alaska	0.010	0.004
Alabama	1.289	0.509
Arkansas	0.516	0.204
Arizona	0.454	0.179
California	0.041	0.016
Colorado	0.706	0.279
Connecticut	0.053	0.021
Delaware	0.072	0.028
Florida	1.232	0.487
Georgia	1.227	0.484
Hawaii	0.024	0.009
Iowa	0.727	0.287
Illinois	1.594	0.629
Indiana	2.097	0.828
Kansas	0.723	0.285
Kentucky	1.525	0.602
Louisiana	0.601	0.237
Massachusetts	0.172	0.068
Maryland	0.490	0.193
Maine	0.001	0.001
Michigan	1.303	0.514
Minnesota	0.695	0.274
Missouri	1.393	0.550
Mississippi	0.291	0.115
Montana	0.377	0.149
Navajo Nation	0.600	0.237
North Carolina	1.133	0.447
North Dakota	1.564	0.617
Nebraska	0.421	0.166
New Hampshire	0.063	0.025
New Jersey	0.153	0.060
New Mexico	0.299	0.118
Nevada	0.285	0.112

State	Annual EGU Hg budget (tons)	
	2010–2017	2018 and thereafter
New York	0.393	0.155
Ohio	2.056	0.812
Oklahoma	0.721	0.285
Oregon	0.076	0.030
Pennsylvania	1.779	0.702
South Carolina	0.580	0.229
South Dakota	0.072	0.029
Tennessee	0.944	0.373
Texas	4.656	1.838
Utah	0.506	0.200
Ute Indian Tribe	0.060	0.024
Virginia	0.592	0.234
Washington	0.198	0.078
Wisconsin	0.890	0.351
West Virginia	1.394	0.550
Wyoming	0.952	0.376
Total	38.000	15.000

(4) Each State plan under paragraph (h)(1) of this section shall require EGUs to comply with the monitoring, record keeping, and reporting provisions of part 75 of this chapter with regard to Hg mass emissions.

(5) In addition to meeting the requirements of §60.26, each State plan under paragraph (h)(1) of this section must show that the State has legal authority to:

(i) Adopt emissions standards and compliance schedules necessary for attainment and maintenance of the State's relevant annual EGU Hg budget under paragraph (h)(3) of this section; and

(ii) Require owners or operators of EGUs in the State to meet the monitoring, record keeping, and reporting requirements described in paragraph (h)(4) of this section.

(6)(i) Notwithstanding the provisions of paragraphs (h)(3) and (5)(i) of this section, if a State adopts regulations substantively identical to subpart HHHH of this part (Hg Budget Trading Program), incorporates such subpart by reference into its regulations, or adopts regulations that differ substantively from such subpart only as set forth in paragraph (h)(6)(ii) of this section, then such allowance system in the State's State plan is automatically approved as meeting the requirements of paragraph (h)(3) of this section, provided that the State demonstrates that it has the legal authority to take such action and to implement its responsibilities under such regulations. Before January 1, 2009, a State's regulations shall be considered to be substantively identical to subpart HHHH of this part, or differing substantively

only as set forth in paragraph (h)(6)(ii) of this section, regardless of whether the State's regulations include the definition of "Biomass", paragraph (3) of the definition of "Cogeneration unit", and the second sentence of the definition of "Total energy input" in §60.4102 of this chapter promulgated on October 19, 2007, provided that the State timely submits to the Administrator a State plan that revises the State's regulations to include such provisions. Submission to the Administrator of a State plan that revises the State's regulations to include such provisions shall be considered timely if the submission is made by January 1, 2010.

(ii) If a State adopts an allowance system that differs substantively from subpart HHHH of this part only as follows, then the emissions trading program is approved as set forth in paragraph (h)(6)(i) of this section.

(A) The State may decline to adopt the allocation provisions set forth in §§60.4141 and 60.4142 and may instead adopt any methodology for allocating Hg allowances.

(B) The State's methodology under paragraph (h)(6)(ii)(A) of this section must not allow the State to allocate Hg allowances for a year in excess of the amount in the State's annual EGU Hg budget for such year under paragraph (h)(3) of this section;

(C) The State's methodology under paragraph (h)(6)(ii)(A) of this section must require that, for EGUs commencing operation before January 1, 2001, the State will determine, and notify the Administrator of, each unit's allocation of Hg allowances by November 17, 2006 for 2010, 2011, and 2012 and by October 31, 2009 and October 31 of each year thereafter for the fourth year after the year of the notification deadline; and

(D) The State's methodology under paragraph (h)(6)(ii)(A) of this section must require that, for EGUs commencing operation on or after January 1, 2001, the State will determine, and notify the Administrator of, each unit's allocation of Hg allowances by October 31 of the year for which the Hg allowances are allocated.

(7) If a State adopts an allowance system that differs substantively from subpart HHHH of this part, other than as set forth in paragraph (h)(6)(ii) of this section, then such allowance system is not automatically approved as set forth in paragraph (h)(6)(i) or (ii) of this section and will be reviewed by the Administrator for approvability in accordance with the other provisions of paragraphs (h)(2) through (5) of this section and the other applicable requirements for a State plan under this subpart, provided that the Hg allowances issued under such allowance system shall not, and the State plan under paragraph (h)(1) of this section shall state that such Hg allowances shall not, qualify as Hg allowances under any allowance system approved under paragraph (h)(6)(i) or (ii) of this section.

(8) The terms used in this paragraph (h) shall have the following meanings:

Administrator means the Administrator of the United States Environmental Protection Agency or the Administrator's duly authorized representative.

Allocate or allocation means, with regard to Hg allowances, the determination of the amount of Hg allowances to be initially credited to a source.

Biomass means—(1) Any organic material grown for the purpose of being converted to energy;

(2) Any organic byproduct of agriculture that can be converted into energy; or

(3) Any material that can be converted into energy and is nonmerchantable for other purposes, that is segregated from other nonmerchantable material, and that is;

(i) A forest-related organic resource, including mill residues, precommercial thinnings, slash, brush, or byproduct from conversion of trees to merchantable material; or

(ii) A wood material, including pallets, crates, dunnage, manufacturing and construction materials (other than pressure-treated, chemically-treated, or painted wood products), and landscape or right-of-way tree trimmings.

Boiler means an enclosed fossil-or other fuel-fired combustion device used to produce heat and to transfer heat to recirculating water, steam, or other medium.

Bottoming-cycle cogeneration unit means a cogeneration unit in which the energy input to the unit is first used to produce useful thermal energy and at least some of the reject heat from the useful thermal energy application or process is then used for electricity production.

Coal means any solid fuel classified as anthracite, bituminous, subbituminous, or lignite by the American Society of Testing and Materials (ASTM) Standard Specification for Classification of Coals by Rank D388–77, 90, 91, 95, 98a, or 99 (Reapproved 2004)ε1 (incorporated by reference, see §60.17).

Coal-derived fuel means any fuel (whether in a solid, liquid, or gaseous state) produced by the mechanical, thermal, or chemical processing of coal.

Coal-fired means combusting any amount of coal or coal-derived fuel, alone or in combination with any amount of any other fuel, during any year.

Cogeneration unit means a stationary, coal-fired boiler or stationary, coal-fired combustion turbine:

(1) Having equipment used to produce electricity and useful thermal energy for industrial, commercial, heating, or cooling purposes through the sequential use of energy; and

(2) Producing during the 12-month period starting on the date the unit first produces electricity and during any calendar year after which the unit first produces electricity:

(i) For a topping-cycle cogeneration unit,

(A) Useful thermal energy not less than 5 percent of total energy output; and

(B) Useful power that, when added to one-half of useful thermal energy produced, is not less then 42.5 percent of total energy input, if useful thermal energy produced is 15 percent or more of total energy output, or not less than 45 percent of total energy input, if useful thermal energy produced is less than 15 percent of total energy output.

(ii) For a bottoming-cycle cogeneration unit, useful power not less than 45 percent of total energy input;

(3) Provided that the total energy input under paragraphs (2)(i)(B) and (2)(ii) of this definition shall equal the unit's total energy input from all fuel except biomass if the unit is a boiler.

Combustion turbine means:

(1) An enclosed device comprising a compressor, a combustion, and a turbine and in which the flue gas resulting from the combustion of fuel in the combustion passes through the turbine, rotating the turbine; and

(2) If the enclosed device under paragraph (1) of this definition is combined cycle, any associated heat recovery steam generator and steam turbine.

Commence operation means to have begun any mechanical, chemical, or electronic process, including, with regard to a unit, start-up of a unit's combustion chamber.

Electric generating unit or EGU means:

(1)(i) Except as provided in paragraphs (2) and (3) of this definition, a stationary, coal-fired boiler or stationary, coal-fired combustion turbine in the State serving at any time, since the later of November 15, 1990 or the start-up of the unit's combustion chamber, a generator with nameplate capacity of more than 25 megawatts electric (MWe) producing electricity for sale.

(ii) If a stationary boiler or stationary combustion turbine that, under paragraph (1)(i) of this definition, is not an electric generating unit begins to combust coal or coal-derived fuel or to serve a generator with nameplate capacity of more than 25 MWe producing electricity for sale, the unit shall become an electric generating unit as provided in paragraph (1)(i) of this definition on the first date on which it both combusts coal or coal-derived fuel and serves such generator.

(2) A unit that meets the requirements set forth in paragraph (2)(i)(A) of this definition shall not be an electric generating unit:

(i)(A) A unit that is an electric generating unit under paragraph (1)(i) or (ii) of this definition:

(1) Qualifying as a cogeneration unit during the 12-month period starting on the date the unit first produces electricity and continuing to qualify as a cogeneration unit; and

(2) Not serving at any time, since the later of November 15, 1990 or the start-up of the unit's combustion chamber, a generator with nameplate capacity of more than 25 MWe supplying in any calendar year more than one-third of the unit's potential electric output capacity or 219,000 megawatt-hours (MWh), whichever is greater, to any utility power distribution system for sale.

(B) If a unit qualifies as a cogeneration unit during the 12-month period starting on the date the unit first produces electricity and meets the requirements of paragraph (2)(i)(A) of this definition for at least one calendar year, but subsequently no longer meets all such requirements, the unit shall become an electric generating unit starting on the earlier of January 1 after the first calendar year during which the unit first no longer qualifies as a cogeneration unit or January 1 after the first calendar year during which the unit no longer meets the requirements of paragraph (2)(i)(A)(2) of this definition.

(3) A "solid waste incineration unit" as defined in Clean Air Act section 129(g)(1) combusting "municipal waste" as defined in Clean Air Act section 129(g)(5) shall not be an electric generating unit if it is subject to one of the following rules:

(i) An EPA-approved State plan for implementing subpart Cb of part 60 of this chapter, "Emissions Guidelines and Compliance Times for Large Municipal Waste Combustors That Are Constructed On or Before September 20, 1994";

(ii) Subpart Eb of part 60 of this chapter, "Standards of Performance for Large Municipal Waste Combustors for Which Construction is Commenced After September 20, 1994 or for Which Modification or Reconstruction is Commenced After June 19, 1996";

(iii) Subpart AAAA of part 60 of this chapter, "Standards of Performance for Small Municipal Waste Combustors for Which Construction is Commenced After August 30, 1999 or for Which Modification or Reconstruction is Commenced After June 6, 2001";

(iv) An EPA-approved State Plan for implementing subpart BBBB of part 60 of this chapter, "Emission Guidelines and Compliance Times for Small Municipal Waste Combustion Units Constructed On or Before August 30, 1999";

(v) Subpart FFF of part 62 of this chapter, "Federal Plan Requirements for Large Municipal Waste Combustors Constructed On or Before September 20, 1994; or

(vi) Subpart JJJ of 40 CFR part 62, "Federal Plan Requirements for Small Municipal Waste Combustion Units Constructed On or Before August 30, 1999".

Generator means a device that produces electricity.

Gross electrical output means, with regard to a cogeneration unit, electricity made available for use, including any such electricity used in the power production process (which process includes, but is not limited to, any on-site processing or treatment of fuel combusted at the unit and any on-site emission controls).

Gross thermal energy means, with regard to a cogeneration unit, useful thermal energy output plus, where such output is made available for an industrial or commercial process, any heat contained in condensate return or makeup water.

Heat input means, with regard to a specified period of time, the product (in million British thermal units per unit time, MMBTU/time) of the gross calorific value of the fuel (in Btu per pound, Btu/lb) divided by 1,000,000 Btu/MMBTU and multiplied by the fuel feed rate into a combustion device (in lb of fuel/time), as measured, recorded, and reported to the Administrator by the Hg designated representative and determined by the Administrator in accordance with §§60.4170 through 60.4176 and excluding the heat derived from preheated combustion air, reticulated flue gases, or exhaust from other sources.

Hg allowance means a limited authorization issued by the permitting authority to emit one ounce of Hg during a control period of the specified calendar year for which the authorization is allocated or of any calendar year thereafter.

Life-of-the-unit, firm power contractual arrangement means a unit participation power sales agreement under which a customer reserves, or is entitled to receive, a specified amount or percentage of nameplate capacity and associated energy generated by any specified unit and pays its proportional amount of such unit's total costs, pursuant to a contract:

(1) For the life of the unit;

(2) For a cumulative term of no less than 30 years, including contracts that permit an election for early termination; or

(3) For a period no less than 25 years or 70 percent of the economic useful life of the unit determined as of the time the unit is built, with option rights to purchase or release some portion of the nameplate capacity and associated energy generated by the unit at the end of the period.

Maximum design heat input means, starting from the initial installation of a unit, the maximum amount of fuel per hour (in Btu/hr) that a unit is capable of combusting on a steady-state basis as specified by the manufacturer of the unit, or, starting from the completion of any subsequent physical change in the unit resulting in a decrease in the maximum amount of fuel per hour (in Btu per hour, Btu/hr) that a unit is capable of combusting on a steady-state basis, such decreased maximum amount as specified by the person conducting the physical change.

Nameplate capacity means, starting from the initial installation of a generator, the maximum electrical generating output (in MW) that the generator is capable of producing on a steady-state basis and during continuous operation (when not restricted by seasonal or other derates) as specified by the manufacturer of the generator or, starting from the completion of any subsequent physical change in the generator resulting in an increase in the maximum electrical generating output (in MW) that the generator is capable of producing on a steady-state basis and during continuous operation (when not restricted by seasonal or other derates), such increased maximum amount as specified by the person conducting the physical change.

Operator means any person who operates, controls, or supervises an EGU or a source that includes an EGU and shall include, but not be limited to, any holding company, utility system, or plant manager of such EGU or source.

Ounce means 2.84 × 107 micrograms.

Owner means any of the following persons:

(1) With regard to a Hg Budget source or a Hg Budget unit at a source, respectively:

(i) Any holder of any portion of the legal or equitable title in a Hg Budget unit at the source or the Hg Budget unit;

(ii) Any holder of a leasehold interest in a Hg Budget unit at the source or the Hg Budget unit; or

(iii) Any purchaser of power from a Hg Budget unit at the source or the Hg Budget unit under a life-of-the-unit, firm power contractual arrangement; provided that, unless expressly provided for in a leasehold agreement, owner shall not include a passive lessor, or a person who has an equitable interest through such lessor, whose rental payments are not based (either directly or indirectly) on the revenues or income from such Hg Budget unit; or

(2) With regard to any general account, any person who has an ownership interest with respect to the Hg allowances held in the general account and who is subject to the binding agreement for the Hg authorized account representative to represent the person's ownership interest with respect to Hg allowances.

Potential electrical output capacity means 33 percent of a unit's maximum design heat input, divided by 3,413 Btu per kilowatt-hour (Btu/kWh), divided by 1,000 kWh per megawatt-hour (kWh/MWh), and multiplied by 8,760 hr/yr.

Sequential use of energy means:

(1) For a topping-cycle cogeneration unit, the use of reject heat from electricity production in a useful thermal energy application or process; or

(2) For a bottoming-cycle cogeneration unit, the use of reject heat from useful thermal energy application or process in electricity production.

Source means all buildings, structures, or installations located in one or more contiguous or adjacent properties under common control of the same person or persons.

State means:

(1) For purposes of referring to a governing entity, one of the States in the United States, the District of Columbia, or, if approved for treatment as a State under part 49 of this chapter, the Navajo Nation or Ute Indian Tribe that adopts the Hg Budget Trading Program pursuant to §60.24(h)(6); or

(2) For purposes of referring to a geographic area, one of the States in the United States, the District of Columbia, the Navajo Nation Indian country, or the Ute Tribe Indian country.

Topping-cycle cogeneration unit means a cogeneration unit in which the energy input to the unit is first used to produce useful power, including electricity, and at least some of the reject heat from the electricity production is then used to provide useful thermal energy.

Total energy input means, with regard to a cogeneration unit, total energy of all forms supplied to the cogeneration unit, excluding energy produced by the cogeneration unit itself. Each form of energy supplied shall be measured by the lower heating value of that form of energy calculated as follows:

$$LHV = HHV - 10.55(W + 9H)$$

Where:
LHV = lower heating value of fuel in Btu/lb,
HHV = higher heating value of fuel in Btu/lb,
W = Weight % of moisture in fuel, and
H = Weight % of hydrogen in fuel.

Total energy output means, with regard to a cogeneration unit, the sum of useful power and useful thermal energy produced by the cogeneration unit.

Unit means a stationary coal-fired boiler or a stationary coal-fired combustion turbine.

Useful power means, with regard to a cogeneration unit, electricity or mechanical energy made available for use, excluding any such energy used in the power production process (which

process includes, but is not limited to, any on-site processing or treatment of fuel combusted at the unit and any on-site emission controls).

Useful thermal energy means, with regard to a cogeneration unit, thermal energy that is:

(1) Made available to an industrial or commercial process (not a power production process), excluding any heat contained in condensate return or makeup water;

(2) Used in a heat application (e.g. , space heating or domestic hot water heating); or

(3) Used in a space cooling application (i.e. , thermal energy used by an absorption chiller).

Utility power distribution system means the portion of an electricity grid owned or operated by a utility and dedicated to delivering electricity to customers.

[40 FR 53346, Nov. 17, 1975, as amended at 60 FR 65414, Dec. 19, 1995; 65 FR 76384, Dec. 6, 2000; 70 FR 28649, May 18, 2005; 71 FR 33398, June 9, 2006; 72 FR 59204, Oct. 19, 2007]

§ 60.25 Emission inventories, source surveillance, reports.

(a) Each plan shall include an inventory of all designated facilities, including emission data for the designated pollutants and information related to emissions as specified in appendix D to this part. Such data shall be summarized in the plan, and emission rates of designated pollutants from designated facilities shall be correlated with applicable emission standards. As used in this subpart, "correlated" means presented in such a manner as to show the relationship between measured or estimated amounts of emissions and the amounts of such emissions allowable under applicable emission standards.

(b) Each plan shall provide for monitoring the status of compliance with applicable emission standards. Each plan shall, as a minimum, provide for:

(1) Legally enforceable procedures for requiring owners or operators of designated facilities to maintain records and periodically report to the State information on the nature and amount of emissions from such facilities, and/or such other information as may be necessary to enable the State to determine whether such facilities are in compliance with applicable portions of the plan. Submission of electronic documents shall comply with the requirements of 40 CFR part 3—(Electronic reporting).

(2) Periodic inspection and, when applicable, testing of designated facilities.

(c) Each plan shall provide that information obtained by the State under paragraph (b) of this section shall be correlated with applicable emission standards (see §60.25(a)) and made available to the general public.

(d) The provisions referred to in paragraphs (b) and (c) of this section shall be specifically identified. Copies of such provisions shall be submitted with the plan unless:

(1) They have been approved as portions of a preceding plan submitted under this subpart or as portions of an implementation plan submitted under section 110 of the Act, and

(2) The State demonstrates:

(i) That the provisions are applicable to the designated pollutant(s) for which the plan is submitted, and

(ii) That the requirements of §60.26 are met.

(e) The State shall submit reports on progress in plan enforcement to the Administrator on an annual (calendar year) basis, commencing with the first full report period after approval of a plan or after promulgation of a plan by the Administrator. Information required under this paragraph must be included in the annual report required by §51.321 of this chapter.

(f) Each progress report shall include:

(1) Enforcement actions initiated against designated facilities during the reporting period, under any emission standard or compliance schedule of the plan.

(2) Identification of the achievement of any increment of progress required by the applicable plan during the reporting period.

(3) Identification of designated facilities that have ceased operation during the reporting period.

(4) Submission of emission inventory data as described in paragraph (a) of this section for designated facilities that were not in operation at the time of plan development but began operation during the reporting period.

(5) Submission of additional data as necessary to update the information submitted under paragraph (a) of this section or in previous progress reports.

(6) Submission of copies of technical reports on all performance testing on designated facilities conducted under paragraph (b)(2) of this section, complete with concurrently recorded process data.

[40 FR 53346, Nov. 17, 1975, as amended at 44 FR 65071, Nov. 9, 1979; 70 FR 59887, Oct. 13, 2005]

§ 60.26 Legal authority.

(a) Each plan shall show that the State has legal authority to carry out the plan, including authority to:

(1) Adopt emission standards and compliance schedules applicable to designated facilities.

(2) Enforce applicable laws, regulations, standards, and compliance schedules, and seek injunctive relief.

(3) Obtain information necessary to determine whether designated facilities are in compliance with applicable laws, regulations, standards, and compliance schedules, including authority to require recordkeeping and to make inspections and conduct tests of designated facilities.

(4) Require owners or operators of designated facilities to install, maintain, and use emission monitoring devices and to make periodic reports to the State on the nature and amounts of emissions from such facilities; also authority for the State to make such data available to the public as reported and as correlated with applicable emission standards.

(b) The provisions of law or regulations which the State determines provide the authorities required by this section shall be specifically identified. Copies of such laws or regulations shall be submitted with the plan unless:

(1) They have been approved as portions of a preceding plan submitted under this subpart or as portions of an implementation plan submitted under section 110 of the Act, and

(2) The State demonstrates that the laws or regulations are applicable to the designated pollutant(s) for which the plan is submitted.

(c) The plan shall show that the legal authorities specified in this section are available to the State at the time of submission of the plan. Legal authority adequate to meet the requirements of paragraphs (a)(3) and (4) of this section may be delegated to the State under section 114 of the Act.

(d) A State governmental agency other than the State air pollution control agency may be assigned responsibility for carrying out a portion of a plan if the plan demonstrates to the Administrator's satisfaction that the State governmental agency has the legal authority necessary to carry out that portion of the plan.

(e) The State may authorize a local agency to carry out a plan, or portion thereof, within the local agency's jurisdiction if the plan demonstrates to the Administrator's satisfaction that the local agency has the legal authority necessary to implement the plan or portion thereof, and that the authorization does not relieve the State of responsibility under the Act for carrying out the plan or portion thereof.

§ 60.27 Actions by the Administrator.

(a) The Administrator may, whenever he determines necessary, extend the period for submission of any plan or plan revision or portion thereof.

(b) After receipt of a plan or plan revision, the Administrator will propose the plan or revision for approval or disapproval. The Administrator will, within four months after the date required for submission of a plan or plan revision, approve or disapprove such plan or revision or each portion thereof.

(c) The Administrator will, after consideration of any State hearing record, promptly prepare and publish proposed regulations setting forth a plan, or portion thereof, for a State if:

(1) The State fails to submit a plan within the time prescribed;

(2) The State fails to submit a plan revision required by §60.23(a)(2) within the time prescribed; or

(3) The Administrator disapproves the State plan or plan revision or any portion thereof, as unsatisfactory because the requirements of this subpart have not been met.

(d) The Administrator will, within six months after the date required for submission of a plan or plan revision, promulgate the regulations proposed under paragraph (c) of this section with such modifications as may be appropriate unless, prior to such promulgation, the State has adopted and submitted a plan or plan revision which the Administrator determines to be approvable.

(e)(1) Except as provided in paragraph (e)(2) of this section, regulations proposed and promulgated by the Administrator under this section will prescribe emission standards of the same stringency as the corresponding emission guideline(s) specified in the final guideline document published under §60.22(a) and will require final compliance with such standards as expeditiously as practicable but no later than the times specified in the guideline document.

(2) Upon application by the owner or operator of a designated facility to which regulations proposed and promulgated under this section will apply, the Administrator may provide for the application of less stringent emission standards or longer compliance schedules than those otherwise required by this section in accordance with the criteria specified in §60.24(f).

(f) Prior to promulgation of a plan under paragraph (d) of this section, the Administrator will provide the opportunity for at least one public hearing in either:

(1) Each State that failed to hold a public hearing as required by §60.23(c); or

(2) Washington, DC or an alternate location specified in the Federal Register.

[40 FR 53346, Nov. 17, 1975, as amended at 65 FR 76384, Dec. 6, 2000]

§ 60.28 Plan revisions by the State.

(a) Plan revisions which have the effect of delaying compliance with applicable emission standards or increments of progress or of establishing less stringent emission standards shall be submitted to the Administrator within 60 days after adoption in accordance with the procedures and requirements applicable to development and submission of the original plan.

(b) More stringent emission standards, or orders which have the effect of accelerating compliance, may be submitted to the Administrator as plan revisions in accordance with the procedures and requirements applicable to development and submission of the original plan.

(c) A revision of a plan, or any portion thereof, shall not be considered part of an applicable plan until approved by the Administrator in accordance with this subpart.

§ 60.29 Plan revisions by the Administrator.

After notice and opportunity for public hearing in each affected State, the Administrator may revise any provision of an applicable plan if:

(a) The provision was promulgated by the Administrator, and

(b) The plan, as revised, will be consistent with the Act and with the requirements of this subpart.

Appendix J

40 CFR Part 62 Subpart A

APPENDIX J--40 CFR PART 62 SUBPART A

Note: CFR text for 40 CFR Part 62 subpart A accessed Jul. 13, 2010 at e-CFR web site: http://ecfr.gpoaccess.gov.

PART 62—APPROVAL AND PROMULGATION OF STATE PLANS FOR DESIGNATED FACILITIES AND POLLUTANTS

Subpart A—General Provisions

§ 62.01 Definitions.

As used in this part, all terms not defined herein shall have the meaning given to them in the Clean Air Act and in part 60 of this chapter.

§ 62.02 Introduction.

(a) This part sets forth the Administrator's approval and disapproval of State plans for the control of pollutants and facilities under section 111(d), and section 129 as applicable, of the Act, and the Administrator's promulgation of such plans or portions of plans thereof. Approval of a plan or any portion of a plan is based on a determination by the Administrator that it meets the requirements of section 111(d), and section 129 as applicable, of the Act and provisions of part 60 of this chapter.

(b)(1) If a State does not submit a complete, approvable plan, the Administrator may then promulgate a substitute plan or part of a plan. The promulgated provision, plus the approved parts of the State plan, constitute the applicable plan for purposes of the act.

(2) The part 60 subpart A of this chapter general provisions and appendices to part 60 apply to part 62, except as follows: 40 CFR 60.7(a)(1), 60.7(a)(3), and 60.8(a) and where special provisions set forth under the applicable subpart of this part shall apply instead of any conflicting provisions.

(c) The Administrator will promulgate substitute provisions for the disapproved regulatory provisions only. If a nonregulatory provision is disapproved, however, it will be noted in this part and a detailed explanation will be sent to the State.

(d) All approved regulatory provisions of each plan are incorporated by reference in this part. Section 62.12 provides information on availability of applicable plans. The Administrator and State and local agencies shall enforce (1) regulatory provisions of a plan approved or promulgated by the Administrator, and (2) all permit conditions or denials issued in carrying out the approved or promulgated regulations for the review of designated facilities.

(e) Each State's plan is dealt with in a separate subpart, with separate headings for different pollutants and facilities. The plans shall include an introductory section identifying the plan by name and the date of its submittal. Additional sections are included as necessary to specifically identify disapproved provisions, to set forth reasons for disapproval, and to set forth provisions of the plan promulgated by the Administrator. Except as otherwise specified, all supplemental information submitted to the Administrator with respect to any plan has been submitted by the Governor of the State.

(f) Revisions to applicable plans will be included in this part when approved or promulgated by the Administrator.

(g) Substitute plans promulgated by the Administrator for States that do not have approved plans are contained in separate subparts that appear after the subparts for States. These

Federal plans include sections identifying the applicability of the plan, emission limits, compliance schedules, recordkeeping and reporting, performance testing, and monitoring requirements.
[43 FR 51393, Nov. 3, 1978, as amended at 63 FR 63201, Nov. 12, 1998; 68 FR 5158, Jan. 31, 2003]

§ 62.03 Extensions.

The Administrator may, whenever he determines necessary, extend the period for submission of any plan or plan revision or portion thereof.

§ 62.04 Approval status.

The approval status of each State's plan or portions thereof, are set forth in each subpart. All plans are approved unless specifically disapproved in the appropriate subpart.

§ 62.05 Legal authority.

(a) The Administrator's determination of the absence or inadequacy of legal authority required to be included in the plan is set forth in each subpart. This includes the legal authority of local agencies and State governmental agencies other than an air pollution control agency if such other agencies are assigned responsibility for carrying out a plan or portion thereof.

(b) No legal authority as such is promulgated by the Administrator. Where required regulatory provisions are not included in the plan by the State because of inadequate authority, substitute provisions are promulgated by the Administrator.

§ 62.06 Negative declarations.

A State may submit to the Administrator a letter certifying that no designated facilities exist in the State if such is the case. The negative declaration will be in lieu of a plan.

§ 62.07 Emission standards, compliance schedules.

(a) In each subpart, emission standards and compliance schedules which have been disapproved by the Administrator are identified, and those promulgated by the Administrator are set forth.

(b) The Administrator's approval or promulgation of any compliance schedule shall not affect the responsibility of the owner or operator to comply with any applicable emission limitation on or after the date for final compliance specified in the applicable schedule.

§ 62.08 Emission inventories and source surveillance.

(a) Each subpart identifies the plan provisions for source surveillance which are disapproved, and sets forth the Administrator's promulgation of necessary provisions for requiring designated sources to maintain records, make reports, and submit information.

(b) The Administrator will not promulgate provisions for disapproved State or local agency procedures for testing, inspection, investigation, or detection. However, detailed critiques of such portions will be provided to the State.

§ 62.09 Revision of plans by Administrator.

After notice and opportunity for public hearing in each affected State, the Administrator may revise any provision of an applicable plan if:

(a) The provision was promulgated by the Administrator and

(b) The plan, as revised, will be consistent with the Act and with the requirements of part 60, subpart B of this chapter.

§ 62.10 Submission to Administrator.

Except as otherwise provided in §60.23 of this chapter, all requests, reports, applications, submittals, and other communications to the Administrator pursuant to this part shall be submitted in duplicate and addressed to the appropriate Regional Office of the Environmental Protection Agency, to the attention of the Director, Air and Hazardous Materials Division (Environmental Programs Division in Region II). The Regional Offices are as follows:

Region and jurisdiction covered	Address
I—Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont	JFK Federal Building, Boston, Mass. 02203.
II—New York, New Jersey, Puerto Rico, Virgin Islands	Federal Office Building, 26 Federal Plaza, New York, N.Y. 10007.
III—Delaware, District of Columbia, Maryland, Pennsylvania, Virginia, West Virginia	Air Protection Division, Mail Code 3AP00, 1650 Arch Street, Philadelphia, PA 19103–1129.
IV—Alabama, Florida, Georgia, Mississippi, Kentucky, North Carolina, South Carolina, Tennessee	345 Courtland NE., Atlanta, Ga. 30308.
V—Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin	Mail Code A–17J, 77 West Jackson Blvd., Chicago, Il 60604–3590.
VI—Arkansas, Louisiana, New Mexico, Oklahoma, Texas	1st International Building, 1201 Elm St., Dallas, Tex. 75270.
VII—Iowa, Kansas, Missouri, Nebraska	Air, RCRA, and Toxics Division, 901 N. 5th Street, Kansas City, KS 66101.
VIII—Colorado, Montana, North Dakota, South Dakota, Utah, Wyoming	Director, Air Program, Office of Partnerships and Regulatory Assistance, Mail Code 8P–AR, 1595 Wynkoop Street, Denver, CO 80202–1129.
IX—Arizona, California, Hawaii, Nevada, Guam, American Samoa	215 Fremont St., San Francisco, Calif. 94105.
X—Washington, Oregon, Idaho, Alaska	1200 6th Ave., Seattle, Wash. 98101.

[43 FR 51393, Nov. 3, 1978, as amended at 62 FR 1834, Jan. 14, 1997; 68 FR 35729, June 17, 2003; 73 FR 24871, May 6, 2008; 74 FR 66923, Dec. 17, 2009]

§ 62.11 Severability.

The provisions promulgated in this part and the various applications thereof are distinct and severable. If any provision of this part or the application thereof to any person or circumstances is held invalid, such invalidity shall not affect other provisions or application of such provision to other persons or circumstances which can be given effect without the invalid provision or application.

§ 62.12 Availability of applicable plans.

Copies of the applicable plans will be available for public inspection at the following locations:

(a) The offices of the Directors, Air and Hazardous Materials Divisions at EPA Regional Offices I, III–X, and the Director, Environmental Programs Division at EPA Regional Office II. The addresses and jurisdictions covered by these appear in §62.10.

(b) Public Information Reference Unit, Library Systems Branch, EPA (PM 213), 401 M St., SW., Washington, DC 20460.

§ 62.13 Federal plans.

The Federal plans apply to owners and operators of affected facilities that are not covered by an EPA approved and currently effective State or Tribal plan. This Federal plan, or portions thereof, also applies to each affected facility located in any State or portion of Indian country whose approved State or Tribal plan for that area is subsequently vacated in whole or in part. Affected facilities are defined in each Federal plan.

(a) The substantive requirements of the municipal waste combustor Federal plan are contained in subpart FFF of this part. These requirements include emission limits, compliance schedules, testing, monitoring, and reporting and recordkeeping requirements.

(b) The substantive requirements of the municipal solid waste landfills Federal plan are contained in subpart GGG of this part. These requirements include emission limits, compliance schedules, testing, monitoring, and reporting and recordkeeping requirements.

(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.

(d) The substantive requirements of the commercial and industrial solid waste incineration units Federal plan are contained in subpart III of this part. These requirements include emission limits, compliance schedules, testing, monitoring, and reporting and recordkeeping requirements.

(e) The substantive requirements of the small municipal waste combustion unit Federal plan are contained in subpart JJJ of this part. These requirements include emission limits, compliance schedules, testing, monitoring, and reporting and recordkeeping requirements.

[63 FR 63201, Nov. 12, 1998, as amended at 65 FR 49881, Aug. 15, 2000; 68 FR 5158, Jan. 31, 2003; 68 FR 57539, Oct. 3, 2003]

Appendix K

40 CFR Part 60 Subparts Ce (EG) and Ec (NSPS)

K1 40 CFR Part 60 Subpart Ce
K2 40 CFR Part 60 Subpart Ec

Appendix K1

40 CFR Part 60 Subpart Ce

APPENDIX K1--40 CFR PART 60 SUBPART Ce

Note: CFR text for 40 CFR Part 60 subpart Ce accessed Apr. 30, 2010 at e-CFR web site: http://ecfr.gpoaccess.gov.

Subpart Ce—Emission Guidelines and Compliance Times for Hospital/Medical/Infectious Waste Incinerators

Source: 62 FR 48379, Sept. 15, 1997, unless otherwise noted.

§ 60.30e Scope.

This subpart contains emission guidelines and compliance times for the control of certain designated pollutants from hospital/medical/infectious waste incinerator(s) (HMIWI) in accordance with sections 111 and 129 of the Clean Air Act and subpart B of this part. The provisions in these emission guidelines supersede the provisions of §60.24(f) of subpart B of this part.

§ 60.31e Definitions.

Terms used but not defined in this subpart have the meaning given them in the Clean Air Act and in subparts A, B, and Ec of this part.

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 (incorporated by reference, see §60.17).

§ 60.32e Designated facilities.

(a) Except as provided in paragraphs (b) through (h) of this section, the designated facility to which the guidelines apply is each individual HMIWI:

(1) For which construction was commenced on or before June 20, 1996, or for which modification was commenced on or before March 16, 1998.

(2) For which construction was commenced after June 20, 1996 but no later than December 1, 2008, or for which modification is commenced after March 16, 1998 but no later than April 6, 2010.

(b) A combustor is not subject to this subpart during periods when only pathological waste, low-level radioactive waste, and/or chemotherapeutic waste (all defined in §60.51c) is burned, provided the owner or operator of the combustor:

(1) Notifies the Administrator of an exemption claim; and

(2) Keeps records on a calendar quarter basis of the periods of time when only pathological waste, low-level radioactive waste, and/or chemotherapeutic waste is burned.

(c) Any co-fired combustor (defined in §60.51c) is not subject to this subpart if the owner 60.32or operator of the co-fired combustor:

(1) Notifies the Administrator of an exemption claim;

(2) Provides an estimate of the relative weight of hospital waste, medical/infectious waste, and other fuels and/or wastes to be combusted; and

(3) Keeps 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.

(d) Any combustor required to have a permit under Section 3005 of the Solid Waste Disposal Act is not subject to this subpart.

(e) Any combustor which meets the applicability requirements under subpart Cb, Ea, or Eb of this part (standards or guidelines for certain municipal waste combustors) is not subject to this subpart.

(f) Any pyrolysis unit (defined in §60.51c) is not subject to this subpart.

(g) Cement kilns firing hospital waste and/or medical/infectious waste are not subject to this subpart.

(h) Physical or operational changes made to an existing HMIWI unit solely for the purpose of complying with emission guidelines under this subpart are not considered a modification and do not result in an existing HMIWI unit becoming subject to the provisions of subpart Ec (see §60.50c).

(i) Beginning September 15, 2000, or on the effective date of an EPA approved operating permit program under Clean Air Act title V and the implementing regulations under 40 CFR part 70 in the State in which the unit is located, whichever date is later, designated facilities subject to this subpart shall operate pursuant to a permit issued under the EPA-approved operating permit program.

(j) The requirements of this subpart as promulgated on September 15, 1997, shall apply to the designated facilities defined in paragraph (a)(1) of this section until the applicable compliance date of the requirements of this subpart, as amended on October 6, 2009. Upon the compliance date of the requirements of this subpart, designated facilities as defined in paragraph (a)(1) of this section are no longer subject to the requirements of this subpart, as promulgated on September 15, 1997, but are subject to the requirements of this subpart, as amended on October 6, 2009.

[60 FR 65414, Dec. 19, 1995, as amended at 74 FR 51402, Oct. 6, 2009]

§ 60.33e Emissions guidelines.

(a) For approval, a State plan shall include the requirements for emissions limits at least as protective as the following requirements, as applicable:

(1) For a designated facility as defined in §60.32e(a)(1) subject to the emissions guidelines as promulgated on September 15, 1997, the requirements listed in Table 1A of this subpart, except as provided in paragraph (b) of this section.

(2) For a designated facility as defined in §60.32e(a)(1) subject to the emissions guidelines as amended on October 6, 2009, the requirements listed in Table 1B of this subpart, except as provided in paragraph (b) of this section.

(3) For a designated facility as defined in §60.32e(a)(2), the more stringent of the requirements listed in Table 1B of this subpart and Table 1A of subpart Ec of this part.

(b) For approval, a State plan shall include the requirements for emissions limits for any small HMIWI constructed on or before June 20, 1996, which is located more than 50 miles from the boundary of the nearest Standard Metropolitan Statistical Area (defined in §60.31e) and which burns less than 2,000 pounds per week of hospital waste and medical/infectious waste that are at least as protective as the requirements in paragraphs (b)(1) and (b)(2) of this section, as applicable. The 2,000 lb/week limitation does not apply during performance tests.

(1) For a designated facility as defined in §60.32e(a)(1) subject to the emissions guidelines as promulgated on September 15, 1997, the requirements listed in Table 2A of this subpart.

(2) For a designated facility as defined in §60.32e(a)(1) subject to the emissions guidelines as amended on October 6, 2009, the requirements listed in Table 2B of this subpart.

(c) For approval, a State plan shall include the requirements for stack opacity at least as protective as the following, as applicable:

(1) For a designated facility as defined in §60.32e(a)(1) subject to the emissions guidelines as promulgated on September 15, 1997, the requirements in §60.52c(b)(1) of subpart Ec of this part.

(2) For a designated facility as defined in §60.32e(a)(1) subject to the emissions guidelines as amended on October 6, 2009 and a designated facility as defined in §60.32e(a)(2), the requirements in §60.52c(b)(2) of subpart Ec of this part.

[74 FR 51403, Oct. 6, 2009]

§ 60.34e Operator training and qualification guidelines.

For approval, a State plan shall include the requirements for operator training and qualification at least as protective as those requirements listed in §60.53c of subpart Ec of this part. The State plan shall require compliance with these requirements according to the schedule specified in §60.39e(e).

§ 60.35e Waste management guidelines.

For approval, a State plan shall include the requirements for a waste management plan at least as protective as those requirements listed in §60.55c of subpart Ec of this part.

§ 60.36e Inspection guidelines.

(a) For approval, a State plan shall require each small HMIWI subject to the emissions limits under §60.33e(b) and each HMIWI subject to the emissions limits under §60.33e(a)(2) and (a)(3) to undergo an initial equipment inspection that is at least as protective as the following within 1 year following approval of the State plan:

(1) At a minimum, an inspection shall include the following:

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

(ii) Ensure proper adjustment of primary and secondary chamber combustion air, and adjust as necessary;

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

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

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

(vi) Inspect motors for proper operation;

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

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

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

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

(xi) Visually inspect waste bed (grates), and repair/seal, as appropriate;

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

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

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

(xv) Inspect bypass stack components;

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

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

(2) Within 10 operating days following an equipment inspection all necessary repairs shall be completed unless the owner or operator obtains written approval from the State agency establishing a date whereby all necessary repairs of the designated facility shall be completed.

(b) For approval, a State plan shall require each small HMIWI subject to the emissions limits under §60.33e(b) and each HMIWI subject to the emissions limits under §60.33e(a)(2) and (a)(3) to undergo an equipment inspection annually (no more than 12 months following the previous annual equipment inspection), as outlined in paragraph (a) of this section.

(c) For approval, a State plan shall require each small HMIWI subject to the emissions limits under §60.33e(b)(2) and each HMIWI subject to the emissions limits under §60.33e(a)(2) and (a)(3) to undergo an initial air pollution control device inspection, as applicable, that is at least as protective as the following within 1 year following approval of the State plan:

(1) At a minimum, an inspection shall include the following:

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

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

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

(2) Within 10 operating days following an air pollution control device inspection, all necessary repairs shall be completed unless the owner or operator obtains written approval from the State agency establishing a date whereby all necessary repairs of the designated facility shall be completed.

(d) For approval, a State plan shall require each small HMIWI subject to the emissions limits under §60.33e(b)(2) and each HMIWI subject to the emissions limits under §60.33e(a)(2) and (a)(3) to undergo an air pollution control device inspection, as applicable, annually (no more than 12 months following the previous annual air pollution control device inspection), as outlined in paragraph (c) of this section.

[60 FR 65414, Dec. 19, 1995, as amended at 74 FR 51403, Oct. 6, 2009]

§ 60.37e Compliance, performance testing, and monitoring guidelines.

(a) Except as provided in paragraph (b) of this section, for approval, a State plan shall include the requirements for compliance and performance testing listed in §60.56c of subpart Ec of this part, with the following exclusions:

(1) For a designated facility as defined in §60.32e(a)(1) subject to the emissions limits in §60.33e(a)(1), the test methods listed in §60.56c(b)(7) and (8), the fugitive emissions testing requirements under §60.56c(b)(14) and (c)(3), the CO CEMS requirements under §60.56c(c)(4), and the compliance requirements for monitoring listed in §60.56c(c)(5)(ii) through (v), (c)(6), (c)(7), (e)(6) through (10), (f)(7) through (10), (g)(6) through (10), and (h).

(2) For a designated facility as defined in §60.32e(a)(1) and (a)(2) subject to the emissions limits in §60.33e(a)(2) and (a)(3), the annual fugitive emissions testing requirements under §60.56c(c)(3), the CO CEMS requirements under §60.56c(c)(4), and the compliance requirements for monitoring listed in §60.56c(c)(5)(ii) through (v), (c)(6), (c)(7), (e)(6) through (10), (f)(7) through (10), and (g)(6) through (10). Sources subject to the emissions limits under §60.33e(a)(2) and (a)(3) may, however, elect to use CO CEMS as specified under §60.56c(c)(4) or bag leak detection systems as specified under §60.57c(h).

(b) Except as provided in paragraphs (b)(1) and (b)(2) of this section, for approval, a State plan shall require each small HMIWI subject to the emissions limits under §60.33e(b) to meet the performance testing requirements listed in §60.56c of subpart Ec of this part. The 2,000 lb/week limitation under §60.33e(b) does not apply during performance tests.

(1) For a designated facility as defined in §60.32e(a)(1) subject to the emissions limits under §60.33e(b)(1), the test methods listed in §60.56c(b)(7), (8), (12), (13) (Pb and Cd), and (14), the annual PM, CO, and HCl emissions testing requirements under §60.56c(c)(2), the annual fugitive emissions testing requirements under §60.56c(c)(3), the CO CEMS requirements under §60.56c(c)(4), and the compliance requirements for monitoring listed in §60.56c(c)(5) through (7), and (d) through (k) do not apply.

(2) For a designated facility as defined in §60.32e(a)(2) subject to the emissions limits under §60.33e(b)(2), the annual fugitive emissions testing requirements under §60.56c(c)(3), the CO CEMS requirements under §60.56c(c)(4), and the compliance requirements for monitoring listed in §60.56c(c)(5)(ii) through (v), (c)(6), (c)(7), (e)(6) through (10), (f)(7) through (10), and (g)(6) through (10) do not apply. Sources subject to the emissions limits under §60.33e(b)(2) may, however, elect to use CO CEMS as specified under §60.56c(c)(4) or bag leak detection systems as specified under §60.57c(h).

(c) For approval, a State plan shall require each small HMIWI subject to the emissions limits under §60.33e(b) that is not equipped with an air pollution control device to meet the following compliance and performance testing requirements:

(1) Establish maximum charge rate and minimum secondary chamber temperature as site-specific operating parameters during the initial performance test to determine compliance with applicable emission limits.

(2) Following the date on which the initial performance test is completed or is required to be completed under §60.8, whichever date comes first, ensure that the designated facility does not operate above the maximum charge rate or below the minimum secondary chamber temperature measured as 3-hour rolling averages (calculated each hour as the average of the previous 3 operating hours) at all times. Operating parameter limits do not apply during performance tests. Operation above the maximum charge rate or below the minimum secondary chamber temperature shall constitute a violation of the established operating parameter(s).

(3) Except as provided in paragraph (c)(4) of this section, operation of the designated facility above the maximum charge rate and below the minimum secondary chamber temperature (each measured on a 3-hour rolling average) simultaneously shall constitute a violation of the PM, CO, and dioxin/furan emissions limits.

(4) The owner or operator of a designated facility may conduct a repeat performance test within 30 days of violation of applicable operating parameter(s) to demonstrate that the designated facility is not in violation of the applicable emissions limit(s). Repeat performance tests conducted pursuant to this paragraph must be conducted under process and control device operating conditions duplicating as nearly as possible those that indicated a violation under paragraph (c)(3) of this section.

(d) For approval, a State plan shall include the requirements for monitoring listed in §60.57c of subpart Ec of this part for HMIWI subject to the emissions limits under §60.33e(a) and (b), except as provided for under paragraph (e) of this section.

(e) For approval, a State plan shall require small HMIWI subject to the emissions limits under §60.33e(b) that are not equipped with an air pollution control device to meet the following monitoring requirements:

(1) Install, calibrate (to manufacturers' specifications), maintain, and operate a device for measuring and recording the temperature of the secondary chamber on a continuous basis, the output of which shall be recorded, at a minimum, once every minute throughout operation.

(2) Install, calibrate (to manufacturers' specifications), maintain, and operate a device which automatically measures and records the date, time, and weight of each charge fed into the HMIWI.

(3) The owner or operator of a designated facility shall 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 shall be obtained for 75 percent of the operating hours per day for 90 percent of the operating hours per calendar quarter that the designated facility is combusting hospital waste and/or medical/infectious waste.

(f) The owner or operator of a designated facility as defined in §60.32e(a)(1) or (a)(2) subject to emissions limits under §60.33e(a)(2), (a)(3), or (b)(2) may use the results of previous emissions tests to demonstrate compliance with the emissions limits, provided that the conditions in paragraphs (f)(1) through (f)(3) of this section are met:

(1) The designated facility's previous emissions tests must have been conducted using the applicable procedures and test methods listed in §60.56c(b) of subpart Ec of this part. Previous emissions test results obtained using EPA-accepted voluntary consensus standards are also acceptable.

