**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 60**

**[AD–FRL–5878–8]**

**RIN 2060–AC62**

## Standards of Performance for New Stationary Sources and Emission Guidelines for Existing Sources: Hospital/Medical/Infectious Waste Incinerators

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This action promulgates new source performance standards (NSPS or standards) and emission guidelines (EG or guidelines) to reduce air emissions from hospital/medical/infectious waste incinerator(s) (HMIWI) by adding subpart Ec, standards of performance for new HMIWI, and subpart Ce, emission guidelines for existing HMIWI, to 40 CFR part 60. The standards and guidelines implement sections 111 and 129 of the Clean Air Act (CAA) as amended in 1990. The standards and guidelines apply to units whose primary purpose is the combustion of hospital waste and/or medical/infectious waste. Sources are required to achieve emission levels reflecting the maximum degree of reduction in emissions of air pollutants that the Administrator has determined is achievable, taking into consideration the cost of achieving such emission reduction, any nonair-quality health and environmental impacts, and energy requirements. The promulgated standards and guidelines establish emission limits for particulate matter (PM), opacity, sulfur dioxide ($SO_2$), hydrogen chloride (HCl), oxides of nitrogen ($NO_X$), carbon monoxide (CO), lead (Pb), cadmium (Cd), mercury (Hg), dioxins and dibenzofurans (dioxins/furans), and fugitive ash emissions. Some of the pollutants being regulated are considered to be carcinogens and at sufficient concentrations can cause toxic effects following exposure. The standards and guidelines also establish requirements for HMIWI operator training/qualification, waste management plans, and testing/monitoring of pollutants and operating parameters. Additionally, the guidelines for existing HMIWI contain equipment inspection requirements and the standards for new HMIWI include siting requirements.

**DATES:** *Effective Dates.* The standards for new sources (§ 60.17 and §§ 60.50c through 60.58c) are effective as of March 16, 1998 and the emission guidelines for existing sources (§ 60.30 and §§ 60.30e through 60.39e) are effective as of November 14, 1997. The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of March 16, 1998. See **SUPPLEMENTARY INFORMATION** for a discussion of the schedule for judicial review.

*Comments.* Comments on the Information Collection Request (ICR) document associated with the final standards for new sources are requested, as discussed in section VI.B of this preamble. Comments on the ICR document must be received on or before November 14, 1997. Refer to Section VI.B for further information on this request for comment.

**ADDRESSES:** *Comments.* As noted above, comments on the ICR document associated with the final standards for new sources are requested. See section VI.B and the **SUPPLEMENTARY INFORMATION** section of this preamble for further information on obtaining a copy of the ICR document and addresses for submitting comments on the ICR document.

*Background Information.* The principal background information for the final standards and guidelines includes a background information document entitled ''Hospital/Medical/Infectious Waste Incinerators: Background Information for Promulgated Standards and Guidelines—Summary of Public Comments and Responses'' (EPA–453/R–97–006b), which contains a summary of all the public comments submitted regarding the changes to the standards and guidelines that were discussed in the June 20, 1996 **Federal Register** document (61 FR 31736) and the EPA's response to these comments. Background information documents which present the economic and regulatory impacts of the standards and guidelines entitled: (1) ''Hospital/Medical/Infectious Waste Incinerators: Background Information for Promulgated Standards and Guidelines—Analysis of Economic Impacts for Existing Sources'' (EPA–453/R–97–007b); (2) ''Hospital/Medical/Infectious Waste Incinerators: Background Information for Promulgated Standards and Guidelines—Analysis of Economic Impacts for New Sources'' (EPA–453/R–97–008b); and (3) ''Hospital/Medical/Infectious Waste Incinerators: Background Information for Promulgated Standards and Guidelines—Regulatory Impact Analysis for New and Existing Facilities'' (EPA–453/R–97–009b) are available. Also a document entitled ''Fact Sheet: New Hospital/Medical/Infectious Waste Incinerators—Promulgated Subpart Ec Standards,'' which succinctly summarizes the final standards, and a document entitled ''Fact Sheet: Existing Hospital/Medical/Infectious Waste Incinerators—Promulgated Subpart Ce Emission Guidelines,'' which succinctly summarizes the guidelines, are available. See **SUPPLEMENTARY INFORMATION** for instructions and addresses for obtaining these documents.

*Docket.* Docket No. A–91–61, which contains supporting information used in developing the standards and guidelines, is available for public inspection and copying between 8:00 a.m. and 4:00 p.m., Monday through Friday except for Federal holidays at the following address: U.S. Environmental Protection Agency, Air and Radiation Docket and Information Center (Mail Code 6102), 401 M Street SW, Washington DC 20460 (phone: (202) 260–7548). The docket is located at the above address in room M–1500, Waterside Mall (ground floor, central mall). A reasonable fee may be charged for copying.

**FOR FURTHER INFORMATION CONTACT:** Mr. Rick Copland at (919) 541–5265, Combustion Group, Emission Standards Division (MD–13), U. S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711 (copland.rick@epamail.epa.gov) or any of the EPA Regional Office contacts listed in Table 1 below.

TABLE 1.—CONTACTS IN EPA REGIONAL OFFICES

| Region | Contact | Phone No. |
|---|---|---|
| I (Boston) | Susan Lancey | (617) 565–3587 |
| II (New York) | Christine DeRosa | (212) 637–4022 |
| III (Philadelphia) | James Topsale | (215) 566–2190 |
| IV (Atlanta) | Scott Davis | (404) 562–9127 |
| V (Chicago) | Douglas Aburano (MI) | (312) 353–6960 |

TABLE 1.—CONTACTS IN EPA REGIONAL OFFICES—Continued

| Region | Contact | Phone No. |
|---|---|---|
| | Ryan Bahr (IN) | (312) 353–4366 |
| | Scott Hamilton (OH) | (312) 353–4775 |
| | Charles Hatten (WI) | (312) 886–6031 |
| | Mark Palermo (IL) | (312) 886–6082 |
| | Rick Tonielli (MN) | (312) 886–6068 |
| VI (Dallas) | Mick Cote | (214) 665–7219 |
| VII (Kansas City) | Wayne Kaiser | (913) 551–7603 |
| VIII (Denver) | Meredith Bond | (303) 312–6438 |
| IX (San Francisco) | Patricia Bowlin | (415) 744–1188 |
| X (Seattle) | Catherine Woo | (206) 553–1814 |

**SUPPLEMENTARY INFORMATION:**

**Regulated Entities**

Entities potentially regulated by the standards and guidelines are those which operate hospital/medical/infectious waste incinerators. Regulated categories and entities include those listed in Table 2.

TABLE 2.—REGULATED ENTITIES[a]

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

[a] This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by the standards or guidelines for HMIWI. This table lists the types of entities that EPA is now aware could potentially be regulated. Other types of entities not listed in the table could also be regulated. To determine whether your facility is regulated by the standards or guidelines for hospital/medical/ infectious waste incinerators, you should carefully examine the applicability criteria in sections 60.50c and 60.51c of the promulgated standards, section 60.32e of the promulgated guidelines, and in section III.A of today's notice. If you have questions regarding the applicability of the HMIWI standards and guidelines to a particular entity, consult a person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

**Documents Available Electronically**

This **Federal Register** document discusses: (1) The standards for new HMIWI, (2) the guidelines for existing HMIWI, and (3) a request for public comment on the ICR document. This preamble and regulatory text are available electronically via the Internet. Also available electronically are FACT SHEETS, which summarize the final standards and guidelines. They are suggested reading for persons requiring an overview of the standards and guidelines. Hard copies of the FACT SHEETS can also be obtained by calling Donna Collins at (919) 541–5578. The following five items are available electronically in file ''MWIFINAL.ZIP'':

1. ''Fact Sheet: New Hospital/ Medical/Infectious Waste Incinerators—Promulgated Subpart Ec Standards.''

