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.

* * * * *

(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.

* * * * *

Subpart Ce—[Amended]

* * * * *

■ 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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