(2) The HMIWI at the designated facility shall currently be operated in a manner (e.g., with charge rate, secondary chamber temperature, etc.) that would be expected to result in the same or lower emissions than observed during the previous emissions test(s), and the HMIWI may not have been modified such that emissions would be expected to exceed (notwithstanding normal test-to-test variability) the results from previous emissions test(s).

(3) The previous emissions test(s) must have been conducted in 1996 or later.

[60 FR 65414, Dec. 19, 1995, as amended at 74 FR 51403, Oct. 6, 2009]

§ 60.38e Reporting and recordkeeping guidelines.

(a) Except as provided in paragraphs (a)(1) and (a)(2) of this section, for approval, a State plan shall include the reporting and recordkeeping requirements listed in §60.58c(b) through (g) of subpart Ec of this part.

(1) For a designated facility as defined in §60.32e(a)(1) subject to emissions limits under §60.33e(a)(1) or (b)(1), excluding §60.58c(b)(2)(ii) (fugitive emissions), (b)(2)(viii) (NO_X reagent), (b)(2)(xvii) (air pollution control device inspections), (b)(2)(xviii) (bag leak detection system alarms), (b)(2)(xix) (CO CEMS data), and (b)(7) (siting documentation).

(2) For a designated facility as defined in §60.32e(a)(1) or (a)(2) subject to emissions limits under §60.33e(a)(2), (a)(3), or (b)(2), excluding §60.58c(b)(2)(xviii) (bag leak detection system alarms), (b)(2)(xix) (CO CEMS data), and (b)(7) (siting documentation).

(b) For approval, a State plan shall require the owner or operator of each HMIWI subject to the emissions limits under §60.33e to:

(1) As specified in §60.36e, maintain records of the annual equipment inspections that are required for each HMIWI subject to the emissions limits under §60.33e(a)(2), (a)(3), and (b), and the annual air pollution control device inspections that are required for each HMIWI subject to the emissions limits under §60.33e(a)(2), (a)(3), and (b)(2), any required maintenance, and any repairs not completed within 10 days of an inspection or the timeframe established by the State regulatory agency; and

(2) Submit an annual report containing information recorded under paragraph (b)(1) of this section no later than 60 days following the year in which data were collected. Subsequent reports shall be sent no later than 12 calendar months following the previous report (once the unit is subject to permitting requirements under Title V of the Act, the owner or operator must submit these reports semiannually). The report shall be signed by the facilities manager.
[60 FR 65414, Dec. 19, 1995, as amended at 74 FR 51404, Oct. 6, 2009]

§ 60.39e Compliance times.

(a) Each State in which a designated facility is operating shall submit to the Administrator a plan to implement and enforce the emissions guidelines as specified in paragraphs (a)(1) and (a)(2) of this section:

(1) Not later than September 15, 1998, for the emissions guidelines as promulgated on September 15, 1997.

(2) Not later than October 6, 2010, for the emissions guidelines as amended on October 6, 2009.

(b) Except as provided in paragraphs (c) and (d) of this section, State plans shall provide that designated facilities comply with all requirements of the State plan on or before the date 1 year after EPA approval of the State plan, regardless of whether a designated facility is identified in the State plan inventory required by §60.25(a) of subpart B of this part.

(c) State plans that specify measurable and enforceable incremental steps of progress towards compliance for designated facilities planning to install the necessary air pollution control equipment may allow compliance on or before the date 3 years after EPA approval of the State plan (but not later than September 16, 2002), for the emissions guidelines as promulgated on September 15, 1997, and on or before the date 3 years after approval of an amended State plan (but not later than October 6, 2014), for the emissions guidelines as amended on October 6, 2009). Suggested measurable and enforceable activities to be included in State plans are:

(1) Date for submitting a petition for site-specific operating parameters under §60.56c(j) of subpart Ec of this part.

(2) Date for obtaining services of an architectural and engineering firm regarding the air pollution control device(s);

(3) Date for obtaining design drawings of the air pollution control device(s);

(4) Date for ordering the air pollution control device(s);

(5) Date for obtaining the major components of the air pollution control device(s);

(6) Date for initiation of site preparation for installation of the air pollution control device(s);

(7) Date for initiation of installation of the air pollution control device(s);

(8) Date for initial startup of the air pollution control device(s); and

(9) Date for initial compliance test(s) of the air pollution control device(s).

(d) State plans that include provisions allowing designated facilities to petition the State for extensions beyond the compliance times required in paragraph (b) of this section shall:

(1) Require that the designated facility requesting an extension submit the following information in time to allow the State adequate time to grant or deny the extension within 1 year after EPA approval of the State plan:

(i) Documentation of the analyses undertaken to support the need for an extension, including an explanation of why up to 3 years after EPA approval of the State plan is sufficient time to comply with the State plan while 1 year after EPA approval of the State plan is not sufficient. The documentation shall also include an evaluation of the option to transport the

waste offsite to a commercial medical waste treatment and disposal facility on a temporary or permanent basis; and

(ii) Documentation of measurable and enforceable incremental steps of progress to be taken towards compliance with the emission guidelines.

(2) Include procedures for granting or denying the extension; and

(3) If an extension is granted, require compliance with the emissions guidelines on or before the date 3 years after EPA approval of the State plan (but not later than September 16, 2002), for the emissions guidelines as promulgated on September 15, 1997, and on or before the date 3 years after EPA approval of an amended State plan (but not later than October 6, 2014), for the emissions guidelines as amended on October 6, 2009.

(e) For approval, a State plan shall require compliance with §60.34e—Operator training and qualification guidelines and §60.36e—Inspection guidelines by the date 1 year after EPA approval of a State plan.

(f) The Administrator shall develop, implement, and enforce a plan for existing HMIWI located in any State that has not submitted an approvable plan within 2 years after September 15, 1997, for the emissions guidelines as promulgated on September 15, 1997, and within 2 years after October 6, 2009 for the emissions guidelines as amended on October 6, 2009. Such plans shall ensure that each designated facility is in compliance with the provisions of this subpart no later than 5 years after September 15, 1997, for the emissions guidelines as promulgated on September 15, 1997, and no later than 5 years after October 6, 2009 for the emissions guidelines as amended on October 6, 2009.

[60 FR 65414, Dec. 19, 1995, as amended at 74 FR 51404, Oct. 6, 2009]

Table 1A to Subpart Ce of Part 60—Emissions Limits for Small, Medium, and Large HMIWI at Designated Facilities as Defined in §60.32e(a)(1)

Pollutant	Units (7 percent oxygen, dry basis)	Emissions limits			Averaging time[1]	Method for demonstrating compliance[2]
		HMIWI size				
		Small	Medium	Large		
Particulate matter	Milligrams per dry standard cubic meter (mg/dscm) (grains per dry standard cubic foot (gr/dscf))	115 (0.05)	69 (0.03)	34 (0.015)	3-run average (1-hour minimum sample time per run)	EPA Reference Method 5 of appendix A–3 of part 60, or EPA Reference Method 26A or 29 of appendix A–8 of part 60.
Carbon monoxide	Parts per million by volume (ppmv)	40	40	40	3-run average (1-hour minimum sample time per run)	EPA Reference Method 10 or 10B of appendix A–4 of part 60.
Dioxins/furans	Nanograms per dry standard cubic meter total dioxins/furans (ng/dscm) (grains per billion dry standard cubic feet ($gr/10^9$dscf)) or ng/dscm TEQ ($gr/10^9$dscf)	125 (55) or 2.3 (1.0)	125 (55) or 2.3 (1.0)	125 (55) or 2.3 (1.0)	3-run average (4-hour minimum sample time per run)	EPA Reference Method 23 of appendix A–7 of part 60.
Hydrogen chloride	ppmv	100 or 93%	100 or 93%	100 or 93%	3-run average (1-hour minimum sample time	EPA Reference Method 26 or 26A of appendix A–8 of part 60.

Pollutant	Units (7 percent oxygen, dry basis)	Emissions limits			Averaging time[1]	Method for demonstrating compliance[2]
		HMIWI size				
		Small	Medium	Large		
					per run)	
Sulfur dioxide	ppmv	55	55	55	3-run average (1-hour minimum sample time per run)	EPA Reference Method 6 or 6C of appendix A–4 of part 60.
Nitrogen oxides	ppmv	250	250	250	3-run average (1-hour minimum sample time per run)	EPA Reference Method 7 or 7E of appendix A–4 of part 60.
Lead	mg/dscm (grains per thousand dry standard cubic feet (gr/10^3dscf))	1.2 (0.52) or 70%	1.2 (0.52) or 70%	1.2 (0.52) or 70%	3-run average (1-hour minimum sample time per run)	EPA Reference Method 29 of appendix A–8 of part 60.
Cadmium	mg/dscm (gr/10^3dscf)	0.16 (0.07) or 65%	0.16 (0.07) or 65%	0.16 (0.07) or 65%	3-run average (1-hour minimum sample time per run)	EPA Reference Method 29 of appendix A–8 of part 60.
Mercury	mg/dscm (gr/10^3dscf)	0.55 (0.24) or 85%	0.55 (0.24) or 85%	0.55 (0.24) or 85%	3-run average (1-hour minimum sample time per run)	EPA Reference Method 29 of appendix A–8 of part 60.

[1]Except as allowed under §60.56c(c) for HMIWI equipped with CEMS.
[2]Does not include CEMS and approved alternative non-EPA test methods allowed under §60.56c(b).

[60 FR 65414, Dec. 19, 1995, as amended at 74 FR 51405, Oct. 6, 2009]

Table 1B to Subpart Ce of Part 60—Emissions Limits for Small, Medium, and Large HMIWI at Designated Facilities as Defined in §60.32e(a)(1) and (a)(2)

Pollutant	Units (7 percent oxygen, dry basis)	Emissions limits			Averaging time[1]	Method for demonstrating compliance[2]
		HMIWI size				
		Small	Medium	Large		
Particulate matter	Milligrams per dry standard cubic meter (mg/dscm) (grains per dry standard cubic foot (gr/dscf))	66 (0.029)	46 (0.020)	25 (0.011)	3-run average (1-hour minimum sample time per run)	EPA Reference Method 5 of appendix A–3 of part 60, or EPA Reference Method 26A or 29 of appendix A–8 of part 60.
Carbon monoxide	Parts per million by volume (ppmv)	20	5.5	11	3-run average (1-hour minimum sample time per run)	EPA Reference Method 10 or 10B of appendix A–4 of part 60.

Pollutant	Units (7 percent oxygen, dry basis)	Emissions limits			Averaging time[1]	Method for demonstrating compliance[2]
		HMIWI size				
		Small	Medium	Large		
Dioxins/furans	Nanograms per dry standard cubic meter total dioxins/furans (ng/dscm) (grains per billion dry standard cubic feet ($gr/10^9$dscf)) or ng/dscm TEQ ($gr/10^9$dscf)	16 (7.0) or 0.013 (0.0057)	0.85 (0.37) or 0.020 (0.0087)	9.3 (4.1) or 0.054 (0.024)	3-run average (4-hour minimum sample time per run)	EPA Reference Method 23 of appendix A–7 of part 60.
Hydrogen chloride	ppmv	44	7.7	6.6	3-run average (1-hour minimum sample time per run)	EPA Reference Method 26 or 26A of appendix A–8 of part 60.
Sulfur dioxide	ppmv	4.2	4.2	9.0	3-run average (1-hour minimum sample time per run)	EPA Reference Method 6 or 6C of appendix A–4 of part 60.
Nitrogen oxides	ppmv	190	190	140	3-run average (1-hour minimum sample time per run)	EPA Reference Method 7 or 7E of appendix A–4 of part 60.
Lead	mg/dscm (grains per thousand dry standard cubic feet ($gr/10^3$dscf))	0.31 (0.14)	0.018 (0.0079)	0.036 (0.016)	3-run average (1-hour minimum sample time per run)	EPA Reference Method 29 of appendix A–8 of part 60.
Cadmium	mg/dscm ($gr/10^3$dscf)	0.017 (0.0074)	0.013 (0.0057)	0.0092 (0.0040)	3-run average (1-hour minimum sample time per run)	EPA Reference Method 29 of appendix A–8 of part 60.
Mercury	mg/dscm ($gr/10^3$dscf)	0.014 (0.0061)	0.025 (0.011)	0.018 (0.0079)	3-run average (1-hour minimum sample time per run)	EPA Reference Method 29 of appendix A–8 of part 60.

[1]Except as allowed under §60.56c(c) for HMIWI equipped with CEMS.
[2]Does not include CEMS and approved alternative non-EPA test methods allowed under §60.56c(b).

[74 FR 51406, Oct. 6, 2009]

Table 2A to Subpart Ceof Part 60—Emissions Limits for Small HMIWI Which Meet the Criteria Under §60.33e(b)(1)

Pollutant	Units (7 percent oxygen, dry basis)	HMIWI emissions limits	Averaging time[1]	Method for demonstrating compliance[2]
Particulate	mg/dscm (gr/dscf)	197 (0.086)	3-run average (1-	EPA Reference Method 5 of

Pollutant	Units (7 percent oxygen, dry basis)	HMIWI emissions limits	Averaging time[1]	Method for demonstrating compliance[2]
matter			hour minimum sample time per run)	appendix A–3 of part 60, or EPA Reference Method 26A or 29 of appendix A–8 of part 60.
Carbon monoxide	ppmv	40	3-run average (1-hour minimum sample time per run)	EPA Reference Method 10 or 10B of appendix A–4 of part 60.
Dioxins/furans	ng/dscm total dioxins/furans (gr/10^9dscf) or ng/dscm TEQ (gr/10^9dscf)	800 (350) or 15 (6.6)	3-run average (4-hour minimum sample time per run)	EPA Reference Method 23 of appendix A–7 of part 60.
Hydrogen chloride	ppmv	3,100	3-run average (1-hour minimum sample time per run)	EPA Reference Method 26 or 26A of appendix A–8 of part 60.
Sulfur dioxide	ppmv	55	3-run average (1-hour minimum sample time per run)	EPA Reference Method 6 or 6C of appendix A–4 of part 60.
Nitrogen oxides	ppmv	250	3-run average (1-hour minimum sample time per run)	EPA Reference Method 7 or 7E of appendix A–4 of part 60.
Lead	mg/dscm (gr/10^3dscf)	10 (4.4)	3-run average (1-hour minimum sample time per run)	EPA Reference Method 29 of appendix A–8 of part 60.
Cadmium	mg/dscm (gr/10^3dscf)	4 (1.7)	3-run average (1-hour minimum sample time per run)	EPA Reference Method 29 of appendix A–8 of part 60.
Mercury	mg/dscm (gr/10^3dscf)	7.5 (3.3)	3-run average (1-hour minimum sample time per run)	EPA Reference Method 29 of appendix A–8 of part 60.

[1]Except as allowed under §60.56c(c) for HMIWI equipped with CEMS.
[2]Does not include CEMS and approved alternative non-EPA test methods allowed under §60.56c(b).

[74 FR 51407, Oct. 6, 2009]

Table 2B to Subpart Ceof Part 60—Emissions Limits for Small HMIWI Which Meet the Criteria Under §60.33e(b)(2)

Pollutant	Units (7 percent oxygen, dry basis)	HMIWI Emissions limits	Averaging time[1]	Method for demonstrating compliance[2]
Particulate matter	mg/dscm (gr/dscf)	87 (0.038)	3-run average (1-hour minimum sample time per	EPA Reference Method 5 of appendix A–3 of part 60, or EPA Reference Method 26A or 29 of

Pollutant	Units (7 percent oxygen, dry basis)	HMIWI Emissions limits	Averaging time[1]	Method for demonstrating compliance[2]
			run)	appendix A–8 of part 60.
Carbon monoxide	ppmv	20	3-run average (1-hour minimum sample time per run)	EPA Reference Method 10 or 10B of appendix A–4 of part 60.
Dioxins/furans	ng/dscm total dioxins/furans (gr/10^9dscf) or ng/dscm TEQ (gr/10^9dscf)	240 (100) or 5.1 (2.2)	3-run average (4-hour minimum sample time per run)	EPA Reference Method 23 of appendix A–7 of part 60.
Hydrogen chloride	ppmv	810	3-run average (1-hour minimum sample time per run)	EPA Reference Method 26 or 26A of appendix A–8 of part 60.
Sulfur dioxide	ppmv	55	3-run average (1-hour minimum sample time per run)	EPA Reference Method 6 or 6C of appendix A–4 of part 60.
Nitrogen oxides	ppmv	130	3-run average (1-hour minimum sample time per run)	EPA Reference Method 7 or 7E of appendix A–4 of part 60.
Lead	mg/dscm (gr/10^3dscf)	0.50 (0.22)	3-run average (1-hour minimum sample time per run)	EPA Reference Method 29 of appendix A–8 of part 60.
Cadmium	mg/dscm (gr/10^3dscf)	0.11 (0.048)	3-run average (1-hour minimum sample time per run)	EPA Reference Method 29 of appendix A–8 of part 60.
Mercury	mg/dscm (gr/10^3dscf)	0.0051 (0.0022)	3-run average (1-hour minimum sample time per run)	EPA Reference Method 29 of appendix A–8 of part 60.

[1]Except as allowed under §60.56c(c) for HMIWI equipped with CEMS.
[2]Does not include CEMS and approved alternative non-EPA test methods allowed under §60.56c(b).

[74 FR 51407, Oct. 6, 2009]

Appendix K2

40 CFR Part 60 Subpart Ec

APPENDIX K2--40 CFR PART 60 SUBPART Ec

Note: CFR text for 40 CFR Part 60 subpart Ec accessed Jun. 11, 2010 at e-CFR web site: http://ecfr.gpoaccess.gov.

Subpart Ec—Standards of Performance for Hospital/Medical/Infectious Waste Incinerators for Which Construction is Commenced After June 20, 1996
Source: 62 FR 48382, Sept. 15, 1997, unless otherwise noted.

§ 60.50c Applicability and delegation of authority.

(a) Except as provided in paragraphs (b) through (h) of this section, the affected facility to which this subpart applies is each individual hospital/medical/infectious waste incinerator (HMIWI):

(1) For which construction is commenced after June 20, 1996 but no later than December 1, 2008; or

(2) For which modification is commenced after March 16, 1998 but no later than April 6, 2010.

(3) For which construction is commenced after December 1, 2008; or

(4) For which modification is commenced after April 6, 2010.

(b) A combustor is not subject to this subpart during periods when only pathological waste, low-level radioactive waste, and/or chemotherapeutic waste (all defined in §60.51c) is burned, provided the owner or operator of the combustor:

(1) Notifies the Administrator of an exemption claim; and

(2) Keeps records on a calendar quarter basis of the periods of time when only pathological waste, low-level radioactive waste and/or chemotherapeutic waste is burned.

(c) Any co-fired combustor (defined in §60.51c) is not subject to this subpart if the owner or operator of the co-fired combustor:

(1) Notifies the Administrator of an exemption claim;

(2) Provides an estimate of the relative amounts of hospital waste, medical/infectious waste, and other fuels and wastes to be combusted; and

(3) Keeps 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.

(d) Any combustor required to have a permit under section 3005 of the Solid Waste Disposal Act is not subject to this subpart.

(e) Any combustor which meets the applicability requirements under subpart Cb, Ea, or Eb of this part (standards or guidelines for certain municipal waste combustors) is not subject to this subpart.

(f) Any pyrolysis unit (defined in §60.51c) is not subject to this subpart.

(g) Cement kilns firing hospital waste and/or medical/infectious waste are not subject to this subpart.

(h) Physical or operational changes made to an existing HMIWI solely for the purpose of complying with emission guidelines under subpart Ce are not considered a modification and do not result in an existing HMIWI becoming subject to this subpart.

(i) In delegating implementation and enforcement authority to a State under section 111(c) of the Clean Air Act, the following authorities shall be retained by the Administrator and not transferred to a State:

(1) The requirements of § 60.56c(i) establishing operating parameters when using controls other than those listed in § 60.56c(d).

(2) Approval of alternative methods of demonstrating compliance under §60.8 including:

(i) Approval of CEMS for PM, HCl, multi-metals, and Hg where used for purposes of demonstrating compliance,

(ii) Approval of continuous automated sampling systems for dioxin/furan and Hg where used for purposes of demonstrating compliance, and

(iii) Approval of major alternatives to test methods;

(3) Approval of major alternatives to monitoring;

(4) Waiver of recordkeeping requirements; and

(5) Performance test and data reduction waivers under §60.8(b).

(j) Affected facilities subject to this subpart are not subject to the requirements of 40 CFR part 64.

(k) The requirements of this subpart shall become effective March 16, 1998

(l) Beginning September 15, 2000, or on the effective date of an EPA-approved operating permit program under Clean Air Act title V and the implementing regulations under 40 CFR part 70 in the State in which the unit is located, whichever date is later, affected facilities subject to this subpart shall operate pursuant to a permit issued under the EPA approved State operating permit program.

(m) The requirements of this subpart as promulgated on September 15, 1997, shall apply to the affected facilities defined in paragraph (a)(1) and (2) of this section until the applicable compliance date of the requirements of subpart Ce of this part, as amended on October 6, 2009. Upon the compliance date of the requirements of the amended subpart Ce of this part, affected facilities as defined in paragraph (a) of this section are no longer subject to the requirements of this subpart, but are subject to the requirements of subpart Ce of this part, as amended on October 6, 2009, except where the emissions limits of this subpart as promulgated on September 15, 1997 are more stringent than the emissions limits of the amended subpart Ce of this part. Compliance with subpart Ce of this part, as amended on October 6, 2009 is required on or before the date 3 years after EPA approval of the State plan for States in which an affected facility as defined in paragraph (a) of this section is located (but not later than the date 5 years after promulgation of the amended subpart).

(n) The requirements of this subpart, as amended on October 6, 2009, shall become effective April 6, 2010.

[62 FR 48382, Sept. 15, 1997, as amended at 74 FR 51408, Oct. 6, 2009]

§ 60.51c Definitions.

Bag leak detection system means an instrument that is capable of monitoring PM loadings in the exhaust of a fabric filter in order to detect bag failures. A bag leak detection system includes, but is not limited to, an instrument that operates on triboelectric, light-scattering, light-transmittance, or other effects to monitor relative PM loadings.

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.

Commercial HMIWI means a HMIWI which offers incineration services for hospital/medical/infectious waste generated offsite by firms unrelated to the firm that owns the HMIWI.

Continuous emission monitoring system or CEMS means a monitoring system for continuously measuring and recording the emissions of a pollutant from an affected facility.

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 (2);

(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 shall operate within established parameters as much as possible, and monitoring of all applicable operating parameters shall 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,

$$C=PV\times 15{,}000/8{,}500$$

Where:
C=HMIWI capacity, lb/hr

PV=primary chamber volume, ft3
15,000=primary chamber heat release rate factor, Btu/ft3 /hr
8,500=standard waste heating value, Btu/lb;

(2) For batch HMIWI,

$C=PV\times 4.5/8$

Where:
C=HMIWI capacity, lb/hr
PV=primary chamber volume, ft3
4.5=waste density, lb/ft3
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);

(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 reagent flow rate means 90 percent of the highest 3-hour average reagent flow rate at the inlet to the selective noncatalytic reduction technology (taken, at a minimum, once

every minute) measured during the most recent performance test demonstrating compliance with the NO_X emissions 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, dioxin/furan, and NO_X emissions limits.

Modification or Modified HMIWI means any change to an HMIWI unit after the effective date of these standards 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 shall commence no less than 2 hours after the last charge to the incinerator. For intermittent HMIWI, shutdown shall commence no less than 4 hours after the last charge to the incinerator. For batch HMIWI, shutdown shall commence no less than 5 hours after the high-air phase of combustion has been completed.

Small HMIWI means:

(1) Except as provided in (2);

(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.

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

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.

[62 FR 48382, Sept. 15, 1997, as amended at 74 FR 51408, Oct. 6, 2009]

§ 60.52c Emission limits.

(a) On and after the date on which the initial performance test is completed or is required to be completed under §60.8, whichever date comes first, no owner or operator of an affected facility shall cause to be discharged into the atmosphere:

(1) From an affected facility as defined in §60.50c(a)(1) and (2), any gases that contain stack emissions in excess of the limits presented in Table 1A to this subpart.

(2) From an affected facility as defined in §60.50c(a)(3) and (4), any gases that contain stack emissions in excess of the limits presented in Table 1B to this subpart.

(b) On and after the date on which the initial performance test is completed or is required to be completed under §60.8, whichever date comes first, no owner or operator of an affected facility shall cause to be discharged into the atmosphere:

(1) From an affected facility as defined in §60.50c(a)(1) and (2), any gases that exhibit greater than 10 percent opacity (6-minute block average).

(2) From an affected facility as defined in §60.50c(a)(3) and (4), any gases that exhibit greater than 6 percent opacity (6-minute block average).

(c) On and after the date on which the initial performance test is completed or is required to be completed under §60.8, whichever date comes first, no owner or operator of an affected facility as defined in §60.50c(a)(1) and (2) and utilizing a large HMIWI, and in §60.50c(a)(3) and (4), shall cause to be discharged into the atmosphere visible emissions of combustion ash from an ash conveying system (including conveyor transfer points) in excess of 5 percent of the observation period (i.e., 9 minutes per 3-hour period), as determined by EPA Reference Method 22 of appendix A–1 of this part, except as provided in paragraphs (d) and (e) of this section.

(d) The emission limit specified in paragraph (c) of this section does not cover visible emissions discharged inside buildings or enclosures of ash conveying systems; however, the emission limit does cover visible emissions discharged to the atmosphere from buildings or enclosures of ash conveying systems.

(e) The provisions specified in paragraph (c) of this section do not apply during maintenance and repair of ash conveying systems. Maintenance and/or repair shall not exceed 10 operating days per calendar quarter unless the owner or operator obtains written approval from

the State agency establishing a date whereby all necessary maintenance and repairs of ash conveying systems shall be completed.
[62 FR 48382, Sept. 15, 1997, as amended at 74 FR 51409, Oct. 6, 2009]

§ 60.53c Operator training and qualification requirements.

(a) No owner or operator of an affected facility shall allow the affected facility to operate at any time unless a fully trained and qualified HMIWI operator is accessible, either at the facility or available 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.

(b) Operator training and qualification shall be obtained through a State-approved program or by completing the requirements included in paragraphs (c) through (g) of this section.

(c) Training shall be obtained by completing an HMIWI operator training course that includes, at a minimum, the following provisions:

(1) 24 hours of training on the following subjects:

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

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

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

(iv) Combustion controls and monitoring;

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

(vi) 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);

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

(viii) Actions to correct malfunctions or conditions that may lead to malfunction;

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

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

(xi) Work safety procedures;

(xii) Pre-startup inspections; and

(xiii) Recordkeeping requirements.

(2) An examination designed and administered by the instructor.

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

(d) Qualification shall be obtained by:

(1) Completion of a training course that satisfies the criteria under paragraph (c) of this section; and

(2) 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 of two qualified HMIWI operators.

(e) Qualification is valid from the date on which the examination is passed or the completion of the required experience, whichever is later.

(f) To maintain qualification, the trained and qualified HMIWI operator shall 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.

(g) A lapsed qualification shall be renewed by one of the following methods:

(1) For a lapse of less than 3 years, the HMIWI operator shall complete and pass a standard annual refresher course described in paragraph (f) of this section.

(2) For a lapse of 3 years or more, the HMIWI operator shall complete and pass a training course with the minimum criteria described in paragraph (c) of this section.

(h) The owner or operator of an affected facility shall maintain documentation at the facility that address the following:

(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) HMIWI startup, shutdown, and malfunction procedures;

(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 periodic 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.

(i) The owner or operator of an affected facility shall establish a program for reviewing the information listed in paragraph (h) of this section annually with each HMIWI operator (defined in §60.51c).

(1) The initial review of the information listed in paragraph (h) of this section shall be conducted within 6 months after the effective date of this subpart or prior to assumption of responsibilities affecting HMIWI operation, whichever date is later.

(2) Subsequent reviews of the information listed in paragraph (h) of this section shall be conducted annually.

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

§ 60.54c Siting requirements.

(a) The owner or operator of an affected facility for which construction is commenced after September 15, 1997 shall prepare an analysis of the impacts of the affected facility. The analysis shall consider air pollution control alternatives that minimize, on a site-specific basis, to the maximum extent practicable, potential risks to public health or the environment. In considering such alternatives, the analysis may consider costs, energy impacts, non-air environmental impacts, or any other factors related to the practicability of the alternatives.

(b) Analyses of facility impacts prepared to comply with State, local, or other Federal regulatory requirements may be used to satisfy the requirements of this section, as long as they include the consideration of air pollution control alternatives specified in paragraph (a) of this section.

(c) The owner or operator of the affected facility shall complete and submit the siting requirements of this section as required under §60.58c(a)(1)(iii).

§ 60.55c Waste management plan.

The owner or operator of an affected facility shall prepare a waste management plan. The waste management plan shall identify both the feasibility and the approach to separate certain components of solid waste from the health care waste stream in order to reduce the amount of toxic emissions from incinerated waste. A waste management plan may include, but is not limited to, elements such as segregation and recycling of paper, cardboard, plastics, glass, batteries, food waste, and metals (e.g., aluminum cans, metals-containing devices); segregation of non-recyclable wastes (e.g., polychlorinated biphenyl-containing waste, pharmaceutical waste, and mercury-containing waste, such as dental waste); and purchasing recycled or recyclable products. A 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. 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 emissions reductions expected to be achieved, and any other environmental or energy impacts they might have. The American Hospital Association publication entitled "An Ounce of Prevention: Waste Reduction Strategies for Health Care Facilities" (incorporated by reference, see §60.17) shall be considered in the development of the waste management plan. The owner or operator of each commercial HMIWI company shall conduct training and education programs in waste segregation for each of the company's waste generator clients and ensure that each client prepares its own waste management plan that includes, but is not limited to, the provisions listed previously in this section.

[74 FR 51409, Oct. 6, 2009]

§ 60.56c Compliance and performance testing.

(a) The emissions limits apply at all times.

(b) The owner or operator of an affected facility as defined in §60.50c(a)(1) and (2), shall conduct an initial performance test as required under §60.8 to determine compliance with the emissions limits using the procedures and test methods listed in paragraphs (b)(1) through (b)(6) and (b)(9) through (b)(14) of this section. The owner or operator of an affected facility as defined in §60.50c(a)(3) and (4), shall conduct an initial performance test as required under §60.8 to determine compliance with the emissions limits using the procedures and test methods listed in paragraphs (b)(1) through (b)(14). The use of the bypass stack during a performance test shall invalidate the performance test.

(1) All performance tests shall consist of a minimum of three test runs conducted under representative operating conditions.

(2) The minimum sample time shall be 1 hour per test run unless otherwise indicated.

(3) EPA Reference Method 1 of appendix A of this part shall be used to select the sampling location and number of traverse points.

(4) EPA Reference Method 3, 3A, or 3B of appendix A–2 of this part shall be used for gas composition analysis, including measurement of oxygen concentration. EPA Reference Method 3, 3A, or 3B of appendix A–2 of this part shall be used simultaneously with each of the other EPA reference methods. As an alternative to EPA Reference Method 3B, ASME PTC–19–10–1981–Part 10 may be used (incorporated by reference, see §60.17).

(5) The pollutant concentrations shall be adjusted to 7 percent oxygen using the following equation:

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

where:
C_{adj}=pollutant concentration adjusted to 7 percent oxygen;
C_{meas}=pollutant concentration measured on a dry basis (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, percent.

(6) EPA Reference Method 5 of appendix A–3 or Method 26A or Method 29 of appendix A–8 of this part shall be used to measure the particulate matter emissions. As an alternative, PM CEMS may be used as specified in paragraph (c)(5) of this section.

(7) EPA Reference Method 7 or 7E of appendix A–4 of this part shall be used to measure NO_X emissions.

(8) EPA Reference Method 6 or 6C of appendix A–4 of this part shall be used to measure SO_2 emissions.

(9) EPA Reference Method 9 of appendix A–4 of this part shall be used to measure stack opacity. As an alternative, demonstration of compliance with the PM standards using bag leak detection systems as specified in §60.57c(h) or PM CEMS as specified in paragraph (c)(5) of this section is considered demonstrative of compliance with the opacity requirements.

(10) EPA Reference Method 10 or 10B of appendix A–4 of this part shall be used to measure the CO emissions. As specified in paragraph (c)(4) of this section, use of CO CEMS are required for affected facilities under §60.50c(a)(3) and (4).

(11) EPA Reference Method 23 of appendix A–7 of this part shall be used to measure total dioxin/furan emissions. As an alternative, an owner or operator may elect to sample dioxins/furans by installing, calibrating, maintaining, and operating a continuous automated sampling system for monitoring dioxin/furan emissions as specified in paragraph (c)(6) of this section. For Method 23 of appendix A–7 sampling, the minimum sample time shall be 4 hours per test run. If the affected facility has selected the toxic equivalency standards for dioxins/furans, under §60.52c, the following procedures shall be used to determine compliance:

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

(ii) For each dioxin/furan congener measured in accordance with paragraph (b)(9)(i) of this section, multiply the congener concentration by its corresponding toxic equivalency factor specified in table 2 of this subpart.

(iii) Sum the products calculated in accordance with paragraph (b)(9)(ii) of this section to obtain the total concentration of dioxins/furans emitted in terms of toxic equivalency.

(12) EPA Reference Method 26 or 26A of appendix A–8 of this part shall be used to measure HCl emissions. As an alternative, HCl CEMS may be used as specified in paragraph (c)(5) of this section.

(13) EPA Reference Method 29 of appendix A–8 of this part shall be used to measure Pb, Cd, and Hg emissions. As an alternative, Hg emissions may be measured using ASTM D6784–02 (incorporated by reference, see §60.17). As an alternative for Pb, Cd, and Hg, multi-metals CEMS or Hg CEMS, may be used as specified in paragraph (c)(5) of this section. As an

alternative, an owner or operator may elect to sample Hg by installing, calibrating, maintaining, and operating a continuous automated sampling system for monitoring Hg emissions as specified in paragraph (c)(7) of this section.

(14) The EPA Reference Method 22 of appendix A–7 of this part shall be used to determine compliance with the fugitive ash emissions limit under §60.52c(c). The minimum observation time shall be a series of three 1-hour observations.

(c) Following the date on which the initial performance test is completed or is required to be completed under §60.8, whichever date comes first, the owner or operator of an affected facility shall:

(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 paragraph (b) of this section.

(2) Except as provided in paragraphs (c)(4) and (c)(5) of this section, determine compliance with the PM, CO, and HCl emissions 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 paragraph (b) of this section. If all three performance tests over a 3-year period indicate compliance with the emissions limit for a pollutant (PM, CO, or HCl), the owner or operator may forego a performance test for that pollutant for the subsequent 2 years. At a minimum, a performance test for PM, CO, and HCl shall be conducted 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 emissions limit for a pollutant (PM, CO, or HCl), the owner or operator may forego a performance test for that pollutant for an additional 2 years. If any performance test indicates noncompliance with the respective emissions limit, a performance test for that pollutant shall be conducted annually until all annual performance tests over a 3-year period indicate compliance with the emissions limit. The use of the bypass stack during a performance test shall invalidate the performance test.

(3) For an affected facility as defined in §60.50c(a)(1) and (2) and utilizing a large HMIWI, and in §60.50c(a)(3) and (4), determine compliance with the visible emissions limits for fugitive emissions from flyash/bottom ash storage and handling by conducting a performance test using EPA Reference Method 22 of appendix A–7 on an annual basis (no more than 12 months following the previous performance test).

(4) For an affected facility as defined in §60.50c(a)(3) and (4), determine compliance with the CO emissions limit using a CO CEMS according to paragraphs (c)(4)(i) through (c)(4)(iii) of this section:

(i) Determine compliance with the CO emissions limit using a 24-hour block average, calculated as specified in section 12.4.1 of EPA Reference Method 19 of appendix A–7 of this part.

(ii) Operate the CO CEMS in accordance with the applicable procedures under appendices B and F of this part.

(iii) Use of a CO CEMS may be substituted for the CO annual performance test and minimum secondary chamber temperature to demonstrate compliance with the CO emissions limit.

(5) Facilities using CEMS to demonstrate compliance with any of the emissions limits under §60.52c shall:

(i) For an affected facility as defined in §60.50c(a)(1) and (2), determine compliance with the appropriate emissions limit(s) using a 12-hour rolling average, calculated each hour as the average of the previous 12 operating hours.

(ii) For an affected facility as defined in §60.50c(a)(3) and (4), determine compliance with the appropriate emissions limit(s) using a 24-hour block average, calculated as specified in section 12.4.1 of EPA Reference Method 19 of appendix A–7 of this part.

(iii) Operate all CEMS in accordance with the applicable procedures under appendices B and F of this part. For those CEMS for which performance specifications have not yet been promulgated (HCl, multi-metals), this option for an affected facility as defined in §60.50c(a)(3) and (4) takes effect on the date a final performance specification is published in the Federal Register or the date of approval of a site-specific monitoring plan.

(iv) For an affected facility as defined in §60.50c(a)(3) and (4), be allowed to substitute use of an HCl CEMS for the HCl annual performance test, minimum HCl sorbent flow rate, and minimum scrubber liquor pH to demonstrate compliance with the HCl emissions limit.

(v) For an affected facility as defined in §60.50c(a)(3) and (4), be allowed to substitute use of a PM CEMS for the PM annual performance test and minimum pressure drop across the wet scrubber, if applicable, to demonstrate compliance with the PM emissions limit.

(6) An affected facility as defined in §60.50c(a)(3) and (4) using a continuous automated sampling system to demonstrate compliance with the dioxin/furan emissions limits under §60.52c shall record the output of the system and analyze the sample according to EPA Reference Method 23 of appendix A–7 of this part. This option to use a continuous automated sampling system takes effect on the date a final performance specification applicable to dioxin/furan from monitors is published in the Federal Register or the date of approval of a site-specific monitoring plan. The owner or operator of an affected facility as defined in §60.50c(a)(3) and (4) who elects to continuously sample dioxin/furan emissions instead of sampling and testing using EPA Reference Method 23 of appendix A–7 shall install, calibrate, maintain, and operate a continuous automated sampling system and shall comply with the requirements specified in §60.58b(p) and (q) of subpart Eb of this part.

(7) An affected facility as defined in §60.50c(a)(3) and (4) using a continuous automated sampling system to demonstrate compliance with the Hg emissions limits under §60.52c shall record the output of the system and analyze the sample at set intervals using any suitable determinative technique that can meet appropriate performance criteria. This option to use a continuous automated sampling system takes effect on the date a final performance specification applicable to Hg from monitors is published in the Federal Register or the date of approval of a site-specific monitoring plan. The owner or operator of an affected facility as defined in §60.50c(a)(3) and (4) who elects to continuously sample Hg emissions instead of sampling and testing using EPA Reference Method 29 of appendix A–8 of this part, or an approved alternative method for measuring Hg emissions, shall install, calibrate, maintain, and operate a continuous automated sampling system and shall comply with the requirements specified in §60.58b(p) and (q) of subpart Eb of this part.

(d) Except as provided in paragraphs (c)(4) through (c)(7) of this section, the owner or operator of an affected facility 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 shall:

(1) Establish the appropriate maximum and minimum operating parameters, indicated in table 3 of this subpart for each control system, as site specific operating parameters during the initial performance test to determine compliance with the emission limits; and

(2) Following the date on which the initial performance test is completed or is required to be completed under §60.8, whichever date comes first, ensure that the affected facility does not operate above any of the applicable maximum operating parameters or below any of the applicable minimum operating parameters listed in table 3 of this subpart and measured as 3-

hour rolling averages (calculated each hour as the average of the previous 3 operating hours) at all times except during periods of startup, shutdown and malfunction. Operating parameter limits do not apply during performance tests. Operation above the established maximum or below the established minimum operating parameter(s) shall constitute a violation of established operating parameter(s).

(e) Except as provided in paragraph (i) of this section, for affected facilities equipped with a dry scrubber followed by a fabric filter:

(1) Operation of the affected facility above the maximum charge rate and below the minimum secondary chamber temperature (each measured on a 3-hour rolling average) simultaneously shall constitute a violation of the CO emission limit.

(2) Operation of the affected facility above the maximum fabric filter inlet temperature, above the maximum charge rate, and below the minimum dioxin/furan sorbent flow rate (each measured on a 3-hour rolling average) simultaneously shall constitute a violation of the dioxin/furan emission limit.

(3) Operation of the affected facility above the maximum charge rate and below the minimum HCl sorbent flow rate (each measured on a 3-hour rolling average) simultaneously shall constitute a violation of the HCl emission limit.

(4) Operation of the affected facility above the maximum charge rate and below the minimum Hg sorbent flow rate (each measured on a 3-hour rolling average) simultaneously shall constitute a violation of the Hg emission limit.

(5) Use of the bypass stack shall constitute a violation of the PM, dioxin/furan, HCl, Pb, Cd and Hg emissions limits.

(6) Operation of the affected facility as defined in §60.50c(a)(3) and (4) above the CO emissions limit as measured by the CO CEMS specified in paragraph (c)(4) of this section shall constitute a violation of the CO emissions limit.

(7) For an affected facility as defined in §60.50c(a)(3) and (4), failure to initiate corrective action within 1 hour of a bag leak detection system alarm; or failure to operate and maintain the fabric filter such that the alarm is not engaged for more than 5 percent of the total operating time in a 6-month block reporting period shall constitute a violation of the PM emissions limit. If inspection of the fabric filter demonstrates that no corrective action is required, no alarm time is counted. If corrective action is required, each alarm is counted as a minimum of 1 hour. If it takes longer than 1 hour to initiate corrective action, the alarm time is counted as the actual amount of time taken to initiate corrective action. If the bag leak detection system is used to demonstrate compliance with the opacity limit, this would also constitute a violation of the opacity emissions limit.

(8) Operation of the affected facility as defined in §60.50c(a)(3) and (4) above the PM, HCl, Pb, Cd, and/or Hg emissions limit as measured by the CEMS specified in paragraph (c)(5) of this section shall constitute a violation of the applicable emissions limit.

(9) Operation of the affected facility as defined in §60.50c(a)(3) and (4) above the dioxin/furan emissions limit as measured by the continuous automated sampling system specified in paragraph (c)(6) of this section shall constitute a violation of the dioxin/furan emissions limit.

(10) Operation of the affected facility as defined in §60.50c(a)(3) and (4) above the Hg emissions limit as measured by the continuous automated sampling system specified in paragraph (c)(7) of this section shall constitute a violation of the Hg emissions limit.

(f) Except as provided in paragraph (i) of this section, for affected facilities equipped with a wet scrubber:

(1) Operation of the affected facility above the maximum charge rate and below the minimum pressure drop across the wet scrubber or below the minimum horsepower or amperage to the system (each measured on a 3-hour rolling average) simultaneously shall constitute a violation of the PM emission limit.

(2) Operation of the affected facility above the maximum charge rate and below the minimum secondary chamber temperature (each measured on a 3-hour rolling average) simultaneously shall constitute a violation of the CO emission limit.

(3) Operation of the affected facility above the maximum charge rate, below the minimum secondary chamber temperature, and below the minimum scrubber liquor flow rate (each measured on a 3-hour rolling average) simultaneously shall constitute a violation of the dioxin/furan emission limit.

(4) Operation of the affected facility above the maximum charge rate and below the minimum scrubber liquor pH (each measured on a 3-hour rolling average) simultaneously shall constitute a violation of the HCl emission limit.

(5) Operation of the affected facility above the maximum flue gas temperature and above the maximum charge rate (each measured on a 3-hour rolling average) simultaneously shall constitute a violation of the Hg emission limit.

(6) Use of the bypass stack shall constitute a violation of the PM, dioxin/furan, HCl, Pb, Cd and Hg emissions limits.

(7) Operation of the affected facility as defined in §60.50c(a)(3) and (4) above the CO emissions limit as measured by the CO CEMS specified in paragraph (c)(4) of this section shall constitute a violation of the CO emissions limit.

(8) Operation of the affected facility as defined in §60.50c(a)(3) and (4) above the PM, HCl, Pb, Cd, and/or Hg emissions limit as measured by the CEMS specified in paragraph (c)(5) of this section shall constitute a violation of the applicable emissions limit.

(9) Operation of the affected facility as defined in §60.50c(a)(3) and (4) above the dioxin/furan emissions limit as measured by the continuous automated sampling system specified in paragraph (c)(6) of this section shall constitute a violation of the dioxin/furan emissions limit.

(10) Operation of the affected facility as defined in §60.50c(a)(3) and (4) above the Hg emissions limit as measured by the continuous automated sampling system specified in paragraph (c)(7) of this section shall constitute a violation of the Hg emissions limit.

(g) Except as provided in paragraph (i) of this section, for affected facilities equipped with a dry scrubber followed by a fabric filter and a wet scrubber:

(1) Operation of the affected facility above the maximum charge rate and below the minimum secondary chamber temperature (each measured on a 3-hour rolling average) simultaneously shall constitute a violation of the CO emission limit.

(2) Operation of the affected facility above the maximum fabric filter inlet temperature, above the maximum charge rate, and below the minimum dioxin/furan sorbent flow rate (each measured on a 3-hour rolling average) simultaneously shall constitute a violation of the dioxin/furan emission limit.

(3) Operation of the affected facility above the maximum charge rate and below the minimum scrubber liquor pH (each measured on a 3-hour rolling average) simultaneously shall constitute a violation of the HCl emission limit.

(4) Operation of the affected facility above the maximum charge rate and below the minimum Hg sorbent flow rate (each measured on a 3-hour rolling average) simultaneously shall constitute a violation of the Hg emission limit.

(5) Use of the bypass stack shall constitute a violation of the PM, dioxin/furan, HCl, Pb, Cd and Hg emissions limits.

(6) Operation of the affected facility as defined in §60.50c(a)(3) and (4) above the CO emissions limit as measured by the CO CEMS specified in paragraph (c)(4) of this section shall constitute a violation of the CO emissions limit.

(7) For an affected facility as defined in §60.50c(a)(3) and (4), failure to initiate corrective action within 1 hour of a bag leak detection system alarm; or failure to operate and maintain the fabric filter such that the alarm is not engaged for more than 5 percent of the total operating time in a 6-month block reporting period shall constitute a violation of the PM emissions limit. If inspection of the fabric filter demonstrates that no corrective action is required, no alarm time is counted. If corrective action is required, each alarm is counted as a minimum of 1 hour. If it takes longer than 1 hour to initiate corrective action, the alarm time is counted as the actual amount of time taken to initiate corrective action. If the bag leak detection system is used to demonstrate compliance with the opacity limit, this would also constitute a violation of the opacity emissions limit.

(8) Operation of the affected facility as defined in §60.50c(a)(3) and (4) above the PM, HCl, Pb, Cd, and/or Hg emissions limit as measured by the CEMS specified in paragraph (c)(5) of this section shall constitute a violation of the applicable emissions limit.

(9) Operation of the affected facility as defined in §60.50c(a)(3) and (4) above the dioxin/furan emissions limit as measured by the continuous automated sampling system specified in paragraph (c)(6) of this section shall constitute a violation of the dioxin/furan emissions limit.

(10) Operation of the affected facility as defined in §60.50c(a)(3) and (4) above the Hg emissions limit as measured by the continuous automated sampling system specified in paragraph (c)(7) of this section shall constitute a violation of the Hg emissions limit.

(h) The owner or operator of an affected facility as defined in §60.50c(a)(3) and (4) equipped with selective noncatalytic reduction technology shall:

(1) Establish the maximum charge rate, the minimum secondary chamber temperature, and the minimum reagent flow rate as site specific operating parameters during the initial performance test to determine compliance with the emissions limits;

(2) Following the date on which the initial performance test is completed or is required to be completed under §60.8, whichever date comes first, ensure that the affected facility does not operate above the maximum charge rate, or below the minimum secondary chamber temperature or the minimum reagent flow rate measured as 3-hour rolling averages (calculated each hour as the average of the previous 3 operating hours) at all times. Operating parameter limits do not apply during performance tests.

(3) Except as provided in paragraph (i) of this section, operation of the affected facility above the maximum charge rate, below the minimum secondary chamber temperature, and below the minimum reagent flow rate simultaneously shall constitute a violation of the NO_X emissions limit.

(i) The owner or operator of an affected facility may conduct a repeat performance test within 30 days of violation of applicable operating parameter(s) to demonstrate that the affected facility is not in violation of the applicable emissions limit(s). Repeat performance tests conducted pursuant to this paragraph shall be conducted using the identical operating parameters that indicated a violation under paragraph (e), (f), (g), or (h) of this section.