2. ''Fact Sheet: Existing Hospital/ Medical/Infectious Waste Incinerators—Promulgated Subpart Ce Emission Guidelines.''

3. **Federal Register** document for this promulgation: ''Standards of Performance for New Stationary Sources and Emission Guidelines for Existing Sources: Hospital/Medical/Infectious Waste Incinerators'' (this document).

4. ''Hospital/Medical/Infectious Waste Incinerators: Background Information for Promulgated Standards and Guidelines—Summary of Public Comments and Responses'' (EPA–453/ R–97–006b).

5. Information Collection Request document for these standards for new sources: ''Supporting Statement for ICR No. 1730.02—1997 Standards for New Hospital/Medical/Infectious Waste Incinerators (Subpart Ec).''

The documents are available via the Internet at ''http://www.epa.gov/ttn/ oarpg/rules.html''. The documents are also available via the Internet through the Unified Air Toxics Website at ''http://www.epa.gov/oar/oaqps/airtox/ ''.

**Judicial Review**

Under section 307(b)(1) of the Clean Air Act, judicial review of the actions taken by this notice is available by filing a petition for review in the U.S. Court of Appeals for the District of Columbia Circuit within 60 days of today's publication of this rule. Under section 307(b)(2) of the Clean Air Act, the requirements that are in today's notice may not be challenged later in the civil or criminal proceedings brought by the EPA to enforce these requirements.

**Preamble Outline**

The following outline is provided to aid in locating information in the introductory text (preamble) to the final standards and guidelines.

## I. Acronyms, Abbreviations, and Measurement Units

The following acronyms, abbreviations, and measurement units are provided to clarify the preamble to the final standards and guidelines.

### *A. Acronyms*

APCD air pollution control device
APTI Air Pollution Training Institute
CAA Clean Air Act
CAAA Clean Air Act Amendments of 1990
CEMS continuous emissions monitoring system(s)
CFBC circulating fluidized bed combustor
CFR Code of Federal Regulations
DI dry injection
EPA U.S. Environmental Protection Agency
EG emission guidelines
FF fabric filter
FR Federal Register
HAP hazardous air pollutant(s)
HMIWI hospital/medical/infectious waste incinerator(s)
ICCR Industrial Combustion Coordinated Rulemaking
ICR information collection request
MACT maximum achievable control technology
MSW municipal solid waste
MWC municipal waste combustor(s)
MWI medical waste incinerator(s)
MWP medical waste pyrolysis
MWTA Medical Waste Tracking Act
NAPH National Association of Public Hospitals
NSPS new source performance standards
NSR new source review
NYSDOH New York State Department of Health
OAQPS Office of Air Quality Planning and Standards
OMB Office of Management and Budget
ORD Office of Research and Development
PSD prevention of significant deterioration
RCRA Resource Conservation and Recovery Act
RFA Regulatory Flexibility Act
RMW regulated medical waste
SBA Small Business Administration
SBREFA Small Business Regulatory Enforcement Fairness Act
SMSA standard metropolitan statistical area
SWDA Solid Waste Disposal Act

### *B. Abbreviations and Measurement Units*

bps=bits per second
Btu=British thermal units
Btu/yr=British thermal units per year
Cd=cadmium
CDD/CDF=dioxins/furans
CO=carbon monoxide
dioxins=polychlorinated dibenzo-p-dioxins
dscf=dry standard cubic feet (at 14.7 pounds per square inch, 68°F)
dscm=dry standard cubic meters (at 14.7 pounds per square inch, 68°F)
°F=degrees Fahrenheit
$ft^3$=cubic feet
furans=polychlorinated dibenzofurans
g=gram (454 grams per pound)
g/yr=grams per year
gr=grains (7,000 grains per pound)
HCl=hydrogen chloride
Hg=mercury
$m^3$=cubic meter (35.3 cubic feet per cubic meter)
mg=milligrams ($10^{-3}$ grams)
Mg=megagram (1.1 tons per megagram)
Mg/yr=megagrams per year
$MMm^3$=million cubic meters
MW=megawatt
MW-hr/yr=megawatt-hours per year
ng=nanogram ($10^{-9}$ grams)
$NO_X$=nitrogen oxides
Pb=lead
PM=particulate matter
ppmv=parts per million by volume
$SO_2$=sulfur dioxide
TEQ basis=2,3,7,8-tetrachlorinated dibenzo-p-dioxin toxic equivalent based on the 1989 international toxic equivalency factors
tons/d=tons per day
total mass basis=total mass of tetra- through octa-chlorinated dibenzo-p-dioxins and dibenzofurans

## II. Introduction

### *A. Purpose of the Standards and Guidelines*

The 1990 Clean Air Act Amendments (CAAA) reflect growing public concern about the large volume of toxic air pollutants released from numerous categories of emission sources. Title III of the CAAA specifically enumerated 189 hazardous air pollutants (HAP) and instructed EPA to protect public health by reducing emissions of these pollutants from the sources that release them. The EPA's standards are to be issued in two phases. The first phase standards are designed to bring all sources up to the level of emissions control achieved by those that are already well-controlled. The second phase standards, due a few years later, are to require further emission reductions in any case in which the first phase measures were not by themselves sufficient to fully protect the public health.

In this context, the CAAA singled out waste incineration for special attention. Congress recognized both a high level of public concern about the incineration of municipal, medical, and other solid wastes and a number of special management concerns for these types of sources. Consequently, section 129 of the CAA directs EPA to apply the two-phase control approach to various categories of solid waste incinerators, including hospital/ medical/infectious waste incinerator(s) (HMIWI). Today's action promulgates standards and guidelines for new and existing HMIWI under section 129. Current methods of medical waste incineration cause the release of a wide array of air pollutants, including several pollutants of particular public health concern.

The EPA estimates that there are approximately 2,400 HMIWI operating in the United States, which combust approximately 767 thousand Mg (846 thousand tons) of hospital waste and medical/infectious waste annually. Emissions from HMIWI contain organics (dioxins/furans), particulates (PM), metals (Cd, Pb, and Hg), acid gases (HCl and $SO_2$), and $NO_X$. These pollutants can have adverse effects on both public health and welfare. Pollutants of principal concern to public health include dioxins/furans, PM, Pb, Cd, and Hg. Today's standards and guidelines are set forth as emission limits and will significantly reduce HMIWI emissions.

Several States, including New York, California, and Texas, have adopted relatively stringent regulations in the past few years limiting emissions from HMIWI. The implementation of these regulations has brought about very large reductions in HMIWI emissions and the associated risk to public health in those States. Today EPA is promulgating nationally applicable emission standards and guidelines for HMIWI that build on the experience of these leading States. Like the State regulations, the standards and guidelines promulgated today are based on the use of add-on air pollution control systems. These standards and

guidelines implement the first phase requirements of section 129 described above. As described in detail below, section 129, like section 112, of the CAA instructs the Agency to set performance standards that challenge industry to meet or exceed the pollution control standards established by better controlled similar facilities. In this way, the overall state of environmental practice is raised for large segments of industry, a basic level of health protection is provided to all communities, situations in which uncertainty about total risk and hazard result in no protection for the exposed public are avoided, and yet the cost of pollution control to industry is constrained to levels already absorbed by similar operations. Eight years later, in a second phase, EPA will evaluate whether the residual public health risk warrants additional control.