(j) The owner or operator of an affected facility using an air pollution control device other than a dry scrubber followed by a fabric filter, a wet scrubber, a dry scrubber followed by a

fabric filter and a wet scrubber, or selective noncatalytic reduction technology to comply with the emissions limits under §60.52c shall petition the Administrator for other site-specific operating parameters to be established during the initial performance test and continuously monitored thereafter. The owner or operator shall not conduct the initial performance test until after the petition has been approved by the Administrator.

(k) The owner or operator of an affected facility may conduct a repeat performance test at any time to establish new values for the operating parameters. The Administrator may request a repeat performance test at any time.

[62 FR 48382, Sept. 15, 1997, as amended at 65 FR 61753, Oct. 17, 2000; 74 FR 51409, Oct. 6, 2009]

§ 60.57c Monitoring requirements.

(a) Except as provided in §60.56c(c)(4) through (c)(7), the owner or operator of an affected facility shall 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 to this subpart (unless CEMS are used as a substitute for certain parameters as specified) such that these devices (or methods) measure and record values for these operating parameters at the frequencies indicated in Table 3 of this subpart at all times.

(b) The owner or operator of an affected facility as defined in §60.50c(a)(3) and (4) that uses selective noncatalytic reduction technology shall install, calibrate (to manufacturers' specifications), maintain, and operate devices (or establish methods) for monitoring the operating parameters listed in §60.56c(h) such that the devices (or methods) measure and record values for the operating parameters at all times. Operating parameter values shall be measured and recorded at the following minimum frequencies:

(1) Maximum charge rate shall be measured continuously and recorded once each hour;

(2) Minimum secondary chamber temperature shall be measured continuously and recorded once each minute; and

(3) Minimum reagent flow rate shall be measured hourly and recorded once each hour.

(c) The owner or operator of an affected facility shall install, calibrate (to manufacturers' specifications), maintain, and operate a device or method for measuring the use of the bypass stack including date, time, and duration.

(d) The owner or operator of an affected facility using an air pollution control device other than a dry scrubber followed by a fabric filter, a wet scrubber, a dry scrubber followed by a fabric filter and a wet scrubber, or selective noncatalytic reduction technology to comply with the emissions limits under §60.52c shall install, calibrate (to manufacturers' specifications), maintain, and operate the equipment necessary to monitor the site-specific operating parameters developed pursuant to §60.56c(j).

(e) The owner or operator of an affected facility shall 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 shall be obtained for 75 percent of the operating hours per day for 90 percent of the operating days per calendar quarter that the affected facility is combusting hospital waste and/or medical/infectious waste.

(f) The owner or operator of an affected facility as defined in §60.50c(a)(3) and (4) shall ensure that each HMIWI subject to the emissions limits in §60.52c undergoes an initial air pollution control device inspection that is at least as protective as the following:

(1) At a minimum, an inspection shall include the following:

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

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

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

(2) Within 10 operating days following an air pollution control device inspection, all necessary repairs shall be completed unless the owner or operator obtains written approval from the Administrator establishing a date whereby all necessary repairs of the designated facility shall be completed.

(g) The owner or operator of an affected facility as defined in §60.50c(a)(3) and (4) shall ensure that each HMIWI subject to the emissions limits under §60.52c undergoes an air pollution control device inspection annually (no more than 12 months following the previous annual air pollution control device inspection), as outlined in paragraphs (f)(1) and (f)(2) of this section.

(h) For affected facilities as defined in §60.50c(a)(3) and (4) that use an air pollution control device that includes a fabric filter and are not demonstrating compliance using PM CEMS, determine compliance with the PM emissions limit using a bag leak detection system and meet the requirements in paragraphs (h)(1) through (h)(12) of this section for each bag leak detection system.

(1) Each triboelectric bag leak detection system may be installed, calibrated, operated, and maintained according to the "Fabric Filter Bag Leak Detection Guidance," (EPA–454/R–98–015, September 1997). This document is available from the U.S. Environmental Protection Agency (U.S. EPA); Office of Air Quality Planning and Standards; Sector Policies and Programs Division; Measurement Policy Group (D–243–02), Research Triangle Park, NC 27711. This document is also available on the Technology Transfer Network (TTN) under Emissions Measurement Center Continuous Emissions Monitoring. Other types of bag leak detection systems shall be installed, operated, calibrated, and maintained in a manner consistent with the manufacturer's written specifications and recommendations.

(2) The bag leak detection system shall be certified by the manufacturer to be capable of detecting PM emissions at concentrations of 10 milligrams per actual cubic meter (0.0044 grains per actual cubic foot) or less.

(3) The bag leak detection system sensor shall provide an output of relative PM loadings.

(4) The bag leak detection system shall be equipped with a device to continuously record the output signal from the sensor.

(5) The bag leak detection system shall be equipped with an audible alarm system that will sound automatically when an increase in relative PM emissions over a preset level is detected. The alarm shall be located where it is easily heard by plant operating personnel.

(6) For positive pressure fabric filter systems, a bag leak detector shall be installed in each baghouse compartment or cell.

(7) For negative pressure or induced air fabric filters, the bag leak detector shall be installed downstream of the fabric filter.

(8) Where multiple detectors are required, the system's instrumentation and alarm may be shared among detectors.

(9) The baseline output shall be established by adjusting the range and the averaging period of the device and establishing the alarm set points and the alarm delay time according to section 5.0 of the "Fabric Filter Bag Leak Detection Guidance."

(10) Following initial adjustment of the system, the sensitivity or range, averaging period, alarm set points, or alarm delay time may not be adjusted. In no case may the sensitivity be increased by more than 100 percent or decreased more than 50 percent over a 365-day period

unless such adjustment follows a complete fabric filter inspection that demonstrates that the fabric filter is in good operating condition. Each adjustment shall be recorded.

(11) Record the results of each inspection, calibration, and validation check.

(12) Initiate corrective action within 1 hour of a bag leak detection system alarm; operate and maintain the fabric filter such that the alarm is not engaged for more than 5 percent of the total operating time in a 6-month block reporting period. If inspection of the fabric filter demonstrates that no corrective action is required, no alarm time is counted. If corrective action is required, each alarm is counted as a minimum of 1 hour. If it takes longer than 1 hour to initiate corrective action, the alarm time is counted as the actual amount of time taken to initiate corrective action.

[62 FR 48382, Sept. 15, 1997, as amended at 74 FR 51412, Oct. 6, 2009]

§ 60.58c Reporting and recordkeeping requirements.

(a) The owner or operator of an affected facility shall submit notifications, as provided by §60.7. In addition, the owner or operator shall submit the following information:

(1) Prior to commencement of construction;

(i) A statement of intent to construct;

(ii) The anticipated date of commencement of construction; and

(iii) All documentation produced as a result of the siting requirements of §60.54c.

(2) Prior to initial startup;

(i) The type(s) of waste to be combusted;

(ii) The maximum design waste burning capacity;

(iii) The anticipated maximum charge rate; and

(iv) If applicable, the petition for site-specific operating parameters under §60.56c(j).

(b) The owner or operator of an affected facility shall maintain the following information (as applicable) for a period of at least 5 years:

(1) Calendar date of each record;

(2) Records of the following data:

(i) Concentrations of any pollutant listed in §60.52c or measurements of opacity as determined by the continuous emission monitoring system (if applicable);

(ii) Results of fugitive emissions (by EPA Reference Method 22) tests, if applicable;

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

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

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

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

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

(viii) For affected facilities as defined in §60.50c(a)(3) and (4), amount and type of NO_X reagent used during each hour of operation, as applicable;

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

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

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

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

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

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

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

(xvi) For affected facilities complying with §60.56c(j) and §60.57c(d), the owner or operator shall maintain all operating parameter data collected;

(xvii) For affected facilities as defined in §60.50c(a)(3) and (4), records of the annual air pollution control device inspections, any required maintenance, and any repairs not completed within 10 days of an inspection or the timeframe established by the Administrator.

(xviii) For affected facilities as defined in §60.50c(a)(3) and (4), records of each bag leak detection system alarm, the time of the alarm, the time corrective action was initiated and completed, and a brief description of the cause of the alarm and the corrective action taken, as applicable.

(xix) For affected facilities as defined in §60.50c(a)(3) and (4), concentrations of CO as determined by the continuous emissions monitoring system.

(3) Identification of calendar days for which data on emission rates or operating parameters specified under paragraph (b)(2) of this section have not been 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.

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

(5) Identification of calendar days for which data on emission rates or operating parameters specified under paragraph (b)(2) of this section exceeded the applicable limits, with a description of the exceedances, reasons for such exceedances, and a description of corrective actions taken.

(6) The results of the initial, annual, and any subsequent performance tests conducted to determine compliance with the emissions limits and/or to establish or re-establish operating parameters, as applicable, and a description, including sample calculations, of how the operating parameters were established or re-established, if applicable.

(7) All documentation produced as a result of the siting requirements of §60.54c;

(8) Records showing the names of HMIWI operators who have completed review of the information in §60.53c(h) as required by §60.53c(i), including the date of the initial review and all subsequent annual reviews;

(9) 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;

(10) Records showing the names of the HMIWI operators who have met the criteria for qualification under §60.53c and the dates of their qualification; and

(11) Records of calibration of any monitoring devices as required under §60.57c(a) through (d).

(c) The owner or operator of an affected facility shall submit the information specified in paragraphs (c)(1) through (c)(4) of this section no later than 60 days following the initial performance test. All reports shall be signed by the facilities manager.

(1) The initial performance test data as recorded under §60.56c(b)(1) through (b)(14), as applicable.

(2) The values for the site-specific operating parameters established pursuant to §60.56c(d), (h), or (j), as applicable, and a description, including sample calculations, of how the operating parameters were established during the initial performance test.

(3) The waste management plan as specified in §60.55c.

(4) For each affected facility as defined in §60.50c(a)(3) and (4) that uses a bag leak detection system, analysis and supporting documentation demonstrating conformance with EPA guidance and specifications for bag leak detection systems in §60.57c(h).

(d) An annual report shall be submitted 1 year following the submissions of the information in paragraph (c) of this section and subsequent reports shall be submitted no more than 12 months following the previous report (once the unit is subject to permitting requirements under title V of the Clean Air Act, the owner or operator of an affected facility must submit these reports semiannually). The annual report shall include the information specified in paragraphs (d)(1) through (11) of this section. All reports shall be signed by the facilities manager.

(1) The values for the site-specific operating parameters established pursuant to §60.56(d), (h), or (j), as applicable.

(2) The highest maximum operating parameter and the lowest minimum operating parameter, as applicable, for each operating parameter recorded for the calendar year being reported, pursuant to §60.56(d), (h), or (j), as applicable.

(3) The highest maximum operating parameter and the lowest minimum operating parameter, as applicable, for each operating parameter recorded pursuant to §60.56(d), (h), or (j) for the calendar year preceding the year being reported, in order to provide the Administrator with a summary of the performance of the affected facility over a 2-year period.

(4) Any information recorded under paragraphs (b)(3) through (b)(5) of this section for the calendar year being reported.

(5) Any information recorded under paragraphs (b)(3) through (b)(5) of this section for the calendar year preceding the year being reported, in order to provide the Administrator with a summary of the performance of the affected facility over a 2-year period.

(6) If a performance test was conducted during the reporting period, the results of that test.

(7) If no exceedances or malfunctions were reported under paragraphs (b)(3) through (b)(5) of this section for the calendar year being reported, a statement that no exceedances occurred during the reporting period.

(8) Any use of the bypass stack, the duration, reason for malfunction, and corrective action taken.

(9) For affected facilities as defined in §60.50c(a)(3) and (4), records of the annual air pollution control device inspection, any required maintenance, and any repairs not completed within 10 days of an inspection or the timeframe established by the Administrator.

(10) For affected facilities as defined in §60.50c(a)(3) and (4), records of each bag leak detection system alarm, the time of the alarm, the time corrective action was initiated and completed, and a brief description of the cause of the alarm and the corrective action taken, as applicable.

(11) For affected facilities as defined in §60.50c(a)(3) and (4), concentrations of CO as determined by the continuous emissions monitoring system.

(e) The owner or operator of an affected facility shall submit semiannual reports containing any information recorded under paragraphs (b)(3) through (b)(5) of this section no later than 60 days following the reporting period. The first semiannual reporting period ends 6 months following the submission of information in paragraph (c) of this section. Subsequent

reports shall be submitted no later than 6 calendar months following the previous report. All reports shall be signed by the facilities manager.

(f) All records specified under paragraph (b) of this section shall be maintained onsite in either paper copy or computer-readable format, unless an alternative format is approved by the Administrator.

(g) For affected facilities, as defined in §60.50c(a)(3) and (4), that choose to submit an electronic copy of stack test reports to EPA's WebFIRE data base, as of December 31, 2011, the owner or operator of an affected facility shall enter the test data into EPA's data base using the Electronic Reporting Tool located at http://www.epa.gov/ttn/chief/ert/ert_tool.html.
[62 FR 48382, Sept. 15, 1997, as amended at 74 FR 51413, Oct. 6, 2009]

Table 1A to Subpart Ec of Part 60—Emissions Limits for Small, Medium, and Large HMIWI at Affected Facilities as Defined in §60.50c(a)(1) and (2)

Pollutant	Units (7 percent oxygen, dry basis)	Emissions limits			Averaging time[1]	Method for demonstrating compliance[2]
		HMIWI size				
		Small	Medium	Large		
Particulate matter	Milligrams per dry standard cubic meter (grains per dry standard cubic foot)	69 (0.03)	34 (0.015)	34 (0.015)	3-run average (1-hour minimum sample time per run)	EPA Reference Method 5 of appendix A–3 of part 60, or EPA Reference Method M 26A or 29 of appendix A–8 of part 60.
Carbon monoxide	Parts per million by volume	40	40	40	3-run average (1-hour minimum sample time per run)	EPA Reference Method 10 or 10B of appendix A–4 of part 60.
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)	125 (55) or 2.3 (1.0)	25 (11) or 0.6 (0.26)	25 (11) or 0.6 (0.26)	3-run average (4-hour minimum sample time per run)	EPA Reference Method 23 of appendix A–7 of part 60.
Hydrogen chloride	Parts per million by volume	15 or 99%	15 or 99%	15 or 99%5.1	3-run average (1-hour minimum sample time per run)	EPA Reference Method 26 or 26A of appendix A–8 of part 60.
Sulfur dioxide	Parts per million by volume	55	55	55	3-run average (1-hour minimum sample time per run)	EPA Reference Method 6 or 6C of appendix A–4 of part 60.
Nitrogen oxides	Parts per million by volume	250	250	250	3-run average (1-hour minimum sample time per run)	EPA Reference Method 7 or 7E of appendix A–4 of part 60.

Pollutant	Units (7 percent oxygen, dry basis)	Emissions limits			Averaging time[1]	Method for demonstrating compliance[2]
		HMIWI size				
		Small	Medium	Large		
Lead	Milligrams per dry standard cubic meter (grains per thousand dry standard cubic feet	1.2 (0.52) or 70%	0.07 (0.03) or 98%	0.07 (0.03) or 98%	3-run average (1-hour minimum sample time per run)	EPA Reference Method 29 of appendix A–8 of part 60.
Cadmium	Milligrams per dry standard cubic meter (grains per thousand dry standard cubic feet) or percent reduction	0.16 (0.07) or 65%	0.04 (0.02) or 90%	0.04 (0.02) or 90%	3-run average (1-hour minimum sample time per run)	EPA Reference Method 29 of appendix A–8 of part 60.
Mercury	Milligrams per dry standard cubic meter (grains per thousand dry standard cubic feet) or percent reduction	0.55 (0.24) or 85%	0.55 (0.24) or 85%	0.55 (0.24) or 85%	3-run average (1-hour minimum sample time per run)	EPA Reference Method 29 of appendix A–8 of part 60.

[1]Except as allowed under §60.56c(c) for HMIWI equipped with CEMS.
[2]Does not include CEMS and approved alternative non-EPA test methods allowed under §60.56c(b).

[74 FR 51414, Oct. 6, 2009]

Table 1B to Subpart Ec of Part 60—Emissions Limits for Small, Medium, and Large HMIWI at Affected Facilities as Defined in §60.50c(a)(3) and (4)

Pollutant	Units (7 percent oxygen, dry basis)	Emissions limits			Averaging time[1]	Method for demonstrating compliance[2]
		HMIWI size				
		Small	Medium	Large		
Particulate matter	Milligrams per dry standard cubic meter (grains per dry standard cubic foot)	66 (0.029)	22 (0.0095)	18 (0.0080)	3-run average (1-hour minimum sample time per run)	EPA Reference Method 5 of appendix A–3 of part 60, or EPA Reference Method M 26A or 29 of appendix A–8 of part 60.
Carbon monoxide	Parts per million by volume	20	1.8	11	3-run average (1-hour minimum sample time per run)	EPA Reference Method 10 or 10B of appendix A–4 of part 60.
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)	16 (7.0) or 0.013 (0.0057)	0.47 (0.21) or 0.014 (0.0061)	9.3 (4.1) or 0.035 (0.015)	3-run average (4-hour minimum sample time per run)	EPA Reference Method 23 of appendix A–7 of part 60.
Hydrogen chloride	Parts per million by volume	15	7.7	5.1	3-run average (1-hour minimum	EPA Reference Method 26 or 26A of appendix A–8 of part

Pollutant	Units (7 percent oxygen, dry basis)	Emissions limits			Averaging time[1]	Method for demonstrating compliance[2]
		HMIWI size				
		Small	Medium	Large		
					sample time per run)	60.
Sulfur dioxide	Parts per million by volume	1.4	1.4	1.6	3-run average (1-hour minimum sample time per run)	EPA Reference Method 6 or 6C of appendix A–4 of part 60.
Nitrogen oxides	Parts per million by volume	67	67	130	3-run average (1-hour minimum sample time per run)	EPA Reference Method 7 or 7E of appendix A–4 of part 60.
Lead	Milligrams per dry standard cubic meter (grains per thousand dry standard cubic feet)	0.31 (0.14)	0.018 (0.0079)	0.00069 (0.00030)	3-run average (1-hour minimum sample time per run)	EPA Reference Method 29 of appendix A–8 of part 60.
Cadmium	Milligrams per dry standard cubic meter (grains per thousand dry standard cubic feet) or percent reduction	0.017 (0.0074)	0.0098 (0.0043)	0.00013 (0.000057)	3-run average (1-hour minimum sample time per run)	EPA Reference Method 29 of appendix A–8 of part 60.
Mercury	Milligrams per dry standard cubic meter (grains per thousand dry standard cubic feet) or percent reduction	0.014 (0.0061)	0.0035 (0.0015)	0.0013 (0.00057)	3-run average (1-hour minimum sample time per run)	EPA Reference Method 29 of appendix A–8 of part 60.

[1]Except as allowed under §60.56c(c) for HMIWI equipped with CEMS.
[2]Does not include CEMS and approved alternative non-EPA test methods allowed under §60.56c(b).

[74 FR 51414, Oct. 6, 2009]

Table 2 of Subpart Ec to Part 60—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 to Subpart Ec of Part 60—Operating Parameters To Be Monitored and Minimum Measurement and Recording Frequencies

Operating parameters to be monitored	Minimum frequency		Control system		
	Data measurement	Data recording	Dry scrubber followed by fabric filter	Wet scrubber	Dry scrubber followed by fabric filter and wet scrubber
Maximum operating parameters:					
Maximum charge rate	Continuous	1×hour	✓	✓	✓
Maximum fabric filter inlet temperature	Continuous	1×minute	✓		✓
Maximum flue gas temperature	Continuous	1×minute	✓	✓	
Minimum operating parameters:					
Minimum secondary chamber temperature	Continuous	1×minute	✓	✓	✓
Minimum dioxin/furan sorbent flow rate	Hourly	1×hour	✓		✓
Minimum HCI sorbent flow rate	Hourly	1×hour	✓		✓
Minimum mercury (Hg) sorbent flow rate	Hourly	1×hour	✓		✓
Minimum pressure drop across the wet scrubber or minimum horsepower or amperage to wet scrubber	Continuous	1×minute		✓	✓
Minimum scrubber liquor flow rate	Continuous	1×minute		✓	✓
Minimum scrubber liquor pH	Continuous	1×minute		✓	✓

Appendix L

Federal Register Notice for Amended Emission Guidelines and NSPS (40 CFR Part 60 Subparts Ce and Ec)

Federal Register

Tuesday,
October 6, 2009

Part II

Environmental Protection Agency

40 CFR Part 60
Standards of Performance for New Stationary Sources and Emissions Guidelines for Existing Sources: Hospital/ Medical/Infectious Waste Incinerators; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 60

[EPA–HQ–OAR–2006–0534; FRL–8959–9]

RIN 2060–A004

Standards of Performance for New Stationary Sources and Emissions Guidelines for Existing Sources: Hospital/Medical/Infectious Waste Incinerators

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: On September 15, 1997, EPA adopted new source performance standards (NSPS) and emissions guidelines (EG) for hospital/medical/infectious waste incinerators (HMIWI). The NSPS and EG were established under Sections 111 and 129 of the Clean Air Act (CAA or Act). In a response to a suit filed by the Sierra Club and the Natural Resources Defense Council (Sierra Club), the U.S. Court of Appeals for the District of Columbia Circuit (the Court) remanded the HMIWI regulations on March 2, 1999, for further explanation of EPA's reasoning in determining the minimum regulatory ''floors'' for new and existing HMIWI. The HMIWI regulations were not vacated and were fully implemented by September 2002. On February 6, 2007, we published our proposed response to the Court's remand. Following recent court decisions and receipt of public comments regarding the proposal, we re-assessed our response to the remand, and on December 1, 2008, we published another proposed response and solicited public comments. This action promulgates our response to the Court's remand and also satisfies the CAA Section 129(a)(5) requirement to conduct a review of the standards every 5 years.

DATES: The amendments to 40 CFR 60.32e, 60.33e, 60.36e, 60.37e, 60.38e, 60.39e, Table 1A and 1B to subpart Ce, and Tables 2A and 2B to subpart Ce are effective as of December 7, 2009. The amendments to 40 CFR 60.17, 60.50c, 60.51c, 60.52c, 60.55c, 60.56c, 60.57c, 60.58c, and Tables 1A and 1B to subpart Ec are effective as of April 6, 2010. The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of April 6, 2010.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–HQ–OAR–2006–0534 and Legacy Docket ID No. A–91–61. All documents in the docket are listed on the *http://www.regulations.gov* Web site. Although listed in the index, some information is not publicly available, *e.g.,* confidential business information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *http://www.regulations.gov* or in hard copy at the EPA Docket Center, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the EPA Docket Center is (202) 566–1742.

FOR FURTHER INFORMATION CONTACT: Mr. Ketan D. Patel, Natural Resources and Commerce Group, Sector Policies and Programs Division (E143–03), Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–9736; fax number: (919) 541–3470; e-mail address: *patel.ketan@epa.gov.*

SUPPLEMENTARY INFORMATION:

Organization of This Document. The following outline is provided to aid in locating information in this preamble.

I. General Information

A. Does the Final Action Apply to Me?

Regulated Entities. Categories and entities potentially affected by the final action are those which operate hospital/medical/infectious waste incinerators (HMIWI). The new source performance standards (NSPS) and emissions guidelines (EG) for HMIWI affect the following categories of sources:

Category	NAICS Code	Examples of potentially regulated entities
Industry	622110, 622310, 325411, 325412, 562213, 611310.	Private hospitals, other health care facilities, commercial research laboratories, commercial waste disposal companies, private universities.
Federal Government	622110, 541710, 928110	Federal hospitals, other health care facilities, public health service, armed services.

Category	NAICS Code	Examples of potentially regulated entities
State/local/Tribal Government	622110, 562213, 611310	State/local hospitals, other health care facilities, State/local waste disposal services, State universities.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by the final action. To determine whether your facility would be affected by the final action, you should examine the applicability criteria in 40 CFR 60.50c of subpart Ec and 40 CFR 60.32e of subpart Ce. If you have any questions regarding the applicability of the final action to a particular entity, contact the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

B. Where Can I Get a Copy of This Document?

In addition to being available in the docket, an electronic copy of this final action will also be available on the Worldwide Web (WWW) through the Technology Transfer Network (TTN). Following signature, a copy of the final action will be posted on the TTN's policy and guidance page for newly proposed or promulgated rules at the following address: *http://www.epa.gov/ttn/oarpg/*. The TTN provides information and technology exchange in various areas of air pollution control.

C. Judicial Review

Under Section 307(b)(1) of the Clean Air Act (CAA or Act), judicial review of this final rule is available only by filing a petition for review in the U.S. Court of Appeals for the District of Columbia Circuit (the Court) by December 7, 2009. Under Section 307(d)(7)(B) of the CAA, only an objection to this final rule that was raised with reasonable specificity during the period for public comment can be raised during judicial review. CAA Section 307(d)(7)(B) also provides a mechanism for EPA to convene a proceeding for reconsideration, ''[i]f the person raising an objection can demonstrate to EPA that it was impracticable to raise such objection within [the period for public comment] or if the grounds for such objection arose after the period for public comment (but within the time specified for judicial review) and if such objection is of central relevance to the outcome of the rule.'' Any person seeking to make such a demonstration to us should submit a Petition for Reconsideration to the Office of the Administrator, Environmental Protection Agency, Room 3000, Ariel Rios Building, 1200 Pennsylvania Ave., NW., Washington, DC 20460, with a copy to the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section, and the Associate General Counsel for the Air and Radiation Law Office, Office of General Counsel (Mail Code 2344A), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20004. Moreover, under Section 307(b)(2) of the CAA, the requirements established by this final rule may not be challenged separately in any civil or criminal proceedings brought by EPA to enforce these requirements.

II. Background

Section 129 of the CAA, entitled ''Solid Waste Combustion,'' requires EPA to develop and adopt new source performance standards (NSPS) and emissions guidelines (EG) for solid waste incineration units pursuant to CAA Sections 111 and 129. Sections 111(b) and 129(a) of the CAA (NSPS program) address emissions from new HMIWI, and CAA Sections 111(d) and 129(b) (EG program) address emissions from existing HMIWI. The NSPS are directly enforceable Federal regulations, and under CAA Section 129(f)(1) become effective 6 months after promulgation. Under CAA Section 129(f)(2), the EG become effective and enforceable as expeditiously as practicable after EPA approves a State plan implementing the EG but no later than 3 years after such approval or 5 years after the date the EG are promulgated, whichever is earlier.

A HMIWI is defined as any device used to burn hospital waste or medical/infectious waste. Hospital waste means discards generated at a hospital, and 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 (*e.g.,* vaccines, cultures, blood or blood products, human pathological waste, sharps). As explained in EPA's regulations, hospital/medical/infectious waste does not include household waste, hazardous waste, or human and animal remains not generated as medical waste. A HMIWI typically is a small, dual-chamber incinerator that burns on average about 800 pounds per hour (lb/hr) of waste. Smaller units burn as little as 15 lb/hr while larger units burn as much as 3,700 lb/hr, on average.

Incineration of hospital/medical/infectious waste causes the release of a wide array of air pollutants, some of which exist in the waste feed material and are released unchanged during combustion, and some of which are generated as a result of the combustion process itself. These pollutants include particulate matter (PM); heavy metals, including lead (Pb), cadmium (Cd), and mercury (Hg); toxic organics, including chlorinated dibenzo-p-dioxins/dibenzofurans (CDD/CDF); carbon monoxide (CO); nitrogen oxides (NO_X); and acid gases, including hydrogen chloride (HCl) and sulfur dioxide (SO_2). In addition to the use of pollution prevention measures (*i.e.,* waste segregation) and good combustion control practices, HMIWI are typically controlled by wet scrubbers or dry sorbent injection fabric filters (dry scrubbers).

Waste segregation is the separation of certain components of the waste stream in order to reduce the amount of air pollution emissions associated with that waste when incinerated. The separated waste may include paper, cardboard, plastics, glass, batteries, aluminum cans, food waste, or metals. Separation of these types of wastes reduces the amount of chlorine- and metal-containing wastes being incinerated, which results in lower potential emissions of HCl, CDD/CDF, Hg, Cd, and Pb.

Combustion control includes the proper design, construction, operation, and maintenance of HMIWI to destroy or prevent the formation of air pollutants prior to their release to the atmosphere. Test data indicate that as secondary chamber residence time and temperature increase, emissions decrease. Combustion control is most effective in reducing CDD/CDF, PM, and CO emissions. The 2-second combustion level, which includes a minimum secondary chamber temperature of 1800 °F and residence time of 2 seconds, is considered to be the best level of combustion control (*i.e.,* good combustion) that is applied to HMIWI. Wet scrubbers and dry scrubbers provide control of PM, CDD/CDF, HCl, and metals, but do not influence CO or NO_X and have little impact on SO_2 at the low concentrations emitted by HMIWI. (*See* Legacy Docket ID No. A–91–61, item II–A–111; 60 FR 10669, 10671–10677; and 61 FR 31742–31743.)

The CAA sets forth a two-stage approach to regulating emissions from

incinerators. EPA has substantial discretion to distinguish among classes, types and sizes of incinerator units within a category while setting standards. In the first stage of setting standards, CAA Section 129(a)(2) requires EPA to establish technology-based emissions standards that reflect the maximum levels of control EPA determines are achievable for new and existing units, after considering costs, non-air quality health and environmental impacts, and energy requirements associated with the implementation of the standards. Section 129(a)(5) then directs EPA to review those standards and revise them as necessary every 5 years. In the second stage, Section 129(h)(3) requires EPA to determine whether further revisions of the standards are necessary in order to provide an ample margin of safety to protect public health or to prevent (taking into consideration costs, energy, safety and other relevant factors) an adverse environmental effect. *See, e.g., NRDC and LEAN* v. *EPA,* 529 F.3d 1077, 1079–80 (DC Cir. 2008) (addressing the similarly required two-stage approach under CAA Sections 112(d) and (f), and upholding EPA's implementation of same).

In setting forth the methodology EPA must use to establish the first-stage technology-based NSPS and EG, CAA Section 129(a)(2) provides that standards ''applicable to solid waste incineration units promulgated under Section 111 and this Section shall reflect the maximum degree of reduction in emissions of [certain listed air pollutants] that the Administrator, taking into consideration the cost of achieving such emissions reduction, and any non-air quality health and environmental impacts and energy requirements, determines is achievable for new and existing units in each category.'' This level of control is referred to as a ''maximum achievable control technology,'' or MACT, standard.

In promulgating a MACT standard, EPA must first calculate the minimum stringency levels for new and existing solid waste incineration units in a category, generally based on levels of emissions control achieved or required to be achieved by the subject units. The minimum level of stringency is called the MACT ''floor,'' and CAA Section 129(a)(2) sets forth differing levels of minimum stringency that EPA's standards must achieve, based on whether they regulate new and reconstructed sources, or existing sources. For new and reconstructed sources, CAA Section 129(a)(2) provides that the ''degree of reduction in emissions that is deemed achievable [* * *] shall not be less stringent than the emissions control that is achieved in practice by the best controlled similar unit, as determined by the Administrator.'' Emissions standards for existing units may be less stringent than standards for new units, but ''shall not be less stringent than the average emissions limitation achieved by the best performing 12 percent of units in the category (excluding units which first met lowest achievable emissions rates 18 months before the date such standards are proposed or 30 months before the date such standards are promulgated, whichever is later).''

The MACT floors form the least stringent regulatory option EPA may consider in the determination of MACT standards for a source category. EPA must also determine whether to control emissions ''beyond-the-floor,'' after considering the costs, non-air quality health and environmental impacts, and energy requirements of such more stringent control. EPA made such MACT floor and beyond-the-floor determinations and on September 15, 1997, adopted NSPS (40 CFR part 60, subpart Ec) and EG (40 CFR part 60, subpart Ce) using this approach for entities which operate HMIWI. The NSPS and EG are designed to reduce air pollution emitted from new and existing HMIWI, including HCl, CO, Pb, Cd, Hg, PM, CDD/CDF (total, or 2,3,7,8-tetrachlorinated dibenzo-p-dioxin toxic equivalent (TEQ)), NO_X, SO_2, and opacity. The 1997 NSPS apply to HMIWI for which construction began after June 20, 1996, or for which modification began after March 16, 1998. The 1997 NSPS became effective on March 16, 1998, and apply as of that date or at start-up of a HMIWI, whichever is later. The 1997 EG apply to HMIWI for which construction began on or before June 20, 1996, and required compliance by September 2002.

On November 14, 1997, the Sierra Club and the Natural Resources Defense Council (Sierra Club) filed suit in the Court. The Sierra Club claimed that EPA violated CAA Section 129 by setting emissions standards for HMIWI that are less stringent than required by Section 129(a)(2); that EPA violated Section 129 by not including pollution prevention or waste minimization requirements; and that EPA had not adequately considered the non-air quality health and environmental impacts of the standards.

On March 2, 1999, the Court issued its opinion in *Sierra Club* v. *EPA,* 167 F.3d 658 (DC Cir. 1999). While the Court rejected the Sierra Club's statutory arguments under CAA Section 129, the Court remanded the rule to EPA for further explanation regarding how EPA derived the MACT floors for new and existing HMIWI. Furthermore, the Court did not vacate the regulations, and the regulations have remained in effect during the remand.

On February 6, 2007, EPA proposed a response to the HMIWI remand. The proposed response was based on a reassessment of information and data that were available at the time of promulgation in 1997, in light of the EPA's understanding of the Court's rulings in the *Sierra Club, National Lime Association (NLA) II, Cement Kiln Recycling Coalition (CKRC)* and other cases discussed in our 2007 proposal notice. The proposed response would have revised some of the emissions limits in both the NSPS and EG. Relative to the NSPS, the emissions limits for CO, Pb, Cd, Hg, PM, and CDD/CDF would have been revised. Relative to the EG, the emissions limits for HCl, Pb, Cd, and CDD/CDF would have been revised. EPA believed that the revised emissions limits proposed in February 2007 as a result of its response to the remand could be achieved with the same emissions control technology currently used by HMIWI to meet the 1997 rule.

On December 1, 2008, EPA re-proposed its response to the Court's remand. EPA's decision to re-propose was based on a number of factors, including further rulings by the U.S. Court of Appeals that were issued after our 2007 proposal was published. In addition, public comments regarding the 2007 proposal raised issues that, upon further consideration, we believed would best be addressed through a re-proposal. One issue regarded the use of emissions limits included in State regulations and State-issued permits as surrogates for estimated actual emissions limitations achieved. Another issue regarded EPA's previous reliance on control technology performance as the sole indicator of HMIWI performance in making MACT floor determinations, which did not necessarily account for other factors that affect emissions (*e.g.,* waste mix, combustion conditions).

As mentioned above, every 5 years after adopting a MACT standard under Section 129, CAA Section 129(a)(5) requires EPA to review and, if appropriate, revise the incinerator standards. In addition to responding to the Court's remand, today's final action constitutes the first 5-year review of the HMIWI standards.

III. Summary of the Final Rule and Changes Since Proposal

A. Remand Response

Today's final response to the remand revises the December 2008 proposed emissions limits for both the NSPS and EG. The emissions limits are being revised in response to a public comment on the December 2008 re-proposal, which requested that EPA adjust the statistical approach used to account for variability in the data and consider the distribution of the emissions data in determining the MACT floor emissions limits. The revised statistical approach results in generally higher limits compared to the December 2008 re-proposal. (*See* section IV.C.6 of this preamble for further information about this revised approach.) We expect most sources should be able to meet the revised limits using control technology already available to the industry (*e.g.,* wet scrubbers, dry scrubbers, or some combination of these controls). (*See* section IV.C.2 of this preamble for further information.) Similar to the 2008 re-proposal, the emissions limits in today's final action do not include percent reduction alternative standards, as discussed further in section IV.D.4 of this preamble.

Table 1 of this preamble summarizes the NSPS emissions limits being promulgated in this action in response to the Court remand for new HMIWI.

TABLE 1—SUMMARY OF EMISSIONS LIMITS PROMULGATED IN RESPONSE TO THE REMAND FOR NEW HMIWI

Pollutant (units)	Unit size [1]	Final remand response limit [2]
HCl (ppmv)	L	5.1
	M	7.7
	S	15
CO (ppmv)	L	11
	M	1.8
	S	20
Pb (mg/dscm)	L	0.00069
	M	0.018
	S	0.31
Cd (mg/dscm)	L	0.00013
	M	0.0098
	S	0.017
Hg (mg/dscm)	L	0.0013
	M	0.0035
	S	0.014
PM (gr/dscf)	L	0.0080
	M	0.0095
	S	0.029
CDD/CDF, total (ng/dscm)	L	9.3
	M	0.47
	S	16
CDD/CDF, TEQ (ng/dscm)	L	0.035
	M	0.014
	S	0.013
NO_X (ppmv)	L	130
	M, S	67
SO_2 (ppmv)	L	1.6
	M, S	1.4
Opacity (%)	L, M, S	6.0

[1] L = Large (>500 lb/hr of waste); M = Medium (>200 to ≤500 lb/hr of waste); S = Small (≤200 lb/hr of waste).
[2] All emissions limits are reported as corrected to 7 percent oxygen.

Table 2 of this preamble summarizes the emissions limits being promulgated in this action in response to the Court remand for existing HMIWI.

TABLE 2—SUMMARY OF EG EMISSIONS LIMITS PROMULGATED IN RESPONSE TO THE REMAND FOR EXISTING HMIWI

Pollutant (units)	Unit size [1]	Final remand response limit [2]
HCl (ppmv)	L	6.6
	M	7.7
	S	44
	SR	810
CO (ppmv)	L	11
	M	5.5
	S, SR	20
Pb (mg/dscm)	L	0.036
	M	0.018
	S	0.31
	SR	0.50
Cd (mg/dscm)	L	0.0092

TABLE 2—SUMMARY OF EG EMISSIONS LIMITS PROMULGATED IN RESPONSE TO THE REMAND FOR EXISTING HMIWI—Continued

Pollutant (units)	Unit size [1]	Final remand response limit [2]
	M	0.013
	S	0.017
	SR	0.11
Hg (mg/dscm)	L	0.018
	M	0.025
	S	0.014
	SR	0.0051
PM (gr/dscf)	L	0.011
	M	0.020
	S	0.029
	SR	0.038
CDD/CDF, total (ng/dscm)	L	9.3
	M	0.85
	S	16
	SR	240
CDD/CDF, TEQ (ng/dscm)	L	0.054
	M	0.020
	S	0.013
	SR	5.1
NO_X (ppmv)	L	140
	M, S	190
	SR	130
SO_2 (ppmv)	L	9.0
	M, S	4.2
	SR	55
Opacity (%)	L, M, S, SR	6.0

[1] L = Large (>500 lb/hr of waste); M = Medium (>200 to ≤500 lb/hr of waste); S = Small (≤200 lb/hr of waste); SR = Small Rural (Small HMIWI >50 miles from boundary of nearest SMSA, burning <2,000 lb/wk of waste).
[2] All emissions limits are reported as corrected to 7 percent oxygen.

B. Clean Air Act Section 129(a)(5) 5-Year Review Response

We are promulgating our response to the remand in *Sierra Club* such that the revised MACT standards, reflecting floor levels determined by actual emissions data, would be more stringent than what we proposed in 2007 for both the remand response and the 5-year review, with the exceptions noted and discussed in sections IV.A. and IV.B of this preamble. Consequently, we believe that our obligation to conduct a 5-year review based on implementation of the 1997 emissions standards will also be fulfilled through this action's final remand response, even as amended compared to the 2008 re-proposed standards. This is supported by the fact that the revised MACT floor determinations and emissions limits associated with the remand response are based on performance data for the 57 currently operating HMIWI that are subject to the 1997 standards, and by the final rule's accounting for non-technology factors that affect HMIWI emissions performance, which the 2007 proposed remand response and 5-year review did not fully consider. Thus, the final remand response more than addresses the technology review's goals of assessing the performance efficiency of the installed equipment and ensuring that the emissions limits reflect the performance of the technologies required by the MACT standards. In addition, the final remand response addresses whether new technologies and processes and improvements in practices have been demonstrated at sources subject to the emissions limits. Accordingly, the remand response in this final action fulfills EPA's obligations regarding the first 5-year review of the HMIWI standards and, therefore, replaces the 2007 proposal's 5-year review proposed revisions.

C. Other Amendments

This final action puts forward the same changes based on information received during implementation of the HMIWI NSPS and EG that were proposed in 2007 and 2008. The changes proposed in 2007 included provisions allowing existing sources to use previous emissions test results to demonstrate compliance with the revised emissions limits; annual inspections of air pollution control devices (APCD); a one-time visible emissions test of ash handling operations; CO continuous emissions monitoring systems (CEMS) and bag leak detection systems for new sources; and several approved monitoring alternatives. The 2008 proposal included changes regarding requirements for NO_x and SO_2 emissions testing for all HMIWI; performance testing requirements for small rural HMIWI; monitoring requirements for HMIWI that install selective non-catalytic reduction (SNCR) technology to reduce NO_x emissions; and procedures for test data submittal. The changes included in this final action include revised provisions regarding waste segregation and removal of exemptions regarding startup, shutdown, and malfunction (SSM). The removal of SSM exemptions is discussed in section III.F of this preamble. The performance testing and monitoring amendments, electronic data submittal provisions, waste segregation amendments, and miscellaneous other amendments are summarized in the following sections.

1. Performance Testing and Monitoring Amendments

The amendments require all HMIWI to demonstrate initial compliance with the revised NO_x and SO_2 emissions limits. The 1997 standards did not require testing and demonstration of compliance with the NO_x and SO_2

emissions limits. In addition to demonstrating initial compliance with the NO_x and SO_2 emissions limits, small rural HMIWI are required to demonstrate initial compliance with the other seven regulated pollutants' emissions limits and the opacity standard. Under the 1997 standards, small rural HMIWI were required to demonstrate only initial compliance with the PM, CO, CDD/CDF, Hg, and opacity standards. Small rural HMIWI also are required to determine compliance with the PM, CO, and HCl emissions limits by conducting an annual performance test. On an annual basis, small rural HMIWI are required by the 1997 standards to demonstrate compliance with the opacity limit. The amendments allow sources to use results of their previous emissions tests to demonstrate initial compliance with the revised emissions limits as long as the sources certify that the previous test results are representative of current operations. Only those sources who could not so certify and/or whose previous emissions tests do not demonstrate compliance with one or more revised emissions limits would be required to conduct another emissions test for those pollutants. (Note that most sources were already required under the 1997 standards to test for HCl, CO, and PM on an annual basis, and those annual tests are still required.)

The amendments require, for existing HMIWI, annual inspections of scrubbers, fabric filters, and other air pollution control devices that may be used to meet the emissions limits. The amendments require a visible emissions test of the ash handling operations using Method 22 in appendix A–7 of this part to be conducted during the next performance test. For new HMIWI, the amendments require CO CEMS; bag leak detection systems for fabric-filter controlled units; annual inspections of scrubbers, fabric filters, and other air pollution control devices that may be used to meet the emissions limits; and Method 22 visible emissions testing of the ash handling operations to be conducted during each compliance test. For existing HMIWI, use of CO CEMS is an approved option, and specific language with requirements for CO CEMS is included in the amendments. For new and existing HMIWI, use of PM, HCl, multi-metals, and Hg CEMS, and integrated sorbent trap Hg monitoring and dioxin monitoring (continuous sampling with periodic sample analysis) also are approved options, and specific language for those options is included in the amendments. HMIWI that install SNCR technology to reduce NO_X emissions are required to monitor the reagent (*e.g.,* ammonia or urea) injection rate and secondary chamber temperature.

2. Electronic Data Submittal

The EPA must have performance test data to conduct effective 5-year reviews of CAA Section 129 standards, as well as for many other purposes, including compliance determinations, development of emissions factors, and determining annual emissions rates. In conducting 5-year reviews, EPA has found it burdensome and time-consuming to collect emissions test data because of varied locations for data storage and varied data storage methods. One improvement that has occurred in recent years is the availability of stack test reports in electronic format as a replacement for burdensome paper copies.

In this action, we are taking a step to improve data accessibility. HMIWI have the option of submitting to an EPA electronic database an electronic copy of annual stack test reports. Data entry will be through an electronic emissions test report structure used by the staff as part of the emissions testing project. The electronic reporting tool (ERT) was developed with input from stack testing companies who generally collect and compile performance test data electronically. The ERT is currently available, and access to direct data submittal to EPA's electronic emissions database (WebFIRE) will become available December 31, 2011.[1]

Please note that the option to submit source test data electronically to EPA will not require any additional performance testing. In addition, when a facility elects to submit performance test data to WebFIRE, there will be no additional requirements for data compilation. Instead, we believe industry will benefit from development of improved emissions factors, fewer follow-up information requests, and better regulation development, as discussed below. The information to be reported is already required in the existing test methods and is necessary to evaluate the conformance to the test method. One major advantage of electing to submit source test data through the ERT is to provide a standardized method to compile and store all the documentation required to be reported by this rule. Another important benefit of submitting these data to EPA at the time the source test is conducted is that it will substantially reduce the effort involved in data collection activities in the future. Specifically, because EPA would already have adequate source category data to conduct residual risk assessments or technology reviews, there would be fewer data collection requests (*e.g.,* CAA Section 114 letters). This results in a reduced burden on both affected facilities (in terms of reduced manpower to respond to data collection requests) and EPA (in terms of preparing and distributing data collection requests). Finally, another benefit of electing to submit these data to WebFIRE electronically is that these data will greatly improve the overall quality of the existing and new emissions factors by supplementing the pool of emissions test data upon which the emissions factor is based and by ensuring that data are more representative of current industry operational procedures. A common complaint we hear from industry and regulators is that emissions factors are outdated or not representative of a particular source category. Receiving most performance tests will ensure that emissions factors are updated and more accurate. In summary, receiving test data already collected for other purposes and using them in the emissions factors development program will save industry, State/local/Tribal agencies, and EPA time and money.

The electronic data base that will be used is EPA's WebFIRE, which is a Web site accessible through EPA's TTN. The WebFIRE Web site was constructed to store emissions test data for use in developing emissions factors. A description of the WebFIRE data base can be found at *http://cfpub.epa.gov/oarweb/index.cfm?action=fire.main.* The ERT will be able to transmit the electronic report through EPA's Central Data Exchange (CDX) network for storage in the WebFIRE data base. Although ERT is not the only electronic interface that can be used to submit source test data to the CDX for entry into WebFIRE, it makes submittal of data very straightforward and easy. A description of the ERT can be found at *http://www.epa.gov/ttn/chief/ert/ert_tool.html.* The ERT can be used to document stack tests data for various pollutants including PM (EPA Method 5 of appendix A–3), SO_2 (EPA Method 6 or 6C of appendix A–4), NO_X (EPA Method 7 or 7E of appendix A–4), CO (EPA Method 10 of appendix A–4), Cd (EPA Method 29 of appendix A–8), Pb (Method 29), Hg (Method 29), and HCl (EPA Method 26A of appendix A–8). Presently, the ERT does not handle dioxin/furan stack test data (EPA

[1] *See http://cfpub.epa.gov/oarweb/index.cfm?action=fire.main, http://www.epa.gov/ttn/chief/ert/ert_tool.html.*

Method 23 of appendix A–7), but the tool is being upgraded to handle dioxin/furan stack test data. The ERT does not currently accept opacity data or CEMS data.

3. Waste Segregation

The amendments revise the waste management plan provisions for new and existing HMIWI. Commenters on the 2008 re-proposal recommended that EPA minimize or eliminate from the HMIWI waste stream any plastic wastes, Hg and other hazardous wastes (*e.g.,* Hg-containing dental waste, Hg-containing devices), pharmaceuticals, and confidential documents and other paper products that could be shredded and recycled. One commenter recommended that EPA take action to regulate emissions of polychlorinated biphenyls (PCBs) and polycyclic organic matter (POM) from HMIWI. To address the various commenters' concerns, the waste management plan provisions in §§ 60.35e and 60.55c are revised to promote the segregation of the aforementioned wastes. (*See* section IV.H of this preamble for further information about the change to waste management plan provisions.)

5. Miscellaneous Other Amendments

The amendments revise the definition of ''Minimum secondary chamber temperature'' to read ''*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, and dioxin/furan emissions limits.''

The amendments add definitions for ''Bag leak detection system,'' ''commercial HMIWI,'' and ''minimum reagent flow rate.'' ''*Bag leak detection system''* is defined to mean ''an instrument that is capable of monitoring PM loadings in the exhaust of a fabric filter in order to detect bag failures,'' and examples of such a system are provided. ''*Commercial HMIWI''* is defined to mean ''a HMIWI which offers incineration services for hospital/medical/infectious waste generated offsite by firms unrelated to the firm that owns the HMIWI.'' ''*Minimum reagent flow rate''* is defined to mean ''90 percent of the highest 3-hour average reagent flow rate at the inlet to the selective noncatalytic reduction technology (taken, at a minimum, once every minute) measured during the most recent performance test demonstrating compliance with the NO_X emissions limit.''

The amendments require HMIWI to submit, along with each test report, a description, including sample calculations, of how operating parameters are established during the initial performance test and, if applicable, re-established during subsequent performance tests.

To provide greater clarity, the amendments also include averaging times and EPA reference test methods in the emissions limit tables for existing and new sources. It should be noted that the averaging times and EPA reference test methods added to the emissions limits tables are not new requirements but simply a restating of requirements presented elsewhere in the HMIWI regulations. Also, the inclusion of these additional table columns should not be interpreted as reopening the 1997 standards themselves.

The amendments also incorporate by reference two alternatives to EPA reference test methods (ASME PTC 19.10–1981 and ASTM D6784–02) to provide HMIWI with greater flexibility in demonstrating compliance. These alternative methods are described in greater detail in section VIII.I of this preamble and were first presented in the preamble to the December 1, 2008 re-proposal.

D. Implementation Schedule for Existing Hospital/Medical/Infectious Waste Incinerators

Under the amendments to the EG, and consistent with CAA Section 129, revised State plans containing the revised existing source emissions limits and other requirements in the amendments will be due within 1 year after promulgation of the amendments. That is, revised State plans have to be submitted to EPA on October 6, 2010.

The amendments to the EG then allow existing HMIWI to demonstrate compliance with the amended standards as expeditiously as practicable after approval of a State plan, but no later than 3 years from the date of such approval or 5 years after promulgation of the revised standards, whichever is earlier. Because many HMIWI will find it necessary to retrofit existing emissions control equipment and/or install additional emissions control equipment in order to meet the revised limits, States may wish to consider providing the maximum compliance period allowed by CAA Section 129(f)(2).

In revising the emissions limits in a State plan, a State has two options. First, it could include both the current and the new emissions limits in its revised State plan, which would allow a phased approach in applying the new limits. That is, the State plan would make it clear that the 1997 emissions limits remain in force and apply until the date the revised existing source emissions limits are effective (as defined in the State plan). States whose existing HMIWI do not find it necessary to improve their performance in order to meet the revised emissions limits may want to consider a second approach, where the State would insert the revised emissions limits in place of the 1997 emissions limits, follow procedures in 40 CFR part 60, subpart B, and submit a revised State plan to EPA for approval. If the revised State plan contains only the revised emissions limits (*i.e.,* the 1997 emissions limits are not retained), then the revised emissions limits must become effective immediately, since the 1997 limits would be removed from the State plan.

EPA will revise the existing Federal plan to incorporate the changes to existing source emissions limits and other requirements that EPA is promulgating. The Federal plan applies to HMIWI in any State without an approved State plan. The amendments to the Federal plan for the EG would require existing HMIWI demonstrate compliance with the amended standards not later than 5 years after today's final rule, as required by CAA Section 129(b)(3).

E. Changes to the Applicability Date of the 1997 New Source Performance Standards

HMIWI are treated differently under the amended standards than they were under the 1997 standards in terms of whether they are ''existing'' or ''new'' sources, and there are new dates defining what are ''new'' sources and imposing compliance deadlines regarding the amended standards. All HMIWI that complied with the NSPS as promulgated in 1997 are ''existing'' sources under the amended standards and are required to meet the emissions limits under the revised EG or the 1997 NSPS, whichever is more stringent, by the applicable compliance date for the revised EG. (Note that the HCl emissions limit for small HMIWI and the PM emissions limit for medium HMIWI are more stringent under the 1997 NSPS than under the revised EG, and HMIWI that complied with those 1997 NSPS are required to continue to do so.) In the interim, those sources will continue to be subject to the NSPS as promulgated in 1997 until the date for compliance with the revised EG. Units for which construction is commenced after the December 1, 2008 proposal, or for which modification is commenced on or after the date 6 months after today's

promulgation of the amended NSPS, are ''new'' units subject to more stringent revised NSPS emissions limits.

Thus, under these specific amendments, units that commenced construction after June 20, 1996, and on or before December 1, 2008, or that are modified before the date 6 months after the date of promulgation of the revised final NSPS, continue to be or would become subject to the 40 CFR part 60, subpart Ec NSPS emissions limits that were promulgated in 1997 until the applicable compliance date for the revised EG, at which time those units must comply with the amended ''existing'' source EG or 1997 NSPS, whichever is more stringent for each pollutant. Similarly, HMIWI that met the 1997 EG must meet the revised EG by the applicable compliance date for the revised EG. HMIWI that commence construction after December 1, 2008 or that are modified 6 months or more after the date of promulgation of the revised NSPS must meet the revised NSPS emissions limits being added to the subpart Ec NSPS within 6 months after the promulgation date of the amendments or upon startup, whichever is later.

This approach is justified because most HMIWI will have to install additional emissions controls to comply with the revised standards. CAA Sections 129(g)(2) and (3) define ''new solid waste incineration unit'' and ''modified solid waste incineration unit'' based on whether construction of the new unit commences after the date of proposed standards under Section 129 and on whether modification occurs after the effective date of a Section 129 standard, respectively. While these definitions might be read as referring to the dates EPA first proposes standards for the source category as a whole and on which such standards first become effective for the source category, we are interpreting and applying them in this rulemaking to refer to the proposal and effective dates for standards under this new rulemaking record. The evident intent of the definitions plus the substantive new unit and modified unit provisions is that it is technically more challenging and potentially more costly to retrofit a control system to an existing unit than to incorporate controls when a unit is initially designed.

F. Startup, Shutdown, and Malfunction Exemption

The 1997 standards included provisions in 40 CFR 60.56c and 60.37e that exempted HMIWI from the standards during periods of SSM, provided that no hospital waste or medical/infectious waste is charged to the unit during those SSM periods. Neither our 2007 proposal nor our 2008 re-proposal would have changed these provisions. However, soon after the date of our re-proposal, the U.S. Court of Appeals in *Sierra Club* v. *EPA,* 551 F.3d 1019 (DC Cir. 2008), vacated provisions in EPA's CAA Section 112 regulations governing emissions of hazardous air pollutants during SSM periods. Specifically, the Court vacated 40 CFR 63.6(f)(1) and 63.6(h)(1), which, when incorporated into CAA Section 112(d) standards for specific source categories, exempt sources from the requirement to comply with otherwise applicable Section 112(d) standards during periods of SSM. While the Court's vacatur did not have a direct impact on source category-specific SSM exemptions such as those contained in the 1997 HMIWI standards, one commenter on the 2008 re-proposal stressed that the legality of SSM exemptions such as those in the 1997 standards is questionable, and urged EPA to remove the exemptions in the final rule. For the reasons set forth later in this notice responding to comments, today's final rule removes the SSM exemption from the HMIWI standards, such that the emissions limits under these subparts apply at all times.

IV. Summary of Major Comments and Responses

A total of 22 separate sets of public comments were received on the December 1, 2008 re-proposal. (One additional comment, received after the deadline for public comments, was an addendum to an earlier comment. *See http://www.regulations.gov*, docket ID no. EPA–HQ–OAR–2006–0534, for the complete public comments.) The comment period ended on February 17, 2009. In addition to the comment letters, speaker comments from a January 15, 2009, public hearing on the re-proposal were recorded, and a transcript of the hearing was placed in the project docket (document no. EPA–HQ–OAR–2006–0534–0361). The following sections summarize the major public comments received on the re-proposal and present EPA's responses to those comments. The major comment topics are applicability; subcategorization; MACT floor approach; emissions limits; monitoring; emissions testing; alternatives to on-site incineration; medical waste segregation; startup, shutdown, and malfunction; and economic impacts.

A. Applicability

Comment: While this issue was not raised in our re-proposal, one commenter stated that subpart Ec should be amended to exempt units already complying with subpart AAAA—the NSPS for new small municipal waste combustors (MWCs)—or subpart BBBB—the EG for existing small MWCs—consistent with the exemptions provided to MWCs in the 1997 HMIWI rule.

Response: We are aware of two HMIWI at one facility that are currently subject to rules for both HMIWI and small MWCs. We have considered the appropriateness of exempting the two units from the HMIWI rule or creating a separate HMIWI subcategory for the units, and have concluded that exemptions and creation of a separate subcategory are not warranted. One issue is the technological feasibility for the facility to meet both the HMIWI and small MWC rules if there is the possibility that the facility would have to implement different control strategies to meet the limits in both rules. (Note that we do not currently have any information to suggest that the facility would find it technically impossible to meet both the revised HMIWI standards and the small MWC standards.) For example, if the HMIWI rule were to include stringent CO limits and the small MWC rule were to include stringent NO_X limits, it may be challenging for the facility to meet the limits of both rules simultaneously by controlling secondary chamber temperature; increasing the temperature to reduce CO emissions would invariably increase NO_X emissions. However, by choosing to burn both types of waste and operate as both a small MWC and a HMIWI, the facility has the responsibility to meet whatever set of rules that applies based on its operating scenario and could avoid this situation by choosing to burn one type of waste or the other exclusively, or at least reducing the other type of waste to co-fired levels. Also, the facility already employs additional control strategies besides combustion control for reducing NO_X emissions (urea injection).

The facility typically burns 50 percent hospital/medical/infectious (HMI) waste and 50 percent municipal waste in its two units. If we were to grant an exemption to the HMIWI rule for this facility due to it being subject to the small MWC rule and the facility were to increase the amount of HMI waste burned to 70 percent and reduce the amount of municipal waste burned to 30 percent, we could create a total compliance loophole for the facility, given that the small MWC rule includes a co-fired exemption for units burning 30 percent or less of municipal waste. This would be an unacceptable outcome.

Another option to address this situation would be to create a hybrid waste subcategory to include the two units, based on the rationale that the units are burning a unique mixture of waste. However, we did not provide an opportunity to comment on such an option in the re-proposal, and have not had the opportunity to develop a record to support such a new approach or its possibly unique regulatory framework. Moreover, it is also not clear that such a hybrid subcategory would fit within the statutory divisions of incinerator categories set forth in Section 129(a)(1) of the CAA. Therefore, we decided not to pursue that option for the final rule.

We believe it is reasonable for the facility to be subject to both the HMIWI and small MWC rules when switching back and forth among the types of waste burned, since this ensures that, when the facility operates as either a HMIWI or small MWC, it is regulated as such and does not avoid compliance obligations that all other incinerators operating continuously as either HMIWI or small MWC must meet. We do not expect that continuing to require the facility to comply with both rules will be overly burdensome. The facility should be able to control to the more stringent of the two rules.

B. Subcategorization

Comment: Four commenters stated that EPA's rationale for subcategorization does not reflect any analysis of how the proposed subcategories will help assure that what has been ''achieved'' by better performers in a proposed subcategory results in a standard that is ''achievable'' by other sources in that subcategory. Two of the commenters argued that, without this assessment, the final subcategory decisions will be arbitrary and may result in standards that are unlawfully stringent. The commenters urged EPA to provide the necessary assessment and rationale for its subcategory proposal. Another commenter further urged EPA to reconsider its decision to retain the categories defined by the 1997 HMIWI rule without defining additional subcategories. The commenter suggested that EPA could keep the relation between ''achieved'' and ''achievable'' by grouping existing units based on control technology type and that EPA could address variability by establishing subcategories that take into account non-technology factors that affect emissions, as the commenter claimed is required under Section 112(d)(3).[2]

Three commenters stated that EPA must develop a new subcategory for commercial facilities, based on the claimed significant operational differences between commercial and so-called ''captive'' units that are attached to HMI waste generators. The commenters defined a captive unit as one that is co-owned and co-operated by the generator of the waste, while a commercial operator is in business to receive wastes from third parties. The commenters stated that commercial HMIWI, unlike operators of captive units, cannot use alternative forms of disposal (*e.g.,* landfills), and claimed that EPA views their only alternative to the standards as closure. According to the commenters, EPA not only has the authority under Section 129(a)(2) to further subcategorize HMIWI, but it is also mandated to do so due to an overly stringent standard that is not ''achievable'' by commercial units. The commenters claimed that wastes sent to a commercial unit are more heterogeneous than for captive units. They also noted that the handling of medical wastes is subject to numerous Federal and State requirements related to worker and public health and safety, which the commenters claimed makes segregation of wastes hazardous and impractical for operators of commercial facilities. Thus, the commenters argued that waste segregation cannot be a control ''achieved in practice'' that can be used to determine floors for commercial units.

The same three commenters also argued that EPA provides no rationale for its retention of the small rural class in the re-proposed rule, and that its prior rationale regarding the unavailability of alternative means of medical waste treatment beyond 50 miles from the nearest standard metropolitan statistical area (SMSA) is unsupported. According to the commenters, EPA's proposed retention of the small rural subcategory is arbitrary and capricious.

Another commenter recommended that EPA establish new size classifications, claiming that the distribution of HMIWI no longer matches the three size categories EPA identified in 1995 when the rule was first being developed. The commenter also noted that current standards are based on subcategories defined in terms of feed rates with no corresponding heating value. According to the commenter, a reference waste heating characteristic must be established to adjust or rate incinerators, given that there is currently no consistency or basis for determining equivalent charging rate.

The same commenter further recommended that, based on its facility's unique attributes—extremely large processing capacity, customer generated waste material variability, waste mix, waste-to-energy heat recovery technology, CEMS, 2+ second combustion gas retention time, and high British thermal unit (BTU) waste content—EPA should place its facility in a separate subcategory for extra-large HMIWI. The commenter provided a list of suggested standards for such a subcategory, based on upper confidence limits (UCLs) calculated using EPA's methodology, that indicate 7 of the 11 promulgated standards applicable to it could be tightened. The commenter noted that residual risk analyses conducted under Maryland's stringent air toxics regulations (provided in the commenter's public comments) show that the resulting ambient emissions would meet all applicable requirements.

Response: Regarding the commenters' argument that EPA must show how the proposed subcategories will result in a standard that is ''achievable,'' we do not believe that the CAA requires such an analysis. In facing a similar claim, the U.S. Court of Appeals for the DC Circuit recently rejected the argument that a facility's claimed differences between itself and other members of a source category in the plywood and composite wood products (PCWP) MACT rule compels EPA to set a unique standard that is achievable for that source. In *NRDC* v. *EPA,* 489 F.3d 1364 (DC Cir. 2007), Louisiana-Pacific Corp. (L–P) objected to EPA's refusal to establish a separate subcategory for its wet/wet press process apart from the subcategory of all other press processes, claiming that, at L–P's plant, EPA's identified MACT floor control technology was not feasible and that L–P would experience greater costs in complying with the MACT floor compared to other press operators. *Id.,* at 1375–76. The Court denied L–P's claims, explaining that ''cost is not a factor that EPA may permissibly consider in setting a MACT floor. [* * *] To the extent that L–P maintains that it cannot comply with the MACT floor based on complete enclosure and capture of emissions because it cannot enclose its presses, L–P also relies on an incorrect premise that the MACT level of emissions reduction is invalid if it is based on control technology that a source cannot install. The 2004 rule does not require a source to use any particular method to

[2] While the commenter cited to CAA Section 112(d)(3), which does not literally apply to NSPS and EG promulgated under Sections 111 and 129, we assume the commenter was referring to factors relevant to MACT floor analyses in general, including those under Section 129(a)(2).

achieve compliance: If L–P cannot use enclosure and capture, it may utilize other compliance techniques. Hence, L–P fails to show that EPA was arbitrary or capricious in refusing to create a subcategory for it.'' *Id.* at 1376. The option provided by one commenter to subcategorize based on control technology type is inappropriate, as it would essentially endorse the type of unique treatment that L–P demanded in the PCWP rule and that the Court rejected. Moreover, we are unaware of any situations in the HMIWI industry where one type of control would be technically applicable, but not another, such that subcategorizing based on the ability to use certain controls would be justified.

We evaluated three different subcategory options to try and address the concerns stated by the commenters. The three options included: (1) Option 1—no change to existing size categories; (2) Option 2—creating a commercial subcategory (as suggested by three commenters) and redistributing the size categories for the captive HMIWI (as suggested by another commenter); and (3) Option 3—redistributing the existing size categories to more evenly distribute the number of HMIWI (also suggested by the other commenter).

Under Option 1, the size distributions would remain the same—large (>500 lb/hr of waste), medium (>200 to ≤500 lb/hr of waste), and small (≤200 lb/hr of waste), with the latter category divided into small rural and non-rural subcategories based on distance from the nearest SMSA.

Under Option 2, commercial HMIWI would be categorized separately from captive HMIWI, and the captive HMIWI further subcategorized as follows—large (>1,000 lb/hr of waste), medium (>500 to ≤1,000 lb/hr of waste), and small (≤500 of waste), with no further subcategorization of the latter category.

Under Option 3, the sizes would be redistributed as follows—large (>1,500 lb/hr of waste), medium (>500 to ≤1,500 lb/hr of waste), and small (≤500 lb/hr of waste), with the latter category divided into small rural and non-rural subcategories as under Option 1.

We conducted MACT floor analyses on all three options, using the following methodology, which is described in more detail later in this notice—(1) Ranking the emissions data from lowest to highest for each pollutant; (2) determining the units in the MACT floor for each pollutant; (3) determining the distribution of test run data for the MACT floor units; and (4) calculating a 99 percent UCL for each pollutant based on that distribution, using Student's t-test statistics. We developed floor-based emissions limits based on these UCL values, rounding up to two significant figures. We compared the emissions limits to average emissions estimates for each HMIWI and determined whether the HMIWI would meet the limits. We estimated the number of HMIWI expected to meet *at least* nine limits, eight limits, seven limits, *etc.* under each option. Based on our analysis, Options 1, 2, and 3 resulted in similar numbers of HMIWI meeting the limits. (For more detailed results, *see* 2009 memorandum entitled ''Revised MACT Floors, Data Variability Analysis, and Emission Limits for Existing and New HMIWI,'' which is included in the docket for today's rulemaking.)

However, since we did not propose any subcategorization option other than the small, medium and large size subcategories identified in the 1997 rule, and did not provide an opportunity to comment on this issue in the re-proposal, we have concluded that it would not be appropriate at this time to promulgate emissions limits based on Options 2 and 3. Moreover, we do not see a compelling need to make the adjustments of Options 2 or 3, given that similar numbers of HMIWI meet the limits under all three options. Simply re-adjusting the size thresholds to reflect an even distribution of units post-MACT compliance among the subcategories is not necessarily reasonable, whereas the size thresholds from the 1997 rule continue to correspond to the basic distinctions between the subcategories of units as currently operated. Therefore, we selected Option 1 (no change to existing size subcategories) as the best subcategory option on which to base the emissions limits for promulgation.

Two other subcategory options were considered and rejected without further analysis. The two options include (1) an extra-large subcategory for one HMIWI facility (as suggested by one commenter), and (2) a mixed waste subcategory for another HMIWI facility (an outgrowth of a comment by another commenter, as discussed in the previous section). In addition to the fact that we did not provide opportunity to comment on this issue, we found no basis for creating a new subcategory for this particular rulemaking to fit a single facility.

We disagree with the argument by three commenters that EPA's retention of the small rural subcategory is unsupported by any rationale. As we explained in the September 15, 1997 notice of final rulemaking (62 FR 48370), alternative means of medical waste treatment may not be available to some facilities that operate small HMIWI in rural or remote locations. Facilities that operate small HMIWI in remote locations could be faced with unique adverse impacts if required to meet the more stringent emissions limits associated with small non-rural HMIWI. Therefore, we continue to support subcategorizing facilities based on the location of the facility and the amount of waste burned, as allowed under Section 129(a)(2). The only remaining small rural units are in Alaska and Hawaii, and the options are very limited for alternative medical waste treatment in those States. There are a very limited number of landfills and MWC facilities in those States, and there are no commercial HMIWI. (The basis for this information is a 2004 Chartwell Information document entitled *Directory & Atlas of Solid Waste Facilities*.)

C. MACT Floor Approach

1. MACT-on-MACT

Comment: Several commenters argued that EPA's recalculation of the 1997 MACT floors using post-MACT compliance data results in so-called ''MACT-on-MACT'' standards that cannot be achieved and are contrary to the CAA and the intent of Congress. Three of the commenters stated that the CAA provides for a one-time setting of the MACT floor based on what sources achieved at the time of the initial promulgation, not at the time of subsequent revisions. According to those three commenters, the proposed standards would force the HMIWI industry to shut down and prevent installation of new HMIWI, without any consideration of the costs of additional reductions or whether the emissions posed any risks to human health and the environment. The commenters urged EPA to use the population of pre-1997 HMIWI and their emissions data to establish the revised MACT floors. One commenter stated that new data should only be used for those units that have the same control equipment in place as when EPA undertook the original rulemaking.

Three of the commenters objected to EPA's arguments for using the post-MACT compliance data, namely that EPA is no longer confident in the regulatory limits used in 1997 (based on a comparison of the regulatory limits and emissions test data in the 1997 record) and that the EPA questions their use as surrogates because they do not account for non-technology factors (based on waste segregation data EPA received after the 2007 proposal). Specifically, the three commenters stated that EPA provides no justification for its change in using the post-MACT

compliance data, noting that the Court, in *Sierra Club* v. *EPA,* 167 F.3d 658 (DC Cir. 1999), upheld EPA's data-gathering for the 1997 rule, and did not dispute that EPA could make estimates based on the lack of data. The three commenters further stated that EPA provides no support for reassessing its determination in 1997 that emissions controls significantly impact emissions, which the commenters indicated is a finding that EPA continues to assert and that is supported by the data.

Regarding EPA's claim that it reset the floors in response to the remand of the regulation in *Sierra Club* v. *EPA,* 167 F.3d 658 (DC Cir. 1999), the same three commenters argued that the Court's remand was limited and did not vacate the 1997 floors. According to the commenters, EPA cites no legal support that subsequent case law invalidates a promulgated regulation not at issue in that case. The commenters stated that, in the past, EPA has declined to account for changes in law after its decision to impose new regulatory obligations, based in part on the general presumption against law having a retroactive effect. According to the commenters, this approach is supported by case law, which holds that agencies are required to apply the law at the time the decision is made. *Aaacon Auto Transport* v. *ICC,* 792 F.2d 1156, 1161 (DC Cir. 1986). The commenters also noted that the 2002 data used to set the proposed standards would not have been available had the EPA responded to the 1999 remand in a more timely manner.

The three commenters also argued that new public comments raising issues with the 1997 floors are out of time and insufficient to require EPA to go beyond the Court's remand order. The commenters pointed out that Section 307(b) of the CAA requires any challenges to regulations to be filed within 60 days, which has been held up in the relevant case law. According to the commenters, any required revisions to address the Court's limited remand does not justify reopening the time period for judicial challenge of the floors. The commenters also argued that another exception to the 60-day jurisdictional bar, that there was a substantive violation of the statute, does not apply since the Court did not find the 1997 floors in conflict with the statute.

Response: First, we disagree with the commenters' assertion that we are employing a MACT-on-MACT approach to set limits that are not achievable by HMIWI. The purpose of this action is not to force units who have complied with a lawfully adopted MACT standard to have to subsequently comply with another round of updated MACT standards, but to respond to the Court's ruling that questioned the basis for the 1997 MACT standards and revise them such that they are clearly compliant with the Court's several pronouncements of how MACT should be set in the first instance. Moreover, the actual emissions data upon which the revised standards rely comes directly from HMIWI that have in fact achieved the resulting levels, which necessarily belies the assertion that no HMIWI can achieve them. Regarding the commenters' argument that our recalculation of the MACT floors was contrary to the CAA and intent of Congress, it is clear from the Court's opinion in *Sierra Club* v. *EPA* that EPA needed to revisit the MACT floors in order to respond to the Court's concerns about the MACT floor approach we used in 1997, as noted in its remand of the HMIWI regulations. The Court explicitly ''conclude[d] that there are serious doubts about the reasonableness of EPA's treatment of the floor requirements, and remand[ed] the rule for further explanation.'' 167 F.3d at 660. Regarding the existing source floors, the Court even went so far as to suggest that, based on its review of the record for the 1997 rule, ''EPA's method looks hopelessly irrational.'' *Id.* at 664. Ultimately, the Court ordered the case ''remanded to EPA for further explanation of its reasoning in determining the 'floors' for new and existing [HMIWI].'' *Id.* at 666. This remedy squarely placed the responsibility on EPA to either develop an explanation for the MACT standards derived from the 1997 data set that fully addressed the Court's concerns, or develop a different methodology and/or data set that did so.

In the 2008 re-proposal, we decided to use post-compliance data to recalculate the MACT floors because, based on our analysis, it became impossible to fully address the Court's concerns about the suitability of using regulatory limits and uncontrolled emissions values from the 1997 data set in rationally explaining the MACT floors for the 1997 rule. To respond to those concerns, we conducted an analysis comparing the regulatory limits used in the 1997 data set to actual emissions data for those HMIWI, and we determined that the regulatory limits used to establish the MACT floors were not representative of actual operation and did not account for non-technology factors that affected HMIWI emissions performance. (For further information, *see* 2008 memorandum ''Comparison of Regulatory Limits with Emissions Test Data,'' which is included in the docket.) Since it was no longer possible to obtain actual emissions data from the full set of HMIWI that were operating at the time of the 1997 rule's promulgation, the most available alternative was to use the actual emissions data we received from sources who chose to remain in operation and comply with the 1997 MACT standards. With such data, we could actually identify the emissions levels achieved by use of the MACT technologies and control measures that HMIWI employed in order to meet the 1997 standards—technology and measures which we had at that time assumed would be necessary to comply with the standards. This verifying approach was eminently reasonable, since it relied upon data that HMIWI recorded and reported specifically for purposes of demonstrating compliance with the 1997 HMIWI MACT standards, and it addressed the Court's stated concerns regarding the existing source floors. Those concerns, namely, were that permit levels might not accurately estimate actual emissions performance if sources are over-achieving the permit limits (167 F.3d at 663), and that the assumption that unpermitted HMIWI did not deploy emissions controls of any sort was not substantiated (*Id.* at 664).

While we agree with the commenters that control technology has a major impact on pollutant emissions from HMIWI, we also acknowledge that factors other than control technology (*e.g.,* waste mix, combustion conditions) can affect pollutant emissions and should be accounted for in the MACT floor analysis. These non-control technology factors, however, were not considered or reflected by the permit data and uncontrolled emissions values data used in the 1997 rule. Therefore, we needed to take further steps in order to be able to account for these factors and ''provide a reasonable estimate of the performance of the top 12 percent of units.'' *Id.* at 662. It is true that the Court in *Sierra Club* did not rule that EPA had impermissibly ignored these factors. *Id.* at 666. However, subsequent case law, specifically *National Lime Ass'n* v. *EPA,* 233 F.3d 625 (DC Cir. 2000) (NLA II), *Cement Kiln Recycling Coalition* v. *EPA,* 255 F.3d 855 (DC Cir. 2001) (CKRC), and *Sierra Club* v. *EPA,* 479 F.3d 875 (DC Cir. 2007) (Brick MACT case), have made it abundantly clear that, in any MACT analysis, EPA is currently expected by the Court to address non-technology factors. Based on the actual emissions data we received, which necessarily reflects both the use of

control technologies and any non-technology measures the best performing sources happen to use, we were able to provide the ''reasonable estimate'' of the best performers' emissions levels that the Court required in its remand. Therefore, we stand by the reassessment we presented in the re-proposal, although, as discussed later in this notice, we have made some adjustments in our statistical analysis to correct for errors in the 2008 re-proposal.

Regarding the commenters' arguments about the impact of subsequent case law, we do not expect that we could reasonably respond to the Court's 1999 remand of the HMIWI rule in a manner that knowingly disregards other flaws in EPA's prior MACT methodology that the Court has since identified. In a recent MACT ruling in which the Court found that EPA had failed to follow the rulings issued in other MACT cases, the Court admonished the EPA that if ''[EPA] disagrees with the Clean Air Act's requirements for setting emissions standards, it should take its concerns to Congress. If EPA disagrees with this court's interpretation of the Clean Air Act, it should seek rehearing en banc or file a petition for a writ of certiorari. In the meantime, it must obey the Clean Air Act as written by Congress and interpreted by this court.'' 479 F.3d at 884. EPA takes this directive seriously and acted consistently with the Court decisions in preparing this response to the remand. We do not believe that the Court would view its own post-1999 MACT rulings as having changed ''the law'' (namely, the MACT requirement of Sections 112 and 129) such that following those rulings' instructions would reflect retroactive application of ''new'' law. The commenters' reliance on *Aaacon Auto Transport* v. *ICC,* 792 F.2d 1156 (DC Cir. 1986) is inapposite, as that case addressed an entirely different situation of retroactive application of a new statutory provision; here, instead, the governing statutory requirements have not changed, EPA is acting in response to a Court's ruling that it had not adequately shown that it had complied with those provisions, and the Agency is acting subsequent to further rulings that interpret those same provisions and purport to set forth general directions for EPA to follow in all cases.

As for the comment that EPA could not have relied upon the 2002 compliance data if it had more swiftly responded to the remand, this only suggests that if EPA had acted earlier the EPA would have been forced to take additional steps to require the HMIWI industry to supply emissions data. In no way would this support EPA disregarding the 2002 data we have in-hand and allow us to continue to rely upon data that does not reasonably estimate emissions levels achieved by the best performing units. Based on our analysis of the record, we determined that the 1997 floors did not in all cases meet the requirements of the CAA as interpreted by the DC Circuit. We attempted to explain one set of revisions to the 1997 floors in a subsequent (February 2007) **Federal Register** notice that relied upon the 1997 data set, and received new public comments on that notice and took account of new case law that convinced us that a new approach was required. Consequently, we have chosen on our own to re-open the issues addressed in the 2008 re-proposal.

Comment: One commenter stated that EPA's approach to revising HMIWI standards under CAA Section 129(a)(5) is correct. The commenter said that revising the MACT floors to reflect the actual performance of the relevant best units satisfies Section 129(a)(5). However, four other commenters objected to revising the floors under the technology review provisions of Section 129(a)(5). The commenters argued that Section 129(a)(5) does not require resetting the floors, but only requires EPA to consider developments in pollution control at the sources and revise the standards based on our evaluation of the costs and non-air quality impacts. The commenters stated that the use of new emissions data is inconsistent with the reasoning EPA presented in other contexts (*e.g.,* in the coke ovens residual risk/technology review rulemaking) that MACT floors need not be recalculated when the EPA conducts its technology review under CAA Section 112(d)(6). The commenters also argued that this approach is inconsistent with the Court's decision on litigation challenging the Hazardous Organic NESHAP (HON) residual risk/technology review rule that there need not be an ''inexorable downward ratcheting effect'' for the MACT floors. *See NRDC and LEAN* v. *EPA,* 529 F.3d 1077, 1083–84 (DC Cir. 2008). One of the commenters also claimed that EPA's approach sets a precedent for all other sources subject to Section 129 or Section 112 MACT standards that could have dire implications on the future viability of rules covering other sources (*e.g.,* MWCs or waste-to-energy facilities).

Response: Regarding the comment from the first commenter, as noted in the preamble to the December 2008 re-proposal (73 FR 72971), we do not interpret Section 129(a)(5), together with Section 111, as generally requiring EPA to recalculate MACT floors in connection with this periodic review when such review is not conducted together with any other action requiring EPA to reassess the MACT floor. *See, e.g.,* 71 FR 27324, 27327–28 (May 10, 2006) (''Standards of Performance for New Stationary Sources and Emission Guidelines for Existing Sources: Large Municipal Waste Combustors; Final Rule''); *see also, NRDC and LEAN* v. *EPA,* 529 F.3d 1077, 1083–84 (DC Cir. 2008) (upholding EPA's interpretation that the periodic review requirement in CAA Section 112(d)(6) by itself does not impose an obligation to recalculate MACT floors). However, in the unique case of HMIWI, MACT floor recalculations for the 2008 re-proposal were conducted in order to respond to the Court's concerns stated in its remand of the 1997 regulations, the public comments received on the February 2007 proposal, and recent court decisions, specifically *Sierra Club* v. *EPA,* 479 F.3d (DC Cir. 2007) (Brick MACT). This recalculation would have been necessary even if the periodic review requirement of Section 129(a)(5) did not exist. However, Section 129(a)(5) does exist, and EPA must, in addition to responding to the Court's remand, satisfy its requirements. As we previously explained and continue to believe, in this case, our obligation to conduct a 5-year review based on implementation of the 1997 emissions standards is fulfilled through our current remand response. This is supported by the fact that the revised MACT floor determinations and emissions limits associated with the current remand response are based on performance data for the 57 currently operating HMIWI that are subject to the 1997 standards, and by our accounting for non-technology factors that affect HMIWI emissions performance, which the 2007 proposed remand response and 5-year review did not fully consider. Thus, our current remand response more than adequately addresses the technology review's goals of assessing the performance efficiency of the installed equipment and ensuring that the emissions limits reflect the performance of the technologies required by the MACT standards. In addition, the current remand response addresses whether new technologies and processes and improvements in practices have been demonstrated at sources subject to the emissions limits. Accordingly, our current remand response fulfills EPA's obligations regarding the first 5-year review of the HMIWI standards and, therefore,

replaces the 2007 proposal's 5-year review proposed revisions.

2. Pollutant-by-Pollutant Approach

Comment: Numerous commenters objected to our continued use of the EPA's longstanding pollutant-by-pollutant approach to choosing the best performing HMIWI. The commenters argued that this approach essentially created a hypothetical ''super unit'' and resulted in the selection of a set of new and existing MACT floors (and standards) that no one existing source has completely achieved and that cannot be simultaneously achieved by any of the best performing sources. The commenters stated that the ''best performing'' sources must be real sources, not theoretical or hypothetical, based on the statute and legislative history. S. Rep. No. 228, 101st Cong., 1st Sess. 169 (1989). According to the commenters, the proposed standards do not reflect the performance of actual sources, and as such, these proposed standards are not legal under Section 129.

One commenter argued that Section 129(a)(2) (and the similar Section 112(d)(3)) does not speak in terms of the best performing source for each listed pollutant but the best existing source for all pollutants and what these sources can achieve on an overall basis. The commenter claimed that Congress abandoned Section 112's previous focus on individual pollutant standards in the 1990 CAA Amendments and also adopted the technology-based multi-pollutant approach to regulating toxics in use under the Clean Water Act (CWA). *See* S. Rep. No. 228, 101st Cong., 1st Sess. 133–34 (1989). The commenter concluded that if one source can achieve a tight degree of control for one pollutant but not for another, there may be no justification for including it in the set of sources from which the floor is calculated. *See, e.g., Tanners' Council of America* v. *Train,* 540 F.2d 1188, 1193 (4th Cir. 1976) (CWA effluent limitations guidelines were deemed not achievable where plants in EPA's data base were ''capable of meeting the limitations for some, but not all, of the pollutant parameters'').

Two commenters stated that under CAA Sections 129(a)(2) and 112(d)(2) consideration of a higher level of control than the average aggregate levels achieved by the best sources (*i.e.,* using the pollutant-by-pollutant approach instead of basing floors on levels of the full set of pollutants achieved by particular units) must be done only as a ''beyond-the-floor'' assessment, required to weigh economics and other factors, and not be ''hidden'' in the floor evaluation, in which costs may not be considered.

Multiple commenters also questioned the technical feasibility of EPA's pollutant-by-pollutant approach. According to the commenters, establishing MACT standards based on the best achievable emissions limits for each type of pollution control equipment assumes that the equipment can be combined in the same system and that the emissions limits of each system are additive. The commenters stated that, in practice, this outcome is likely not achievable due to the challenge of finding pollution control equipment (*e.g.,* fabric filters for PM removal and wet scrubbers for HCl removal) that can work in concert with each other. The commenters said that EPA should consider how the different emissions controls may interfere with each other if employed simultaneously. As an example, one commenter noted that employing a wet scrubber to control HCl would saturate the gas stream, which would bind the bags in the fabric filter used to control PM, thereby compromising the filter's effectiveness. Some of the commenters also noted that the interrelationships between pollutants must be considered in order to ensure that the emissions control is operating effectively for control of all of the related pollutants, and not just a single pollutant. For example, commenters noted that improving combustion to control CO may affect NO_X.

Multiple commenters suggested EPA should revisit the MACT floors for HMIWI and choose the best performing sources on an overall basis, so that at least one source can meet all of the new source standards and a certain portion of the existing sources can meet the existing source standards. One commenter suggested that EPA combine the individual pollutants into a single analysis to determine which control provides the best overall control or otherwise determine that the MACT floor resulting from the analysis is actually achieved by those sources identified as the ''best controlled.'' According to various commenters, one possible way for doing this would be to establish rankings for how a HMIWI performs for each of the regulated pollutants and then sum the individual pollutant rankings to determine the overall ranking for the HMIWI.

Response: We disagree with the commenters who object to setting MACT floors on a pollutant-by-pollutant basis. We continue to interpret Section 129 as supporting the pollutant-by-pollutant approach. Section 129(a)(4) says that the standards promulgated under Section 129 shall specify numerical emissions limitations for each pollutant enumerated in that provision. Section 129(a)(2) requires EPA to establish standards requiring ''maximum degree of reduction of emissions.'' ''Maximum degree of reduction of emissions,'' in turn is defined in Section 129(a)(2) as including a minimum level of control (the so-called MACT floor). EPA, therefore, believes—and has long believed—that the combination of Section 129(a)(4), requiring numerical standards for each enumerated pollutant, and Section 129(a)(2), requiring that each such standard be at least as stringent as the MACT floor, supports, if not requires, that floors be derived for each pollutant based on the emissions levels achieved for each pollutant.

We also disagree with the commenters who complain that there may not be any operating unit that currently employs the complete suite of MACT technologies and meets the revised limits. The suite of MACT floor controls identified by the final rule approach (specifically, the combination of dry and wet control systems) is already used by four existing HMIWI that meet most of the MACT floor standards. For example, one HMIWI, equipped with a high-efficiency particulate air (HEPA) filtering system, carbon bed adsorber, and rotary atomizing wet scrubber, is estimated to meet all nine revised emissions limits in the final rule; another HMIWI, equipped with a lime injection system, powdered activated carbon injection system, baghouse, and vertical upflow two-stage multi-microventuri scrubber system, is estimated to meet eight of the nine revised limits. Also, an estimated 42 of the 57 HMIWI are estimated to meet both the CO and NO_X revised limits simultaneously with existing combustion controls. (*See* 2009 memorandum entitled ''Revised Compliance Costs and Economic Inputs for Existing HMIWI,'' which is included in the docket for today's rulemaking.) The MACT control techniques for the various pollutants are fully integratable and compatible. There do not appear to be any conflicts where meeting the standard for one pollutant may jeopardize the achievability of meeting another pollutant's limit. This conclusion is supported in part by a review of available data and information. As discussed above, there are currently four units that are achieving most, if not all, of the floor standards (based on actual data for each pollutant) using the complete suite of

MACT floor controls. Thus, we conclude that our approach results in compatible MACT controls. Further, an evaluation of the emissions data from units that have measured data for all pollutants supports our conclusion. Our analysis shows that 12 percent (7 of 57 units) simultaneously meet all of the MACT floor emissions levels. (For further information, *see* 2009 memorandum entitled ''Revised Compliance Costs and Economic Inputs for Existing HMIWI,'' which is included in the docket for today's rulemaking.)

We also disagree with commenters claiming that it is inappropriate to consider a suite of floor control techniques that may not be currently in use by the source category. There is no reason not to consider emissions data and controls in use at sources that may be the best performers from some pollutants but not for other pollutants. The MACT floor controls applicable for one pollutant do not preclude the use of MACT floor controls for another pollutant. Therefore, it is appropriate to consider controls at sources employing MACT controls for some pollutants, but not all. For example, floor controls for existing large HMIWI include wet scrubbers for HCl control, dry scrubbers or combination dry/wet systems for PM and metals control, activated carbon injection for CDD/CDF control, and wet scrubbers or dry scrubbers for SO_2 control. As noted previously, wet and dry systems are demonstrated to be compatible, and it would be inappropriate to exclude from the MACT floor pool those units equipped with wet or dry systems because some of the control systems do better with some pollutants (*e.g.,* wet scrubbers with HCl) than others (*see* previous memorandum).

EPA disagrees strongly with commenters arguing that Congress has directly addressed the issue of whether the MACT floor can be established on a pollutant-by-pollutant basis. With respect to the MACT floor mandate of Section 112, there appears, rather, to be a substantial ambiguity in the statutory language about whether the MACT floor is to be based on the performance of an entire source or on the performance achieved in controlling particular hazardous air pollutants. The language regarding best performing ''sources'' (or, for new sources, ''source'') could apply either to the sources' (or source's) performance as a whole, or performance as to a particular pollutant or pollutants. The same is true of the definition of ''emission limitation'' in Section 302(k), which refers to ''air pollutants,'' but does not address whether the limitation must apply to every pollutant emitted by a source, or just some of them. (The same is true of the reference to ''air pollutants'' (in the plural) in Section 112(d)(2).) In this regard, we note that commenters in other MACT rulemakings have assumed that Section 129, which governs today's rule and which uses language essentially identical to Section 112 in mandating MACT, requires a pollutant-by-pollutant approach to establishing floors, because EPA is commanded to establish standards for enumerated pollutants under Section 129(a)(4). We further note that the DC Circuit, when reviewing the floor determinations we made in 1997 for HMIWI under Section 129 in *Sierra Club* v. *EPA,* noted that they were set pollutant-by-pollutant and found no error in this approach (*see* 167 F.3d at 660) (although this aspect of the rule was not challenged specifically). Indeed, the commenters who object so vehemently to the pollutant-by-pollutant approach in this rule raised no such objection when the opportunity to litigate the same approach in establishing the 1997 HMIWI standards was first presented.

EPA also believes that the commenters' reference to basing MACT floors on the performance of a hypothetical or theoretical unit, so that the limits are not based on those achieved in practice, is not only wrong factually (*see* above), but just re-begs the question of what the language in Sections 112(d)(3) and 129(a)(2) is referring to. We did not base the controls or emissions levels on theoretical sources, but on the performance of actual units in the HMIWI source category. All of the MACT floors are achieved in practice (since they are based on actual performance data). Moreover, the DC Circuit has emphasized that EPA may use any reasonable means to determine what levels of performance are achieved in practice. *Sierra Club* v. *EPA,* 167 F.3d at 663, 665. The commenters' reliance on cases that they claim preclude EPA's use of a pollutant-by-pollutant approach does not compel a unit-based approach, and the issue is not critical to EPA's position in any event, since the record shows that some units are meeting all of the floor limits and many are meeting several of them. At the very least, the *CMA* v. *EPA* decision under the CWA supports the proposition that a technology-based standard can be considered achievable even if all limits are not yet met by a single unit. Since the floor standards are demonstrably being achieved in practice by some sources, this issue is largely academic.

In short, EPA is not persuaded that the floors must be established on the basis of a unit's performance for all pollutants overall. We continue to believe, as we explained in the 1997 final rule, that such a reading would lead to results that are at odds with evident congressional intent (and with the Court's rulings in NLA II, CKRC and Brick MACT). To argue that Congress compelled this type of result is at odds with both the language of Sections 112 and 129 and common sense. Indeed, it would necessarily suggest that EPA could continue to adopt floors that reflect ''no emissions reduction,'' even after the DC Circuit so emphatically forbade that approach in the Brick MACT ruling (*Sierra Club* v. *EPA,* 479 F.3d 875 (DC Cir. 2007).

As we stated in the preamble to the 1997 regulation (62 FR 48363), we recognize that the pollutant-by-pollutant approach for determining the MACT floor can, as it does in this case, cause the overall cost of the regulation to increase compared to what would result under a unit-based methodology. For example, the pollutant-by-pollutant approach for the HMIWI regulation results in a stringent MACT floor for HCl based on control using a wet scrubber, and stringent MACT floors for PM and metals based on control using a dry scrubber. We interpret Section 129 of the CAA to require that the MACT floor be determined in this manner, and we believe that Congress did in fact intend that sources subject to regulations developed under Section 129 meet emissions limits that are achieved by the best controlled unit for each pollutant, as long as the control systems are compatible with each other. To our knowledge, there is no technical reason why these two air pollution control systems cannot be combined. (62 FR 48363–4) Combined dry/wet scrubber systems are currently in operation on several HMIWI. In response to commenters' concerns regarding the technical feasibility of combined dry/wet systems, available data on the performance of combined dry/wet scrubber systems indicate that the MACT floor emissions levels are achievable and technically feasible. The performance of dry scrubbers with activated carbon injection and the performance of wet scrubbers are well-documented. The available data for combination dry/wet systems provide no indication of operational or emissions problems that occur as a result of combining dry and wet control systems. Regarding the inverse relationship between CO and NO_X with regard to combustion control, it is incumbent upon the HMIWI facility to determine whether combustion

conditions can be adjusted to meet both standards and, if not, install add-on NO_X controls as necessary, *e.g.,* SNCR systems.

The MACT floor reflects the least stringent emissions standards that EPA may adopt in accordance with Section 129(a)(2) regardless of costs. Other statutory provisions are relevant, although they also do not decisively address this issue. Section 129(a)(4) requires MACT standards for, at a minimum, PM, opacity, SO_2, HCl, NO_X, CO, Pb, Cd, Hg, and CDD/CDF emitted by HMIWI. This provision certainly appears to direct maximum reduction of each specified pollutant. Moreover, although the provisions do not state whether there is to be a separate floor for each pollutant, the fact that Congress singled out these pollutants suggests that the floor level of control need not be limited by the performance of devices that only control some of these pollutants well. (62 FR 48364)

Regarding the commenter's suggestion that EPA choose the best performing sources on an overall basis, so that at least one source can meet all of the new source standards and a certain portion of the existing sources can meet the existing source standards, we reviewed this approach and found that the suggested approach does not consistently result in emissions limits that are at least as stringent as would have resulted in 1997 if we had actual emissions data and used the correct methodology. We estimate that four emissions limits for large and small non-rural HMIWI and five emissions limits for medium and small rural HMIWI calculated using the suggested overall unit-based approach would be higher than the 1997 emissions limits. Further, because not all pollutants are required to be tested (*e.g.,* NO_X and SO_2), a substantial fraction of available emissions data would have to be discarded in order to rank only those HMIWI with a complete set of data for all nine pollutants (PM, SO_2, HCl, NO_X, CO, Pb, Cd, Hg, and CDD/CDF). Specifically, we would have to discard emissions data for 30 percent of large, 40 percent of medium, 100 percent of small non-rural, and 50 percent of small rural HMIWI in order to calculate MACT floors using the suggested approach. (*See* 2009 memorandum entitled ''Revised MACT Floors, Data Variability Analysis, and Emission Limits for Existing and New HMIWI,'' which is included in the docket for today's rulemaking.)

A unit-based approach would tend to result in least common denominator floors where, as here, multiple pollutants are emitted, whereby floors would no longer be reflecting performance by the best performing sources for those pollutants. For example, if the best performing 12 percent of units for HAP metals did not control acid gases as well as a different 12 percent of units, the floors for acid gases and metals would not reflect best performance. Having separate floors for metals and acid gases in this example certainly promotes the stated purpose of the floor to provide a minimum level of control reflecting what best performing units have demonstrated the ability to do.

Similarly, a unit-based approach that employs ranking of a weighted average of pollutants would require EPA to assume priority for certain pollutants (one unit may have lower NO_X emissions but higher CDD/CDF, for example). This approach would similarly tend to require EPA to disregard the factual levels reflecting the best performers for individual performers, but based on value judgments regarding the risks presented by various pollutants. Such considerations are antithetical to strictly performance-based analyses such as MACT floor determinations. Indeed, reviewing EPA's primary copper smelters MACT standard, the DC Circuit rejected the argument that risk-based considerations have any place in the MACT context (*see Sierra Club* v. *EPA,* 353 F.3d 976 (DC Cir. 2004).

3. Adequacy of Emissions Test Data

Comment: Multiple commenters argued that the proposed standards are flawed because EPA has not demonstrated that the actual emissions data on which the proposed rule is based adequately represent the full range of performance of tested facilities. According to various commenters, the emissions data were derived from performance tests conducted under ''representative operating conditions,'' rather than the ''worst reasonably foreseeable circumstances'' contemplated by the case law. *See Sierra Club* v. *EPA,* 167 F.3d 658, 665 (DC Cir. 1999). Commenters stated that the proposed emissions limits did not adequately account for variability, and said EPA should have sought out more test data and specifically requested continuous monitoring data to properly characterize variability.

Another commenter specifically recommended that EPA gather additional data on emissions of medium HMIWI such as theirs before finalizing the rule to ensure each medium HMIWI has data sufficiently accurate and representative to properly set a MACT standard in accordance with the CAA Amendments. According to the commenter, rigorous quality assurance/quality control (QA/QC) procedures should also be applied to the test data.

One commenter stated that, because the new regulations are solely based on previous stack testing, the actual emissions tests need to be reviewed by EPA for technical accuracy, as well as consistency. Although there may have been insufficient time under the court-ordered schedule, the commenter argued that proposed standards cannot be defended technically in the absence of such an analysis.