The EPA's Office of Research and Development (ORD) is preparing a national inventory of dioxin emissions as part of its Dioxin Reassessment. This effort will include emission estimates for HMIWI. Since the effort is not yet complete, the results are not included in this package. The ORD is considering a very similar approach to that used in this rulemaking and anticipates generating similar emission estimates.

*B. Implementation of the Emission Guidelines*

The subpart Ce emission guidelines are unique in that, unlike the subpart Ec NSPS, the guidelines are not direct Federal requirements for HMIWI. The subpart Ec NSPS are Federal requirements that apply to all new HMIWI units that commence construction after June 20, 1996 or to existing HMIWI units that commence modification after March 16, 1998. The subpart Ce emission guidelines require States to develop section 111(d)/129 State plans to regulate existing HMIWI built on or before June 20, 1996. These State plans must be submitted to EPA for approval and must be at least as protective as the guidelines. Together, 40 CFR part 60, subpart B and subpart Ce specify the content and the general rules for adopting and submitting the section 111(d)/129 State plans.

The CAA requires that each State submit a State plan to EPA within 1 year of EPA's adoption of the guidelines. State plans must contain specific information and legal mechanisms necessary to implement the guidelines. The State must make available to the public the State plan and provide opportunity for discussion of the State plan in a public hearing prior to submittal to EPA. The State must submit the final plan to EPA by September 15, 1998. The EPA then has 6 months to approve or disapprove the State plan. Plan approval or disapproval will be published in the **Federal Register**. If a State plan is disapproved, EPA will state the reasons for disapproval in the **Federal Register**. The State can respond to EPA's concerns and submit a revised plan. If a State does not submit an approvable State plan by September 15, 1999, EPA will adopt and implement a Federal plan that applies to existing HMIWI in the State.

1. Implementation Activities

The EPA is preparing an Enabling Document to assist States with implementing the HMIWI guidelines. The EPA Regional Offices will mail hard copies of the Enabling Document to their State contacts. This document should be publicly available in the next few weeks. The public can access this document electronically via the Internet at ''http://www.epa.gov/ttn/oarpg/rules.html'' or ''http://www.epa.gov/oar/oaqps/airtox/''.

In September 1997, EPA plans to broadcast a telecourse to States, regions, and the public on the HMIWI rule and on implementation requirements. State field offices will be notified of the telecourse. The EPA's distance learning network telecourse schedule, as well as a list of telecourse sites, is available at http://134.67.104.12/html/apti/aptc.htm.

Finally, EPA will host its annual Air Toxics Workshop for EPA Regions and States in Research Triangle Park in late August 1997. A 1-hour session is scheduled to provide States an overview of the HMIWI rule and to discuss implementation issues. The Air Toxics Workshop provided for EPA Regions and States is not open to the public. Opportunities for public participation in the implementation process are discussed below.

2. Public Involvement

Public participation, under the provision of the CAA, is an important right and responsibility of citizens in the State process of developing, adopting, and implementing section 111(d)/ 129 State plans. As with State Implementation Plans (SIP) for criteria pollutants, EPA regulations in 40 CFR part 60, subpart B, make it clear that citizen input on section 111(d)/129 State plans is encouraged in order to help define appropriate emission standards and retrofit schedules. Under Subpart B, some minimum public participation requirements are as follows:

a. Reasonable notice of one or more public hearing(s) at least 30 days before the hearing;

b. One or more public hearing(s) on the section 111(d)/129 State plan (or revision) conducted at location(s) within the State, if requested;

c. Date, time, and place of hearing(s) prominently advertised in each region affected;

d. Availability of draft section 111(d)/129 State plan for public inspection in at least one location in each region to which it will apply;

e. Notice of hearing provided to EPA Regional Administrator, local affected agencies, and to other States affected;

f. Certification that the public hearing, if held, was conducted in accordance with Subpart B State procedures; and

g. Hearing records must be retained for a minimum of 2 years; these records must include the list of commenters, their affiliation, summary of each presentation and/or comments submitted, and the State's responses to those comments.

*C. Technical Basis of the Standards and Guidelines*

Section 129 requires the EPA to develop numerical emission limitations in the standards for new HMIWI and guidelines for existing HMIWI for the following: Particulate matter (PM), opacity, sulfur dioxide ($CO_2$), hydrogen chloride (HCl), oxides of nitrogen ($NO_X$), carbon monoxide (CO), lead (Pb), cadmium (Cd), mercury (Hg), and dioxins and dibenzofurans (dioxin/furan). Section 129 requires that the standards and guidelines reflect the maximum degree of reduction in emissions of air pollutants, taking into consideration the cost of achieving such emission reduction, any nonair-quality health and environmental impacts, and energy requirements that the Administrator determines are achievable for a particular category of sources. This control level is commonly referred to as the ''maximum achievable control technology'' or ''MACT.'' Section 129 also provides that standards for new sources may not be less stringent than the emissions control achieved in practice by the best controlled similar unit. This is commonly referred to as the ''MACT floor'' for new HMIWI. Additionally, section 129 provides that the emission limitations in the guidelines for existing HMIWI may not be less stringent than the average emission limitation achieved by the best performing 12 percent of units in the category. This is commonly referred to as the ''MACT floor'' for existing HMIWI.

The CAA requires EPA to evaluate standards and guidelines more stringent than the MACT floor, considering costs and other impacts described above. If EPA concludes that more stringent standards and/or guidelines are achievable considering costs and other impacts, then the standards and/or guidelines would be established at these more stringent levels (i.e., MACT would be more stringent than the MACT floor). The EPA may establish NSPS or EG at the MACT floor only if EPA concludes that the costs and/or other impacts associated with the more stringent requirements are unreasonable. In no case may EPA establish emission limitations less stringent than the MACT floor.

Technical data on the number and size of HMIWI, control technologies in use, permit emission limits, and emission test data were used to determine the MACT floors for new and existing HMIWI and to define regulatory options more stringent than the MACT floors. The types of data EPA considered in selecting final standards and guidelines included emissions information from literature and State and local agencies; and emissions test data provided by industry or gathered during EPA's HMIWI emissions test program. Overall, the EPA used performance test data from over 30 HMIWI to develop the standards and guidelines.

In keeping with the Administrator's ''reinventing government'' initiative, several of the changes to the guidelines and standards were made to streamline the regulations and provide increased flexibility while optimizing environmental control by using common sense initiatives. Examples of these changes include the following: (1) Reduced testing for HMIWI demonstrating compliance with the required emission levels; (2) narrowing the definition of medical waste; (3) clarification of siting requirements for new HMIWI; (4) allowing HMIWI operators to receive training and qualification through a State-approved training program; (5) requiring facilities to develop a waste management plan instead of banning materials from waste streams; (6) revised text to clarify that the emission limits do not apply during periods when units are burning only pathological, chemotherapeutic, and/or low-level radioactive waste; (7) exemption for plants firing small amounts of hospital waste and/or medical/infectious waste (10 percent or less by weight); (8) allowing certain records to be maintained in either electronic or paper format without duplication; and (9) establishing emission limits for existing HMIWI that may be met with either a wet or dry scrubber. All of these changes are discussed further in sections III, IV, and V of this preamble and in ''Hospital/Medical/Infectious Waste Incinerators: Background Information for Promulgated Standards and Guidelines—Summary of Public Comments and Responses (EPA–453/R–97–006b). These changes improve the effectiveness and efficiency of the standards and guidelines without any reduction in environmental protection.