The same commenter also stated that revisions to EPA's incinerator test protocol are needed to ensure that the unit is being tested at proper design conditions. At a minimum, the commenter said that incinerator temperature, waste input rate and constituents, auxiliary fuel consumption, quench rates (air and water), and chemical feed rates need to be recorded during an incinerator test to determine whether the operating and testing conditions were representative of the higher emissions rates that can be experienced during normal operations. Given that emissions are determined by waste characteristics, the commenter recommended that a standardized realistic worst-case test waste be used, which includes specific criteria components, as well as moisture content and heating value. Incinerators would be tested with the standard waste and the top 12 percent identified.

Response: First, in response to industry commenters who claim we should have gathered more data, we note that nothing precluded them from giving us more data to consider in responding to the Court's remand, if they felt that the data submitted to us for purposes of showing compliance with the 1997 standards was not representative of their normal operations. We have reasonably used the data available to us at the time we conducted this rulemaking, in the absence of being provided with any other data. We agree with the commenters that emissions tests might provide information on representative operations only where owners and operators conducting the tests have endeavored to reflect such representative operations at the time of the tests. However, when conducting tests to establish various parameters to be monitored, owners and operators may also endeavor to produce data for a wide range of operating conditions. Moreover, we have taken several steps to try and account for the emissions and operational variability, including (1) obtaining additional emissions test data

from States and EPA Regions representing all available annual test results for each unit, (2) using individual test run data for the best-performing 12 percent of sources to calculate UCL values, (3) using a substantial confidence interval (specifically, a 99 percent UCL value), and (4) closely reviewing how the data are distributed (*e.g.,* normally, lognormally). Also, EPA's own review of emissions factors shows that the variability of emissions between facilities is greater than the variability within facilities.

We believe that the data quality concerns expressed by the commenters have been addressed in a number of ways. First, EPA test methods incorporate data quality assurance and quality control steps and acceptance criteria at several levels. These provisions assure that the data produced are of quality sufficient for decision making, including compliance, when the methods are followed and the acceptance criteria are met. Second, States further assure that testers adhere to the test methods by providing third party oversight and review of compliance tests conducted by industry, such as that being discussed here. The States also implement the source testing audit program when available, further assuring the high quality of emissions testing data. Third, through internal and contractor support efforts for this regulatory project, EPA conducted additional review of the initial emissions test data to check for completeness and appropriate characterization of process operations. Finally, EPA reviewed and accounted for variability inherent in the emissions data used in establishing the applicable emissions limit including applying statistical confidence intervals.

Regarding the comment about revisions to EPA's incinerator test protocol, the factors cited by the commenter could be considered in setting site-specific compliance conditions. Such an approach may be useful at the next technology review. The commenter's suggestion that EPA use a standardized waste for testing is questionable, unless EPA wanted to establish a certification testing program like the residential wood combustion rule. However, such a program would be cumbersome and could potentially eliminate a majority of the industry.

Comment: Three commenters stated that EPA did not consider the accuracy and precision of the EPA test methods in proposing the emissions limits for new and existing HMIWI. To support their argument, the commenters referenced the findings of the Reference Method Accuracy and Precision (ReMAP) program co-sponsored by the American Society of Mechanical Engineers (ASME). According to the commenters, one of the main objectives of the ReMAP project was to ensure emissions limits would properly consider the inherent accuracy and precision limits of the test methods used to demonstrate compliance, such that a facility would not be in violation of a limit as a result of this inherent variability. The commenters noted that the ReMAP program established Precision Metrics for various reference methods and corresponding pollutants (*e.g.,* ±42 percent for CDD/CDF Method 23), and they compared these Precision Metrics to actual stack concentrations and proposed emissions limits for several pollutants. Based on this comparison, the commenters concluded that EPA did not adequately address these Precision Metrics in establishing the proposed limits.

Response: As noted above, we already took into account variability inherent in the data representing emissions and process operations in establishing the emissions limit. By using UCLs to set our emissions limits, we have inherently accounted for measurement precision. In fact, the adjustments we made to the average stack concentrations for the best-performing 12 percent of units to calculate the final emissions limits more than account for the Precision Metrics cited by the commenters. Thus, any additional adjustments of measurement to account for method precision are unnecessary.

Comment: One commenter stated that there are significant deficiencies in the emissions data used to establish the standards. Some of the standards are based on data from a limited number of stack tests. According to the commenter, there needs to be a standard for the minimum number of stack tests that must be performed before its data can be used as the basis for determining the top 12 percent performing incinerators. Because of the waste characteristics and variability, the commenter recommended a minimum of four tests. The commenter noted that some of the units included in the top 12 percent are specialty incinerators, which the commenter said are not representative of the subcategory as a whole. The commenter also noted that another unit incinerates municipal waste, which the commenter argued should cause its data to be invalid for the proposed HMIWI standards. According to the commenter, municipal waste would be expected to have a makeup that produces significantly lower emissions for some pollutants (*e.g.,* CDD/CDF, Cd). The commenter recommended developing a testing metric (*e.g.,* heating value, flue gas per pound of feed) and applying it to the data used to indicate possible flaws (*e.g.,* variations and/or abnormalities) which would spur further investigation into the validity of the data. Of the 45 emissions tests used to develop emissions limits for the large subcategory, the commenter concluded that 38 of those tests could be considered invalid because of too little testing or the unrepresentative content of the incinerated waste stream.

Response: Regarding the commenter's argument about claimed deficiencies in the emissions data used to establish the standards, we do not believe that data from high quality tests should be dismissed simply because there are only a few tests. As noted above, we have reasonably relied upon the data we had available to us, and we have already taken steps to alleviate concerns about the representativeness of the measured data used to establish the emissions limit, including calculating UCL estimates using standard statistical conventions.

Regarding the commenter's concerns about the specialty incinerators and the facility that also incinerates municipal waste, we evaluated creating separate subcategories for captive units (which would include the specialty incinerators) and a separate subcategory for mixed waste units, but as noted above, we ultimately rejected both options because we did not provide an opportunity to comment on the issue of subcategorization in the December 2008 re-proposal or a record that would justify such a significant change in categorization. Another option to address the facility incinerating municipal waste would be to use only the emissions data from those tests conducted with 100 percent medical waste, but that would limit the number of tests for that facility. Also, we have found a significant amount of overlap in emissions (including CDD/CDF and Cd) between the different test conditions at the facility (*e.g.,* 100 percent medical waste, 50 percent medical waste, 20 percent medical waste, *etc.*), suggesting that such a distinction in waste type is not very meaningful in this case. (*See* 2008 memorandum entitled ''Documentation of HMIWI Test Data Database,'' which is included in the docket.)

Comment: Three commenters stated that some emissions test data were improperly excluded from the dataset, including data deemed ''non-compliant,'' data collected at HMIWI subsequently shut down, and data collected under specific ''test

conditions.'' The commenters argued that emissions test data from compliance tests that were conducted in accordance with the applicable reference test methods for affected HMIWI should not be arbitrarily excluded from the re-stated MACT dataset, because that undermines the entire data evaluation process. The commenters stated that EPA provides no rationale for arbitrarily including data in some instances, and excluding them in others. Thus, according to the commenters, EPA's proposed standards are arbitrary and capricious. The commenters said that inclusion of all valid test data provides a better representation of the inherent variability of the various test methods and source operation. According to the commenters, EPA's MACT floor dataset was inconsistent, leading EPA to rely on an unrepresentative set of data. The commenters recommended that EPA provide a clear description of ''representative HMIWI operation'' so that consistent criteria are applied to evaluate whether valid emissions test data were properly included or excluded from the MACT floor dataset.

Response: Non-compliant emissions data from the initial tests of HMIWI were not included in the emissions database used to establish the emissions limits. At the time of the initial test, operators were still in the process of establishing their operating parameters and tuning their emissions control devices and operating conditions to comply with the regulation. Any non-compliant emissions data from the initial test would be expected to trigger a change in HMIWI operation in order to come back into compliance with the 1997 standards. Consequently, the non-compliant emissions data from these tests would not be representative of the typical operation of these HMIWI.

If non-compliant emissions data from an annual test were substantially higher than the emissions typically seen from the facility or were substantially higher than the emissions limit, this strongly suggested that there was a problem during the test and indicated that the test results would not be representative of the typical operation of the HMIWI. Such data were excluded from the pollutant averages for the particular facility. (It should be noted that the data that were excluded amount to less than 1 percent of the total set of emissions data for the industry.) For example, the emissions data from tests on one unit did not meet the PM or Cd emissions limit during an August 2006 annual test. A subsequent retest of this unit for those same pollutants in November 2006 showed PM emissions results less than 10 percent of those measured earlier, and Cd emissions results about 0.1 percent of the previously measured results. Consequently, we believe that the August 2006 PM and Cd test results were not representative of the typical operation of the HMIWI, and they were not included in the test data database. The PM and Cd retest data from the November 2006 retest were included instead. (*See* previous memorandum.)

We also excluded test data if we found errors in the calculations or the test methods, or some important elements of the data needed to calculate emissions in the form of the standard were missing. For example, we excluded the TEQ emissions estimates provided for a 2005 annual test at a second HMIWI because the reported TEQ estimates were greater than the total CDD/CDF estimates provided, a clearly incorrect result. The total CDD/CDF estimates were believed to be the correct values because they were well within the applicable emissions limit, while the TEQ estimates were a few times higher than the applicable limit. The 2001 annual test results for HCl at a third HMIWI were deemed invalid because the HCl sample train did not meet the method's ±95 percent sample collection efficiency requirement. There was believed to be some contamination in the sample collection and/or recovery during the 2005 Pb test at a fourth HMIWI, so a retest in February 2006 was conducted. The Pb results from the February 2006 retest were included with the results of the 2005 annual test in the test data database, replacing the 2005 Pb results. The first HCl test run during a 2006 test at a fifth HMIWI was below the detection limit, and the laboratory that analyzed the samples did not provide a detection limit for this test run. In this case, we decided to delete the results for this particular test run and calculated the HCl average for the 2006 test using the results from the other two test runs. Similarly, the second Hg test run during the 2003 test at a sixth HMIWI was reported to be below the detection limit, but the data summary did not include the measured Hg detection limit. Attempts to obtain the detection limit for this test run from the facility were unsuccessful. Consequently, we decided to delete the results for this test run and calculated the Hg average for the 2003 test using the results from the other two test runs. (*See* previous memorandum.)

A couple of annual compliance tests were excluded from the unit averages because they were conducted under test conditions (*e.g.,* reduced emissions control) that were not considered representative of the typical operation of the HMIWI. The exclusion of these tests had little impact on most of the pollutant averages for these HMIWI, and it should be noted that these HMIWI are not in the MACT floors of the pollutants of interest. One HMIWI was unable to meet the CDD/CDF emissions limit during the 2003 and 2004 annual compliance tests conducted without activated carbon. Only when activated carbon injection was included as a second test condition during the 2004 annual compliance test was the facility able to meet the CDD/CDF emissions limit. Consequently, we determined that the second test condition was more representative of the typical, current operation of the HMIWI. During a Hg annual compliance test, another HMIWI was unable to meet the Hg percent reduction limit under the test condition with a lower activated carbon injection rate, but was able to meet the limit under the test condition with a higher activated carbon injection rate. The Hg data meeting the limit were considered representative of the typical operation of the HMIWI, and the other Hg data were rejected. (*See* previous memorandum.)

Regarding the argument that EPA improperly excluded data available from HMIWI that subsequently shut down, we believe that it is appropriate in this particular rulemaking to base the MACT floor on emissions data from facilities that are currently operating, since those are the facilities that would be complying with the rule.

Comment: Three commenters stated that the treatment of individual ''non-detect'' data points within the MACT floor dataset should be consistent and should represent the actual detection level of the pollutant of concern. The commenters noted that non-detect or zero data provided as part of the latest data request were considered equal to the method detection limit, while CDD/CDF test data already in EPA's project files were calculated at one-half the detection limit. While this approach may be valid for total CDD/CDF, the commenters argued that it could have a profound effect on TEQ.

Response: In response to the commenters, it should be noted that section 9 of EPA Method 23 specifies that ''[a]ny PCDD's or PCDF's that are reported as below the measurement detection level (MDL) shall be counted as zero for the purpose of calculating the total concentration of PCDD's and PCDF's in the sample.'' The CDD/CDF results reported in the facilities' initial test reports and provided by States and EPA Regions in the annual test summaries reflect this computation approach. Consequently, by using one-half the detection limit in our review of

CDD/CDF data in full test reports, we were being conservative in our estimation of CDD/CDF emissions. Nonetheless, we looked at those HMIWI in the MACT floor for total CDD/CDF and TEQ to determine whether using the full detection limit would make a substantial difference. When we averaged in the results with all other CDD/CDF results for each facility, we found on average essentially no difference in total CDD/CDF emissions estimates (less than 1 percent) and only a small difference in TEQ emissions estimates (0.1 to 20 percent) for the four HMIWI size categories. (*See* 2009 memorandum entitled ''Comparison of CDD/CDF Non-Detect Data—Full Detection Limit vs. ½ Detection Limit,'' which is included in the docket for today's rulemaking.)

4. Non-Technology Factors

Comment: Numerous commenters stated that the variability in non-technology factors, such as the materials and composition fed to combustion devices, must be adequately addressed in the rulemaking process in order to promulgate a feasible rule, *Sierra Club,* 479 F.3d at 883 and *Cement Kiln Recycling Coalition* v. *EPA,* 255 F.3d 855, 865 (DC Cir. 2001). According to various commenters, EPA did not identify the non-technology factors in the proposed rule or quantify their effect on actual emissions performance, but instead claimed, without supporting evidence, that using actual emissions levels accurately reflects emissions performance resulting from the use of add-on controls and other emissions reduction measures. Commenters argued that the failure to make these findings renders the proposed standards arbitrary. Another commenter disagreed, stating that EPA's proposed floor approach for new and existing HMIWI is generally correct and that EPA correctly observed that the use of actual emissions levels accounts for all emissions reduction strategies.

Response: With regard to the commenters' argument, the CAA does not require EPA to quantify the emissions reductions resulting from all non-technology factors, but instead focuses on identifying the emissions levels achieved by best performing sources no matter what means they use to achieve them. This approach is supported by the DC Circuit's decision in the Brick MACT case, which stressed the importance of identifying emissions ''levels'' achieved by sources. There can be no dispute that both the composition and level of emissions exiting the incinerator reflect both the add-on control technologies used by a unit (*e.g.,* dry scrubber, wet scrubber, activated carbon) that control the emissions and the non-technology factors (*e.g.,* waste material quantity and composition, combustion conditions) that influence the level and composition of emissions. As the *Sierra Club* Court noted in 1999, the less mercury fed into the waste stream, the less mercury emissions will be coming out of the stack. Whatever combination of add-on controls and non-technology measures a unit is employing will, therefore, necessarily affect the resulting emissions levels that are reflected in the actual emissions data upon which the revised floors are set. It would be impossible for those data to not reflect all those measures. This situation is quite the opposite of what was presented in the 1997 rulemaking, in which the floors were primarily derived from permit and regulatory levels that were not necessarily reflective of actual emissions performance but were assumed to reflect levels achievable by add-on control only. At that time, to adjust floors downward to account for non-technology factors, it might indeed have been necessary to be able to quantify additional emissions reductions attributable to such measures. Similarly, as the 2007 proposed remand response still in large part relied upon the permit and regulatory levels, not knowing the quantified reductions achieved by non-technology measures frustrated estimating the emissions levels achieved in practice by HMIWI. But this is simply not an issue under a methodology that depends upon the measured emissions levels that result from whatever mix of add-on or non-technology controls is being used, as under the 2008 re-proposal and today's final rule. The non-technology factors cannot help but affect the actual emissions data, and they are, therefore, necessarily accounted for in the actual emissions data-based floors.

EPA's data gathering effort for this rulemaking included not just initial and annual emissions test data obtained from EPA Regions, State/local governments, and HMIWI facilities, but also a waste segregation practices questionnaire sent to nine representative entities in the HMIWI category (six hospitals, one pharmaceutical facility, one university, and one company that owns 8 of the 14 commercial HMIWI). (*See* 2008 memoranda entitled ''Documentation of HMIWI Test Data Database'' and ''Summary of Industry Responses to HMIWI Waste Segregation Information Collection Request,'' which are included in the docket.) While our analysis of the emissions test data indicates a strong relationship between add-on control and emissions (*e.g.,* wet scrubbers achieve superior HCl control, while dry scrubbers achieve superior PM and metals control), our review of the questionnaire responses indicates that non-technology factors also play a role in emissions reduction. All of the survey respondents, except for the commercial company, practice onsite waste segregation to reduce the volume of waste being incinerated. Most of the respondents started the practice of waste segregation in the 1980s and 1990s. Five respondents also accept offsite waste and require the offsite waste generators to employ waste segregation practices. The commercial company encourages waste segregation from its waste generator clients through a number of efforts, including a waste management plan, contract requirements and waste acceptance protocols, a dental waste management program, and educational programs and supporting posters. All of the respondents that practice onsite waste segregation separate batteries and fluorescent bulbs (*i.e.,* mercury waste) from the HMI waste stream. Eight respondents separate paper and/or cardboard, four separate glass, and three separate plastics from the HMI waste stream. Other materials that are separated from the HMI waste stream include hazardous waste, waste oil, wood, construction debris, refrigerants, and various metals and metals-containing materials (*e.g.,* aluminum, copper, lead, mercury, steel, and electronics). (For further information, *see* 2008 memorandum ''Summary of Industry Responses to HMIWI Waste Segregation Information Collection Request,'' which is included in the docket.) These waste segregation efforts would certainly have an impact on the emissions of CDD/CDF, mercury, and other pollutants from these HMIWI and would be reflected in the emissions levels measured during their initial and annual emissions tests and used in our test data analysis. As noted previously, the nine entities surveyed were believed to be representative of the HMIWI industry as a whole, so the conclusions reached for the nine entities are also expected to apply to the entire industry as well.

5. Straight Emissions Approach

Comment: Two commenters argued that the parenthetical language in the Brick MACT decision equating the best performers with ''those with the lowest emissions levels'' (straight emissions approach) was only a legal dictum to

which EPA is not bound, and which is not cited in either the CKRC decision or the CAA. The commenters cited *Sierra Club* v. *EPA,* 479 F.3d 875, 880 (DC Cir. 2007) (Brick MACT), and *Cement Kiln Recycling Coalition* v. *EPA,* 255 F.3d 855, 861 (DC Cir. 2001). In citing EPA's justification for the MACT floor approach used in the hazardous waste combustor rulemaking, the commenters stated EPA's position that the CAA does not require the Agency to equate the best performers with the lowest emitters. The commenters specifically cited EPA's statement that, ''as a legal matter, CAA Section 112(d)(3) does not specifically address the question of whether 'best performing' sources are those with the lowest net emissions, or those which control HAP emissions most efficiently.''

The commenters also noted that, since the Brick MACT decision, EPA has determined that there are other ways to rank the best performing sources and set the MACT floors than a straight emissions approach, such as the approach used in the hazardous waste combustor rulemaking, which combined the hazardous waste fed to the source and the source's system removal efficiency (SRE). According to the commenters, the ''SRE Feed'' methodology better identifies who the lowest emitters will be over time, better assesses their performance (*i.e.,* how much they will emit as they operate), and better accounts for variability (*e.g.,* non-technology factors).

Response: It is not necessary to adopt a position regarding whether the Brick MACT Court's references to ''emissions levels'' is dictum or binding for purposes of this rulemaking. In the 1999 HMIWI case, the Court very clearly stated that EPA's duty here was to use data that allowed the Agency to reasonably estimate the emissions performance of the best performing units. We have discovered that the permit and regulatory data upon which the 1997 rule was based do not reliably serve this purpose. Conversely, the actual emissions data from HMIWI do enable us to estimate the performance of the best performers. We believe that the use of actual emissions data, appropriately adjusted for variability using statistical methods, sufficiently accounts for the performance and variability of HMIWI operation. Regarding the commenters' reference to CAA Section 112(d)(3) to support their argument regarding the definition of ''best performing'' sources, we assume the commenters also meant Section 129, which governs this rule.

We do not think the SRE Feed methodology can be successfully adapted to determine MACT floors for HMIWI. This is because the SRE Feed approach requires knowledge of the amount of hazardous materials fed into the system and knowledge of the system's removal efficiency for those specific materials, neither of which is known or measured in the HMIWI industry. Such materials are mixed in with other waste and cannot reasonably be measured separately, especially given the occupational safety regulations to which HMIWI operators are subject.

6. Statistical Approach

Comment: Multiple commenters stated that the statistical methodology EPA used to establish MACT floors did not properly account for underlying non-technology factors such as feed material quantity or composition or for normal operational variability within and across unit operations, which led to unattainable emissions limits.

Three of those commenters supported the conditional use of the 99.9 percent UCL to quantify ''emissions limitation achieved'' as it applies to variability above average emissions. However, the three commenters had concerns about EPA's methods used to calculate statistical parameters. The commenters stated that EPA should characterize emissions data distributions before calculating statistics, instead of assuming all data are normally distributed. Otherwise, according to the commenters, it is difficult to determine if the statistics are valid. When data are not normally distributed, the commenters recommended that EPA transform the data prior to conducting its statistical calculations. The commenters noted that EPA used the NORMSINV function in Microsoft Excel to calculate the 99.9 percent UCL, which assumes that the actual mean and variance of a data set is known. According to the commenters, when the mean and variance are estimated from random samples or a small subset of the total population, such as stack test runs, the 99.9 percent UCL should be calculated with the Student t-statistic using the TINV function in Excel, not normal statistics.

Two other commenters objected to the use of the 99.9 percent UCL to account for variability in determining emissions limits. One of the commenters argued that EPA provides insufficient explanation or justification of its use of the 99.9 percent UCL. According to the commenter, if the performance of the best performing HMIWI, on average, is estimated to meet the emissions limit 99.9 percent of the time, then it would be expected to exceed the emissions limit 8.76 hours per year, which does not comply with the requirement that each source must meet the specified floor every day and under all operating conditions. Therefore, the commenter argued that the 99.9 percent UCL procedure used by EPA is deficient and must be revised.

The other commenter stated that EPA's use of a 99.9 percent UCL to estimate individual units' variability marks a sharp departure from EPA's approach in other rulemakings (*e.g.,* 90 percent and 95 percent UCL), and said that EPA offers no real explanation for this departure from past practice or why a 99.9 percent UCL would account for variability but a lower UCL, such as 99 percent or 95 percent or 90 percent, would not. The commenter recommended that EPA correct its floor approach to avoid the overcompensation for variability seen with some of the floors for new units.

Two commenters stated that a more realistic assessment of an individual unit's ability to meet an emissions limit during a compliance test would use the 99.9 percent UCL for that unit/pollutant instead of the average value.

Four commenters disagreed with EPA's decision to use individual test run results to account for variability in setting MACT floors for new and existing sources. The commenters urged EPA to use complete performance test results instead. One of the commenters argued that EPA is arbitrarily using different measures of performance for establishing emissions standards on the one hand (using test runs) and measuring compliance with these standards on the other (using whole tests), without explaining why different measurement approaches are appropriate. According to the commenter, it appears likely that disaggregating test results leads to less protective floors by creating false variability in individual units' performance. The commenter recommended that EPA calculate the floors with and without disaggregating individual test runs to ensure that its floors are not less stringent as a result of that approach. The other commenters noted that data limitations may not leave EPA an alternative to using test run results in some cases, but they recommended that EPA use complete test results where enough data exist to characterize emissions variability.

Response: Based on the responses to our waste segregation practices questionnaire, we believe that most HMIWI are practicing (or encouraging the practice of) waste segregation of materials such as batteries, fluorescent bulbs, paper, glass, plastics, and metals-containing materials, which we expect

to impact the emissions of CDD/CDF, mercury, and other pollutants and be reflected in the actual emissions data we use in our analysis. (*See* 2008 memorandum ''Summary of Industry Responses to HMIWI Waste Segregation Information Collection Request,'' which is included in the docket.) Consequently, we believe that using actual emissions data sufficiently and inherently accounts for non-technology factors such as feed material quantity or composition which influence the level and composition of emissions. We also believe that our use of multiple emissions tests and individual test runs for each HMIWI, where possible, and our estimation of 99 percent confidence intervals for MACT floor data sufficiently accounts for variability. The use of multiple emissions tests allows us to evaluate ''between-test variability,'' which can occur even where conditions appear to be the same when two or more tests are conducted. As we noted in the preamble to the December 1, 2008 re-proposal (73 FR 72976, 72980), variations in emissions may be caused by different settings for emissions testing equipment, different field teams conducting the testing, differences in sample handling, or different laboratories analyzing the results. Identifying an achieved emissions level needs to account for these differences between tests, in order for ''a uniform standard [to] be capable of being met under most adverse conditions which can reasonably be expected to recur[.]'' (*See NLA I,* 627 F.2d at 431, n. 46.) (*See* also *Portland Cement Ass'n,* 486 F.2d at 396 (noting industry point that ''a single test offered a weak basis'' for inferring that plants could meet the standards).) The use of individual test runs (as opposed to test averages or unit averages) allows us to evaluate ''within-test variability.'' A single test at a unit usually includes at least three separate test runs. (*See* § 63.7(e)(3) (for MACT standards under Section 112 of the CAA), and § 60.8(f) (for NSPS under CAA Section 111).) Each data point should be viewed as a snapshot of actual performance. Along with an understanding of the factors that may affect performance, each of these snapshots gives information about the normal, and unavoidable, variation in emissions that would be expected to recur over time. To account for pollutant-specific variability at the best-performing unit (for new source MACT) or best-performing 12 percent of units (for existing source MACT), we used emissions data for each test run conducted by those units. The amount of pollutant-specific test data for those HMIWI varies widely for each size category. Given the limited amount of test data and the uncertainty regarding that short-term emissions test data, we have decided that using the 99 percent UCL is an appropriate method of estimating variability. The UCL represents the statistical likelihood that a value, in this case an emissions value from the best performing source, will fall at or below the UCL value. (Further discussion regarding the 99 percent UCL is provided later in this section.)

After reviewing the commenters' suggestion that we characterize emissions data distributions before calculating statistics, we took a closer look at our statistical approach. In statistics, skewness is a measure of the degree of asymmetry of a distribution. Normal distributions typically have a skewness of zero. Consequently, to determine whether the emissions test data used in our UCL calculations had a normal or lognormal distribution, we estimated the skewness of the data using the SKEW function in Excel. Except as specified below, those datasets with a skewness value greater than zero (when rounded to a whole number) were categorized as lognormal, and all other datasets were categorized as normal. Those data categorized as lognormal were transformed (by taking the natural log of the data) prior to the calculation of UCL values. When there were only a few data points (*e.g.,* one emissions test with three test runs), which is the case for most datasets for small HMIWI, it was not possible to make a definitive determination that the data were distributed normally or lognormally. (In fact, assuming a lognormal distribution for those data often resulted in UCL values that were substantially higher than the 1997 promulgated limits.) In those cases, we decided to use the normal distribution in calculating UCL values, a conservative assumption which provided a more protective emissions limit. When we had more data and could make a more definitive determination about a dataset's distribution, we treated the data as noted previously. In most cases, we found that the larger datasets are lognormally distributed, although there are some cases where they appear to be distributed normally, and we treated the data as such when doing our UCL calculations. We believe this approach is more accurate and obtained more representative results than those at re-proposal.

Regarding the commenters' suggestion about using Student's t-statistics in calculating the UCL values, we also decided to revisit our statistical approach. We agree that we have only a relatively small, random sample of emissions data available for our analysis, which calls for the use of the Student's t-test, in accordance with standard statistical practice. Consequently, we have decided to use the TINV function in Excel (specifically the one-tailed t-value), rather than the NORMSINV function, to calculate the UCL values. This approach (using the Student's t-test) is consistent with approaches being taken in other EPA rulemakings, such as Portland Cement.

In response to public comments on the size of the confidence limits used at re-proposal and in light of the aforementioned changes in our statistical approach, we also decided to reevaluate the percentiles used in the UCL values. We evaluated four different percentiles (90, 95, 99, and 99.9 percent). The 99.9 percent UCL values estimated for the 2009 final rule are substantially higher than the highest test runs for the MACT floor units and are frequently higher than the emissions limits in the September 15, 1997 promulgated standards, indicating the 99.9th percentile overcompensates for variability. Lower percentiles (*e.g.,* 90, 95, and 99 percent) are inherently more stable than the 99.9th percentile, with less uncertainty (less variability) than the 99.9th percentile from a statistical standpoint. However, the 90 and 95 percent UCL values are frequently lower than the highest test runs for the MACT floor units and the stringent emissions limits in the December 1, 2008 re-proposal, indicating that those percentiles provide insufficient compensation for variability.

The 99 percent UCL values are somewhat higher than the emissions limits in the December 1, 2008 re-proposal but are well below the emissions limits in the September 15, 1997 promulgated standards. The 99 percent UCL values are more in line with the highest test runs for the MACT floor units than the other percentiles, indicating that the 99 percent UCL provides a more reasonable compensation for variability. This approach results in standards more representative of the level of emissions reduction that the best performing sources are actually achieving. Accordingly, we have decided to use the 99 percent UCL to estimate emissions limits for the 2009 final rule.

We disagree with one commenter's argument that the 99.9 percent UCL must provide for the floor to be met every day and under all operating conditions. The UCL is not about time, but about the population of data. Accounting for variability using the 99.9 percent UCL goes beyond the absolute

average but does not produce expectations of 0.1 percent noncompliance. Setting the emissions limit at the UCL accounts for the possibility of variability and the possibility that the average is outside the range. These statistical procedures are used to help us identify the average emissions limitation achieved by the best performing units, as Section 129(a)(2) of the CAA requires. Also, there is no practical upper limit as to what a facility can emit, so the argument that that EPA must set a floor at a level that equates to what a facility can meet at all times is not consistent with the CAA's requirement that EPA estimate the emissions levels achieved by best performing units.

Regarding the comment about our decision to use individual test run results to account for variability, we felt it was necessary to use test run results when we had data limitations (*e.g.,* for small HMIWI) and for consistency decided to take the same approach where data were more plentiful. As noted previously, we believe that each data point should be viewed as a snapshot of actual performance, which gives information about the variation in emissions that would be expected to recur over time.

D. Emissions Limits

1. HCl, CDD/CDF, and Metals Emissions Limits

Comment: One commenter argued that EPA's proposed HCl standards of 2.4 parts per million by volume (ppmv) for existing sources and 0.75 ppmv for new sources are based on biased data of indeterminate quality and are unachievable. The commenter also claimed that setting the HCl standards at such low levels will negatively impact the development and application of CEMS, due to the lack of correlation between Method 26A and CEMS at concentrations comparable to the proposed standards. According to the commenter, the test results (Methods 26 and 26A and RCRA SW 846 Method 0050) that EPA used to set the HCl standards contain a known bias at low levels of HCl, varying widely with temperature and moisture at HCl levels below 20 ppmv (all three methods), and having a negative bias at HCl levels below 5 ppmv (Method 26A). The commenter noted that all of the top performers in the large, medium, and small non-rural categories use wet scrubbers to control HCl emissions, and will have considerable moisture in the stack gas. Thus, the data from every one of these sources has the potential to be biased. The commenter argued that HCl data below 20 ppmv are not usable and/or representative and are technically indefensible. The commenter recommended that EPA follow the example of Office of Solid Waste (OSW), which corrected all HCl values below 20 ppmv to 20 ppmv, used a statistical method to impute a standard deviation for these test runs, and calculated a floor standard based on those values.

Response: We are basing the HCl standards in this rulemaking on the data we have available to us from the HMIWI source category, and can base them only on that data. The sensitivity of Method 26A for HCl is 0.04 ppmv. Moisture is only an issue with Method 26A if the testing contractor does not perform the method correctly. Unless we are given data to the contrary, we assume that the HCl data in our dataset are correct. These data, for this particular rulemaking, support the HCl standards being adopted today.

Nonetheless, we acknowledge that the HCl standards in our re-proposal were very close to the method detection limit for HCl. The changes in statistical approach for the final rule have resulted in increases to the HCl standards above 5 ppmv, which should address some of the concerns listed above. Furthermore, based on reported HCl emissions data for all HMIWI, we estimate that 64 percent of large, 82 percent of medium, and 100 percent of small/small rural HMIWI will be capable of meeting the revised HCl standards, on average, based on their currently used control measures. It should also be noted that HMIWI subject to the 1997 NSPS have been meeting the 15 ppmv HCl standard in that rule, which is below the 20 ppmv threshold level that the commenter cited.

Comment: One commenter recommended that EPA set beyond-the-floor standards for both HCl and chlorinated organic pollutants (including CDD/CDF) based on removing chlorinated plastics from the waste stream. According to the commenter, it is well established that the combustion of chlorinated plastics increases emissions of HCl as well as CDD/CDF and other chlorinated pollutants. The commenter stated that it is achievable for HMIWI to remove chlorinated plastics from the waste stream that they burn. The commenter said that EPA can gather data that will quantify the total amount of HCl that is attributable to the combustion of chlorinated plastics and set a standard reflecting the maximum degree of reduction that is achievable through the removal of chlorinated plastics from the waste stream.

The same commenter also recommended that EPA set beyond-the-floor standards for metals based on removing all metals from the waste stream before combustion, consistent with the requirements under Section 129(a)(2) and (3), which obligate EPA to require the maximum degree of reduction in emissions that is achievable through the use of methods and technologies before, during, and after combustion. The commenter stated that metals do not belong in an incinerator because they cannot be destroyed by incineration and are especially dangerous to public health and deleterious to the environment. As far as the commenter knew, EPA has never disagreed that removing metals from the HMIWI waste stream is achievable technically and economically, and the commenter noted that EPA has data from the MWC rulemaking that show materials separation requirements are effective and cost-effective. (*See* Docket A–89–08, various items.)

Given the language of Section 129 that requires the maximum degree of reduction in emissions that is achievable through the use of pre-combustion measures, the commenter argued that EPA has a duty to gather information on these measures and evaluate such measures in its beyond-the-floor analysis. According to the commenter, EPA's failure to gather information about the precise reduction of emissions that will result from such measures and failure to provide any explanation for rejecting such a standard is unlawful and arbitrary. The commenter noted that EPA has committed to set final standards by September 2009, and stated that EPA should not delay issuance of final standards to conduct this data gathering, but should commence data gathering now and revise the HMIWI regulations to include beyond-the-floor standards in the future.

Response: As we explained in the 2008 re-proposal, the identified beyond-the-floor add-on control measures we analyzed were not reasonable on a cost-effectiveness basis, especially in light of the significantly more stringent floor levels as compared to the 1997 rule's standards. We read the commenter's suggestion that we examine additional beyond-floor measures but without delaying final action on the re-proposal as recommending that we conduct the requested data gathering and analysis for those measures in a subsequent rulemaking action. A possible opportunity for that would be the next review of the rule under Sections 129(a)(5) and (h)(3). In the interim,

however, we have decided to revise the waste management plan provisions in §§ 60.35e and 60.55c to promote the segregation of chlorinated plastics and metals to the extent possible.

2. CO Emissions Limits

Comment: One commenter argued that the proposed CO emissions limits will be unattainable by many applicable units, based on the emissions data provided in the docket. The commenter stated that the add-on controls evaluated by EPA do not reduce CO emissions, and that CO emissions can be a function of the feed material composition (which the commenter stated EPA did not evaluate). As a result, the commenter stated, HMIWI operators will have very little latitude or options to meet the proposed CO limits. Three other commenters stated that historical CO CEMS data from well-performing commercial HMIWI demonstrate that the proposed CO emissions limit is not achievable on a continuous basis and argued that the existing 40 ppmv emissions limit must be retained. The commenters further stated that the proposed CO standards must include a reasonable, extended averaging period (*e.g.,* 24 hours) that accounts for the variability of the waste stream and waste characteristics. The commenters noted that the proposed standards are currently based on discrete 3-hour average data developed during performance test conditions, which they said do not account for the typical operational variability. According to the commenters, such snapshot data are also not representative of long-term continuous monitoring, placing facilities with CO CEMS at a competitive disadvantage with any revisions to the CO standard.

The same three commenters also stated that the proposed CO standard in combination with the 7 percent oxygen (O_2) diluent correction factor will pose technological monitoring challenges to HMIWI that either choose or will be required to use CO CEMS, especially given the variability of HMIWI operations and waste feed streams. According to the commenters, costly monitoring systems (*e.g.,* dual range or ambient level monitors) will be needed, resulting in additional QA activities. The commenters further stated that the application of an O_2 correction factor to the measured CO concentration CEMS data may cause artificial exceedances of the CO emissions standard at higher O_2 operating scenarios.

Response: Based on our review of CO emissions data for all HMIWI, we have found many HMIWI outperforming the existing 40 ppmv CO limit. We believe that the CO limits developed using the revised statistical approach are more representative of actual operation, and we estimate that a substantial percentage of HMIWI with their current controls will still be capable of meeting the revised limits (89 percent of large, 76 percent of medium, and 100 percent of small/small rural HMIWI, on average). Therefore, we disagree that the 40 ppmv CO limit must be retained.

Regarding the comment about the 3-hour average basis for the CO limit, it should be noted that the 2008 re-proposal included an amendment to § 60.56c allowing sources using CEMS to demonstrate compliance with the applicable emissions limit on a 24-hour block average, instead of a 12-hour rolling average (as specified in the 1997 final rule). This amended provision should address concerns about the ability of sources equipped with CEMS to demonstrate compliance with emissions limits on a continuous basis (as opposed to a 3-hour annual test) and would be consistent with past rulemakings for incineration units (*e.g.,* large and small MWCs).

Regarding the comment about the application of an O_2 correction factor to the CO CEMS data, it should be noted that correction to consistent standards (*e.g.,* percent O_2) is necessary in order to compare to other units and to an emissions limit. Applying an O_2 correction factor to CO CEMS should only be a problem at O_2 levels greater than 15 percent. For comparison purposes, we reviewed the O_2 levels recorded in initial test reports, and found only about 7 of 57 HMIWI reported O_2 levels above 15 percent during at least one pollutant test run, and we estimate that 6 of those 7 with their current equipment will still meet the revised CO emissions limits, based on a comparison of the revised limits to the average CO concentrations for those HMIWI.

3. Opacity Limits

Comment: Three commenters noted that EPA requested facility test data from 2003 through 2006 for all pollutants except opacity, even though annual opacity testing is required for all units. According to the commenters, if EPA wanted to review and revise the opacity limit pursuant to Section 129(a)(5), it should have requested opacity data and should have used those data in the re-establishment of the MACT standards. Instead, the commenters said, the proposed opacity limit was inappropriately established from a single continuous opacity monitoring system (COMS) located at a single HMIWI. The commenters argued that data from a single unit are insufficient to set an emissions limit that must be continuously achieved, and they said that EPA must seek additional monitoring data. The commenters also noted that compliance with the proposed opacity limit established by COMS is demonstrated using a different measurement methodology (Method 9).

The same three commenters, plus a fourth commenter, stated that the methodology that EPA used to establish the 2 percent opacity limit fails to account for actual opacity monitoring capabilities and normal operational variability, such as that included in PS–1 (40 CFR part 60, appendix B). According to the commenters, the inherent potential error of a COMS meeting PS–1 could greatly exceed the proposed opacity limit value. The fourth commenter argued that opacity under the worst foreseeable circumstances for the best-performing units would thus easily violate the MACT floor, which the commenter said would violate *Sierra Club.* 167 F.3d at 665.

All four commenters noted that, similar to COMS accuracy, Method 9 calls for recording visual observations to the nearest 5 percent at 15-second intervals. The commenters stated that using a compliance method with inherent potential accuracy levels exceeding the proposed 2 percent opacity limit appears problematic.

Given the limitations of Method 9 and the variability of all the HMIWI subject to the revised opacity standard, the first three commenters recommended that EPA establish an opacity standard based on Method 9 data instead of COMS data from a single unit. All four commenters argued that the current 10 percent opacity limit is reasonable, and would allow conventional compliance determination methods to be used, accounting for their limitations.

Response: The commenters' argument about how we established the proposed opacity limit is somewhat misleading. While we acknowledge that opacity data were inadvertently not included in the 2007–08 test data request, we already had opacity data for nearly 90 percent of all HMIWI from their initial compliance tests, and our initial opacity MACT floor analysis was based on the best-performing 12 percent of sources for opacity. As we stated in the preamble to the December 1, 2008 re-proposal (73 FR 72983), based on the opacity averages alone, without any accounting for variability, the MACT floor for opacity for existing and new units would have been 0 percent. We tried to account for variability by looking at the single highest opacity reading for HMIWI in the MACT floor

for PM, based on opacity being an appropriate surrogate for PM. We based our MACT floor opacity limit on the single highest COMS reading (1.1 percent) for one of the HMIWI in the MACT floor for PM. Because we commonly set opacity standards based on whole numbers and could not round down without risking having the MACT floor unit not meet the standard, we rounded up and proposed an opacity limit of 2 percent for both new and existing HMIWI. However, we now believe this analysis was incomplete. The analysis did not account for two other HMIWI in the MACT floor for PM that could more effectively account for variability for opacity. The maximum opacity averages for these two HMIWI are 5.87 and 4.17 percent. (*See* 2008 memorandum entitled ''Documentation of HMIWI Test Data Database,'' which is included in the docket.) The opacity data for these two HMIWI were measured using Method 9. Using the same approach that we used at re-proposal, we are establishing an opacity limit of 6 percent, by rounding up the highest opacity average of 5.87 percent to the nearest whole number.

Regarding the commenters' arguments that the inherent potential error of a COMS meeting PS–1 could exceed the proposed opacity limits, the potential error (about 4 percent opacity at the highest) is not the same as expected error (more on the order of 0.5 percent). Nonetheless, the increase in the opacity limit to 6 percent should address the commenters' concerns on this issue.

We disagree with the commenters' argument that a 10 percent opacity limit be used to allow conventional compliance determination methods. While opacity is read in 5 percent increments, average opacity can be any number above 0. Method 9 values are averages of 24 readings, which can include readings of 0 and an occasional 5 or 10 percent.

Regarding the commenters' argument that only Method 9 data should be used to establish the opacity standard because that is the measurement method that would be used to demonstrate compliance, the commenters' argument is moot, since the revised opacity standard is now based on Method 9 results.

4. Percent Reduction Limits

Comment: One commenter agreed with EPA's proposed elimination of percent reduction alternatives. According to the commenter, EPA correctly noted that standards based only on control technology performance do not reflect the effects of non-technology factors and, therefore, do not reflect the best units' actual performance. Therefore, the commenter said, allowing units the option to meet these percent reduction limits instead of emissions standards contravenes Section 129, and EPA appropriately proposed to delete the percent reduction limits.

Three other commenters argued that the percent reduction compliance option that was available in the 1997 rule and in the 2007 proposed rule should be re-evaluated and retained for commercial HMIWI, since the ability for such units to reduce emissions is due almost exclusively to the effectiveness of the control equipment (and not waste segregation). According to the commenters, commercial HMIWI facilities, unlike captive units, cannot practically control the waste that is put in the containers they process, and applicable regulations from the U.S. Occupational Safety and Health Administration (OSHA) preclude them from practicing waste segregation at the time of treatment. Thus, the commenters noted, they experience extreme variability during stack tests (especially for volatile metals Cd, Pb, and Hg) and will experience higher inlet concentrations than captive units; since they operate at the same control efficiency, they will exhibit higher stack emissions. The commenters stated that the percent reduction option is a better assessment of the performance of the control system for commercial units.

Response: We have decided not to include percent reduction limits in the final rule. In addition to the reasons we provided in the re-proposal, while commercial HMIWI facilities face greater challenges in controlling the waste they receive, compared to ''captive'' units, they are nonetheless capable of taking steps to educate their customers (*i.e.,* waste generators) regarding waste segregation and should also have some control based on the waste management plans, contract requirements, and waste acceptance protocols they negotiate with their customers. Consequently, non-technology factors are under their control to a limited extent, which does not support their rationale for a percent reduction limit. The effect of raw material inputs on emissions from HMIWI could instead be downplayed by a percent reduction limit that allows more emissions provided a given level of removal efficiency.

5. PCB and POM Emissions Limits

Comment: One commenter noted that EPA has interpreted the CAA as allowing the Agency to meet the requirements of Section 112(c)(6) by setting standards for incinerator emissions of 112(c)(6) pollutants under Section 129. According to the commenter, EPA has acknowledged that HMIWI account for a large portion of the aggregate emissions of both PCBs and POM. Thus, to satisfy Section 112(c)(6), the commenter argued that EPA must use its authority under Section 129(a)(4) to set emissions standards for both of these pollutants. Noting EPA's argument that its standards for CDD/CDF and Hg ''effectively reduce'' emissions of PCBs and POM and thus satisfy Section 112(c)(6), the commenter said that Section 112(c)(6) requires that these HAP be subject to MACT standards. Because the best performing units used to set these standards may be achieving reductions in PCBs and POM by means other than just controlling CDD/CDF and Hg emissions—*e.g.,* by ensuring that no PCB-containing wastes are put in the incinerator or by not incinerating chlorinated plastics—the commenter argued that EPA's standards for CDD/CDF and Hg do not constitute lawful MACT standards for PCBs and POM and, therefore, do not satisfy Section 112(c)(6).

Response: For the reasons we set forth in the 2008 re-proposal (*see* 73 FR at 72991–92) and in the preamble for today's rule (*see* section VII), we continue to take the view that while the rule does not identify specific limits for POM and PCB, emissions of those pollutants are nonetheless ''subject to regulation'' for purposes of Section 112(c)(6). While we have not identified specific numerical limits for POM and PCB, we believe CO serves as an effective surrogate for those pollutants, because CO, like POM and PCBs, is formed as a byproduct of combustion. We believe that dioxins/furans also serve as an effective surrogate for PCBs, because the compounds act similarly and, thus, are expected to be controlled similarly using HMIWI emissions control technology—*e.g.,* wet scrubbers or fabric filters (with or without activated carbon). Furthermore, recent HMIWI emissions test data for PCBs and dioxins/furans show that HMIWI well-controlled for dioxins/furans also achieve low PCB emissions. (*See* 2008 memorandum entitled ''Documentation of HMIWI Test Data Database,'' which is included in the docket.) It should also be noted that PCBs are generally found in higher concentrations than dioxins/furans (also the case for HMIWI), so HMIWI equipped with the aforementioned emissions controls would be even more effective at reducing PCB emissions. Consequently, we have concluded that the emissions

limits for CO function as a surrogate for control of both POM and PCBs, and the limits for dioxins/furans function as a surrogate for PCBs, such that it is not necessary to promulgate numerical emissions limits for POM and PCBs with respect to HMIWI to satisfy CAA Section 112(c)(6).

To further address POM and PCB emissions, the final rule also includes revised waste management plan provisions in §§ 60.35e and 60.55c that encourage segregation of the types of wastes that lead to these emissions, such as chlorinated plastics and PCB-containing wastes.

E. Monitoring

Comment: One commenter argued that the monitoring requirements in the HMIWI regulations are inadequate because they do not provide for emissions monitoring as required by Section 129. According to the commenter, EPA's exclusive reliance on parameter monitoring for most pollutants and units is unlawful. The commenter stated that EPA must require all HMIWI to use the available CEMS (*e.g.,* HCl, Hg, metals, CDD/CDF) to monitor their emissions. The commenter indicated that CEMS are the only requirements that can possibly provide data adequate to ensure compliance with emissions standards and protection of public health and the environment, consistent with Section 129(c)(1).

Two other commenters argued that continuous monitoring of CO with a 24-hour block average should be required of all existing incinerators to assure efficient combustion. However, the two commenters stated that continuous air monitoring of metals and other toxics should not be adopted as an alternative to stack testing until CEMS accuracy and reliability has been fully verified by EPA.