*D. February 1995 Proposal*

On February 27, 1995 (60 FR 10654), EPA published proposed NSPS and EG for HMIWI. The 1995 proposal was the result of several years of effort reviewing available information in light of the CAA requirements described above.

During the data-gathering phase of the HMIWI project, it was difficult to get an accurate count of the nationwide HMIWI population. In addition, it was difficult to find HMIWI with add-on air pollution control systems in place. Information from a few State surveys led to an estimated population of 3,700 existing HMIWI.

The 1995 proposed standards and guidelines contained HMIWI subcategories that were determined based on design differences among different types of incinerators: continuous, intermittent, and batch. These three design types roughly correlate to HMIWI size.

A few HMIWI with various levels of combustion control (no add-on air pollution control) were tested to determine the performance of combustion control in reducing HMIWI emissions. One HMIWI equipped with a wet scrubber (add-on control) was tested to determine the performance capabilities of wet scrubbing systems. A few other HMIWI equipped with dry scrubbing systems (add-on control) were tested to determine the performance capabilities of dry scrubbing systems. These systems were considered typical of air pollution control systems available at the time, and the data appeared to indicate that dry scrubbing systems could achieve much lower emissions than wet scrubbing systems.

As mentioned above, the MACT floor for new HMIWI is to reflect the emissions control achieved by the best controlled similar unit. Dry scrubbing systems were identified on at least one HMIWI in each of the three subcategories (continuous, intermittent, and batch). Consequently, the MACT floor emission levels for the 1995 proposed NSPS reflected the performance capabilities of dry scrubbing systems.

For existing HMIWI under the 1995 proposed emission guidelines, State regulations and permits were used to calculate the average emission limitation achieved by the best performing 12 percent of units. These results were then compared with the results of the emission tests on wet and dry scrubbing systems. This comparison led to the conclusion that the 1995 proposed MACT floor for existing HMIWI would require the use of a dry scrubbing system, even for small existing batch HMIWI.

Following determination of the HMIWI population, subcategories, performance of technology, and MACT floors, the CAA requires EPA to consider standards and guidelines that are more stringent than the floors. However, because the MACT floors calculated for the 1995 proposal were so stringent, EPA was left with few options to consider. Emission limits reflecting the capability of dry scrubbing systems with carbon were proposed for all sizes and types of new and existing HMIWI.

A proposal is essentially a request for public comment on the information used, assumptions made, and conclusions drawn from the evaluation of available information. Following the 1995 proposal, more than 700 comment letters were received, some including new information and some indicating that commenters were in the process of gathering information for EPA to consider. The large amount of new information that was ultimately submitted addressed every aspect of the 1995 proposed standards and guidelines, including: the existing population of HMIWI, HMIWI subcategories, the performance capabilities of air pollution control systems, monitoring and testing, operator training, alternative medical waste treatment technologies, and the definition of medical waste. In almost every case, the new information led to different conclusions, as outlined below.

*E. June 1996 Re-Proposal*

On June 20, 1996, EPA published a **Federal Register** document to: (1) Announce the availability of the new information received following the 1995 proposal, (2) review EPA's assessment of the new information, (3) provide EPA's inclinations as to how the new information might change the final standards and guidelines, and (4) solicit comments on EPA's assessments and inclinations. In the June 20, 1996 **Federal Register** document, EPA indicated that the notice was not a re-

proposal, but merely a notice of supplemental information. However, some commenters stated that the 1996 notice should be considered a re-proposal. Upon consideration of these comments, EPA now considers the 1996 notice to have been a re-proposal. The 1996 notice included all of the elements of a re-proposal, including: A new inventory of sources; new subcategories; revised assessments of emissions and performance of technology; new MACT floors; new regulatory options; revised cost, environmental, and economic impacts; an indication of EPA's selection of MACT; and a request for public comment. More importantly, virtually every aspect of the 1995 proposal was changed significantly by the 1996 notice, making most of the analyses and conclusions from the 1995 notice irrelevant. Therefore, in today's final rule, HMIWI which commenced construction after June 20, 1996 are considered new sources subject to the NSPS under Subpart Ec, and HMIWI which commenced construction on or before June 20, 1996 are considered existing sources subject to the EG under subpart Ce.

The 1996 re-proposal served as a response to most comments on the 1995 proposed rule. Comments on miscellaneous issues that were not addressed in the 1996 re-proposal notice are summarized and responded to in ''Hospital/Medical/Infectious Waste Incinerators: Background Information for Promulgated Standards and Guidelines—Summary of Public Comments and Responses'' (EPA–453/R–97–006b). The 1996 re-proposal notice discussed the reanalyses of new information that led to changes in the 1995 proposed standards and guidelines. Presented below is a brief summary of the reanalyses that occurred following the 1995 proposal and a discussion of the EPA's inclinations that were introduced in the 1996 re-proposal.

Following the 1995 proposal, a number of comments were received regarding the EPA's inventory of existing HMIWI. Most commenters felt that the EPA's inventory was inadequate and should be updated. In response to these concerns, the EPA compiled a new inventory of existing HMIWI based on information received from the American Hospital Association, State agencies, HMIWI vendors, commercial medical waste disposal companies, and other stakeholders. After several revisions, the final HMIWI inventory contained approximately 2,400 existing HMIWI.

The Agency also reanalyzed the HMIWI subcategories based on the new information received after the 1995 proposal. In the 1996 re-proposal, the Agency stated that it was inclined to subcategorize the new and existing population of HMIWI into three subcategories based on waste charging capacity: small (≤200 lb/hr), medium (>200 and ≤500 lb/hr) and large (>500 lb/hr). While these subcategories were based on HMIWI size, they also reflect design differences among HMIWI.

Directly related to the issue of subcategorizing HMIWI by size is the question of how to determine HMIWI size in a manner that is consistent, uniform, and applicable to all HMIWI covered under the standards and guidelines. In the 1996 re-proposal, the EPA stated that it was inclined to base HMIWI capacity on either: (1) Volumetric waste burning capacity factors developed using the design heat release rate of the HMIWI and the heat content of medical waste or (2) an enforceable limit that would restrict waste charge rate.

At the time of the 1995 proposal, relatively few emission test reports were available to the EPA from which to draw conclusions regarding the performance capabilities of various air pollution control systems. Many commenters believed that EPA misjudged the performance capabilities of various air pollution control technologies, especially the capabilities of wet scrubbing systems. Following the 1995 proposal, a number of emission test reports were submitted to EPA. The EPA reviewed the data contained in these emission test reports and, as a result, EPA's conclusions regarding the performance capabilities of various air pollution control technologies were revised and presented in the 1996 re-proposal.

As discussed earlier, the new information submitted led to changes to the HMIWI inventory, subcategories, and conclusions about the performance of technology. Because these factors can influence the MACT floors, a review of the MACT floors was conducted. The recalculated MACT floors and the new conclusions regarding the performance capabilities of air pollution control technologies led to new conclusions regarding what technologies HMIWI would have to use to achieve the MACT floors.