Response: The CAA provides us with broad discretion to establish monitoring requirements as necessary to assure compliance with applicable requirements. As we noted in the preamble to the 1997 final rule (62 FR 48360), the most direct means of ensuring compliance with emissions limits is the use of CEMS. As a matter of policy, the first and foremost option considered by EPA is to require the use of CEMS to demonstrate continuous compliance with specific emissions limits. Other options are considered only when CEMS are not technically available or when the impacts of including such requirements are considered unreasonable (due to high costs, for example). When monitoring options other than CEMS are considered, there is always a tradeoff between the cost of the monitoring requirement and the quality of the information collected with respect to determining actual emissions. While monitoring of operations (operating parameters) cannot provide a direct measurement of emissions, it is usually much less expensive than CEMS, and the information provided can be used to ensure that the incinerator and associated air pollution control equipment are operating properly. This information provides EPA and the public with assurance that the reductions envisioned by the regulations are being achieved. (62 FR 48360–1)

For the 1997 final rule, we developed testing and monitoring costs for a range of options. (*See* Legacy Docket ID No. A–91–61, item IV–B–66.) At that time, we concluded that the cost of CEMS were unreasonably high relative to the cost of the incinerators and emissions controls needed for compliance. (62 FR 48360–1.) For today's final rule, we also compared the costs of CEMS for various pollutants to the costs of the incinerators, emissions controls, and parameter monitors, and reached the same conclusion as we reached before. (For further information, *see* 2009 memoranda entitled ''Revised Baseline Operating Costs for Existing HMIWI'' and ''Revised Compliance Costs and Economic Inputs for Existing HMIWI,'' which are included in the docket for today's rulemaking.) Table 3 of this preamble presents the annual costs for CEMS, parameter monitoring systems, emissions controls, and incinerators, based on model unit cost calculations for all four HMIWI size categories.

TABLE 3—COMPARISON OF ANNUAL COSTS FOR CEMS, PARAMETER MONITORING SYSTEMS, AND EMISSIONS CONTROLS

Pollutant	CEMS	Parameter monitoring systems	Emissions controls	Incinerators
CO	CO CEMS: $149,300 per year (yr).	Combustion control (charge rate, secondary chamber temperature): $6,000–$9,900/yr.	Secondary chamber retrofit: $15,100–$80,800/yr.	Incinerator: $54,800–$366,000/yr.
HCl	HCl CEMS: $171,400/yr.	Packed-bed scrubber (flue gas temperature, scrubber liquor flow rate and pH): $5,200/yr.	Packed-bed scrubber: $51,600–$104,000/yr.	
PM	PM CEMS: $195,200/yr.	Fabric filter (fabric filter inlet temperature): $4,200/yr.	Fabric filter: $130,000–$268,000/yr.	
Metals	Multi-metals CEMS: $57,800/yr.			
Hg	Hg CEMS: $313,900/yr.	Activated carbon injection system (activated carbon injection rate): $4,800/yr.	Activated carbon injection system: $5,400–$56,300/yr.	
CDD/CDF	Sorbent trap biweekly monitoring: $37,900/yr.			

Regarding the comment that CEMS for metals and other toxics should not be adopted until their accuracy and reliability has been fully verified, the re-proposal specified that the CEMS options would be available to a facility only when a final performance specification has been published in the **Federal Register** or when a site-specific monitoring plan has been approved. This should address the commenters' concerns.

F. Emissions Testing

Comment: One commenter appreciated EPA's efforts to improve performance testing requirements and supported the proposed changes. A second commenter objected to the provisions of § 60.37e(f) allowing

submission of previous stack tests to show compliance with proposed emissions standards for existing HMIWI, arguing that most of the stack tests were conducted over 7 years ago, and are also not statistically reliable because so few tests were conducted. The commenter stated that the provisions disregard the attention that Section 129 expected EPA to place on solid waste incinerators.

The second commenter also objected to the proposed one-time test requirement for Pb, Cd, Hg, and CDD/CDF, arguing that a single test result does not provide adequate assurance that the emissions standards have been met or are continuously being achieved by operations combusting a non-homogeneous waste stream. According to the commenter, allowing a one-time test also provides a strong disincentive to installing CEMS on HMIWI. The commenter noted that if EPA still wants to reduce testing requirements, it could provide skip testing provisions for these pollutants similar to existing provisions in § 60.56c(c)(2), especially in future rulemaking, once the industry has demonstrated sustained compliance.

Response: Regarding the comment objecting to the submission of previous stack tests to show compliance with new emissions standards for existing HMIWI, we attempted to address such concerns in § 60.37e(f)(2) and (3), specifying that the HMIWI had to be operated in a manner expected to result in the same or lower emissions, that it could not have been modified such that emissions would be expected to exceed the previous test results, and that emissions test results prior to the year of the 1996 proposal could not be accepted. We believe that these provisions are adequate to ensure an accurate and reliable result. Furthermore, based on the language in the re-proposal, it is unlikely that any commenter could have anticipated a change in the base year (1996) for emissions tests that would be accepted to demonstrate compliance with the revised emissions limits in the final rule, such that the commenter would have had a meaningful opportunity to comment on the issue.

Regarding the comment objecting to the one-time test requirement for metals and CDD/CDF, the annual tests are intended to be surrogates for combustion, particulate, and acid gas control, supplementing existing continuous monitoring requirements. We believe that the annual tests for combustion and particulate control and the continuous emissions monitoring of activated carbon injection are sufficient to ensure compliance with the metals and CDD/CDF emissions limits. However, if the State implementing the HMIWI regulations for existing units in its jurisdiction believes that more frequent metals and CDD/CDF testing is a necessary requirement for those units, they have the option to prepare State plans for EPA review that include those requirements, or to simply require a particular source to conduct such testing. Section 116 of the CAA preserves a State's authority to regulate more stringently under Section 111. Given the more stringent requirements in the HMIWI rule (relative to the 1997 rule) being promulgated today, we do not want to impose additional testing requirements that are not necessary to assure compliance with the requirements of this final rule. Also, we did not provide an opportunity to comment on such additional emissions testing in the December 2008 re-proposal, and we would want to develop a fuller record on any such requirements and provide an opportunity to comment on those requirements before imposing them in a final rule. However, we would be willing to consider such a change at the next technology review, if such a change is necessary to reliably demonstrate compliance.

G. Alternatives to On-Site Incineration

Comment: Five commenters supported alternatives to on-site incineration, such as autoclaving. One of the commenters stated that 90 percent or more of medical waste could be safely diverted from incineration. The commenter further noted that alternative treatment technologies like autoclaves and microwaves work, are available, and are approved by regulatory agencies. The commenter argued that these technologies provide a much healthier alternative to incineration. Another of the commenters suggested EPA supplement its proposed rule to specify a phase-in requirement that diverts all medical waste not required by law or regulation to be incinerated to go to approved alternative non-incineration disposal methods; the commenter also recommended that EPA prohibit autoclave residues from being incinerated. Three of the commenters stated that EPA should initiate a ban on incineration of medical waste, and in the interim give incentives to industries using safer, cleaner alternatives to incinerating medical waste, such as autoclaving and microwaving.

Five other commenters noted the disadvantages associated with incineration alternatives such as autoclaving. One of the commenters noted that EPA's supporting documents for the proposed rule seem to endorse such alternatives but fail to recognize that some facilities generate waste types for which autoclaving and landfilling is not adequate treatment. As examples, another of the commenters noted that numerous research facilities insist that all of their waste be incinerated, and three of the commenters noted that most States and many local governments have imposed requirements on the disposal of these types of wastes and identified incineration as an authorized means of disposal; further, some States expressly require incineration of pathological wastes and/or prohibit autoclaving or landfilling of such wastes. With the proposed emissions limits, the same three commenters expected that HMI waste incineration capacity will disappear, and captive units will be limited by permit from accepting wastes from off-site; as a result, the commenters concluded, some waste generators will be left with a State requirement to incinerate waste, with little or no available HMIWI treatment options and capacity. One commenter noted that that sterilized waste is often transferred to regional MWC facilities for incineration, especially in their metropolitan area, and noted that MWC emissions limits are less stringent than the current and proposed limits for HMIWI. Thus, the commenter concluded, if the HMIWI regulation increases autoclaving and reduces use of their facility, it will have a significant adverse effect on air quality.

One of the commenters stated that EPA's studies for the proposed rule also fail to recognize the environmental impacts of transporting autoclaved medical wastes to regional landfills, such as depletion of landfill space, landfill gas emissions, landfill leachate issues, and impacts of waste transportation traffic. Another commenter noted that autoclaving does not achieve the 90 percent volume reduction that can be achieved with incineration and, with many landfills at or approaching capacity, volume reduction prior to landfilling is a much preferred option.

One commenter also noted that steam sterilization can result in the release of uncontrolled Hg vapors from the autoclaving process, so any medical waste displaced from their facility to autoclaves would result in an increase in Hg emissions from the autoclaves or the MWC. The commenter said that these potential impacts need to be assessed before any standard is adopted.

Response: Section 129 of the CAA provides EPA with the authority to establish emissions limits for the nine specified pollutants (HCl, CO, Pb, Cd,

Hg, PM, CDD/CDF, NO_X, and SO_2). Today's action satisfies EPA's obligation to respond to the Court's remand of the 1997 MACT floor determinations, as well as EPA's duty to conduct its first periodic review of the standards and requirements of the HMIWI rule. While a record that supported complete elimination of emissions of the enumerated pollutants is theoretically possible, the record for today's rule does not show that such an outright ''ban'' of incineration is required to meet EPA's obligations.

We agree with the commenters that it is appropriate to address the disadvantages and environmental impacts associated with incineration alternatives such as autoclaving in background documentation for the HMIWI rule, even though the revised standards in today's rule are floor-based (for which we cannot consider costs) rather than beyond-the-floor-based (where costs are to be considered). We also agree that incineration is sometimes insisted upon or even required by some research facilities and State and local governments, and we have incorporated those comments into the revised background documentation for the final rule.

Regarding the comment that some metropolitan areas require autoclaved waste to be sent to MWC units, while the commenter is correct that MWC limits are currently higher than the 1997 promulgated HMIWI limits and the 2008 re-proposed HMIWI limits, the MWC standards are on remand to the Agency, and EPA will be reviewing those standards. At this juncture, we cannot predict the outcome of that remand response.

Comment: One commenter stated that EPA's studies for the proposed rule fail to recognize and consider all the risks to the public associated with closing captive HMIWI and transporting medical/infectious wastes to large commercial incinerators, especially in regions such as the western U.S., where such commercial incinerators are not well distributed.

Response: We believe that the revised emissions limits are more representative of actual operation at HMIWI and will impact fewer HMIWI than the December 2008 re-proposal, which should address the commenter's concerns. Moreover, in this technology- and MACT floor-based rulemaking, we do not believe that we could permissibly adopt standards that are less stringent than the floor based on considerations of risk. *See Sierra Club* v. *EPA,* 353 F.3d 976 (DC Cir. 2009).

H. Medical Waste Segregation

Comment: Contrary to what EPA stated in its summary of waste segregation survey responses, two commenters argued that there is ample evidence that the extent to which waste segregation is conducted by our healthcare facilities is far from optimal, and that further waste segregation could easily occur. Multiple commenters recommended that EPA supplement the proposed rule to minimize or eliminate the inclusion of plastic wastes (a chief contributor to dioxin formation), Hg (*e.g.,* Hg-containing dental waste, Hg-containing devices), and other hazardous wastes in the waste sent to incineration; end the burning of confidential documents (*e.g.,* medical records) and other paper products that could be shredded and recycled; and require waste management plans from all generators of medical waste that use incineration as a disposal option. As examples, one of the commenters said captive HMIWI could be required to train staff to minimize inclusion of Hg-containing devices and other heavy metals from the waste stream; and commercial HMIWI could be required to provide educational materials to encourage customers to prevent inappropriate disposal of metals-containing devices and other items into wastes supplied to the commercial HMIWI. Another commenter supported the idea of enhancing waste management practices at the point of generation and noted that their commercial facility offers training sessions with hospitals and institutions on the importance of separating items containing Hg and other hazardous substances from the rest of their medical waste and has implemented and manages recycling programs for paper, bottles, glass, cardboard, metals, construction material, and sharps containers.

To ensure effective waste segregation by commercial facilities, one of the commenters further recommended that EPA revise the regulation to state that incinerator operators are responsible for all of the waste in their possession and the emissions that result, and should clarify for all incinerator operators that the term ''affected source'' in § 60.55c refers to them.

Four commenters noted that the proposed new rule for emissions from HMIWI does not address pharmaceutical drugs, nor does it address how hazardous pharmaceuticals are segregated from non-hazardous. The commenters stated that not all incinerators, such as those in North Carolina, are licensed to burn pharmaceuticals classified as hazardous. The commenters recommended that EPA require each State to develop and implement programs to ensure that hazardous and non-hazardous pharmaceuticals are being segregated.

Response: While EPA's authority to set emissions standards under Section 129(a)(2) reaches only incinerators of solid waste and does not directly extend to generators of waste who are not owners and operators of solid waste incineration units, we are amending the waste management plan provisions in the final rule to promote greater waste segregation (*e.g.,* plastics, metals, PCB-containing wastes, pharmaceuticals). Given the OSHA requirements to which commercial HMIWI operators are subject, those operators cannot be expected to remove certain materials from the waste they receive, but they can be expected to train and educate their clients to conduct their own waste segregation, especially with regard to the materials listed above. We are including language to that effect in the waste management provisions of the final rule.

I. Startup, Shutdown, and Malfunction

Comment: Three commenters argued that EPA should apply to the HMIWI rule the decision issued by the U.S. Court of Appeals for the DC Circuit (*Sierra Club* v. *EPA,* 551 F.3d 1019 (DC Cir. 2008)), which vacated the SSM exemptions in EPA's General Provisions implementing Section 112 on the grounds that the exemptions violate the CAA's requirement that some Section 112 standards apply continuously. The commenters stated that the reasoning provided by the court in its decision also applies to the HMIWI rule.

According to one of the three commenters, the CAA makes clear that EPA may not exempt sources from compliance with Section 129 emissions standards during SSM events and that the current exemptions (found in §§ 60.56c(a) and 60.37e(a)) are unlawful. The commenter noted that EPA restricted the current SSM exemption to periods when no hospital or medical/infectious waste is being charged to HMIWI. However, the commenter said this does not bring EPA's regulations into compliance with the CAA or suffice to protect the public from toxic emissions during periods of SSM, because HMIWI could stop charging HMI waste during an SSM event but still emit toxic pollution through a bypass valve directly to the environment. To the extent EPA is not soliciting comment on the SSM exemption as part of its response to the remand in *Sierra Club* v. *EPA,* 167 F.3d

658 (DC Cir. 1999) or its review of regulations under Section 129(a)(5), the commenter petitioned it to do so under the authorities in *Kennecott Utah Copper Corp.* v. *Department of Interior,* 88 F.3d 1191 (DC Cir. 1996).

A fourth commenter argued that if the SSM court decision is upheld, this would substantially impact the approach for establishing ''worst reasonable foreseeable circumstances'' and the approach for establishing emissions limits based on available data. According to the commenter, emissions and controllability during periods of SSM are different than ''normal operation,'' and the commenter noted that EPA currently sets limits by reviewing data taken during ''normal operation,'' since no one generally conducts stack tests during SSM.

One commenter requested that emissions from SSM events be included in the calculations of a facility's potential to emit, which in turn determines the applicability of some Federal requirements. The commenter also recommended that emissions from SSM events should be included in modeling to ensure that new or expanded sources do not cause ambient air quality to exceed health-based levels. In lieu of modeling, the commenter said there should be actual monitoring of SSM events to accurately determine the individual types of toxic air pollutants and amounts of toxic air pollutant releases. The commenter recommended that there be mandatory penalties for SSM events based on the amounts and toxicity of the emissions. To illustrate the point, the commenter included documentation about bypass events at a local HMIWI. Two additional commenters also requested that EPA conduct modeling to assess the types and amounts of pollutants released during bypass events and take appropriate steps to regulate these ''fugitive'' emissions. All three commenters recommended that pollution control equipment be required for bypass events, whether the event is operator error or violation.

Another commenter recommended that EPA revise the General Provisions or the specific standards to subject SSM periods to appropriate work practice standards, including procedures to minimize emissions during those periods, rather than establish MACT emissions limits that are impossible to meet during SSM. According to the commenter, CAA Section 112(h) allows the Administrator to promulgate a design, equipment, work practice, or operational standard, or combination thereof, in lieu of an emissions standard where it is not feasible to prescribe or enforce an emissions standard. The commenter said that emissions measurement is not practicable during SSM periods.

Response: While the Court's ruling in *Sierra Club* v. *EPA,* 551 F.3d 1019 (DC Cir. 2008), directly affects only the subset of CAA Section 112(d) rules that incorporate § 63.6(f)(1) and (h)(1) by reference and that contain no other regulatory text exempting or excusing compliance during SSM events, the legality of source category-specific SSM provisions such as those adopted in the 1997 HMIWI rule is questionable.

To our knowledge, no HMIWI facilities have ever done any testing during an SSM event, except perhaps the few that have CO CEMS (although under the definition of ''malfunction'' in § 60.51c, operators are directed to monitor all applicable operating parameters during malfunctions until all waste had been combusted or until the malfunction ceases, whichever comes first). It would be very difficult to do any meaningful testing during such an event because the exhaust flow rates, temperatures, and other stack conditions would be highly variable and could foul up the isokinetic emissions test methods (thus invalidating the testing).

The 1997 rule excused exceedance of emissions standards during SSM events only in instances where ''no hospital waste or medical/infectious waste is charged to the affected facility.'' 40 CFR 60.56c(a). This means that in any SSM periods where such waste is being charged and an exceedance of the standards occurs, the source is in violation of the requirements of the standards. Based on the 1997 HMIWI rule's definitions of the terms ''startup'' and ''shutdown,'' no waste should be combusted during these periods, so emissions should be low during them—essentially the emissions from burning natural gas. Under § 60.51c, startup is defined as 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. Shutdown is defined as the period of time after all waste has been combusted in the primary chamber. Shutdown must start no less than 2 hours after the last charge to the incinerator for continuous HMIWI, and no less than 4 hours for intermittent HMIWI. For batch HMIWI, shutdown must commence no less than 5 hours after the high-air phase of combustion has been completed. Consequently, it should not be possible for HMIWI to exceed the applicable emissions limits during startup and shutdown periods. This suggests that the exemption from standards during startup and shutdown is of virtually no utility to HMIWI, such that there is any need for EPA to retain the exemption in today's final rule.

Malfunctions present a similar situation in terms of how the 1997 rule functioned, if a slightly different situation factually. Again, the SSM exemption of § 60.56c(a) applied only where no hospital waste and no medical/infectious waste was being charged. Under §§ 60.56c(a) and 60.37e(a) of the HMIWI rules, facilities are required to stop charging waste as soon as a malfunction is identified and not charge any additional waste. ''Malfunction'' is defined in § 60.51c as 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, but does not include failures caused, in part, by poor maintenance or careless operation. During malfunction periods, operators must operate within established parameters as much as possible and continue to monitor all applicable operating parameters. So, there should be low emissions during such periods, but how low is not known. In any case, the rule as promulgated in 1997 did not excuse exceedances of emissions standards during malfunctions if hospital waste or medical/infectious waste was being charged during the malfunction. Moreover, our final standards established today are based on the best data available to the Agency, and we have no data to support modifying the floors for malfunction periods.

While EPA is still in the relatively early process of formulating its strategy for addressing the SSM court decision and the numerous Section 112 and 129 rules that contain varying provisions regarding SSM events, we are revising the HMIWI rules in today's final rulemaking to delete the 1997 rule's narrow exemption from emissions limits during periods of SSM. As explained above, the exemption and definitions as promulgated in 1997 provided virtually no utility, and we, therefore, expect that today's deletion of the SSM exemption will have very little, if any, impact on HMIWI units' compliance status. In the event that sources, despite their best efforts, fail to comply with applicable standards during SSM events (as defined by the rule), EPA will determine an appropriate response based on, among other things, the good faith efforts of the source to minimize emissions during SSM periods, including preventative and corrective

actions, as well as root cause analyses to ascertain and rectify excess emissions. This approach is consistent with that discussed in a recent letter by Adam M. Kushner, Director, Office of Civil Enforcement, to counsel representing various industry associations, entitled ''Re: Vacatur of Startup, Shutdown, and Malfunction (SSM) Exemption (40 CFR sections 63.6(f)(1) and 63.6(h)(1))'' (July 22, 2009) (included in the docket for today's rulemaking).

For the reasons discussed above, we disagree with the commenter who claimed that, in the context of this rulemaking, removal of the SSM exemption would substantially impact the MACT floor approach. Deletion of the exemption should have no impact on the use and analysis of the MACT compliance data upon which the revised standards are based in this rule. This is because the 1997 rule's exemption provisions already had a very limited focus, in excusing compliance with standards only when HMI waste was not being charged to the incinerator; even under the 1997 rules, if HMI waste was being charged during an SSM event, the standards continued to apply. Moreover, the commenter provided no information to support its position. Therefore, it is similarly unnecessary to accept other commenters' recommendations to specify mandatory penalties during SSM events or impose unique pollution controls for bypass events—these concerns should be adequately addressed by today's removal of the SSM exemption, which includes removal of the 1997 rule's exemption during SSM periods to the prohibition of using a bypass stack.

We also disagree that it is necessary to revise the CAA Section 112 General Provisions of 40 CFR part 63 to impose work practice requirements that apply in lieu of numeric emissions standards during SSM periods, in the context of this CAA Section 129 rulemaking. The commenter who suggested this approach cited CAA Section 112(h) as the basis of authority for such a change, but neither that section of the Act nor the part 63 General Provisions apply to standards promulgated under Section 129, which by its terms requires numeric emissions standards for the pollutants specified in Section 129(a)(4).

J. Economic Impacts

Comment: Two commenters argued that the proposed limits are unattainable without significant financial investment, which they said will ultimately be passed on to an already overburdened healthcare system. The commenters urged EPA to reconsider the proposed rule. One of the commenters suggested EPA keep emissions limits for existing HMIWI at current levels.

A third commenter argued that this sort of rule could also have severe adverse consequences on other industries, as well as the economy, energy and natural resources, and environment. A fourth commenter stated that the level of source shutdowns that has occurred in the HMIWI industry should not be allowed to occur in other Section 112 or 129 source categories, as it would severely cripple the manufacturing base of this country. The commenter urged EPA to consider costs and other impacts when developing rules, as required under Section 129. According to the commenter, the current financial crisis demonstrates the tremendous impact on jobs and the broader economy due to increased operational costs and facility shutdowns.

Response: We estimate that the revised limits for the final rule will be viewed as more attainable than were the 2008 re-proposed standards, and will result in less burdensome economic impacts for the industry. (*See* 2009 memorandum ''Revised MACT Floors, Data Variability Analysis, and Emission Limits for Existing and New HMIWI'' and 2009 report ''Economic Impacts of Revised MACT Standards for Hospital/Medical/Infectious Waste Incinerators,'' which are included in the docket for today's rulemaking.) It should be noted that other rules do not necessarily have to take the same MACT floor approach as that taken in this rule (every industry, every situation is different), so the argument that promulgation of this rule as proposed would adversely affect other regulated industries is not a given. It should also be noted that under Section 129 we cannot consider costs and other impacts when we are establishing MACT floor requirements.

Comment: One commenter disagreed with EPA's estimation of economic impacts, especially as it affects their facility. The commenter specifically questioned EPA description of HMIWI demand as being extremely price insensitive (*i.e.,* that the price charged has little effect on the quantity of medical waste incinerated and can be passed on to customers in full). Based on their years of experience in selling services, the commenter indicated that the demand for medical waste incineration at their facility is a curve reflecting the interplay of different customer groups, rather than a steep curve as presented in EPA's analysis (details provided in public comment). Based on a graphical depiction of their facility's fixed costs, variable costs, and total costs overlaid with the demand structure, the commenter stated that their facility makes only a modest profit and could not operate at any level of volume profitably if the costs of complying with the new regulations are added to the current cost structure (graphical depiction provided in public comment).

The commenter recommended that the economic analysis be revised to reflect the realistic economic impacts on their company. The commenter noted that EPA's estimate of their gross sales ($12 million) is greater than they have averaged in recent years, qualifying them as a small business. The commenter also noted that there are no data or analysis to justify EPA's estimate of their company's profits (greater than $30 million) after adoption of the proposed regulations. According to the commenter, they will in fact be forced out of business.

Three other commenters noted that the economic analysis does not mention the restrictions imposed by State and local governments in resorting to alternative waste treatment methods.

Response: The demand curve we used in our economic analysis was meant to apply to the industry as a whole, and, as such, some assumptions and simplifications were necessary. Nonetheless, we have reviewed the commenter's concerns in revising our economic analysis for the final rule. We acknowledge the mistakes in our previous economic analysis regarding the commenter's profits and sales and have addressed them in our revised economic analysis. We have also addressed the restrictions noted by the other three commenters in the revised analysis. Finally, it should be noted that the revisions to the emissions limits for the final rule should mitigate the economic impacts described here.

Comment: One commenter stated that, although their company is a small entity, they were not given the opportunity to participate in the development of the proposed HMIWI rule, as provided under the Small Business Regulatory Enforcement Fairness Act (SBREFA). According to the commenter, EPA did not conduct the appropriate analysis and incorrectly assumed that their business had annual revenue exceeding the Small Business Size Standards. The commenter provided tax returns documenting their status as a small entity.

Response: We properly accounted for the impacts of the re-proposed rule in 2008 based on our analysis of the data we then had. The base year data we

were using in our economic analysis (2007) showed sales numbers that indicated they were not a small business. After receiving public comments and additional information, we have accounted for any recent changes in small entity status and re-analyzed the economic impacts of the rule on small entities. (*See* 2009 report ''Economic Impacts of Revised MACT Standards for Hospital/Medical/ Infectious Waste Incinerators,'' which is included in the docket for today's rulemaking.) Because we are beyond proposal, we cannot convene a pre-proposal SBREFA panel. After considering the economic impacts of this final rule on small entities, we can certify that today's final rule will not have a significant economic impact on a substantial number of small entities. The one small entity directly regulated by today's final rule is a small business that owns two HMIWI. We have determined that this one small entity may experience an impact of approximately $3.15 million per year to comply with the final rule, resulting in a cost-to-sales ratio of approximately 45 percent. The small entity is a company in Maryland, which owns and operates a commercial facility at that location. There are only nine other commercial facilities, which are owned and operated by other companies, and the closest are in North Carolina and Ohio. Therefore, the entity is a regional monopolist and is able to raise the price by more than the per unit cost increase. We expect there to be a reduction in the amount of its services demanded due to the price change. Because of closures of captive HMIWI, there may also be an increase in the demand for its services that may reduce the decrease in revenues associated with the price increase.

Two other entities are defined as borderline small: Their parent company sales or employment in 2008 are above the SBA size-cutoff for small entities in their North American Industry Classification System (NAICS) codes, but are near enough to the size cut-off that variations in sales or employment over time might move them below the small business criterion. Based on 2008 sales data for these two entities, the cost-to-sales ratio is less than 1 percent for one entity and 1.4 percent for the other. It should be noted that the entity with the higher cost-to-sales ratio (1.4 percent) is a commercial unit and would have the ability to pass the cost along to their customers and would be expected to be able to afford compliance. Therefore, neither entity is likely to incur significant impacts. (*See* 2009 memorandum entitled ''Updated Sales Information for Companies Considered Borderline Small Entities,'' which is included in the docket for today's rulemaking.)

Although today's final rule will not have a significant economic impact on a substantial number of small entities, we nonetheless have tried to reduce the impact of this rule on small entities, to the extent allowed under this CAA MACT floor rulemaking. For each subcategory of HMIWI, we are promulgating emissions limits that are based on the MACT floor level of control, which is the minimum level of stringency that can be considered in establishing MACT standards. Under the CAA and the case law, EPA can set standards no less stringent than the MACT floor and, therefore, we were unable to eliminate the impact of the emissions limits on the small entity that would be regulated by the final rule. We nevertheless worked to minimize the costs of testing and monitoring requirements to the extent possible under the statute, in light of our final impacts analysis.

V. Impacts of the Final Action for Existing Units

Over the last three years, about 25 percent (19 of 76 units) of the existing HMIWI have ceased operation. This trend is not surprising, and supports EPA's analysis, which shows that even in the absence of increased regulatory requirements, less expensive alternative waste disposal options are available for almost all facilities that operate HMIWI. Therefore, EPA expects this trend of unit closures to continue even in the absence of the regulatory changes. The additional costs imposed by this action are likely to accelerate the trend towards alternative waste disposal options. Our analysis suggests that sources are likely to respond to the increased regulatory requirements by choosing to minimize the current cost of on-site incineration (*e.g.,* improve waste segregation), use alternative waste disposal options, or send the waste to an off-site commercial incinerator.

The EPA's objective is not to discourage continued use of HMIWI; EPA's objective is to adopt EG for existing HMIWI that fulfill the requirements of CAA Section 129. In doing so, the primary outcome associated with adoption of these EG may be an increase in the use of alternative waste disposal and a decrease in the use of HMIWI. Consequently, EPA's impact analyses of the final rule include complete analyses of two potential scenarios. The first scenario, which will be referred to as the ''MACT compliance'' option for the remainder of this preamble, assumes that all units continue operation and take the necessary steps to achieve compliance. The second scenario, which will be referred to as the ''alternative disposal'' option for the remainder of this preamble, assumes that all facilities choose to discontinue operation of their HMIWI in favor of an alternative waste disposal option. While several different disposal options, such as sending waste to a municipal waste combustor or commercial HMIWI or using chemical treatment (*e.g.,* ozone, electropyrolysis, chlorine compounds, alkali agents), thermal treatment (*e.g.,* plasma arc, microwave technologies), or mechanical systems (*e.g.,* shredding, compacting) may be available to some facilities, EPA assessed the impacts of another alternative waste disposal option. This option involves on-site sterilization of the waste using an autoclave followed by landfilling of the sterilized waste. EPA selected the autoclave/landfilling option because it is a widely available and highly used alternative. The results of both the MACT compliance and autoclave/ landfilling options are provided in the discussion of impacts. While the likely outcome of the rule revisions is somewhere in between the two options that EPA selected for analysis (some units will comply with the standards and some will discontinue operations), EPA's analyses provide a broad picture of potential impacts.

As explained in section IV.A.2 of this preamble, the revised emissions limits for existing HMIWI are based on the average of the best performing 12 percent of sources for each pollutant in each subcategory. This final action requires varying degrees of improvements in performance by most HMIWI. Depending on the current configuration of each unit and air pollution controls, the improvements could be achieved either through the addition of add-on APCD, improvement of existing add-on APCD, increase in sorbent usage rates, and various combustion improvements. More specifically, the improvements anticipated include: Most wet scrubber-controlled units adding a fabric filter-based system for improved control of PM and metals; most units with fabric filter-based systems adding a packed-bed wet scrubber for improved control of HCl; adding activated carbon injection or increasing activated carbon usage rate for improved Hg and dioxin control; upgrading fabric filter performance for improved control of PM and metals; increasing lime or caustic

use for improved control of HCl and, in a few instances, SO_2; and combustion improvements primarily associated with decreasing CO emissions. We also project that a few units may require add-on controls (SNCR) to meet the revised NO_X emissions levels. Facilities may resubmit their most recent compliance test data for each pollutant if the data show that their HMIWI meets the revised emissions limits. In these instances, facilities must certify that the test results are representative of current operations. Those facilities would then not be required to test for those pollutants to prove initial compliance with the revised emissions limits.

A. What Are the Primary Air Impacts?

EPA estimates that reductions of approximately 393,000 pounds per year (lb/yr) of the regulated pollutants would be achieved if all existing HMIWI improved performance to meet the revised emissions limits. If all HMIWI selected an alternative disposal method, reductions of approximately 1.52 million lb/yr would be achieved. Table 4 shows the estimated reductions by pollutant for the two scenarios for the 57 HMIWI currently operating.

TABLE 4—PROJECTED EMISSIONS REDUCTIONS FOR MACT COMPLIANCE AND ALTERNATIVE DISPOSAL OPTIONS FOR EXISTING HMIWI

Pollutant	Reductions achieved through meeting MACT (lb/yr)	Reductions achieved through alternative disposal (lb/yr)
HCl	168,000	198,000
CO	1,140	20,200
Pb	313	420
Cd	15.6	35.1
Hg	605	682
PM	3,170	89,900
CDD/CDF, total	0.0678	0.0985
CDD/CDF, TEQ	0.00145	0.00183
NO_X	146,000	1,080,000
SO_2	73,700	126,000
Total	393,000	1,520,000

B. What Are the Water and Solid Waste Impacts?

EPA estimates that, based on the MACT compliance option, approximately 3,840 tons per year (tpy) of additional solid waste and 86,000 gallons per year (gpy) of additional wastewater would be generated as a result of operating additional controls or using increased amounts of various sorbents.

EPA estimates that, based on the alternative disposal option, approximately 15,100 tpy of additional solid waste would be sent to landfills. This option would result in an estimated 5.40 million gpy in wastewater impacts.

C. What Are the Energy Impacts?

EPA estimates that approximately 9,530 megawatt-hours per year (MWh/yr) of additional electricity would be required to support the increased control requirements associated with the MACT compliance option.

For the alternative disposal option, EPA estimates that approximately 12,400 MWh/yr of additional electricity would be required to operate the autoclaves.

D. What Are the Secondary Air Impacts?

Secondary air impacts associated with the MACT compliance option are direct impacts that result from the increase in natural gas and/or electricity use that we estimate may be required to enable facilities to achieve the revised emissions limits. We estimate that the adjustments could result in emissions of 279 lb/yr of PM; 3,260 lb/yr of CO; 2,650 lb/yr of NO_X; and 1,780 lb/yr of SO_2 from the increased electricity and natural gas usage.

For the alternative disposal option, EPA estimates secondary air impacts of 692 lb/yr of PM; 5,040 lb/yr of CO; 2,550 lb/yr of NO_X; and 4,980 lb/yr of SO_2 from the additional electricity that would be required to operate the autoclaves. In addition, EPA estimates that landfilling would result in an additional 626 tpy of methane and 0.0330 lb/yr of mercury emissions.

E. What Are the Cost and Economic Impacts?

EPA estimates that for the MACT compliance option, the national total costs for the 57 existing HMIWI to comply with this final action would be approximately $15.5 million in each of the first 3 years of compliance. This estimate includes the costs that would be incurred based on the anticipated performance improvements (*i.e.,* costs of new APCD and improvements in performance of existing APCD), and the additional monitoring (*i.e.,* annual control device inspections), testing (*i.e.,* initial EPA Method 22 of appendix A–7 test and initial compliance testing), and recordkeeping and reporting costs that would be incurred by all 57 HMIWI as a result of this final action. Approximately 95 percent of the estimated total cost in the first year is for emissions control, and the remaining 5 percent is for monitoring, testing, recordkeeping and reporting.

EPA estimates that for the alternative disposal option, the national total costs for the 57 existing HMIWI to dispose of their solid waste by autoclaving and landfilling would be approximately $10.6 million per year. This estimate includes the costs that would be incurred based on the purchase and operation of autoclaves and the projected landfill tipping fees that would be incurred based on the volume of waste to be landfilled.

Currently, there are 57 existing HMIWI at 51 facilities. They may be divided into two broad categories: (1) Captive HMIWI, which are co-owned and co-located with generating facilities and provide on-site incineration services for waste generated by the hospital, research facility, university, or pharmaceutical operations; and (2) commercial HMIWI, which provide commercial incineration services for waste generated off-site by firms unrelated to the firm that owns the HMIWI. EPA analyzed the impacts on

captive HMIWI and commercial HMIWI using different methods. Of the 57 HMIWI, 14 are commercial and 43 are captive.

Owners of captive HMIWI may choose to incur the costs of complying with the revised HMIWI standards or close the HMIWI and switch to another disposal technology like autoclaving and landfilling or have their waste handled by a commercial disposal service. EPA's estimate of autoclaving and landfilling costs indicate that even without additional regulatory costs, the costs of autoclaving and landfilling may be lower than the costs of incinerating. However, even if all owners of captive HMIWI choose to continue to operate with the additional regulatory cost, the cost-to-sales ratios for firms owning captive HMIWI are low. This reflects the relatively small share of overall costs that are associated with hospital/medical/infectious waste management at these firms. Of the 35 firms owning captive HMIWI, 22 have costs of compliance that are less than 0.1 percent of firm sales. Of the 13 with costs exceeding 0.1 percent of sales, the largest cost-to-sales ratio is at a captive hospital HMIWI, and is equal to 0.995 percent. Therefore, EPA expects no significant impact on the prices and quantities of the underlying services of the owners of the captive HMIWI, whether the costs are passed on or absorbed.

Impacts on commercial HMIWI are analyzed using the simplifying assumption that they operate as regional monopolists (in general, only one HMIWI is considered as a treatment option by generators located nearby). The approach to modeling the impact for commercial HMIWI seems very appropriate for all of the facilities except for one. The other commercial HMIWI facilities have costs of compliance that are no more than 2.0 percent of revenues. That one facility has a ratio of approximately 45 percent. As noted previously, this facility is a regional monopolist and is able to raise the price by more than the per unit cost increase. We expect there to be a reduction in the amount of its services demanded due to the price change. Because of closures of captive HMIWI, there may also be an increase in the demand for its services that may reduce the decrease in revenues associated with the price increase. For more details regarding EPA's analysis of the economic impacts, *see* the July 2009 docket entry entitled ''Economic Impacts of Revised MACT Standards for Hospital/Medical/Infectious Waste Incinerators.''

VI. Impacts of the Final Action for New Units

Information provided to EPA indicates that negative growth has been the trend for HMIWI for the past several years. While existing units continue to shut down, since promulgation of the HMIWI NSPS in 1997, four new units have been constructed and one unit has been reconstructed. This information indicates that in the absence of further regulation, new HMIWI may be built. However, based on the stringency of revisions being promulgated for the NSPS, sources would likely respond to the final rule by choosing not to construct new HMIWI and would utilize alternative waste disposal options rather than incur the costs of compliance.

Considering this information, EPA does not anticipate any new HMIWI, and therefore, no impacts of the revised NSPS for new units. For purposes of demonstrating that emissions reductions would result from the NSPS in the unlikely event that a new unit is constructed, EPA estimated emissions reductions and other impacts expected for each of three HMIWI model plants.

A. What Are the Primary Air Impacts?

EPA estimated emissions reductions for each of the model plants to demonstrate that the NSPS would, if a new unit were built, reduce emissions compared to a HMIWI meeting the current NSPS. Table 5 of this preamble presents the emissions reductions for the HMIWI model plants. The three model plants (with capacities of 100 lb/hr, 400 lb/hr, and 4,000 lb/hr) represent typical HMIWI. For pollutants where a ''zero'' value is shown, the model plant performance estimate meets the revised new source limit, which is not surprising since the models are based on the performance of the newest sources, which are among the best performers in the industry.

TABLE 5—EMISSIONS REDUCTIONS ON A MODEL PLANT BASIS

Pollutant	Emissions reduction for HMIWI model plants (lb/yr)		
	100 lb/hr capacity	400 lb/hr capacity	4,000 lb/hr capacity
HCl	0	45.8	968
CO	0	7.97	0
Pb	0	0	3.76
Cd	0	0	0.293
Hg	0	0.194	2.40
PM	0	0	170
Dioxins/furans, total	0	5.34×10^{-4}	0
Dioxins/furans, TEQ	0	6.02×10^{-6}	0
NO_X	491	1,780	0
SO_2	37.8	31.9	0
Total	529	1,860	1,140

B. What Are the Water and Solid Waste Impacts?

While EPA believes it is unlikely that any new HMIWI will be constructed, we estimated the following water or solid waste impacts associated with the revised NSPS for three different HMIWI model sizes: For large units, we estimate 7,120 gpy of additional wastewater and 50.8 tpy of additional solid waste; for medium units, we estimate no additional wastewater and 23.6 tpy of additional solid waste; and, for small units, we estimate 29.7 gallons per year of additional wastewater and 2.68 tpy of additional solid waste.

C. What Are the Energy Impacts?

While EPA believes it is unlikely that any new HMIWI will be constructed, we estimated the following energy impacts associated with the revised NSPS for three different HMIWI model sizes: for large units, we estimate that 280 MWh/yr of additional electricity would be

required to support the increased control requirements; for medium units, we estimate 416 MWh/yr; and, for small units, we estimate 9.90 MWh/yr.

D. What Are the Secondary Air Impacts?

Secondary air impacts for new HMIWI are direct impacts that would result from the increase in natural gas and/or electricity use that we estimate may be required to enable facilities to achieve the revised emissions limits. While EPA believes it is unlikely that any new HMIWI will be constructed, we estimated the secondary air impacts associated with the revisions to the NSPS for three different HMIWI model sizes. For large units, we estimate that the adjustments could result in emissions of 15.6 lb/yr of PM; 114 lb/yr of CO; 57.4 lb/yr of NO_X; and 112 lb/yr of SO_2. For medium units, we estimate that the adjustments could result in emissions of 2.71 lb/yr of PM; 119 lb/yr of CO; 142 lb/yr of NO_X; and 0.938 lb/yr of SO_2. For small units, we estimate that the adjustments could result in emissions of 0.551 lb/yr of PM; 4.02 lb/yr of CO; 2.03 lb/yr of NO_X; and 3.97 lb/yr of SO_2.

For the alternative disposal option, EPA estimated secondary air impacts from the additional electricity that would be required to operate autoclaves in lieu of each size of HMIWI. For large units, we estimate secondary emissions of 65.5 lb/yr of PM; 478 lb/yr of CO; 241 lb/yr of NO_X; and 471 lb/yr of SO_2. For medium units, we estimate secondary emissions of 4.98 lb/yr of PM; 36.3 lb/yr of CO; 18.4 lb/yr of NO_X; and 35.8 lb/yr of SO_2. For small units, we estimate secondary emissions of 1.25 lb/yr of PM; 9.09 lb/yr of CO; 4.60 lb/yr of NO_X; and 8.98 lb/yr of SO_2. In addition, EPA estimates that an additional 58.5 tpy of methane and 0.00308 lb/yr of mercury emissions would result from landfilling waste that would have been processed in a large HMIWI, 3.29 tpy of methane and 0.000173 lb/yr of mercury emissions would result from landfilling waste that would have been processed in a medium HMIWI, and 0.549 tpy of methane and 0.0000289 lb/yr of mercury emissions would result from landfilling waste that would have been processed in a small HMIWI.

E. What Are the Cost and Economic Impacts?

While EPA projects that three new HMIWI would be constructed in the absence of the promulgated revisions, we believe that, in response to the promulgated revisions, sources may decide against constructing new HMIWI. Nevertheless, we estimated the following costs associated with installation and operation of air pollution controls needed to meet the revisions to the NSPS: for new large units, $1.08 million per year; for new medium units, $116,000 per year; and, for new small units, $118,000 per year.

EPA's analysis of impacts of the revisions to the HMIWI standards on potential new HMIWI compares the with-regulation estimated prices that would be charged by new large, medium, and small HMIWI to the range of with-regulation prices estimated to be charged by existing commercial HMIWI in various regional markets. This comparison indicates that new large and medium commercial HMIWI may be viable, but new small commercial HMIWI probably would not be viable. On the other hand, generators of hospital/medical/infectious waste could have overarching reasons to purchase and install a new small HMIWI. Comparison of autoclave treatment coupled with off-site landfill disposal shows that, for new facilities as for existing ones, autoclave/landfill treatment and disposal is generally less costly than incineration. Thus, the motivation to improve waste segregation to minimize the waste that must be incinerated is likely to continue, although HMIWI treatment of some wastes will continue to be required by regulation.

VII. Relationship of the Final Action to Section 112(c)(6) of the CAA

Section 112(c)(6) of the CAA requires EPA to identify categories of sources of seven specified pollutants to assure that sources accounting for not less than 90 percent of the aggregate emissions of each such pollutant are subject to standards under CAA Section 112(d)(2) or 112(d)(4). EPA has identified HMIWI as a source category that emits five of the seven CAA Section 112(c)(6) pollutants: POM, dioxins, furans, Hg, and PCBs. (The POM emitted by HMIWI is composed of 16 polyaromatic hydrocarbons (PAH) and extractable organic matter (EOM).) In the **Federal Register** notice *Source Category Listing for Section 112(d)(2) Rulemaking Pursuant to Section 112(c)(6) Requirements,* 63 FR 17838, 17849, Table 2 (1998), EPA identified medical waste incinerators (now referred to as HMIWI) as a source category ''subject to regulation'' for purposes of CAA Section 112(c)(6) with respect to the CAA Section 112(c)(6) pollutants that HMIWI emit. HMIWI are solid waste incineration units currently regulated under CAA Section 129. For purposes of CAA Section 112(c)(6), EPA has determined that standards promulgated under CAA Section 129 are substantively equivalent to those promulgated under CAA Section 112(d). (*See id.* at 17845; *see* also 62 FR 33625, 33632 (1997).) As discussed in more detail below, the CAA Section 129 standards effectively control emissions of the five identified CAA Section 112(c)(6) pollutants. Further, since CAA Section 129(h)(2) precludes EPA from regulating these substantial sources of the five identified CAA Section 112(c)(6) pollutants under CAA Section 112(d), EPA cannot further regulate these emissions under that CAA section. As a result, EPA considers emissions of these five pollutants from HMIWI ''subject to standards'' for purposes of CAA Section 112(c)(6).

As required by the statute, the CAA Section 129 HMIWI standards include numeric emissions limits for the nine pollutants specified in Section 129(a)(4). The combination of waste segregation, good combustion practices, and add-on air pollution control equipment (dry sorbent injection fabric filters, wet scrubbers, or combined fabric filter and wet scrubber systems) effectively reduces emissions of the pollutants for which emissions limits are required under CAA Section 129: Hg, CDD/CDF, Cd, Pb, PM, SO_2, HCl, CO, and NO_x. Thus, the NSPS and EG specifically require reduction in emissions of three of the CAA Section 112(c)(6) pollutants: dioxins, furans, and Hg. As explained below, the air pollution controls necessary to comply with the requirements of the HMIWI NSPS and EG also effectively reduce emissions of the following CAA Section 112(c)(6) pollutants that are emitted from HMIWI: POM and PCBs. Although the CAA Section 129 HMIWI standards as promulgated in 1997 and as revised for the 2009 final rule do not have separate, specific numerical emissions limits for PCBs and POM, emissions of these two CAA Section 112(c)(6) pollutants are effectively controlled by the same control measures used to comply with the numerical emissions limits for the pollutants enumerated in Section 129(a)(4). Specifically, as byproducts of combustion, the formation of PCBs and POM is effectively reduced by the combustion and post-combustion practices required to comply with the CAA Section 129 standards. Any PCBs and POM that do form during combustion are further controlled by the various post-combustion HMIWI controls. The add-on PM control systems (either fabric filter or wet scrubber) and activated carbon injection in the fabric filter-based systems further reduce emissions of these organic pollutants, and also reduce Hg

emissions, as is evidenced by HMIWI performance data. Specifically, the post-MACT compliance tests at currently operating HMIWI that were also operational at the time of promulgation of the 1997 standards show that, for those units, the 1997 HMIWI MACT regulations reduced Hg emissions by about 60 percent and CDD/CDF emissions by about 80 percent from pre-MACT levels. (Note that these reductions do not reflect unit shutdowns, units for which exemptions were granted, or new units.) Moreover, similar controls have been demonstrated to effectively reduce emissions of POM and PCBs from another incineration source category (municipal solid waste combustors). It is, therefore, reasonable to conclude that POM and PCB emissions are substantially controlled at all 57 HMIWI. Thus, while the final rule does not identify specific numerical emissions limits for POM and PCB, emissions of those pollutants are, for the reasons noted above, nonetheless ''subject to regulation'' for purposes of Section 112(c)(6) of the CAA.

In lieu of establishing numerical emissions limits for pollutants such as PCBs and POM, CAA Section 129(a)(4) allows EPA to regulate surrogate substances. While we have not identified specific numerical limits for POM and PCB, we believe CO serves as an effective surrogate for those pollutants, because CO, like POM and PCBs, is formed as a byproduct of combustion. We believe that dioxins/furans also serve as an effective surrogate for PCBs, because the compounds act similarly and, thus, are expected to be controlled similarly using HMIWI emissions control technology—*e.g.,* wet scrubbers or fabric filters (with or without activated carbon). Furthermore, recent HMIWI emissions test data for PCBs and dioxins/furans show that HMIWI well-controlled for dioxins/furans also achieve low PCB emissions. (*See* 2008 memorandum entitled ''Documentation of HMIWI Test Data Database,'' which is included in the docket.) It should also be noted that PCBs are generally found in higher concentrations than dioxins/furans (also the case for HMIWI), so HMIWI equipped with the aforementioned emissions controls would be even more effective at reducing PCB emissions. Consequently, we have concluded, in response to the public comments submitted on this issue, that the emissions limits for CO function as a surrogate for control of both POM and PCBs, and the limits for dioxins/furans function as a surrogate for PCBs, such that it is not necessary to promulgate numerical emissions limits for POM and PCBs with respect to HMIWI to satisfy CAA Section 112(c)(6).

To further address POM and PCB emissions, the final rule also includes revised waste management plan provisions that encourage segregation of the types of wastes that lead to these emissions, such as chlorinated plastics and PCB-containing wastes.

VIII. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866 (58 FR 51735; October 4, 1993), this action is a ''significant regulatory action'' because it is likely to raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. Accordingly, EPA submitted this action to the Office of Management and Budget (OMB) for review under Executive Order 12866, and any changes made in response to OMB recommendations have been documented in the docket for this action.

B. Paperwork Reduction Act

The information collection requirements in this rule have been submitted for approval to OMB under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* The information collection requirements are not enforceable until OMB approves them. The Information Collection Request (ICR) documents prepared by EPA have been assigned EPA ICR number 2335.02 for subpart Ce, 40 CFR part 60, and 1730.08 for subpart Ec, 40 CFR part 60.

The requirements in this final action result in industry recordkeeping and reporting burden associated with review of the amendments for all HMIWI, EPA Method 22 of appendix A–7 testing for all HMIWI, and inspections of scrubbers, fabric filters, and other air pollution control devices that may be used to meet the emissions limits for all HMIWI. Stack testing and development of new parameter limits would be necessary for HMIWI that need to make performance improvements in order to meet the emissions limits and for HMIWI that, prior to this final action, have not been required to demonstrate compliance with certain pollutants. Any new HMIWI would also be required to continuously monitor CO emissions. New HMIWI equipped with fabric filters would also be required to purchase bag leak detectors.

The annual average burden associated with the EG over the first 3 years following promulgation of this final action is estimated to be 44,229 hours at a total annual labor cost of $1,871,571. The total annualized capital/startup costs and operation and maintenance (O&M) costs associated with the monitoring requirements, EPA Method 22 of appendix A–7 testing, storage of data and reports, and photocopying and postage over the three year period of the ICR are estimated at $1,410,168 and $641,591 per year, respectively. (The annual inspection costs are included under the recordkeeping and reporting labor costs.) The annual average burden associated with the NSPS over the first three years following promulgation of this final action is estimated to be 2,705 hours at a total annual labor cost of $102,553. The total annualized capital/startup costs are estimated at $137,658, with total operation and maintenance costs of $116,192 per year. Burden is defined at 5 CFR 1320.3(b).

EPA may not conduct or sponsor, and a person is not required to, a collection of information unless it displays a valid OMB control number. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9. When this ICR is approved by OMB, the EPA will publish a technical amendment to 40 CFR part 9 in the **Federal Register** to display the OMB control numbers for the approved information collection requirements contained in this final rule.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedures Act or any other statute unless the EPA certifies that the final action will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small government organizations, and small government jurisdictions.

For purposes of assessing the impacts of this final action on small entities, small entity is defined as follows: (1) A small business as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; or (3) a small organization that is any not-for-profit enterprise that is independently owned and operated and is not dominant in its field.

After considering the economic impacts of this final rule on small entities, I certify that this action will not

have a significant economic impact on a substantial number of small entities. The one small entity directly regulated by this final action is a small business that owns two HMIWI. We have determined that this one small entity may experience an impact of approximately $3.15 million per year to comply with the final rule, resulting in a cost-to-sales ratio of approximately 45 percent. (*See* 2009 report ''Economic Impacts of Revised MACT Standards for Hospital/Medical/Infectious Waste Incinerators,'' which is included in the docket for today's rulemaking.) The one small entity is a company in Maryland, which owns and operates a commercial facility at that location. There are only nine other commercial facilities, which are owned and operated by other companies, and the closest are in North Carolina and Ohio. Therefore, the entity is a regional monopolist and is able to raise the price by more than the per unit cost increase. We expect there to be a reduction in the amount of its services demanded due to the price change. Because of closures of captive HMIWI there may also be an increase in the demand for its services that may reduce the decrease in revenues associated with the price increase.

Two other entities are defined as borderline small: Their parent company sales or employment in 2008 are above the SBA size-cutoff for small entities in their NAICS codes, but are near enough to the size cut-off that variations in sales or employment over time might move them below the small business criterion. Based on 2008 sales data for these two entities, the cost-to-sales ratio is less than 1 percent for one entity and 1.4 percent for the other. It should be noted that the entity with the higher cost-to-sales ratio (1.4 percent) is a commercial unit and would have the ability to pass the cost along to their customers and would be expected to be able to afford compliance. Therefore, neither entity is likely to incur significant impacts. (*See* 2009 memorandum entitled ''Updated Sales Information for Companies Considered Borderline Small Entities,'' which is included in the docket for today's rulemaking.)

Although the final rule will not have a significant economic impact on a substantial number of small entities, EPA nonetheless conducted an analysis of the impacts of the final rule on the directly regulated small entity and has tried to reduce the impact of this rule on small entities, to the extent allowed under the CAA MACT floor rulemaking. Our impacts analysis is contained in the docket for today's final rulemaking. For each subcategory of HMIWI, we are promulgating emissions limits that are based on the MACT floor level of control, which is the minimum level of stringency that can be considered in establishing MACT standards. Under the CAA and the case law EPA can set standards no less stringent than the MACT floor. Therefore, we were unable to reduce the impact of the emissions limits on the small entity that would be regulated by the final rule. However, we worked to minimize the costs of testing and monitoring requirements in light of our final impacts analysis, to the extent possible under the statute.

D. Unfunded Mandates Reform Act

This final action contains no Federal mandates under the provisions of Title II of the Unfunded Mandates Reform Act (UMRA), 2 U.S.C. 1531–1538 for State, local, or Tribal governments or the private sector. This final action imposes no enforceable duty on any State, local or Tribal governments or the private sector. Therefore, this final action is not subject to the requirements of Section 202 or 205 of the UMRA.

This final action is also not subject to the requirements of Section 203 of UMRA because it contains no regulatory requirements that might significantly or uniquely affect small governments. This final action contains no requirements that apply to such governments, imposes no obligations upon them, and will not result in expenditures by them of $100 million or more in any one year or any disproportionate impacts on them.

E. Executive Order 13132: Federalism

This action does not have Federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. This final action will not impose substantial direct compliance costs on State or local governments, and will not preempt State law. Thus, Executive Order 13132 does not apply to this action.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have Tribal implications, as specified in Executive Order 13175 (65 FR 67249; November 9, 2000). EPA is not aware of any HMIWI owned or operated by Indian Tribal governments. Thus, Executive Order 13175 does not apply to this action.

G. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

EPA interprets Executive Order 13045 (62 FR 19885; April 23, 1997) as applying to those regulatory actions that concern health or safety risks, such that the analysis required under section 5–501 of the Order has the potential to influence the regulation. This final action is not subject to Executive Order 13045 because it is based solely on technology performance.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution or Use

This action is not a ''significant energy action'' as defined in Executive Order 13211 (66 FR 28355; May 22, 2001) because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. EPA estimates that the requirements in this final action would cause most HMIWI to modify existing air pollution control devices (*e.g.,* increase the horsepower of their wet scrubbers) or install and operate new control devices, resulting in approximately 9,530 MWh/yr of additional electricity being used.

Given the negligible change in energy consumption resulting from this final action, EPA does not expect any significant price increase for any energy type. The cost of energy distribution should not be affected by this final action at all since the action would not affect energy distribution facilities. We also expect that any impacts on the import of foreign energy supplies, or any other adverse outcomes that may occur with regards to energy supplies would not be significant. We, therefore, conclude that if there were to be any adverse energy effects associated with this final action, they would be minimal.

I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (''NTTAA''), Public Law 104–113 (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards (VCS) 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 VCS bodies. NTTAA directs EPA to provide Congress, through OMB, explanations when the EPA decides not to use available and applicable VCS.

This final rulemaking involves technical standards. EPA has decided to use two VCS in this final rule. One VCS, ASME PTC 19.10–1981, ''Flue and Exhaust Gas Analyses,'' is cited in this final rule for its manual method of measuring the content of the exhaust gas as an acceptable alternative to EPA Method 3B of appendix A–2. This standard is available from the American Society of Mechanical Engineers (ASME), P.O. Box 2900, Fairfield, NJ 07007–2900; or Global Engineering Documents, Sales Department, 15 Inverness Way East, Englewood, CO 80112.

Another VCS, ASTM D6784–02, ''Standard Test Method for Elemental, Oxidized, Particle-Bound and Total Mercury Gas Generated from Coal-Fired Stationary Sources (Ontario Hydro Method),'' is cited in this final rule as an acceptable alternative to EPA Method 29 of appendix A–8 (portion for mercury only) for measuring mercury. This standard is available from the American Society for Testing and Materials (ASTM), 100 Barr Harbor Drive, Post Office Box C700, West Conshohocken, PA 19428–2959; or ProQuest, 300 North Zeeb Road, Ann Arbor, MI 48106.

While the EPA has identified 16 VCS as being potentially applicable to this final rule, we have decided not to use these VCS in this rulemaking. The use of these VCS would be impractical because they do not meet the objectives of the standards cited in this rule. *See* the docket for this rule for the reasons for these determinations.

Under 40 CFR 60.13(i) of the NSPS General Provisions, a source may apply to EPA for permission to use alternative test methods or alternative monitoring requirements in place of any required testing methods, performance specifications, or procedures in the final rule and any amendments.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898 (59 FR 7629) (February 16, 1994) establishes Federal executive policy on environmental justice. Its main provision directs Federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA has determined that this final rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it increases the level of environmental protection for all affected populations without having any disproportionately high and adverse human health or environmental effects on any population, including any minority or low-income populations.

This action would establish national standards that would result in reductions in emissions of HCl, CO, Cd, Pb, Hg, PM, CDD/CDF, NO_x and SO_2 from all HMIWI and thus decrease the amount of such emissions to which all affected populations are exposed.

K. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801, *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of Congress and to the Comptroller General of the United States. EPA will submit a report containing this final rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2). This final rule will be effective on December 7, 2009.

List of Subjects in 40 CFR Part 60

Environmental protection, Administrative practice and procedure, Air pollution control, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: September 15, 2009.

Lisa P. Jackson,

Administrator.

■ For the reasons stated in the preamble, title 40, chapter I, part 60 of the Code of Federal Regulations is amended as follows:

PART 60—[AMENDED]

■ 1. The authority citation for part 60 continues to read as follows:

Authority: 42 U.S.C. 7401, *et seq.*

Subpart A—[Amended]

■ 2. Section 60.17 is amended by revising paragraphs (a)(90) and (h)(4) to read as follows:

§ 60.17 Incorporations by reference.

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(a) * * *

(90) ASTM D6784–02, Standard Test Method for Elemental, Oxidized, Particle-Bound and Total Mercury in Flue Gas Generated from Coal-Fired Stationary Sources (Ontario Hydro Method), IBR approved for Appendix B to part 60, Performance Specification 12A, Section 8.6.2 and § 60.56c(b)(13) of subpart Ec of this part.

* * * * *

(h) * * *

(4) ANSI/ASME PTC 19.10–1981, Flue and Exhaust Gas Analyses [Part 10, Instruments and Apparatus], IBR approved for § 60.56c(b)(4) of subpart Ec, § 60.106(e)(2) of subpart J, §§ 60.104a(d)(3), (d)(5), (d)(6), (h)(3), (h)(4), (h)(5), (i)(3), (i)(4), (i)(5), (j)(3), and (j)(4), 60.105a(d)(4), (f)(2), (f)(4), (g)(2), and (g)(4), 60.106a(a)(1)(iii), (a)(2)(iii), (a)(2)(v), (a)(2)(viii), (a)(3)(ii), and (a)(3)(v), and 60.107a(a)(1)(ii), (a)(1)(iv), (a)(2)(ii), (c)(2), (c)(4), and (d)(2) of subpart Ja, tables 1 and 3 of subpart EEEE, tables 2 and 4 of subpart FFFF, table 2 of subpart JJJJ, and §§ 60.4415(a)(2) and 60.4415(a)(3) of subpart KKKK of this part.

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Subpart Ce—[Amended]

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■ 3. Section 60.32e is amended by revising paragraph (a) and adding paragraph (j) to read as follows:

§ 60.32e Designated facilities.

(a) Except as provided in paragraphs (b) through (h) of this section, the designated facility to which the guidelines apply is each individual HMIWI:

(1) For which construction was commenced on or before June 20, 1996, or for which modification was commenced on or before March 16, 1998.

(2) For which construction was commenced after June 20, 1996 but no later than December 1, 2008, or for which modification is commenced after March 16, 1998 but no later than April 6, 2010.

* * * * *

(j) The requirements of this subpart as promulgated on September 15, 1997, shall apply to the designated facilities defined in paragraph (a)(1) of this section until the applicable compliance

date of the requirements of this subpart, as amended on October 6, 2009. Upon the compliance date of the requirements of this subpart, designated facilities as defined in paragraph (a)(1) of this section are no longer subject to the requirements of this subpart, as promulgated on September 15, 1997, but are subject to the requirements of this subpart, as amended on October 6, 2009.

■ 4. Section 60.33e is revised to read as follows:

§ 60.33e Emissions guidelines.

(a) For approval, a State plan shall include the requirements for emissions limits at least as protective as the following requirements, as applicable:

(1) For a designated facility as defined in § 60.32e(a)(1) subject to the emissions guidelines as promulgated on September 15, 1997, the requirements listed in Table 1A of this subpart, except as provided in paragraph (b) of this section.

(2) For a designated facility as defined in § 60.32e(a)(1) subject to the emissions guidelines as amended on October 6, 2009, the requirements listed in Table 1B of this subpart, except as provided in paragraph (b) of this section.

(3) For a designated facility as defined in § 60.32e(a)(2), the more stringent of the requirements listed in Table 1B of this subpart and Table 1A of subpart Ec of this part.

(b) For approval, a State plan shall include the requirements for emissions limits for any small HMIWI constructed on or before June 20, 1996, which is located more than 50 miles from the boundary of the nearest Standard Metropolitan Statistical Area (defined in § 60.31e) and which burns less than 2,000 pounds per week of hospital waste and medical/infectious waste that are at least as protective as the requirements in paragraphs (b)(1) and (b)(2) of this section, as applicable. The 2,000 lb/week limitation does not apply during performance tests.

(1) For a designated facility as defined in § 60.32e(a)(1) subject to the emissions guidelines as promulgated on September 15, 1997, the requirements listed in Table 2A of this subpart.

(2) For a designated facility as defined in § 60.32e(a)(1) subject to the emissions guidelines as amended on October 6, 2009, the requirements listed in Table 2B of this subpart.

(c) For approval, a State plan shall include the requirements for stack opacity at least as protective as the following, as applicable:

(1) For a designated facility as defined in § 60.32e(a)(1) subject to the emissions guidelines as promulgated on September 15, 1997, the requirements in § 60.52c(b)(1) of subpart Ec of this part.

(2) For a designated facility as defined in § 60.32e(a)(1) subject to the emissions guidelines as amended on October 6, 2009 and a designated facility as defined in § 60.32e(a)(2), the requirements in § 60.52c(b)(2) of subpart Ec of this part.

■ 5. Section 60.36e is amended as follows:

■ a. By revising paragraph (a) introductory text;

■ b. By revising paragraph (b); and

■ c. By adding paragraphs (c) and (d).

§ 60.36e Inspection guidelines.

(a) For approval, a State plan shall require each small HMIWI subject to the emissions limits under § 60.33e(b) and each HMIWI subject to the emissions limits under § 60.33e(a)(2) and (a)(3) to undergo an initial equipment inspection that is at least as protective as the following within 1 year following approval of the State plan:

* * * * *

(b) For approval, a State plan shall require each small HMIWI subject to the emissions limits under § 60.33e(b) and each HMIWI subject to the emissions limits under § 60.33e(a)(2) and (a)(3) to undergo an equipment inspection annually (no more than 12 months following the previous annual equipment inspection), as outlined in paragraph (a) of this section.

(c) For approval, a State plan shall require each small HMIWI subject to the emissions limits under § 60.33e(b)(2) and each HMIWI subject to the emissions limits under § 60.33e(a)(2) and (a)(3) to undergo an initial air pollution control device inspection, as applicable, that is at least as protective as the following within 1 year following approval of the State plan:

(1) At a minimum, an inspection shall include the following:

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

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

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

(2) Within 10 operating days following an air pollution control device inspection, all necessary repairs shall be completed unless the owner or operator obtains written approval from the State agency establishing a date whereby all necessary repairs of the designated facility shall be completed.

(d) For approval, a State plan shall require each small HMIWI subject to the emissions limits under § 60.33e(b)(2) and each HMIWI subject to the emissions limits under § 60.33e(a)(2) and (a)(3) to undergo an air pollution control device inspection, as applicable, annually (no more than 12 months following the previous annual air pollution control device inspection), as outlined in paragraph (c) of this section.

■ 6. Section 60.37e is amended as follows:

■ a. By revising paragraphs (a), (b) introductory text, and (b)(1);

■ b. By redesignating paragraphs (c) and (d) as paragraphs (d) and (e);

■ c. By redesignating paragraphs (b)(2) through (b)(5) as paragraphs (c)(1) through (c)(4);

■ d. By adding a new paragraph (b)(2);

■ e. By adding paragraph (c) introductory text;

■ f. By revising newly redesignated paragraphs (c)(2) through (c)(4), (d), (e) introductory text, and (e)(3); and

■ g. By adding paragraph (f).

§ 60.37e Compliance, performance testing, and monitoring guidelines.

(a) Except as provided in paragraph (b) of this section, for approval, a State plan shall include the requirements for compliance and performance testing listed in § 60.56c of subpart Ec of this part, with the following exclusions:

(1) For a designated facility as defined in § 60.32e(a)(1) subject to the emissions limits in § 60.33e(a)(1), the test methods listed in § 60.56c(b)(7) and (8), the fugitive emissions testing requirements under § 60.56c(b)(14) and (c)(3), the CO CEMS requirements under § 60.56c(c)(4), and the compliance requirements for monitoring listed in § 60.56c(c)(5)(ii) through (v), (c)(6), (c)(7), (e)(6) through (10), (f)(7) through (10), (g)(6) through (10), and (h).

(2) For a designated facility as defined in § 60.32e(a)(1) and (a)(2) subject to the emissions limits in § 60.33e(a)(2) and (a)(3), the annual fugitive emissions testing requirements under § 60.56c(c)(3), the CO CEMS requirements under § 60.56c(c)(4), and the compliance requirements for monitoring listed in § 60.56c(c)(5)(ii) through (v), (c)(6), (c)(7), (e)(6) through (10), (f)(7) through (10), and (g)(6) through (10). Sources subject to the emissions limits under § 60.33e(a)(2) and (a)(3) may, however, elect to use CO CEMS as specified under § 60.56c(c)(4) or bag leak detection systems as specified under § 60.57c(h).

(b) Except as provided in paragraphs (b)(1) and (b)(2) of this section, for approval, a State plan shall require each small HMIWI subject to the emissions limits under § 60.33e(b) to meet the performance testing requirements listed

in § 60.56c of subpart Ec of this part. The 2,000 lb/week limitation under § 60.33e(b) does not apply during performance tests.

(1) For a designated facility as defined in § 60.32e(a)(1) subject to the emissions limits under § 60.33e(b)(1), the test methods listed in § 60.56c(b)(7), (8), (12), (13) (Pb and Cd), and (14), the annual PM, CO, and HCl emissions testing requirements under § 60.56c(c)(2), the annual fugitive emissions testing requirements under § 60.56c(c)(3), the CO CEMS requirements under § 60.56c(c)(4), and the compliance requirements for monitoring listed in § 60.56c(c)(5) through (7), and (d) through (k) do not apply.

(2) For a designated facility as defined in § 60.32e(a)(2) subject to the emissions limits under § 60.33e(b)(2), the annual fugitive emissions testing requirements under § 60.56c(c)(3), the CO CEMS requirements under § 60.56c(c)(4), and the compliance requirements for monitoring listed in § 60.56c(c)(5)(ii) through (v), (c)(6), (c)(7), (e)(6) through (10), (f)(7) through (10), and (g)(6) through (10) do not apply. Sources subject to the emissions limits under § 60.33e(b)(2) may, however, elect to use CO CEMS as specified under § 60.56c(c)(4) or bag leak detection systems as specified under § 60.57c(h).

(c) For approval, a State plan shall require each small HMIWI subject to the emissions limits under § 60.33e(b) that is not equipped with an air pollution control device to meet the following compliance and performance testing requirements:

* * * * *

(2) Following the date on which the initial performance test is completed or is required to be completed under § 60.8, whichever date comes first, ensure that the designated facility does not operate above the maximum charge rate or below the minimum secondary chamber temperature measured as 3-hour rolling averages (calculated each hour as the average of the previous 3 operating hours) at all times. Operating parameter limits do not apply during performance tests. Operation above the maximum charge rate or below the minimum secondary chamber temperature shall constitute a violation of the established operating parameter(s).

(3) Except as provided in paragraph (c)(4) of this section, operation of the designated facility above the maximum charge rate and below the minimum secondary chamber temperature (each measured on a 3-hour rolling average) simultaneously shall constitute a violation of the PM, CO, and dioxin/furan emissions limits.

(4) The owner or operator of a designated facility may conduct a repeat performance test within 30 days of violation of applicable operating parameter(s) to demonstrate that the designated facility is not in violation of the applicable emissions limit(s). Repeat performance tests conducted pursuant to this paragraph must be conducted under process and control device operating conditions duplicating as nearly as possible those that indicated a violation under paragraph (c)(3) of this section.

(d) For approval, a State plan shall include the requirements for monitoring listed in § 60.57c of subpart Ec of this part for HMIWI subject to the emissions limits under § 60.33e(a) and (b), except as provided for under paragraph (e) of this section.

(e) For approval, a State plan shall require small HMIWI subject to the emissions limits under § 60.33e(b) that are not equipped with an air pollution control device to meet the following monitoring requirements:

* * * * *

(3) The owner or operator of a designated facility shall 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 shall be obtained for 75 percent of the operating hours per day for 90 percent of the operating hours per calendar quarter that the designated facility is combusting hospital waste and/or medical/infectious waste.

(f) The owner or operator of a designated facility as defined in § 60.32e(a)(1) or (a)(2) subject to emissions limits under § 60.33e(a)(2), (a)(3), or (b)(2) may use the results of previous emissions tests to demonstrate compliance with the emissions limits, provided that the conditions in paragraphs (f)(1) through (f)(3) of this section are met:

(1) The designated facility's previous emissions tests must have been conducted using the applicable procedures and test methods listed in § 60.56c(b) of subpart Ec of this part. Previous emissions test results obtained using EPA-accepted voluntary consensus standards are also acceptable.

(2) The HMIWI at the designated facility shall currently be operated in a manner (*e.g.,* with charge rate, secondary chamber temperature, *etc.*) that would be expected to result in the same or lower emissions than observed during the previous emissions test(s), and the HMIWI may not have been modified such that emissions would be expected to exceed (notwithstanding normal test-to-test variability) the results from previous emissions test(s).

(3) The previous emissions test(s) must have been conducted in 1996 or later.

■ 7. Section 60.38e is amended as follows:

■ a. By revising paragraph (a);

■ b. By revising paragraph (b) introductory text; and

■ c. By revising paragraph (b)(1).

§ 60.38e Reporting and recordkeeping guidelines.

(a) Except as provided in paragraphs (a)(1) and (a)(2) of this section, for approval, a State plan shall include the reporting and recordkeeping requirements listed in § 60.58c(b) through (g) of subpart Ec of this part.

(1) For a designated facility as defined in § 60.32e(a)(1) subject to emissions limits under § 60.33e(a)(1) or (b)(1), excluding § 60.58c(b)(2)(ii) (fugitive emissions), (b)(2)(viii) (NO_X reagent), (b)(2)(xvii) (air pollution control device inspections), (b)(2)(xviii) (bag leak detection system alarms), (b)(2)(xix) (CO CEMS data), and (b)(7) (siting documentation).

(2) For a designated facility as defined in § 60.32e(a)(1) or (a)(2) subject to emissions limits under § 60.33e(a)(2), (a)(3), or (b)(2), excluding § 60.58c(b)(2)(xviii) (bag leak detection system alarms), (b)(2)(xix) (CO CEMS data), and (b)(7) (siting documentation).

(b) For approval, a State plan shall require the owner or operator of each HMIWI subject to the emissions limits under § 60.33e to:

(1) As specified in § 60.36e, maintain records of the annual equipment inspections that are required for each HMIWI subject to the emissions limits under § 60.33e(a)(2), (a)(3), and (b), and the annual air pollution control device inspections that are required for each HMIWI subject to the emissions limits under § 60.33e(a)(2), (a)(3), and (b)(2), any required maintenance, and any repairs not completed within 10 days of an inspection or the timeframe established by the State regulatory agency; and

* * * * *

■ 8. Section 60.39e is amended as follows:

■ a. By revising paragraph (a);

■ b. By revising paragraph (c) introductory text;

■ c. By revising paragraph (c)(1);

■ d. By revising paragraph (d)(3); and

■ e. By revising paragraph (f).

§ 60.39e Compliance times.

(a) Each State in which a designated facility is operating shall submit to the Administrator a plan to implement and enforce the emissions guidelines as specified in paragraphs (a)(1) and (a)(2) of this section:

(1) Not later than September 15, 1998, for the emissions guidelines as promulgated on September 15, 1997.

(2) Not later than October 6, 2010, for the emissions guidelines as amended on October 6, 2009.

* * * * *

(c) State plans that specify measurable and enforceable incremental steps of progress towards compliance for designated facilities planning to install the necessary air pollution control equipment may allow compliance on or before the date 3 years after EPA approval of the State plan (but not later than September 16, 2002), for the emissions guidelines as promulgated on September 15, 1997, and on or before the date 3 years after approval of an amended State plan (but not later than October 6, 2014), for the emissions guidelines as amended on October 6, 2009). Suggested measurable and enforceable activities to be included in State plans are:

(1) Date for submitting a petition for site-specific operating parameters under § 60.56c(j) of subpart Ec of this part.

* * * * *

(d) * * *

(3) If an extension is granted, require compliance with the emissions guidelines on or before the date 3 years after EPA approval of the State plan (but not later than September 16, 2002), for the emissions guidelines as promulgated on September 15, 1997, and on or before the date 3 years after EPA approval of an amended State plan (but not later than October 6, 2014), for the emissions guidelines as amended on October 6, 2009.

* * * * *

(f) The Administrator shall develop, implement, and enforce a plan for existing HMIWI located in any State that has not submitted an approvable plan within 2 years after September 15, 1997, for the emissions guidelines as promulgated on September 15, 1997, and within 2 years after October 6, 2009 for the emissions guidelines as amended on October 6, 2009. Such plans shall ensure that each designated facility is in compliance with the provisions of this subpart no later than 5 years after September 15, 1997, for the emissions guidelines as promulgated on September 15, 1997, and no later than 5 years after October 6, 2009 for the emissions guidelines as amended on October 6, 2009.

■ 9. Table 1 to subpart Ce is redesignated as Table 1A and revised to read as follows:

TABLE 1A TO SUBPART Ce OF PART 60—EMISSIONS LIMITS FOR SMALL, MEDIUM, AND LARGE HMIWI AT DESIGNATED FACILITIES AS DEFINED IN § 60.32e(a)(1)

Pollutant	Units (7 percent oxygen, dry basis)	Emissions limits			Averaging time [1]	Method for demonstrating compliance [2]
		HMIWI size				
		Small	Medium	Large		
Particulate matter.	Milligrams per dry standard cubic meter (mg/dscm) (grains per dry standard cubic foot (gr/dscf)).	115 (0.05)	69 (0.03)	34 (0.015)	3-run average (1-hour minimum sample time per run).	EPA Reference Method 5 of appendix A–3 of part 60, or EPA Reference Method 26A or 29 of appendix A–8 of part 60.
Carbon monoxide.	Parts per million by volume (ppmv).	40	40	40	3-run average (1-hour minimum sample time per run).	EPA Reference Method 10 or 10B of appendix A–4 of part 60.
Dioxins/furans	Nanograms per dry standard cubic meter total dioxins/furans (ng/dscm) (grains per billion dry standard cubic feet (gr/10^9 dscf)) or ng/dscm TEQ (gr/10^9 dscf).	125 (55) or 2.3 (1.0).	125 (55) or 2.3 (1.0).	125 (55) or 2.3 (1.0).	3-run average (4-hour minimum sample time per run).	EPA Reference Method 23 of appendix A–7 of part 60.
Hydrogen chloride.	ppmv	100 or 93%	100 or 93%	100 or 93%	3-run average (1-hour minimum sample time per run).	EPA Reference Method 26 or 26A of appendix A–8 of part 60.
Sulfur dioxide	ppmv	55	55	55	3-run average (1-hour minimum sample time per run).	EPA Reference Method 6 or 6C of appendix A–4 of part 60.
Nitrogen oxides.	ppmv	250	250	250	3-run average (1-hour minimum sample time per run).	EPA Reference Method 7 or 7E of appendix A–4 of part 60.
Lead	mg/dscm (grains per thousand dry standard cubic feet (gr/10^3 dscf)).	1.2 (0.52) or 70%.	1.2 (0.52) or 70%.	1.2 (0.52) or 70%.	3-run average (1-hour minimum sample time per run).	EPA Reference Method 29 of appendix A–8 of part 60.

TABLE 1A TO SUBPART Ce OF PART 60—EMISSIONS LIMITS FOR SMALL, MEDIUM, AND LARGE HMIWI AT DESIGNATED FACILITIES AS DEFINED IN § 60.32e(a)(1)—Continued

Pollutant	Units (7 percent oxygen, dry basis)	Emissions limits			Averaging time [1]	Method for demonstrating compliance [2]
		HMIWI size				
		Small	Medium	Large		
Cadmium	mg/dscm (gr/10^3 dscf)	0.16 (0.07) or 65%.	0.16 (0.07) or 65%.	0.16 (0.07) or 65%.	3-run average (1-hour minimum sample time per run).	EPA Reference Method 29 of appendix A–8 of part 60.
Mercury	mg/dscm (gr/10^3 dscf)	0.55 (0.24) or 85%.	0.55 (0.24) or 85%.	0.55 (0.24) or 85%.	3-run average (1-hour minimum sample time per run).	EPA Reference Method 29 of appendix A–8 of part 60.

[1] Except as allowed under § 60.56c(c) for HMIWI equipped with CEMS.
[2] Does not include CEMS and approved alternative non-EPA test methods allowed under § 60.56c(b).

■ 10. Add Table 1B to subpart Ce to read as follows:

TABLE 1B TO SUBPART Ce OF PART 60—EMISSIONS LIMITS FOR SMALL, MEDIUM, AND LARGE HMIWI AT DESIGNATED FACILITIES AS DEFINED IN § 60.32e(a)(1) AND (a)(2)

Pollutant	Units (7 percent oxygen, dry basis)	Emissions limits			Averaging time [1]	Method for demonstrating compliance [2]
		HMIWI size				
		Small	Medium	Large		
Particulate matter.	Milligrams per dry standard cubic meter (mg/dscm) (grains per dry standard cubic foot (gr/dscf)).	66 (0.029)	46 (0.020)	25 (0.011)	3-run average (1-hour minimum sample time per run).	EPA Reference Method 5 of appendix A–3 of part 60, or EPA Reference Method 26A or 29 of appendix A–8 of part 60.
Carbon monoxide.	Parts per million by volume (ppmv).	20	5.5	11	3-run average (1-hour minimum sample time per run).	EPA Reference Method 10 or 10B of appendix A–4 of part 60.
Dioxins/furans	Nanograms per dry standard cubic meter total dioxins/furans (ng/dscm) (grains per billion dry standard cubic feet (gr/10^9 dscf)) or ng/dscm TEQ (gr/10^9 dscf).	16 (7.0) or 0.013 (0.0057).	0.85 (0.37) or 0.020 (0.0087).	9.3 (4.1) or 0.054 (0.024).	3-run average (4-hour minimum sample time per run).	EPA Reference Method 23 of appendix A–7 of part 60.
Hydrogen chloride.	ppmv	44	7.7	6.6	3-run average (1-hour minimum sample time per run).	EPA Reference Method 26 or 26A of appendix A–8 of part 60.
Sulfur dioxide	ppmv	4.2	4.2	9.0	3-run average (1-hour minimum sample time per run).	EPA Reference Method 6 or 6C of appendix A–4 of part 60.
Nitrogen oxides.	ppmv	190	190	140	3-run average (1-hour minimum sample time per run).	EPA Reference Method 7 or 7E of appendix A–4 of part 60.
Lead	mg/dscm (grains per thousand dry standard cubic feet (gr/10^3 dscf)).	0.31 (0.14) ...	0.018 (0.0079).	0.036 (0.016)	3-run average (1-hour minimum sample time per run).	EPA Reference Method 29 of appendix A–8 of part 60.
Cadmium	mg/dscm (gr/10^3 dscf)	0.017 (0.0074).	0.013 (0.0057).	0.0092 (0.0040).	3-run average (1-hour minimum sample time per run).	EPA Reference Method 29 of appendix A–8 of part 60.

TABLE 1B TO SUBPART Ce OF PART 60—EMISSIONS LIMITS FOR SMALL, MEDIUM, AND LARGE HMIWI AT DESIGNATED FACILITIES AS DEFINED IN § 60.32e(a)(1) AND (a)(2)—Continued

Pollutant	Units (7 percent oxygen, dry basis)	Emissions limits			Averaging time [1]	Method for demonstrating compliance [2]
		HMIWI size				
		Small	Medium	Large		
Mercury	mg/dscm (gr/10^3 dscf)	0.014 (0.0061).	0.025 (0.011)	0.018 (0.0079).	3-run average (1-hour minimum sample time per run).	EPA Reference Method 29 of appendix A–8 of part 60.

[1] Except as allowed under § 60.56c(c) for HMIWI equipped with CEMS.
[2] Does not include CEMS and approved alternative non-EPA test methods allowed under § 60.56c(b).

■ 11. Table 2 to subpart Ce is redesignated as Table 2A and revised to read as follows:

TABLE 2A TO SUBPART Ce OF PART 60—EMISSIONS LIMITS FOR SMALL HMIWI WHICH MEET THE CRITERIA UNDER § 60.33e(b)(1)

Pollutant	Units (7 percent oxygen, dry basis)	HMIWI emissions limits	Averaging time [1]	Method for demonstrating compliance [2]
Particulate matter ...	mg/dscm (gr/dscf)	197 (0.086)	3-run average (1-hour minimum sample time per run).	EPA Reference Method 5 of appendix A–3 of part 60, or EPA Reference Method 26A or 29 of appendix A–8 of part 60.
Carbon monoxide ..	ppmv	40	3-run average (1-hour minimum sample time per run).	EPA Reference Method 10 or 10B of appendix A–4 of part 60.
Dioxins/furans	ng/dscm total dioxins/furans (gr/10^9 dscf) or ng/dscm TEQ (gr/10^9 dscf).	800 (350) or 15 (6.6).	3-run average (4-hour minimum sample time per run).	EPA Reference Method 23 of appendix A–7 of part 60.
Hydrogen chloride ..	ppmv	3,100	3-run average (1-hour minimum sample time per run).	EPA Reference Method 26 or 26A of appendix A–8 of part 60.
Sulfur dioxide	ppmv	55	3-run average (1-hour minimum sample time per run).	EPA Reference Method 6 or 6C of appendix A–4 of part 60.
Nitrogen oxides	ppmv	250	3-run average (1-hour minimum sample time per run).	EPA Reference Method 7 or 7E of appendix A–4 of part 60.
Lead	mg/dscm (gr/10^3 dscf).	10 (4.4)	3-run average (1-hour minimum sample time per run).	EPA Reference Method 29 of appendix A–8 of part 60.
Cadmium	mg/dscm (gr/10^3 dscf).	4 (1.7)	3-run average (1-hour minimum sample time per run).	EPA Reference Method 29 of appendix A–8 of part 60.
Mercury	mg/dscm (gr/10^3 dscf).	7.5 (3.3)	3-run average (1-hour minimum sample time per run).	EPA Reference Method 29 of appendix A–8 of part 60.

[1] Except as allowed under § 60.56c(c) for HMIWI equipped with CEMS.
[2] Does not include CEMS and approved alternative non-EPA test methods allowed under § 60.56c(b).

■ 12. Add Table 2B to subpart Ce to read as follows:

TABLE 2B TO SUBPART Ce OF PART 60—EMISSIONS LIMITS FOR SMALL HMIWI WHICH MEET THE CRITERIA UNDER § 60.33e(b)(2)

Pollutant	Units (7 percent oxygen, dry basis)	HMIWI Emissions limits	Averaging time [1]	Method for demonstrating compliance [2]
Particulate matter ...	mg/dscm (gr/dscf)	87 (0.038)	3-run average (1-hour minimum sample time per run).	EPA Reference Method 5 of appendix A–3 of part 60, or EPA Reference Method 26A or 29 of appendix A–8 of part 60.
Carbon monoxide ..	ppmv	20	3-run average (1-hour minimum sample time per run).	EPA Reference Method 10 or 10B of appendix A–4 of part 60.

TABLE 2B TO SUBPART Ce OF PART 60—EMISSIONS LIMITS FOR SMALL HMIWI WHICH MEET THE CRITERIA UNDER § 60.33e(b)(2)—Continued

Pollutant	Units (7 percent oxygen, dry basis)	HMIWI Emissions limits	Averaging time [1]	Method for demonstrating compliance [2]
Dioxins/furans	ng/dscm total dioxins/furans (gr/10^9 dscf) or ng/dscm TEQ (gr/10^9 dscf).	240 (100) or 5.1 (2.2).	3-run average (4-hour minimum sample time per run).	EPA Reference Method 23 of appendix A–7 of part 60.
Hydrogen chloride	ppmv	810	3-run average (1-hour minimum sample time per run).	EPA Reference Method 26 or 26A of appendix A–8 of part 60.
Sulfur dioxide	ppmv	55	3-run average (1-hour minimum sample time per run).	EPA Reference Method 6 or 6C of appendix A–4 of part 60.
Nitrogen oxides	ppmv	130	3-run average (1-hour minimum sample time per run).	EPA Reference Method 7 or 7E of appendix A–4 of part 60.
Lead	mg/dscm (gr/10^3 dscf).	0.50 (0.22)	3-run average (1-hour minimum sample time per run).	EPA Reference Method 29 of appendix A–8 of part 60.
Cadmium	mg/dscm (gr/10^3 dscf).	0.11 (0.048)	3-run average (1-hour minimum sample time per run).	EPA Reference Method 29 of appendix A–8 of part 60.
Mercury	mg/dscm (gr/10^3 dscf).	0.0051 (0.0022)	3-run average (1-hour minimum sample time per run).	EPA Reference Method 29 of appendix A–8 of part 60.

[1] Except as allowed under § 60.56c(c) for HMIWI equipped with CEMS.
[2] Does not include CEMS and approved alternative non-EPA test methods allowed under § 60.56c(b).

Subpart Ec—[Amended]

■ 13. Section 60.50c is amended as follows:
■ a. By revising paragraph (a);
■ b. By revising paragraph (i)(2);
■ c. By adding paragraphs (i)(3) through (i)(5); and
■ d. By adding paragraphs (m) and (n).

§ 60.50c Applicability and delegation of authority.

(a) Except as provided in paragraphs (b) through (h) of this section, the affected facility to which this subpart applies is each individual hospital/medical/infectious waste incinerator (HMIWI):

(1) For which construction is commenced after June 20, 1996 but no later than December 1, 2008; or

(2) For which modification is commenced after March 16, 1998 but no later than April 6, 2010.

(3) For which construction is commenced after December 1, 2008; or

(4) For which modification is commenced after April 6, 2010.

* * * * *

(i) * * *

(1) * * *

(2) Approval of alternative methods of demonstrating compliance under § 60.8 including:

(i) Approval of CEMS for PM, HCl, multi-metals, and Hg where used for purposes of demonstrating compliance,

(ii) Approval of continuous automated sampling systems for dioxin/furan and Hg where used for purposes of demonstrating compliance, and

(iii) Approval of major alternatives to test methods;

(3) Approval of major alternatives to monitoring;

(4) Waiver of recordkeeping requirements; and

(5) Performance test and data reduction waivers under § 60.8(b).

* * * * *

(m) The requirements of this subpart as promulgated on September 15, 1997, shall apply to the affected facilities defined in paragraph (a)(1) and (2) of this section until the applicable compliance date of the requirements of subpart Ce of this part, as amended on October 6, 2009. Upon the compliance date of the requirements of the amended subpart Ce of this part, affected facilities as defined in paragraph (a) of this section are no longer subject to the requirements of this subpart, but are subject to the requirements of subpart Ce of this part, as amended on October 6, 2009, except where the emissions limits of this subpart as promulgated on September 15, 1997 are more stringent than the emissions limits of the amended subpart Ce of this part. Compliance with subpart Ce of this part, as amended on October 6, 2009 is required on or before the date 3 years after EPA approval of the State plan for States in which an affected facility as defined in paragraph (a) of this section is located (but not later than the date 5 years after promulgation of the amended subpart).

(n) The requirements of this subpart, as amended on October 6, 2009, shall become effective April 6, 2010.

■ 14. Section 60.51c is amended as follows:
■ a. By adding a definition for ''Bag leak detection system'';
■ b. By adding a definition for ''Commercial HMIWI''; and
■ c. By adding a definition for ''Minimum reagent flow rate''; and
■ d. By revising the definition for ''Minimum secondary chamber temperature.''

§ 60.51c Definitions.

Bag leak detection system means an instrument that is capable of monitoring PM loadings in the exhaust of a fabric filter in order to detect bag failures. A bag leak detection system includes, but is not limited to, an instrument that operates on triboelectric, light-scattering, light-transmittance, or other effects to monitor relative PM loadings.

* * * * *

Commercial HMIWI means a HMIWI which offers incineration services for hospital/medical/infectious waste generated offsite by firms unrelated to the firm that owns the HMIWI.

* * * * *

Minimum reagent flow rate means 90 percent of the highest 3-hour average reagent flow rate at the inlet to the selective noncatalytic reduction technology (taken, at a minimum, once every minute) measured during the most recent performance test demonstrating compliance with the NO_x emissions 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, dioxin/furan, and NO_X emissions limits.

* * * * *

■ 15. Section 60.52c is amended by revising paragraphs (a) through (c) to read as follows:

§ 60.52c Emissions limits.

(a) On and after the date on which the initial performance test is completed or is required to be completed under § 60.8, whichever date comes first, no owner or operator of an affected facility shall cause to be discharged into the atmosphere:

(1) From an affected facility as defined in § 60.50c(a)(1) and (2), any gases that contain stack emissions in excess of the limits presented in Table 1A to this subpart.

(2) From an affected facility as defined in § 60.50c(a)(3) and (4), any gases that contain stack emissions in excess of the limits presented in Table 1B to this subpart.

(b) On and after the date on which the initial performance test is completed or is required to be completed under § 60.8, whichever date comes first, no owner or operator of an affected facility shall cause to be discharged into the atmosphere:

(1) From an affected facility as defined in § 60.50c(a)(1) and (2), any gases that exhibit greater than 10 percent opacity (6-minute block average).

(2) From an affected facility as defined in § 60.50c(a)(3) and (4), any gases that exhibit greater than 6 percent opacity (6-minute block average).

(c) On and after the date on which the initial performance test is completed or is required to be completed under § 60.8, whichever date comes first, no owner or operator of an affected facility as defined in § 60.50c(a)(1) and (2) and utilizing a large HMIWI, and in § 60.50c(a)(3) and (4), shall cause to be discharged into the atmosphere visible emissions of combustion ash from an ash conveying system (including conveyor transfer points) in excess of 5 percent of the observation period (*i.e.,* 9 minutes per 3-hour period), as determined by EPA Reference Method 22 of appendix A–1 of this part, except as provided in paragraphs (d) and (e) of this section.

* * * * *

■ 16. Section 60.55c is revised to read as follows:

§ 60.55c Waste management plan.

The owner or operator of an affected facility shall prepare a waste management plan. The waste management plan shall identify both the feasibility and the approach to separate certain components of solid waste from the health care waste stream in order to reduce the amount of toxic emissions from incinerated waste. A waste management plan may include, but is not limited to, elements such as segregation and recycling of paper, cardboard, plastics, glass, batteries, food waste, and metals (*e.g.,* aluminum cans, metals-containing devices); segregation of non-recyclable wastes (*e.g.,* polychlorinated biphenyl-containing waste, pharmaceutical waste, and mercury-containing waste, such as dental waste); and purchasing recycled or recyclable products. A 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. 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 emissions reductions expected to be achieved, and any other environmental or energy impacts they might have. The American Hospital Association publication entitled ''An Ounce of Prevention: Waste Reduction Strategies for Health Care Facilities'' (incorporated by reference, *see* § 60.17) shall be considered in the development of the waste management plan. The owner or operator of each commercial HMIWI company shall conduct training and education programs in waste segregation for each of the company's waste generator clients and ensure that each client prepares its own waste management plan that includes, but is not limited to, the provisions listed previously in this section.

■ 17. Section 60.56c is amended as follows:

■ a. By revising paragraph (a);

■ b. By revising paragraph (b) introductory text and paragraphs (b)(4) and (b)(6);

■ c. By redesignating paragraphs (b)(7) through (b)(12) as paragraphs (b)(9) through (b)(14);

■ d. By adding new paragraphs (b)(7) and (b)(8);

■ e. By revising newly redesignated paragraphs (b)(9), (b)(10), (b)(11) introductory text, and (b)(12) through (b)(14);

■ f. By revising paragraphs (c)(2) and (c)(3);

■ g. By redesignating paragraph (c)(4) as paragraph (c)(5);

■ h. By revising newly redesignated paragraph (c)(5);

■ i. By adding paragraphs (c)(4), (c)(6), and (c)(7);

■ j. By revising paragraph (d) introductory text;

■ k. By revising paragraph (e) introductory text and paragraph (e)(5);

■ l. By adding paragraphs (e)(6) through (e)(10);

■ m. By revising paragraph (f) introductory text and paragraph (f)(6);

■ n. By adding paragraphs (f)(7) through (f)(10);

■ o. By revising paragraph (g) introductory text and paragraph (g)(5);

■ p. By adding paragraphs (g)(6) through (g)(10);

■ q. By redesignating paragraphs (h) through (j) as paragraphs (i) through (k);

■ r. By adding paragraph (h); and

■ s. By revising newly redesignated paragraphs (i) and (j).

§ 60.56c Compliance and performance testing.

(a) The emissions limits apply at all times.

(b) The owner or operator of an affected facility as defined in § 60.50c(a)(1) and (2), shall conduct an initial performance test as required under § 60.8 to determine compliance with the emissions limits using the procedures and test methods listed in paragraphs (b)(1) through (b)(6) and (b)(9) through (b)(14) of this section. The owner or operator of an affected facility as defined in § 60.50c(a)(3) and (4), shall conduct an initial performance test as required under § 60.8 to determine compliance with the emissions limits using the procedures and test methods listed in paragraphs (b)(1) through (b)(14). The use of the bypass stack during a performance test shall invalidate the performance test.

* * * * *

(4) EPA Reference Method 3, 3A, or 3B of appendix A–2 of this part shall be used for gas composition analysis, including measurement of oxygen concentration. EPA Reference Method 3, 3A, or 3B of appendix A–2 of this part shall be used simultaneously with each of the other EPA reference methods. As an alternative to EPA Reference Method 3B, ASME PTC–19–10–1981–Part 10 may be used (incorporated by reference, *see* § 60.17).

* * * * *

(6) EPA Reference Method 5 of appendix A–3 or Method 26A or Method 29 of appendix A–8 of this part shall be used to measure the particulate matter emissions. As an alternative, PM CEMS may be used as specified in paragraph (c)(5) of this section.

(7) EPA Reference Method 7 or 7E of appendix A–4 of this part shall be used to measure NO_X emissions.

(8) EPA Reference Method 6 or 6C of appendix A–4 of this part shall be used to measure SO_2 emissions.

(9) EPA Reference Method 9 of appendix A–4 of this part shall be used to measure stack opacity. As an alternative, demonstration of compliance with the PM standards using bag leak detection systems as specified in § 60.57c(h) or PM CEMS as specified in paragraph (c)(5) of this section is considered demonstrative of compliance with the opacity requirements.

(10) EPA Reference Method 10 or 10B of appendix A–4 of this part shall be used to measure the CO emissions. As specified in paragraph (c)(4) of this section, use of CO CEMS are required for affected facilities under § 60.50c(a)(3) and (4).

(11) EPA Reference Method 23 of appendix A–7 of this part shall be used to measure total dioxin/furan emissions. As an alternative, an owner or operator may elect to sample dioxins/furans by installing, calibrating, maintaining, and operating a continuous automated sampling system for monitoring dioxin/furan emissions as specified in paragraph (c)(6) of this section. For Method 23 of appendix A–7 sampling, the minimum sample time shall be 4 hours per test run. If the affected facility has selected the toxic equivalency standards for dioxins/furans, under § 60.52c, the following procedures shall be used to determine compliance:

* * * * *

(12) EPA Reference Method 26 or 26A of appendix A–8 of this part shall be used to measure HCl emissions. As an alternative, HCl CEMS may be used as specified in paragraph (c)(5) of this section.