In the 1996 re-proposal, the EPA defined regulatory options more stringent than the MACT floors for new and existing HMIWI and presented the impacts of the regulatory options. After reviewing the emissions reductions that could be achieved and the impacts of the regulatory options, the EPA presented its inclinations as to which emission levels the final MACT standards and guidelines might reflect. For new medium and large HMIWI, the EPA stated that it was inclined to adopt emission limits that could be achieved with good combustion followed by a high efficiency wet scrubber and a DI/FF system with carbon (i.e., combined dry/wet scrubber with carbon). The EPA stated that it was inclined to adopt emission limits that could be achieved with good combustion and a moderate efficiency wet scrubber for new small HMIWI and for medium existing HMIWI. For large existing HMIWI, the EPA stated that it was inclined to adopt emission limits that could be achieved with the use of good combustion and a high efficiency wet scrubber. The EPA offered no inclinations for the emission limits for small existing HMIWI. Instead, the EPA discussed the regulatory options and impacts for small existing HMIWI and solicited comments on which emission levels would be suitable for the final guidelines.

Many comments were also received regarding the 1995 proposed testing and monitoring requirements. Commenters noted that the proposed 4-hour test run was much longer than the more conventional test run of about 1-hour. Commenters also noted that many hospitals and health care facilities would normally not have sufficient waste on hand to accommodate three, 4-hour test runs and the 1995 proposed emission testing requirements would substantially increase the costs associated with emission testing. In response to these comments, the EPA stated in the 1996 re-proposal that it was inclined to adopt requirements that EPA test methods be followed when performing emissions testing to determine compliance. This requirement would ensure that compliance testing follows the same procedures used to generate the emission data upon which the emission limits in the regulation were based. In most cases, three test runs of about 1 hour each would be necessary to determine compliance. An exception to this requirement would be emission testing to measure dioxin/furan emissions. The procedures outlined in the EPA test method frequently lead to test runs longer than 1 hour to ensure sufficient sample is gathered to accurately measure dioxin/furan emissions.

Numerous comments were received on the 1995 proposed annual emission testing requirements. While some commenters supported the annual testing requirements, others felt that the proposed requirements for inspections, monitoring, and operator training were sufficient and much less expensive than

annual testing. Some commenters suggested that the annual emission test requirement be replaced with a requirement for annual equipment inspection and maintenance. Many of the commenters supportive of the proposed inspection requirements, however, suggested that the requirement for a ''third party'' inspection be deleted. Therefore, EPA stated in the 1996 re-proposal that it was inclined to include inspection and maintenance requirements wherever annual stack testing is not required and that the inspection would not have to be conducted by a third party.

To consider comments on the 1995 proposal regarding the frequency of emission testing and the proposed inspection and monitoring requirements, EPA presented a matrix of testing and monitoring options and their associated costs in the 1996 re-proposal. The EPA noted that almost all of the emission testing and monitoring options under consideration cost more than the incinerator or emission control system that would be installed to meet the emission limits in the regulations. Consequently, the Agency stated that it was inclined to include monitoring of operating parameters and routine Method 9 opacity tests (instead of CO and opacity CEMS) in the final regulations to minimize costs.

With regard to specific air pollution control device (APCD) operating parameters to be monitored, the Agency stated that it was inclined to require monitoring of the same parameters as outlined in the 1995 proposal for dry scrubbers, and the following for wet scrubbers: Scrubber exit temperature, scrubber liquor pH, scrubber liquor flow rate, and energy input to the scrubber (e.g., pressure drop or horsepower).

The EPA also stated in the 1996 re-proposal that it was inclined to require initial and repeat stack testing (annual/skip testing) where the regulations are based on good combustion and wet and/or dry scrubbing systems; and initial stack testing and routine inspections where the regulations are based on the use of good combustion alone. With the annual/skip testing requirement, emission tests would be required for the first 3 years. If these tests show that the facility was in compliance each of these 3 years, then subsequent testing would be done every third year. Under the inclinations presented in the 1996 re-proposal, annual or skip emission testing would only require emission testing of a few key or critical pollutants (i.e., only those necessary to gain a good indication that the air pollution control system is operating properly).

A large number of comments were received on the 1995 proposed definition of medical waste. The majority of the commenters stated that the proposed definition of medical waste was too broad and should be narrowed. The commenters believed that the proposed definition would be adopted by other regulatory agencies, and as the definition became more widespread, that it would eventually force all health care facilities to handle most of their waste as if it were infectious. This would result in an increase in the volume of medical waste requiring special handling, which in turn would result in increased costs to dispose of waste from health care facilities. These commenters stated that health care facilities should be viewed as generating two waste streams: A medical waste stream, which is usually defined by the potential for disease transmission and requires special handling; and a noninfectious waste or ''health care trash'' waste stream, which has no potential for infection and is treated and handled as municipal waste. The commenters urged EPA to narrow the definition of medical waste used in the HMIWI regulations to one that includes only the infectious portion of the waste stream.

In response to the comments concerning the 1995 proposed definition of medical waste, the EPA stated in the 1996 re-proposal that it was inclined to adopt a definition of medical waste that focuses on the infectious or potentially infectious portion of the overall medical waste stream. Given the confusion and number of varying definitions of medical waste in use at the Federal, State and local levels, the EPA stated that it was inclined to adopt a definition of medical waste for the HMIWI regulations from among those definitions already in use. Specifically, the EPA stated that it was inclined to adopt the New York State Department of Health (NYSDOH) definition of medical waste.

In the 1996 re-proposal, the EPA also stated that it was inclined to exclude crematories and incinerators used solely for burning pathological waste (human or animal remains and tissues), incinerators used solely for burning ''off-spec'' or ''out of date'' drugs or pharmaceuticals, and incinerators used solely for burning radioactive-type medical wastes from the HMIWI regulations. The EPA further stated that it was inclined to adopt separate regulations for pyrolysis treatment technologies and requested comment on the merits of continued development of separate pyrolysis regulations.

*F. Stakeholders and Public Involvement*

Throughout the development of the standards and guidelines, EPA conducted meetings with stakeholders to explain EPA conclusions and solicit comments, data, and information. Numerous discussions were held with governmental entities, industry representatives, and environmental groups including, but not limited to, the following: the U.S. Conference of Mayors; the National League of Cities; the National Association of City and County Health Officials; the National Association of Counties; the National Association of Public Hospitals; the Department of Defense; the Department of Veterans Affairs; the American Hospital Association; the Medical Waste Institute; the Sierra Club; the Natural Resources Defense Council; vendors of pyrolysis units, HMIWI, continuous emission monitoring systems, and air pollution control technologies; and the general public.

The standards and guidelines being adopted today were first proposed in the **Federal Register** on February 27, 1995 (60 FR 10654). The preambles for the 1995 proposed standards and guidelines described the rationale for the proposed standards and guidelines. Following the 1995 proposal, the EPA provided interested persons the opportunity to comment through a written comment period and held a public hearing. The public comment period lasted from February 27, 1995 to April 28, 1995 and all late comments were accepted. Over 700 comments were received from private citizens, industry representatives, environmental groups, and governmental entities. Several public meetings and meetings with industry stakeholders were held following the 1995 proposal to discuss EPA's assessment of new information submitted with comments, to gather additional information, and to solicit further comments. As discussed above in sections II.D and II.E, the comments and new information received following the 1995 proposal led to numerous changes to the standards and guidelines.

On June 20, 1996, EPA re-proposed the standards and guidelines in the **Federal Register**. Following the 1996 re-proposal, the EPA held a public meeting to review the contents of the re-proposal and to answer questions so that interested parties could better prepare their written comments. The comment period remained open from June 20, 1996 until August 8, 1996. Again, late comments were accepted. Nearly 70 comments were received. The comments received following the 1996 re-proposal were carefully considered

and changes were made to the HMIWI standards and guidelines where appropriate. Sections III, IV, and V of this preamble discuss the responses to comments on the standards and guidelines that address the major concerns of the commenters on the 1996 re-proposal.