(13) EPA Reference Method 29 of appendix A–8 of this part shall be used to measure Pb, Cd, and Hg emissions. As an alternative, Hg emissions may be measured using ASTM D6784–02 (incorporated by reference, *see* § 60.17). As an alternative for Pb, Cd, and Hg, multi-metals CEMS or Hg CEMS, may be used as specified in paragraph (c)(5) of this section. As an alternative, an owner or operator may elect to sample Hg by installing, calibrating, maintaining, and operating a continuous automated sampling system for monitoring Hg emissions as specified in paragraph (c)(7) of this section.

(14) The EPA Reference Method 22 of appendix A–7 of this part shall be used to determine compliance with the fugitive ash emissions limit under § 60.52c(c). The minimum observation time shall be a series of three 1-hour observations.

* * * * *

(c) * * *

(2) Except as provided in paragraphs (c)(4) and (c)(5) of this section, determine compliance with the PM, CO, and HCl emissions 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 paragraph (b) of this section. If all three performance tests over a 3-year period indicate compliance with the emissions limit for a pollutant (PM, CO, or HCl), the owner or operator may forego a performance test for that pollutant for the subsequent 2 years. At a minimum, a performance test for PM, CO, and HCl shall be conducted 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 emissions limit for a pollutant (PM, CO, or HCl), the owner or operator may forego a performance test for that pollutant for an additional 2 years. If any performance test indicates noncompliance with the respective emissions limit, a performance test for that pollutant shall be conducted annually until all annual performance tests over a 3-year period indicate compliance with the emissions limit. The use of the bypass stack during a performance test shall invalidate the performance test.

(3) For an affected facility as defined in § 60.50c(a)(1) and (2) and utilizing a large HMIWI, and in § 60.50c(a)(3) and (4), determine compliance with the visible emissions limits for fugitive emissions from flyash/bottom ash storage and handling by conducting a performance test using EPA Reference Method 22 of appendix A–7 on an annual basis (no more than 12 months following the previous performance test).

(4) For an affected facility as defined in § 60.50c(a)(3) and (4), determine compliance with the CO emissions limit using a CO CEMS according to paragraphs (c)(4)(i) through (c)(4)(iii) of this section:

(i) Determine compliance with the CO emissions limit using a 24-hour block average, calculated as specified in section 12.4.1 of EPA Reference Method 19 of appendix A–7 of this part.

(ii) Operate the CO CEMS in accordance with the applicable procedures under appendices B and F of this part.

(iii) Use of a CO CEMS may be substituted for the CO annual performance test and minimum secondary chamber temperature to demonstrate compliance with the CO emissions limit.

(5) Facilities using CEMS to demonstrate compliance with any of the emissions limits under § 60.52c shall:

(i) For an affected facility as defined in § 60.50c(a)(1) and (2), determine compliance with the appropriate emissions limit(s) using a 12-hour rolling average, calculated each hour as the average of the previous 12 operating hours.

(ii) For an affected facility as defined in § 60.50c(a)(3) and (4), determine compliance with the appropriate emissions limit(s) using a 24-hour block average, calculated as specified in section 12.4.1 of EPA Reference Method 19 of appendix A–7 of this part.

(iii) Operate all CEMS in accordance with the applicable procedures under appendices B and F of this part. For those CEMS for which performance specifications have not yet been promulgated (HCl, multi-metals), this option for an affected facility as defined in § 60.50c(a)(3) and (4) takes effect on the date a final performance specification is published in the **Federal Register** or the date of approval of a site-specific monitoring plan.

(iv) For an affected facility as defined in § 60.50c(a)(3) and (4), be allowed to substitute use of an HCl CEMS for the HCl annual performance test, minimum HCl sorbent flow rate, and minimum scrubber liquor pH to demonstrate compliance with the HCl emissions limit.

(v) For an affected facility as defined in § 60.50c(a)(3) and (4), be allowed to substitute use of a PM CEMS for the PM annual performance test and minimum pressure drop across the wet scrubber, if applicable, to demonstrate compliance with the PM emissions limit.

(6) An affected facility as defined in § 60.50c(a)(3) and (4) using a continuous automated sampling system to demonstrate compliance with the dioxin/furan emissions limits under § 60.52c shall record the output of the system and analyze the sample according to EPA Reference Method 23 of appendix A–7 of this part. This option to use a continuous automated sampling system takes effect on the date a final performance specification applicable to dioxin/furan from monitors is published in the **Federal Register** or the date of approval of a site-specific monitoring plan. The owner or operator of an affected facility as defined in § 60.50c(a)(3) and (4) who elects to continuously sample dioxin/furan emissions instead of sampling and

testing using EPA Reference Method 23 of appendix A–7 shall install, calibrate, maintain, and operate a continuous automated sampling system and shall comply with the requirements specified in § 60.58b(p) and (q) of subpart Eb of this part.

(7) An affected facility as defined in § 60.50c(a)(3) and (4) using a continuous automated sampling system to demonstrate compliance with the Hg emissions limits under § 60.52c shall record the output of the system and analyze the sample at set intervals using any suitable determinative technique that can meet appropriate performance criteria. This option to use a continuous automated sampling system takes effect on the date a final performance specification applicable to Hg from monitors is published in the **Federal Register** or the date of approval of a site-specific monitoring plan. The owner or operator of an affected facility as defined in § 60.50c(a)(3) and (4) who elects to continuously sample Hg emissions instead of sampling and testing using EPA Reference Method 29 of appendix A–8 of this part, or an approved alternative method for measuring Hg emissions, shall install, calibrate, maintain, and operate a continuous automated sampling system and shall comply with the requirements specified in § 60.58b(p) and (q) of subpart Eb of this part.

(d) Except as provided in paragraphs (c)(4) through (c)(7) of this section, the owner or operator of an affected facility 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 shall:

* * * * *

(e) Except as provided in paragraph (i) of this section, for affected facilities equipped with a dry scrubber followed by a fabric filter:

* * * * *

(5) Use of the bypass stack shall constitute a violation of the PM, dioxin/furan, HCl, Pb, Cd and Hg emissions limits.

(6) Operation of the affected facility as defined in § 60.50c(a)(3) and (4) above the CO emissions limit as measured by the CO CEMS specified in paragraph (c)(4) of this section shall constitute a violation of the CO emissions limit.

(7) For an affected facility as defined in § 60.50c(a)(3) and (4), failure to initiate corrective action within 1 hour of a bag leak detection system alarm; or failure to operate and maintain the fabric filter such that the alarm is not engaged for more than 5 percent of the total operating time in a 6-month block reporting period shall constitute a violation of the PM emissions limit. If inspection of the fabric filter demonstrates that no corrective action is required, no alarm time is counted. If corrective action is required, each alarm is counted as a minimum of 1 hour. If it takes longer than 1 hour to initiate corrective action, the alarm time is counted as the actual amount of time taken to initiate corrective action. If the bag leak detection system is used to demonstrate compliance with the opacity limit, this would also constitute a violation of the opacity emissions limit.

(8) Operation of the affected facility as defined in § 60.50c(a)(3) and (4) above the PM, HCl, Pb, Cd, and/or Hg emissions limit as measured by the CEMS specified in paragraph (c)(5) of this section shall constitute a violation of the applicable emissions limit.

(9) Operation of the affected facility as defined in § 60.50c(a)(3) and (4) above the dioxin/furan emissions limit as measured by the continuous automated sampling system specified in paragraph (c)(6) of this section shall constitute a violation of the dioxin/furan emissions limit.

(10) Operation of the affected facility as defined in § 60.50c(a)(3) and (4) above the Hg emissions limit as measured by the continuous automated sampling system specified in paragraph (c)(7) of this section shall constitute a violation of the Hg emissions limit.

(f) Except as provided in paragraph (i) of this section, for affected facilities equipped with a wet scrubber:

* * * * *

(6) Use of the bypass stack shall constitute a violation of the PM, dioxin/furan, HCl, Pb, Cd and Hg emissions limits.

(7) Operation of the affected facility as defined in § 60.50c(a)(3) and (4) above the CO emissions limit as measured by the CO CEMS specified in paragraph (c)(4) of this section shall constitute a violation of the CO emissions limit.

(8) Operation of the affected facility as defined in § 60.50c(a)(3) and (4) above the PM, HCl, Pb, Cd, and/or Hg emissions limit as measured by the CEMS specified in paragraph (c)(5) of this section shall constitute a violation of the applicable emissions limit.

(9) Operation of the affected facility as defined in § 60.50c(a)(3) and (4) above the dioxin/furan emissions limit as measured by the continuous automated sampling system specified in paragraph (c)(6) of this section shall constitute a violation of the dioxin/furan emissions limit.

(10) Operation of the affected facility as defined in § 60.50c(a)(3) and (4) above the Hg emissions limit as measured by the continuous automated sampling system specified in paragraph (c)(7) of this section shall constitute a violation of the Hg emissions limit.

(g) Except as provided in paragraph (i) of this section, for affected facilities equipped with a dry scrubber followed by a fabric filter and a wet scrubber:

* * * * *

(5) Use of the bypass stack shall constitute a violation of the PM, dioxin/furan, HCl, Pb, Cd and Hg emissions limits.

(6) Operation of the affected facility as defined in § 60.50c(a)(3) and (4) above the CO emissions limit as measured by the CO CEMS specified in paragraph (c)(4) of this section shall constitute a violation of the CO emissions limit.

(7) For an affected facility as defined in § 60.50c(a)(3) and (4), failure to initiate corrective action within 1 hour of a bag leak detection system alarm; or failure to operate and maintain the fabric filter such that the alarm is not engaged for more than 5 percent of the total operating time in a 6-month block reporting period shall constitute a violation of the PM emissions limit. If inspection of the fabric filter demonstrates that no corrective action is required, no alarm time is counted. If corrective action is required, each alarm is counted as a minimum of 1 hour. If it takes longer than 1 hour to initiate corrective action, the alarm time is counted as the actual amount of time taken to initiate corrective action. If the bag leak detection system is used to demonstrate compliance with the opacity limit, this would also constitute a violation of the opacity emissions limit.

(8) Operation of the affected facility as defined in § 60.50c(a)(3) and (4) above the PM, HCl, Pb, Cd, and/or Hg emissions limit as measured by the CEMS specified in paragraph (c)(5) of this section shall constitute a violation of the applicable emissions limit.

(9) Operation of the affected facility as defined in § 60.50c(a)(3) and (4) above the dioxin/furan emissions limit as measured by the continuous automated sampling system specified in paragraph (c)(6) of this section shall constitute a violation of the dioxin/furan emissions limit.

(10) Operation of the affected facility as defined in § 60.50c(a)(3) and (4) above the Hg emissions limit as measured by the continuous automated sampling system specified in paragraph (c)(7) of this section shall constitute a violation of the Hg emissions limit.

(h) The owner or operator of an affected facility as defined in

§ 60.50c(a)(3) and (4) equipped with selective noncatalytic reduction technology shall:

(1) Establish the maximum charge rate, the minimum secondary chamber temperature, and the minimum reagent flow rate as site specific operating parameters during the initial performance test to determine compliance with the emissions limits;

(2) Following the date on which the initial performance test is completed or is required to be completed under § 60.8, whichever date comes first, ensure that the affected facility does not operate above the maximum charge rate, or below the minimum secondary chamber temperature or the minimum reagent flow rate measured as 3-hour rolling averages (calculated each hour as the average of the previous 3 operating hours) at all times. Operating parameter limits do not apply during performance tests.

(3) Except as provided in paragraph (i) of this section, operation of the affected facility above the maximum charge rate, below the minimum secondary chamber temperature, and below the minimum reagent flow rate simultaneously shall constitute a violation of the NO_X emissions limit.

(i) The owner or operator of an affected facility may conduct a repeat performance test within 30 days of violation of applicable operating parameter(s) to demonstrate that the affected facility is not in violation of the applicable emissions limit(s). Repeat performance tests conducted pursuant to this paragraph shall be conducted using the identical operating parameters that indicated a violation under paragraph (e), (f), (g), or (h) of this section.

(j) The owner or operator of an affected facility using an air pollution control device other than a dry scrubber followed by a fabric filter, a wet scrubber, a dry scrubber followed by a fabric filter and a wet scrubber, or selective noncatalytic reduction technology to comply with the emissions limits under § 60.52c shall petition the Administrator for other site-specific operating parameters to be established during the initial performance test and continuously monitored thereafter. The owner or operator shall not conduct the initial performance test until after the petition has been approved by the Administrator.

* * * * *

■ 18. Section 60.57c is amended as follows:

■ a. By revising paragraph (a);

■ b. By redesignating paragraphs (b) through (d) as paragraphs (c) through (e);

■ c. By adding paragraph (b);

■ d. By revising newly redesignated paragraphs (d) and (e); and

■ e. By adding paragraphs (f) through (h).

§ 60.57c Monitoring requirements.

(a) Except as provided in § 60.56c(c)(4) through (c)(7), the owner or operator of an affected facility shall 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 to this subpart (unless CEMS are used as a substitute for certain parameters as specified) such that these devices (or methods) measure and record values for these operating parameters at the frequencies indicated in Table 3 of this subpart at all times.

(b) The owner or operator of an affected facility as defined in § 60.50c(a)(3) and (4) that uses selective noncatalytic reduction technology shall install, calibrate (to manufacturers' specifications), maintain, and operate devices (or establish methods) for monitoring the operating parameters listed in § 60.56c(h) such that the devices (or methods) measure and record values for the operating parameters at all times. Operating parameter values shall be measured and recorded at the following minimum frequencies:

(1) Maximum charge rate shall be measured continuously and recorded once each hour;

(2) Minimum secondary chamber temperature shall be measured continuously and recorded once each minute; and

(3) Minimum reagent flow rate shall be measured hourly and recorded once each hour.

* * * * *

(d) The owner or operator of an affected facility using an air pollution control device other than a dry scrubber followed by a fabric filter, a wet scrubber, a dry scrubber followed by a fabric filter and a wet scrubber, or selective noncatalytic reduction technology to comply with the emissions limits under § 60.52c shall install, calibrate (to manufacturers' specifications), maintain, and operate the equipment necessary to monitor the site-specific operating parameters developed pursuant to § 60.56c(j).

(e) The owner or operator of an affected facility shall 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 shall be obtained for 75 percent of the operating hours per day for 90 percent of the operating days per calendar quarter that the affected facility is combusting hospital waste and/or medical/infectious waste.

(f) The owner or operator of an affected facility as defined in § 60.50c(a)(3) and (4) shall ensure that each HMIWI subject to the emissions limits in § 60.52c undergoes an initial air pollution control device inspection that is at least as protective as the following:

(1) At a minimum, an inspection shall include the following:

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

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

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

(2) Within 10 operating days following an air pollution control device inspection, all necessary repairs shall be completed unless the owner or operator obtains written approval from the Administrator establishing a date whereby all necessary repairs of the designated facility shall be completed.

(g) The owner or operator of an affected facility as defined in § 60.50c(a)(3) and (4) shall ensure that each HMIWI subject to the emissions limits under § 60.52c undergoes an air pollution control device inspection annually (no more than 12 months following the previous annual air pollution control device inspection), as outlined in paragraphs (f)(1) and (f)(2) of this section.

(h) For affected facilities as defined in § 60.50c(a)(3) and (4) that use an air pollution control device that includes a fabric filter and are not demonstrating compliance using PM CEMS, determine compliance with the PM emissions limit using a bag leak detection system and meet the requirements in paragraphs (h)(1) through (h)(12) of this section for each bag leak detection system.

(1) Each triboelectric bag leak detection system may be installed, calibrated, operated, and maintained according to the ''Fabric Filter Bag Leak Detection Guidance,'' (EPA–454/R–98–015, September 1997). This document is available from the U.S. Environmental Protection Agency (U.S. EPA); Office of Air Quality Planning and Standards; Sector Policies and Programs Division; Measurement Policy Group (D–243–02), Research Triangle Park, NC 27711. This

document is also available on the Technology Transfer Network (TTN) under Emissions Measurement Center Continuous Emissions Monitoring. Other types of bag leak detection systems shall be installed, operated, calibrated, and maintained in a manner consistent with the manufacturer's written specifications and recommendations.

(2) The bag leak detection system shall be certified by the manufacturer to be capable of detecting PM emissions at concentrations of 10 milligrams per actual cubic meter (0.0044 grains per actual cubic foot) or less.

(3) The bag leak detection system sensor shall provide an output of relative PM loadings.

(4) The bag leak detection system shall be equipped with a device to continuously record the output signal from the sensor.

(5) The bag leak detection system shall be equipped with an audible alarm system that will sound automatically when an increase in relative PM emissions over a preset level is detected. The alarm shall be located where it is easily heard by plant operating personnel.

(6) For positive pressure fabric filter systems, a bag leak detector shall be installed in each baghouse compartment or cell.

(7) For negative pressure or induced air fabric filters, the bag leak detector shall be installed downstream of the fabric filter.

(8) Where multiple detectors are required, the system's instrumentation and alarm may be shared among detectors.

(9) The baseline output shall be established by adjusting the range and the averaging period of the device and establishing the alarm set points and the alarm delay time according to section 5.0 of the ''Fabric Filter Bag Leak Detection Guidance.''

(10) Following initial adjustment of the system, the sensitivity or range, averaging period, alarm set points, or alarm delay time may not be adjusted. In no case may the sensitivity be increased by more than 100 percent or decreased more than 50 percent over a 365-day period unless such adjustment follows a complete fabric filter inspection that demonstrates that the fabric filter is in good operating condition. Each adjustment shall be recorded.

(11) Record the results of each inspection, calibration, and validation check.

(12) Initiate corrective action within 1 hour of a bag leak detection system alarm; operate and maintain the fabric filter such that the alarm is not engaged for more than 5 percent of the total operating time in a 6-month block reporting period. If inspection of the fabric filter demonstrates that no corrective action is required, no alarm time is counted. If corrective action is required, each alarm is counted as a minimum of 1 hour. If it takes longer than 1 hour to initiate corrective action, the alarm time is counted as the actual amount of time taken to initiate corrective action.

■ 19. Section 60.58c is amended as follows:

■ a. By revising paragraph (a)(2)(iv);

■ b. By redesignating paragraphs (b)(2)(viii) through (b)(2)(xv) as paragraphs (b)(2)(ix) through (b)(2)(xvi);

■ c. By adding paragraph (b)(2)(viii);

■ d. By revising newly designated paragraph (b)(2)(xvi);

■ e. By adding paragraphs (b)(2)(xvii) through (b)(2)(xix);

■ f. By revising paragraphs (b)(6) and (b)(11);

■ g. By revising paragraph (c) introductory text;

■ h. By revising paragraphs (c)(1) and (c)(2);

■ i. By adding paragraph (c)(4);

■ j. By revising paragraph (d) introductory text;

■ k. By revising paragraphs (d)(1) through (d)(3);

■ l. By adding paragraphs (d)(9) through (d)(11); and

■ m. By adding paragraph (g).

§ 60.58c Reporting and recordkeeping requirements.

(a) * * *

(2) * * *

(iv) If applicable, the petition for site-specific operating parameters under § 60.56c(j).

* * * * *

(b) * * *

(2) * * *

(viii) For affected facilities as defined in § 60.50c(a)(3) and (4), amount and type of NO_x reagent used during each hour of operation, as applicable;

* * * * *

(xvi) For affected facilities complying with § 60.56c(j) and § 60.57c(d), the owner or operator shall maintain all operating parameter data collected;

(xvii) For affected facilities as defined in § 60.50c(a)(3) and (4), records of the annual air pollution control device inspections, any required maintenance, and any repairs not completed within 10 days of an inspection or the timeframe established by the Administrator.

(xviii) For affected facilities as defined in § 60.50c(a)(3) and (4), records of each bag leak detection system alarm, the time of the alarm, the time corrective action was initiated and completed, and a brief description of the cause of the alarm and the corrective action taken, as applicable.

(xix) For affected facilities as defined in § 60.50c(a)(3) and (4), concentrations of CO as determined by the continuous emissions monitoring system.

* * * * *

(6) The results of the initial, annual, and any subsequent performance tests conducted to determine compliance with the emissions limits and/or to establish or re-establish operating parameters, as applicable, and a description, including sample calculations, of how the operating parameters were established or re-established, if applicable.

* * * * *

(11) Records of calibration of any monitoring devices as required under § 60.57c(a) through (d).

(c) The owner or operator of an affected facility shall submit the information specified in paragraphs (c)(1) through (c)(4) of this section no later than 60 days following the initial performance test. All reports shall be signed by the facilities manager.

(1) The initial performance test data as recorded under § 60.56c(b)(1) through (b)(14), as applicable.

(2) The values for the site-specific operating parameters established pursuant to § 60.56c(d), (h), or (j), as applicable, and a description, including sample calculations, of how the operating parameters were established during the initial performance test.

* * * * *

(4) For each affected facility as defined in § 60.50c(a)(3) and (4) that uses a bag leak detection system, analysis and supporting documentation demonstrating conformance with EPA guidance and specifications for bag leak detection systems in § 60.57c(h).

(d) An annual report shall be submitted 1 year following the submissions of the information in paragraph (c) of this section and subsequent reports shall be submitted no more than 12 months following the previous report (once the unit is subject to permitting requirements under title V of the Clean Air Act, the owner or operator of an affected facility must submit these reports semiannually). The annual report shall include the information specified in paragraphs (d)(1) through (11) of this section. All reports shall be signed by the facilities manager.

(1) The values for the site-specific operating parameters established

pursuant to § 60.56(d), (h), or (j), as applicable.

(2) The highest maximum operating parameter and the lowest minimum operating parameter, as applicable, for each operating parameter recorded for the calendar year being reported, pursuant to § 60.56(d), (h), or (j), as applicable.

(3) The highest maximum operating parameter and the lowest minimum operating parameter, as applicable, for each operating parameter recorded pursuant to § 60.56(d), (h), or (j) for the calendar year preceding the year being reported, in order to provide the Administrator with a summary of the performance of the affected facility over a 2-year period.

(9) For affected facilities as defined in § 60.50c(a)(3) and (4), records of the annual air pollution control device inspection, any required maintenance, and any repairs not completed within 10 days of an inspection or the timeframe established by the Administrator.

(10) For affected facilities as defined in § 60.50c(a)(3) and (4), records of each bag leak detection system alarm, the time of the alarm, the time corrective action was initiated and completed, and a brief description of the cause of the alarm and the corrective action taken, as applicable.

(11) For affected facilities as defined in § 60.50c(a)(3) and (4), concentrations of CO as determined by the continuous emissions monitoring system.

* * * * *

(g) For affected facilities, as defined in § 60.50c(a)(3) and (4), that choose to submit an electronic copy of stack test reports to EPA's WebFIRE data base, as of December 31, 2011, the owner or operator of an affected facility shall enter the test data into EPA's data base using the Electronic Reporting Tool located at *http://www.epa.gov/ttn/chief/ert/ert_tool.html.*

■ 20. Table 1 to subpart Ec is redesignated as Table 1A and revised to read as follows:

TABLE 1A TO SUBPART Ec OF PART 60—EMISSIONS LIMITS FOR SMALL, MEDIUM, AND LARGE HMIWI AT AFFECTED FACILITIES AS DEFINED IN § 60.50c(a)(1) AND (2)

Pollutant	Units (7 percent oxygen, dry basis)	Emissions limits			Averaging time [1]	Method for demonstrating compliance [2]
		HMIWI size				
		Small	Medium	Large		
Particulate matter.	Milligrams per dry standard cubic meter (grains per dry standard cubic foot).	69 (0.03)	34 (0.015)	34 (0.015)	3-run average (1-hour minimum sample time per run).	EPA Reference Method 5 of appendix A–3 of part 60, or EPA Reference Method M 26A or 29 of appendix A–8 of part 60.
Carbon monoxide.	Parts per million by volume.	40	40	40	3-run average (1-hour minimum sample time per run).	EPA Reference Method 10 or 10B of appendix A–4 of part 60.
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).	125 (55) or 2.3 (1.0).	25 (11) or 0.6 (0.26).	25 (11) or 0.6 (0.26).	3-run average (4-hour minimum sample time per run).	EPA Reference Method 23 of appendix A–7 of part 60.
Hydrogen chloride.	Parts per million by volume.	15 or 99% ...	15 or 99% ...	15 or 99%5.1	3-run average (1-hour minimum sample time per run).	EPA Reference Method 26 or 26A of appendix A–8 of part 60.
Sulfur dioxide	Parts per million by volume.	55	55	55	3-run average (1-hour minimum sample time per run).	EPA Reference Method 6 or 6C of appendix A–4 of part 60.
Nitrogen oxides.	Parts per million by volume.	250	250	250	3-run average (1-hour minimum sample time per run).	EPA Reference Method 7 or 7E of appendix A–4 of part 60.
Lead	Milligrams per dry standard cubic meter (grains per thousand dry standard cubic feet.	1.2 (0.52) or 70%.	0.07 (0.03) or 98%.	0.07 (0.03) or 98%.	3-run average (1-hour minimum sample time per run).	EPA Reference Method 29 of appendix A–8 of part 60.
Cadmium	Milligrams per dry standard cubic meter (grains per thousand dry standard cubic feet) or percent reduction.	0.16 (0.07) or 65%.	0.04 (0.02) or 90%.	0.04 (0.02) or 90%.	3-run average (1-hour minimum sample time per run).	EPA Reference Method 29 of appendix A–8 of part 60.
Mercury	Milligrams per dry standard cubic meter (grains per thousand dry standard cubic feet) or percent reduction.	0.55 (0.24) or 85%.	0.55 (0.24) or 85%.	0.55 (0.24) or 85%.	3-run average (1-hour minimum sample time per run).	EPA Reference Method 29 of appendix A–8 of part 60.

[1] Except as allowed under § 60.56c(c) for HMIWI equipped with CEMS.

[2] Does not include CEMS and approved alternative non-EPA test methods allowed under § 60.56c(b).

■ 21. Add Table 1B to subpart Ec to read as follows:

TABLE 1B TO SUBPART EC OF PART 60—EMISSIONS LIMITS FOR SMALL, MEDIUM, AND LARGE HMIWI AT AFFECTED FACILITIES AS DEFINED IN § 60.50c(a)(3) AND (4)

Pollutant	Units (7 percent oxygen, dry basis)	Emissions limits			Averaging time[1]	Method for demonstrating compliance[2]
		HMIWI size				
		Small	Medium	Large		
Particulate matter.	Milligrams per dry standard cubic meter (grains per dry standard cubic foot).	66 (0.029)	22 (0.0095) ..	18 (0.0080) ..	3-run average (1-hour minimum sample time per run).	EPA Reference Method 5 of appendix A–3 of part 60, or EPA Reference Method M 26A or 29 of appendix A–8 of part 60.
Carbon monoxide.	Parts per million by volume	20	1.8	11	3-run average (1-hour minimum sample time per run).	EPA Reference Method 10 or 10B of appendix A–4 of part 60.
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).	16 (7.0) or 0.013 (0.0057).	0.47 (0.21) or 0.014 (0.0061).	9.3 (4.1) or 0.035 (0.015).	3-run average (4-hour minimum sample time per run).	EPA Reference Method 23 of appendix A–7 of part 60.
Hydrogen chloride.	Parts per million by volume	15	7.7	5.1	3-run average (1-hour minimum sample time per run).	EPA Reference Method 26 or 26A of appendix A–8 of part 60.
Sulfur dioxide	Parts per million by volume	1.4	1.4	1.6	3-run average (1-hour minimum sample time per run).	EPA Reference Method 6 or 6C of appendix A–4 of part 60.
Nitrogen oxides.	Parts per million by volume	67	67	130	3-run average (1-hour minimum sample time per run).	EPA Reference Method 7 or 7E of appendix A–4 of part 60.
Lead	Milligrams per dry standard cubic meter (grains per thousand dry standard cubic feet).	0.31 (0.14) ...	0.018 (0.0079).	0.00069 (0.00030).	3-run average (1-hour minimum sample time per run).	EPA Reference Method 29 of appendix A–8 of part 60.
Cadmium	Milligrams per dry standard cubic meter (grains per thousand dry standard cubic feet) or percent reduction.	0.017 (0.0074).	0.0098 (0.0043).	0.00013 (0.000057).	3-run average (1-hour minimum sample time per run).	EPA Reference Method 29 of appendix A–8 of part 60.
Mercury	Milligrams per dry standard cubic meter (grains per thousand dry standard cubic feet) or percent reduction.	0.014 (0.0061).	0.0035 (0.0015).	0.0013 (0.00057).	3-run average (1-hour minimum sample time per run).	EPA Reference Method 29 of appendix A–8 of part 60.

[1] Except as allowed under § 60.56c(c) for HMIWI equipped with CEMS.
[2] Does not include CEMS and approved alternative non-EPA test methods allowed under § 60.56c(b).

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Appendix M

2010 HMIWI Inventory

APPENDIX M—2010 HMIWI INVENTORY

No.	Facility name	Unit no.	Street address	City	State	Zip	County	EPA Region	Size category	New/ existing
1	Bristol-Myers Squibb Co.		5 Research Parkway, P.O. Box 5100	Wallingford	CT	06492	New Haven	1	L	E
2	Merck & Company, Inc.		126 E. Lincoln Avenue	Rahway	NJ	07065	Union	2	L	E
3	Curtis Bay Energy	Unit 1	3200 Hawkins Point Road	Baltimore	MD	21226	Baltimore City	3	L	E
4	Curtis Bay Energy	Unit 2	3200 Hawkins Point Road	Baltimore	MD	21226	Baltimore City	3	L	E
5	Franklin Square Hospital Center		9000 Franklin Square Drive	Baltimore	MD	21237	Baltimore	3	M	E
6	University of Maryland at Baltimore, Environmental Health and Safety Facility		714 W. Lombard Street	Baltimore	MD	21201	Baltimore City	3	M	E
7	Fort Detrick	Unit 5	Incinerator Complex, Building 393	Fort Detrick	MD	21702	Frederick	3	L	E
8	Fort Detrick	Unit 6	Incinerator Complex, Building 393	Fort Detrick	MD	21702	Frederick	3	L	E
9	Washington County Hospital		251 E. Antietam Street	Hagerstown	MD	21740	Washington	3	M	E
10	Holy Spirit Hospital		503 N. 21st Street	Camp Hill	PA	17011	Cumberland	3	M	E
11	Hamot Medical Center		201 State Street	Erie	PA	16550	Erie	3	L	E
12	Riddle Memorial Hospital		1068 W. Baltimore Pike	Media	PA	19063	Delaware	3	M	E
13	Pennsylvania State University, Animal Diagnostic Lab Incinerator		159A Physical Plant Building, Orchard Road	State College	PA	16802	Centre	3	M	E
14	Merck & Company, Inc.	Unit 2	770 Sumneytown Pike, P.O. Box 4	West Point	PA	19486	Montgomery	3	L	E
15	Merck & Company, Inc.	Unit 5	770 Sumneytown Pike, P.O. Box 4	West Point	PA	19486	Montgomery	3	L	E
16	Charleston Area Medical Center, General Hospital		501 Morris Street	Charleston	WV	25301	Kanawha	3	L	E

No.	Facility name	Unit no.	Street address	City	State	Zip	County	EPA Region	Size category	New/ existing
17	Thomas Memorial Hospital		4605 MacCorkle Avenue S.W.	South Charleston	WV	25309	Kanawha	3	M	E
18	Stericycle, Inc.		254 W. Keene Road	Apopka	FL	32703	Orange	4	L	E
19	Boca Raton Community Hospital		800 Meadows Road	Boca Raton	FL	33486	Palm Beach	4	L	E
20	Bethesda Memorial Hospital		2815 S. Seacrest Boulevard	Boynton Beach	FL	33435	Palm Beach	4	L	E
21	Holy Cross Hospital		4725 N. Federal Highway	Fort Lauderdale	FL	33308	Broward	4	L	E
22	Malcom Randall Veterans Affairs Medical Center		1601 S.W. Archer Road	Gainesville	FL	32608	Alachua	4	M	E
23	Memorial Regional Hospital		3501 Johnson Street	Hollywood	FL	33021	Broward	4	L	E
24	Lakeland Regional Medical Center		1324 Lakeland Hills Boulevard	Lakeland	FL	33805	Polk	4	L	E
25	Department of Veterans Affairs Medical Center		1201 N.W. 16th Street	Miami	FL	33125	Miami-Dade	4	L	E
26	Bayfront Medical Center		701 6th Street S.	St. Petersburg	FL	33701	Pinellas	4	L	E
27	St. Joseph's Hospital		3001 W. Martin Luther King Jr. Boulevard	Tampa	FL	33607	Hillsborough	4	L	E
28	Centers for Disease Control and Prevention--Clifton, Building 18		1600 Clifton Road, N.E.	Atlanta	GA	30333	DeKalb	4	S	N
29	East Carolina University, Health Sciences Campus, HSC Utility Plant		600 Moye Boulevard	Greenville	NC	27834	Pitt	4	L	N
30	Stericycle, Inc.	Unit 1	1168 Porter Avenue	Haw River	NC	27258	Alamance	4	L	E
31	Stericycle, Inc.	Unit 2	1168 Porter Avenue	Haw River	NC	27258	Alamance	4	L	E
32	BMWNC, Inc.	Unit 1	3250 Campus Ridge Road	Matthews	NC	28105	Mecklenburg	4	L	E
33	St. Jude Children's Research Hospital		262 Danny Thomas Place	Memphis	TN	38105	Shelby	4	M	E

No.	Facility name	Unit no.	Street address	City	State	Zip	County	EPA Region	Size category	New/ existing
34	Stericycle, Inc.	Unit 1	Rural Route 4, P.O. Box 243L	Clinton	IL	61727	DeWitt	5	L	E
35	Stericycle, Inc.	Unit 2	Rural Route 4, P.O. Box 243L	Clinton	IL	61727	DeWitt	5	L	E
36	Loyola University Medical Center		2160 S. First Avenue	Maywood	IL	60153	Cook	5	L	E
37	Parkview Hospital		2200 Randallia Drive	Fort Wayne	IN	46805	Allen	5	L	E
38	South Bend Medical Foundation		530 N. Lafayette Boulevard	South Bend	IN	46601	St. Joseph	5	M	E
39	Good Samaritan Hospital		520 S. Seventh Street	Vincennes	IN	47591	Knox	5	M	E
40	Mayo Clinic, Waste Management Facility		7123 L.C. Industrial Park, Rochester Municipal Airport	Rochester	MN	55905	Olmsted	5	L	E
41	Fairfield Medical Center		401 N. Ewing Street	Lancaster	OH	43130	Fairfield	5	S	E
42	MedCentral Health System, Mansfield Hospital		335 Glessner Avenue	Mansfield	OH	44903	Richland	5	L	E
43	Medina General Hospital		1000 E. Washington Street	Medina	OH	44256	Medina	5	M	E
44	Stericycle, Inc.		1901 Pine Avenue S.E.	Warren	OH	44483	Trumbull	5	L	E
45	Waste Management Resource Recovery & Recycling Center	Unit 1	7505 State Highway 65	Anahuac	TX	77514	Chambers	6	L	N
46	Waste Management Resource Recovery & Recycling Center	Unit 2	7505 State Highway 65	Anahuac	TX	77514	Chambers	6	L	N
47	University of Texas Medical Branch		301 University Boulevard, Mail Route 1108	Galveston	TX	77555	Galveston	6	L	E
48	Stericycle, Inc.		3140 N. 7th Street	Kansas City	KS	66115	Wyandotte	7	L	E
49	Rocky Mountain Laboratories		903 S. 4th Street, Building 23	Hamilton	MT	59840	Ravalli	8	M	E
50	Healthcare Environmental Services Inc.		1420 40th Street N.	Fargo	ND	58102	Cass	8	L	E
51	Stericycle, Inc.		90 N. 1100 W.	North Salt Lake	UT	84054	Davis	8	L	E

No.	Facility name	Unit no.	Street address	City	State	Zip	County	EPA Region	Size category	New/ existing
52	Wyoming Medical Center		1233 E. Second Street	Casper	WY	82601	Natrona	8	M	E
53	Kona Community Hospital		79-1019 Haukapila Street	Kealakekua	HI	96750	Hawaii	9	SR	E
54	Yukon-Kuskokwim Delta Regional Hospital		829 Chief Eddie Hoffman Highway, P.O. Box 528	Bethel	AK	99559	Bethel Census Area	10	SR	E

No.	Facility name	Unit no.	Facility type	APCD description	APCD code	State Plan/ Federal Plan/NSPS	Compliance date	Maximum charge rate, lb/hr	Operating hours, hr/yr
1	Bristol-Myers Squibb Co.		Pharmaceutical	Secondary chamber (1800°F) and baghouse	FF	Federal Plan	9/15/2002	1,000	2,072
2	Merck & Company, Inc.		Pharmaceutical	Secondary chamber (1500°F, 1 sec), partial quench, dry acid gas scrubber with dry lime injection, and baghouse	DIFF	Federal Plan	8/15/2001	799	4,321
3	Curtis Bay Energy	Unit 1	Commercial	Secondary chamber, dry scrubber, and baghouse with activated carbon injection	DIFF	State Plan	3/15/2002	7,083	8,736
4	Curtis Bay Energy	Unit 2	Commercial	Secondary chamber, dry scrubber, and baghouse with activated carbon injection	DIFF	State Plan	3/15/2002	7,083	8,736
5	Franklin Square Hospital Center		Hospital	Secondary chamber (1800°F) and venturi scrubber followed by quench chamber and mist eliminator	WS	State Plan	3/15/2002	500	5,408
6	University of Maryland at Baltimore, Environmental Health and Safety Facility		University	Secondary chamber (1832°F) and venturi caustic scrubber with packed-bed scrubber	WS	State Plan	3/15/2002	500	1,440
7	Fort Detrick	Unit 5	Fed military	Secondary chamber and rotary atomizing wet scrubber	WS	State Plan	3/15/2002	1,000	1,300
8	Fort Detrick	Unit 6	Fed military	Secondary chamber and rotary atomizing wet scrubber	WS	State Plan	3/15/2002	1,000	1,300
9	Washington County Hospital		Hospital	Secondary chamber and venturi caustic scrubber	WS	State Plan	3/15/2002	500	2,496

No.	Facility name	Unit no.	Facility type	APCD description	APCD code	State Plan/ Federal Plan/NSPS	Compliance date	Maximum charge rate, lb/hr	Operating hours, hr/yr
10	Holy Spirit Hospital		Hospital	Secondary chamber (1800°F) and venturi scrubber with prequench and NaOH injection	WS	State Plan	9/15/2002	500	3,944
11	Hamot Medical Center		Hospital	Secondary chamber (2000°F, 2 sec), lime injection system, powdered activated carbon injection system, baghouse, and vertical upflow two-stage multi-microventuri scrubber system	DIFF/ WS	State Plan	9/15/2002	1,060	2,080
12	Riddle Memorial Hospital		Hospital	Secondary chamber (1800°F, 2 sec), caustic packed tower scrubber, and high pressure venturi, with activated carbon injection	WS	State Plan	9/15/2002	500	2,920
13	Pennsylvania State University, Animal Diagnostic Lab Incinerator		University	Secondary chamber (1900°F) and rotary atomizing wet scrubber with demister	WS	State Plan	8/15/2001	500	1,022
14	Merck & Company, Inc.	Unit 2	University	Secondary chamber (1900°F) and rotary atomizing wet scrubber with demister	WS	State Plan	8/15/2001	500	1,022
15	Merck & Company, Inc.	Unit 5	Pharmaceutical	Secondary/tertiary chamber (2000°F, 2 sec), water quench followed by sodium bicarbonate injection system with dry reaction chamber and pulse-jet baghouse	DIFF	State Plan	9/15/2002	2,000	865

No.	Facility name	Unit no.	Facility type	APCD description	APCD code	State Plan/ Federal Plan/NSPS	Compliance date	Maximum charge rate, lb/hr	Operating hours, hr/yr
16	Charleston Area Medical Center, General Hospital		Pharmaceutical	Secondary chamber (1800°F, 2.2 sec), water quench followed by sodium bicarbonate injection system and pulse-jet baghouse	DIFF	State Plan	9/15/2002	3,045	5,753
17	Thomas Memorial Hospital		Hospital	Secondary chamber (1800°F, 2 sec), dry injection/baghouse scrubber system with activated carbon	DIFF	State Plan	7/28/2001	1,000	1,248
18	Stericycle, Inc.		Hospital	Secondary chamber (1800°F) and venturi packed tower wet scrubber with caustic injection	WS	State Plan	7/28/2001	470	2,080
19	Boca Raton Community Hospital		Hospital	Secondary chamber (1800°F, 1 sec) and rotary atomizing wet scrubber system with caustic soda injection	WS	State Plan	1/16/2002	730	8,736
20	Bethesda Memorial Hospital		Hospital	Secondary chamber (1800°F, 2 sec) and rotary atomizing scrubber with mist eliminator	WS	State Plan	1/16/2002	1,000	3,024
21	Holy Cross Hospital		Hospital	Secondary chamber (1800°F, 1 sec) and venturi scrubber with packed bed absorption unit using dilute NaOH	WS	State Plan	1/16/2002	1,300	2,964
22	Malcom Randall Veterans Affairs Medical Center		Fed hospital	Secondary chamber (1800°F, 1 sec) and wet scrubber with caustic soda injection	WS	State Plan	1/16/2002	495	1,664

No.	Facility name	Unit no.	Facility type	APCD description	APCD code	State Plan/ Federal Plan/NSPS	Compliance date	Maximum charge rate, lb/hr	Operating hours, hr/yr
23	Memorial Regional Hospital		Hospital	Secondary chamber (1800°F, 1 sec), packed column gas scrubber, and wet ESP	WS/ WESP	State Plan	1/16/2002	1,800	4,992
24	Lakeland Regional Medical Center		Hospital	Secondary chamber (1800°F, 1 sec), lime injection system, and baghouse	DIFF	State Plan	1/16/2002	750	6,247
25	Department of Veterans Affairs Medical Center		Fed hospital	Secondary chamber (1800°F, 1 sec), venturi scrubber, and packed tower absorber	WS	State Plan		1,000	4,160
26	Bayfront Medical Center		Hospital	Secondary chamber (1800°F, 1 sec) and flux force/condensation collision scrubber system using dilute NaOH	WS	State Plan	1/16/2002	1,500	3,352
27	St. Joseph's Hospital		Hospital	Secondary chamber (1800°F, 1 sec), lime injection, baghouse, and venturi scrubber	DIFF/ WS	State Plan	1/16/2002	1,500	8,008
28	Centers for Disease Control and Prevention--Clifton, Building 18		Fed research	Secondary chamber (1800°F, 1.68 sec) and rotary atomizing wet scrubber	WS	NSPS		120	2,920
29	East Carolina University, Health Sciences Campus, HSC Utility Plant		University	Secondary chamber (1985°F), rotary atomizing wet scrubber (with NaOH scrubbing medium), carbon bed adsorber, HEPA filtering system, and heat recovery system	HEPA/ CA/ WS	NSPS		1,000	625

No.	Facility name	Unit no.	Facility type	APCD description	APCD code	State Plan/ Federal Plan/NSPS	Compliance date	Maximum charge rate, lb/hr	Operating hours, hr/yr
30	Stericycle, Inc.	Unit 1	Commercial	Secondary chamber (1800°F, 1 sec), rapid gas quench system, wet scrubber system consisting of a packed bed absorber and venturi scrubber, and demister.	WS	Federal Plan	9/15/2002	1,911	8,400
31	Stericycle, Inc.	Unit 2	Commercial	Secondary chamber (1800°F, 1 sec), rapid gas quench system, wet scrubber system consisting of a packed bed absorber and venturi scrubber, and demister.	WS	Federal Plan	9/15/2002	1,911	8,400
32	BMWNC, Inc.	Unit 1	Commercial	Secondary chamber (1641°F), dry scrubber with lime and activated carbon injection, and baghouse	DIFF	Federal Plan	7/1/2002	1,500	7,456
33	St. Jude Children's Research Hospital		Hospital	Secondary chamber (1528°F) and baghouse with sodium bicarbonate and carbon injection	DIFF	Federal Plan	9/15/2002	500	1,050
34	Stericycle, Inc.	Unit 1	Commercial	Secondary chamber (1800°F), venturi scrubber, and condensing absorber	WS	State Plan	9/15/2002	1,500	7,665
35	Stericycle, Inc.	Unit 2	Commercial	Secondary chamber (1800°F), venturi scrubber, and condensing absorber	WS	State Plan	9/15/2002	1,500	7,558

No.	Facility name	Unit no.	Facility type	APCD description	APCD code	State Plan/ Federal Plan/NSPS	Compliance date	Maximum charge rate, lb/hr	Operating hours, hr/yr
36	Loyola University Medical Center		Hospital	Two secondary chambers (1600°F), twin rotary atomizer scrubber using 50% caustic solution, and two demister pads	WS	State Plan	9/15/2002	1,650	4,800
37	Parkview Hospital		Hospital	Secondary chamber and wet scrubber	WS	State Plan	3/31/2002	1,200	8,395
38	South Bend Medical Foundation		Hospital	Secondary chamber and wet scrubber	WS	State Plan	3/31/2002	470	2,028
39	Good Samaritan Hospital		Hospital	Secondary chamber and multi-chamber spray scrubber	WS	State Plan	3/31/2002	500	2,574
40	Mayo Clinic, Waste Management Facility		Hospital	Secondary chamber (1800°F, 1 sec) and baghouse with lime and carbon injection	DIFF	Federal Plan	8/15/2001	2,000	6,240
41	Fairfield Medical Center		Hospital	Secondary chamber (1800°F, 1 sec) and wet scrubber	WS	Federal Plan	9/15/2002	95	5,018
42	MedCentral Health System, Mansfield Hospital		Hospital	Secondary chamber (1800°F, 2 sec) and baghouse with lime and carbon injection system	DIFF	Federal Plan	9/15/2002	600	3,120
43	Medina General Hospital		Hospital	Secondary chamber (1800°F, 1 sec) and wet scrubber	WS	Federal Plan	9/15/2002	300	3,016
44	Stericycle, Inc.		Commercial	Secondary chamber (1800°F, 2 sec), wet scrubber	WS	Federal Plan	9/15/2002	1,400	7,904
45	Waste Management Resource Recovery & Recycling Center	Unit 1	Commercial	Secondary chamber, baghouse with virgin lime injection, urea injection, and activated carbon injection	DIFF	NSPS		4,167	7,896

No.	Facility name	Unit no.	Facility type	APCD description	APCD code	State Plan/ Federal Plan/NSPS	Compliance date	Maximum charge rate, lb/hr	Operating hours, hr/yr
46	Waste Management Resource Recovery & Recycling Center	Unit 2	Commercial	Secondary chamber, baghouse with virgin lime injection, urea injection, and activated carbon injection	DIFF	NSPS		4,167	7,896
47	University of Texas Medical Branch		Hospital	Secondary chamber, packed tower, and venturi scrubber with activated carbon injection	WS	Federal Plan	9/15/2002	1,500	5,328
48	Stericycle, Inc.		Commercial	Secondary chamber (1800°F, 2 sec), wet scrubber	WS	State Plan	9/15/2002	1,500	8,760
49	Rocky Mountain Laboratories		Fed research	Secondary chamber and wet scrubber	WS	State Plan	9/15/2002	500	1,248
50	Healthcare Environmental Services Inc.		Commercial	Secondary chamber (1800°F) and dry scrubber/baghouse system with lime and carbon injection	DIFF	State Plan	9/15/2002	1,686	1,872
51	Stericycle, Inc.		Commercial	Secondary chamber (1834°F), carbon injection system, ESP, dry scrubber, and wet gas absorber	DI-ESP/ WS	State Plan	9/15/2002	1,935	7,309
52	Wyoming Medical Center		Hospital	Secondary chamber and wet scrubber	WS	State Plan	9/15/2002	400	989
53	Kona Community Hospital		Hospital	Secondary chamber (1900°F, 2 sec), no APCD	CC	Federal Plan	8/15/2001	200	1,430
54	Yukon-Kuskokwim Delta Regional Hospital		Hospital	Secondary chamber, no APCD	CC	Federal Plan		50	1,560

Key:
APCD = Air pollution control device
CA = Carbon adsorber
CC = Combustion control
DI = Dry injection
DIFF = Dry injection fabric filter
E = Existing HMIWI
ESP = Electrostatic precipitator
FF = Fabric filter
HEPA = High-efficiency particulate air
HMIWI = Hospital/medical/infectious waste incinerator(s)
L = Large HMIWI
M = Medium HMIWI
N = New HMIWI
S = Small HMIWI
SR = Small rural HMIWI
WESP = Wet ESP
WS = Wet scrubber

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