## III. Considerations in Developing the Final Standards and Guidelines

Following the June 20, 1996 re-proposal, the EPA received numerous comments concerning applicability of the standards and guidelines, pollution prevention, and the testing and monitoring requirements. Special consideration was given to these issues when developing the final HMIWI standards and guidelines. This section discusses these issues and changes, if any, that were made to the final HMIWI standards and guidelines following the 1996 re-proposal. Additional discussion and responses to specific concerns regarding these and other issues are provided in ''Hospital/Medical/ Infectious Waste Incinerators: Background Information for Promulgated Standards and Guidelines—Summary of Public Comments and Responses'' (EPA–453/ R–97–006b).

### *A. Applicability*

A great deal of interest and discussion has taken place regarding which incinerators should be subject to this rule and which should not. All comments have been considered and the following sections present EPA's final decisions.

#### 1. Definition of Medical Waste

This section discusses the evolution of the definition of medical waste used in determining the applicability of the HMIWI standards and guidelines. In the 1996 re-proposal ''medical waste'' was the term used to describe what is today called ''medical/infectious waste'' in the final HMIWI standards and guidelines. Similarly, the term ''medical waste incinerator'' or ''MWI'' was used to describe what is called ''hospital/ medical/ infectious waste incinerator'' or ''HMIWI'' in the standards and guidelines promulgated today.

Section 129 of the CAA directs the EPA to adopt regulations for solid waste incineration units that combust ''hospital waste, medical waste, and infectious waste.'' Section 129(g)(6) states that the term ''medical waste'' shall have the meaning ''established by the Administrator pursuant to the Solid Waste Disposal Act.'' For the 1995 proposed air emission standards and guidelines for ''MWI,'' EPA adopted the definition of ''medical waste'' from the solid waste regulations codified in 40 CFR part 259, subpart B. As a result, medical waste was defined broadly as any solid waste that is generated in the diagnosis, treatment, or immunization of human beings or animals, in research pertaining thereto, or in the production or testing of biologicals. The broad definition of medical waste in the 1995 proposal was not intended to be used to identify ''infectious'' or ''potentially infectious'' items in the health care waste stream. The EPA's only intention was to define those items likely to be burned in an ''MWI'' for the sake of defining and regulating the air emissions from incinerators used to burn ''hospital waste, medical waste, and infectious waste.''

As discussed earlier, the majority of the comments on the 1995 proposed definition of medical waste stated that the proposed definition was too broad and should be narrowed. Consequently, the 1996 re-proposal announced EPA's inclination to adopt an existing and more narrow definition of medical waste for the purpose of regulating ''MWI.'' Specifically, the EPA stated that it was inclined to adopt the definition of medical waste created by the New York State Department of Health (NYSDOH). While inclined to adopt the NYSDOH definition, the EPA stated in the 1996 re-proposal that it was also considering definitions of medical waste adopted by other regulatory agencies and national associations as well as the 1995 proposed definition. The EPA solicited public comment on the merits of each definition as well as other definitions EPA should consider.

Following the 1996 re-proposal, several commenters supported a definition of medical waste that is limited to potentially infectious materials and several commenters agreed that the NYSDOH definition of medical waste is appropriate. Other commenters suggested that the EPA Office of Solid Waste (OSW) definition of regulated medical waste (RMW) is more appropriate than the NYSDOH definition because Congress intended for EPA to use the Solid Waste Disposal Act (SWDA) definition.

On the other hand, several commenters argued that a broad definition of medical waste is appropriate. The commenters stated that anything burned in an incinerator at a health care facility should be classified as medical waste and pointed out that the CAA requires EPA to regulate emissions from solid waste incineration units ''combusting hospital waste, medical waste and infectious waste.'' The commenters contended that facilities operating onsite incinerators would use them primarily for noninfectious waste, which produces emissions similar to medical waste when burned.

The EPA has concluded that the Medical Waste Tracking Act (MWTA) definition of regulated medical waste is the most appropriate definition of medical/infectious waste for the final HMIWI standards and guidelines. As noted in the proposal and re-proposal, the EPA considered several definitions for purposes of these regulations (e.g., OSHA, NYSDOH, MWTA, AHA). Although the various definitions are not identical, they cover many of the same materials. After considering the comments received, the EPA today is promulgating the MWTA definition under the co-authority of section 2002 of the SWDA, 42 U.S.C. 6912, and sections 129 and 301 of the CAA, 42 U.S.C. 7429 and 7601.

The EPA believes the MWTA definition is the most appropriate because it includes the materials of concern, and will lead to the least confusion in the regulated community because it is a familiar definition. In addition, the MWTA definition has undergone public comment at the Federal level, during both the rulemaking under the MWTA, as well as rulemaking on these regulations. The EPA emphasizes that the MWTA definition being promulgated today is solely for purposes of determining which incineration units are covered by the HMIWI regulations under section 129 of the CAA. It is not for purposes of determining applicability of SWDA requirements. THE MWTA definition, however, does not include hospital waste; thus, EPA also is promulgating today under authority of sections 129 and 301 of the CAA, 42 U.S.C. 7429 and 7601, a definition of hospital waste.

The MWTA differentiates between infectious and noninfectious wastes. The MWTA definition of RMW includes seven classes of waste which are very similar to the classes of infectious waste included in the NYSDOH definition. However, the MWTA definition of RMW is broader than the NYSDOH definition of medical waste because the MWTA definition includes some items (e.g., intravenous bags) which may not be infectious, but are aesthetically unpleasing. The MWTA definition does not include hazardous waste; household waste; ash from incineration of medical/ infectious waste; human corpses, remains, and anatomical parts intended for interment or cremation; or domestic sewage materials.

The EPA recognizes that the MWTA definition does not fully encompass the terms ''hospital waste, medical waste, and infectious waste.'' The MWTA definition, as well as other definitions considered for the final HMIWI regulations, cover ''medical waste and infectious waste,'' but do not cover ''hospital waste.'' Commenters are correct in pointing out that the emissions from combustion of hospital waste are very similar to emissions from the combustion of medical/infectious waste. Therefore, the final HMIWI standards and guidelines contain definitions for ''hospital'' and ''hospital waste'' and the definition of ''medical/infectious waste'' (MWTA definition). The definitions of ''hospital'' and ''hospital waste'' will subject incinerators located at hospitals to the final standards and guidelines, whether they burn ''infectious'' waste, ''noninfectious'' waste, or a combination.

Commenters on the 1995 proposed regulations stated there are very few, if any, incinerators that are used by hospitals to burn only noninfectious hospital trash. Consequently, this inclusion of ''hospital waste'' along with ''medical/infectious waste'' should: minimize the concern about the overly broad definition of medical waste; cover the same incinerators as envisioned in the 1995 proposal and 1996 re-proposal, resulting in the same emission reductions without imposing additional costs; and satisfy the CAA requirement to regulate solid waste incinerators combusting ''hospital waste, medical waste, and infectious waste.'' On the other hand, section 129 directs EPA to develop regulations for four categories of solid waste incinerators. Because municipal waste combustors (MWC), industrial/commercial waste incinerators, and other solid waste incinerators sometimes burn small amounts of hospital waste and/or medical/infectious waste, and because these other categories are already or will be subject to section 129 regulations, the final HMIWI regulations focus on incinerators whose primary purpose is the disposal of hospital waste and/or medical/infectious waste in an effort to avoid duplicative requirements. Combustors subject to subparts Ea, Eb, or Cb (the NSPS and EG for MWC larger than 250 tons per day) have been excluded from coverage under the HMIWI regulations. In addition, any incinerator which burns 10 percent or less by weight hospital waste and medical/infectious waste is not subject to the final HMIWI standards and guidelines. This 10 percent provision is discussed further in section A.2 ''Co-fired Combustors'' (below).

The primary purpose of the MWTA definition of medical waste as used for the HMIWI standards and guidelines is to define items combusted in an HMIWI, and not to define items which could transmit disease. Only a small fraction of ''medical/infectious'' waste is truly ''infectious.'' The EPA believes that to add or remove specific items to or from the MWTA definition, as suggested by some commenters, would create additional regulatory confusion because the revised definition would essentially become a new definition of medical waste if altered. Any waste excluded from the MWTA definition is either covered now or will be covered in the future by other solid waste incinerator regulations.

The final standards and guidelines will apply to hospital/medical/infectious waste incinerators. It should be noted that the definition of medical/infectious waste adopted for the HMIWI regulations is not the government-wide Federal definition, or even the Agency-wide EPA definition of infectious waste. The medical/infectious waste definition contained in the final regulations promulgated today is for use in determining applicability of the HMIWI standards and guidelines only. It should also be noted that ''hospital waste'' is simply waste generated at a hospital. Most of the waste generated at a hospital (85 to 90 percent or more) is simply municipal-type waste that may be recycled or disposed without special treatment. The use of the term ''hospital waste'' in these regulations is for use in determining applicability of the HMIWI standards and guidelines only.

2. Co-fired Combustors

In the 1996 re-proposal, the EPA provided no inclinations regarding the applicability of the HMIWI regulations to combustors that co-fire medical waste with other fuels or wastes. Some examples of units that might be used to co-fire medical waste along with other fuels or wastes include municipal waste combustors (MWC), boilers, and industrial/commercial waste incinerators. During the public comment period following the 1996 re-proposal, several comments were received questioning the applicability of the HMIWI regulations to units that co-fire medical waste with other fuels or wastes.

One commenter provided information on a circulating fluidized bed combustor (CFBC) steam plant which co-fires coal and medical waste. The commenter noted that traditional HMIWI burn materials with low sulfur content and that the proposed $SO_2$ emission limit was arbitrarily set higher than actual HMIWI emissions. The commenter requested that the $SO_2$ emission limit be raised to 100 ppm to accommodate the CFBC without affecting other incinerators that burn medical waste.

Other commenters requested that ''potentially infectious'' medical waste and ''off-spec'' or ''out-of-date'' pharmaceuticals be allowed to be combusted in MWC along with municipal solid waste (MSW) without subjecting MWC to the HMIWI rules. The commenters noted that MWC which co-combust municipal and medical waste are regulated under the MWC emission standards. The commenters recommended that an exclusion be written into the final rule that will allow MWC combusting a minimal amount of medical waste (up to 10 percent of the waste stream) to be excluded from the HMIWI rule. The commenters suggested that, if EPA feels that co-combustion of MSW and medical waste in a small MWC not covered under the MWC standards is an environmental threat, that co-combustion should not be allowed in MWC burning less than 40 tons per day. Other commenters stated that small MWC not regulated under the MWC standards should not be allowed to accept medical waste without complying with the HMIWI regulations.

Other commenters requested that a ''de minimis'' quantity exemption be allowed for facilities that incinerate insignificant quantities of medical waste. Some commenters requested that clinical waste in the amount of 5 to 10 percent of the total waste stream be allowed to be disposed of in a pathological waste incinerator.

Section 129 requires the EPA to develop NSPS and EG for MWC, HMIWI, industrial/commercial waste incinerators, and ''other'' solid waste incinerators. The final NSPS and guidelines applicable to MWC with capacities of greater than 40 tons/day were promulgated in December 1995, but have since been partially vacated and remanded. In this case, it is not the EPA's intent for MWC to be dually covered under both the MWC regulations and the HMIWI regulations. Therefore, combustors subject to Subparts Ea, Eb, or Cb (the NSPS and EG for MWC larger than 250 tons/day) have been excluded from coverage under the HMIWI regulations regardless of the amount of hospital waste or medical/infectious waste combusted. As regulations are developed under Section 129 for the other categories of solid waste incinerators, EPA will make clear which regulations apply to which incinerators. In some cases, incinerators

may be subject to more than one regulation.

Commenters requesting that MWC, boilers, and other industrial processes that co-fire medical waste be exempted from coverage under the HMIWI regulations generally seem to agree that these units combust no more than 10 percent hospital waste and/or medical/ infectious waste. Therefore, the final HMIWI NSPS and guidelines contain the provision that any incinerator or industrial process that combusts less than or equal to 10 percent hospital waste and medical/infectious waste (by weight) is not subject to the HMIWI NSPS and guidelines provided that the facility notifies the Administrator of an exemption claim and maintains records of the amount of hospital waste, medical/ infectious waste, and other fuels or wastes combusted.

As discussed in section A.3 ''Waste Types'' (below), ''off-spec'' or ''out-of-date'' drugs are not considered to be medical/infectious waste as defined in the final HMIWI regulations and are not considered to be hospital waste, unless disposed with the hospital's waste. ''Off-spec'' or ''out-of-date'' drugs are viewed the same as other fuels or wastes (e.g., municipal waste, coal, etc.) under HMIWI regulations. Therefore, incinerators that combust waste pharmaceuticals (i.e., ''off-spec'' or ''out-of-date'' drugs), and combust 10 percent or less hospital waste and medical/infectious waste (by weight) are not subject to the HMIWI regulations. However, any incinerator that combusts waste pharmaceuticals along with more than 10 percent hospital waste and medical/infectious waste is subject to the HMIWI regulations.

As also discussed in section A.3 ''Waste Types'' (below), pathological waste, chemotherapeutic waste, and low-level radioactive waste are considered ''excluded'' wastes. While these wastes sometimes meet the definition of hospital waste or medical/ infectious waste, they are viewed the same as ''other'' fuels or wastes (e.g., municipal waste, coal, etc.) when calculating the amount of hospital waste and medical/infectious waste burned in a co-fired combustor. For example, a combustor burning 90 percent pathological waste with 10 percent hospital waste is a co-fired combustor, even if the pathological waste meets the definition of medical/infectious waste. However, any incinerator that combusts pathological, chemotherapeutic, and/or low-level radioactive waste along with more than 10 percent of other materials meeting the definition of hospital waste and/or medical/infectious waste is subject to the HMIWI regulations.

While incinerators that burn 10 percent or less hospital waste and medical/infectious waste are excluded from the HMIWI regulations, this exclusion does not mean that EPA will not develop regulations which will cover these units in the future. The NSPS and EG that were recently remanded for MWC with capacities between 40 tons/day and 250 tons/day will be revised and repromulgated. Furthermore, the CAA directs the EPA to develop regulations for all solid waste incinerators, including MWC with capacities less than 40 tons/day. The EPA has announced that regulations for other solid waste incinerators will be developed by the year 2000. Thus, burning of hospital waste or medical/ infectious wastes in other solid waste incineration units will be covered by regulations developed within the next few years. Exclusion of incinerators that burn small amounts of hospital waste or medical/infectious waste from the HMIWI regulation is only a temporary deferment from regulation if these units are not presently regulated under section 129.

3. Waste Types

In the 1996 re-proposal, the EPA stated that it was inclined to exclude crematories and incinerators used solely for burning pathological waste from coverage under the HMIWI regulations. The EPA also stated that it was inclined to exclude incinerators used solely for burning low-level radioactive waste or ''off-spec'' and ''out-of-date'' pharmaceuticals. This section discusses the major public comments received regarding exemption of specific wastes from the HMIWI standards and guidelines.

Several commenters requested that crematories and incinerators used solely for burning pathological waste be excluded from the HMIWI regulation. One commenter questioned whether animal waste is to be included, excluded, or partially excluded from the regulation. Another commenter stated that there are no effective alternative disposal options for pathological waste, especially for large domestic animal carcasses (i.e., cows and horses). Several commenters also requested that incinerators used to burn only ''off-spec'' and ''out-of-date'' drugs or low-level radioactive waste be excluded from the regulation. One commenter stated that crematories and incinerators used to burn drugs, low-level radioactive waste, and pathological waste are already covered under other regulations, or will be covered under regulations developed through EPA's Industrial Combustion Coordinated Rulemaking (ICCR) project. Other commenters urged EPA to exclude units permitted under section 3005 of the SWDA from the HMIWI rule. One commenter argued that section 129 of the CAA statutorily prohibits EPA from regulating in the HMIWI rule hazardous waste combustion units which are to be regulated under the Resource Conservation and Recovery Act (RCRA).

Pathological waste, low-level radioactive waste, and chemotherapeutic waste are different from most hospital waste and medical/ infectious waste and are often burned in incinerators which burn these wastes exclusively. While these wastes often times meet the definition of hospital waste or medical/infectious waste, the combustion of these materials warrants separate consideration. Pathological waste, chemotherapeutic waste, and low-level radioactive waste are considered ''excluded'' wastes, regardless of whether the waste meets the definition of hospital waste or medical/infectious waste in the HMIWI regulations. Consequently, in determining the amount of hospital waste and medical/infectious waste burned in a co-fired combustor, these ''excluded'' wastes are included in the calculation as ''other'' wastes (they do not count toward the 10 percent hospital waste and medical/infectious waste), as discussed above in section A.2. In addition, incinerators that are otherwise subject to the HMIWI regulations are exempt during periods when only pathological waste, low-level radioactive waste, and/or chemotherapeutic waste is burned. These latter units must keep records of the periods of time when only pathological, chemotherapeutic, and low-level radioactive wastes are burned.

With regard to crematories, human remains intended for interment or cremation are not hospital waste or medical/infectious waste. Consequently, crematories are not subject to the HMIWI regulations unless they burn waste that meets the definition of hospital waste or medical/infectious waste.

While pathological incinerators, chemotherapeutic and low-level radioactive waste incinerators, and crematories are excluded from the final HMIWI standards and guidelines, this exclusion does not mean that EPA will not develop regulations which will cover these incinerators in the future. The CAA directs the EPA to develop regulations for all solid waste incinerators. The EPA is developing separate regulations which will cover these units as part of the ''other'' category of solid waste incineration

units within the ICCR project. The EPA has announced that regulations for other solid waste incinerators will be developed by the year 2000. Thus, cremation and burning of pathological, chemotherapeutic, and low-level radioactive wastes will be covered by regulations developed within the next few years. Exclusion of crematories and incinerators burning pathological, chemotherapeutic, and low-level radioactive waste from the HMIWI regulation is only a temporary deferment.

Pharmaceutical wastes such as ''off-spec'' or ''out-of-date'' drugs are not considered to be medical/infectious waste as defined in the final HMIWI regulations. Also, pharmaceutical wastes are not considered to be hospital waste unless generated at a hospital and disposed with the hospital's waste. In the HMIWI regulations ''hospital waste'' is defined as discards generated at a hospital, excluding human remains and unused items returned to the manufacturer. Thus, ''out-of-date'' drugs returned by a hospital to a pharmaceutical company for disposal are not considered hospital waste. Waste pharmaceuticals are viewed the same as other fuels and wastes (e.g., municipal waste, coal, etc.) under the HMIWI regulations. Therefore, incinerators that combust waste pharmaceuticals, and combust 10 percent or less hospital waste and medical/infectious waste (by weight) are not subject to the HMIWI regulations. However, any incinerator that combusts waste pharmaceuticals along with more than 10 percent hospital waste and medical/infectious waste is subject to the HMIWI regulations.

Section 129(g)(1) of the CAA specifically exempts from the HMIWI NSPS and guidelines solid waste incinerators required to have a permit under section 3005 of the SWDA. To be consistent with section 129, the final HMIWI standards and guidelines specifically exempt incinerators permitted under section 3005 of the SWDA. In addition, the definition of medical/infectious waste in the final regulations specifically excludes hazardous waste identified or listed under the regulations in 40 CFR Part 261.

4. Cement Kilns

Some commenters pointed out that section 129 clearly addresses incinerators, not cement kilns. Commenters stated that HMIWI and cement kilns using medical waste as fuel are two completely different devices and should not be confused with each other or regulated under the same air emissions control standards. One commenter recommended that if EPA concludes that Congress intended to regulate cement kilns under section 129, EPA should not impose emission limitations and other requirements that were written for HMIWI on cement kilns.

The EPA disagrees with commenters that contend EPA has no authority to regulate cement kilns under section 129. Section 129(a)(1)(A) requires the Administrator to establish performance standards and other requirements for each category of solid waste incineration units. Congress specifically listed in section 129 various categories of solid waste incineration units that EPA must regulate. Section 129(g)(1) broadly defines solid waste incineration unit as ''a distinct operating unit of *any* facility which combusts *any* solid waste material * * *'' (emphasis added). This definition clearly indicates Congress' intent to regulate more than just incinerators because the definition sweeps within its scope any facility that is combusting any solid waste material.

Further evidence of EPA's authority to regulate cement kilns under section 129 is presented in ''Hospital/Medical/Infectious Waste Incinerators: Background Information for Promulgated Standards and Guidelines—Summary of Public Comments and Responses'' (EPA–453/R–97–006b). However, the EPA does recognize that cement kilns are different from HMIWI in size, design, and operation. Accordingly, the EPA is not regulating cement kilns under this regulation, but instead, is determining whether separate regulations under section 129 are appropriate for cement kilns combusting solid waste materials.

*B. Pyrolysis Units*

In the 1996 re-proposal, the EPA stated that it was considering a separate regulation for pyrolysis units that would look very similar to the HMIWI regulation in that it would contain definitions, emissions limitations, monitoring and testing requirements to demonstrate compliance, and reporting and recordkeeping requirements. However, the separate pyrolysis regulation would differ from the HMIWI regulations in that some definitions would be different, the emission limitations would, in many cases, be more stringent than the HMIWI regulations, and the monitoring and testing requirements would reflect the operating parameters that are unique to pyrolysis systems.

Following the 1996 re-proposal, several commenters encouraged EPA to promulgate separate standards for medical waste pyrolysis (MWP) units. One commenter noted that separate regulations would contain emission limits more stringent than the HMIWI regulations and reflect the unique features of pyrolysis units.

Other commenters suggested that EPA modify the 1995 proposed HMIWI regulations to include pyrolysis units and defer the final promulgation of separate pyrolysis regulations. The commenters stated that variations in the operating characteristics among pyrolysis technologies would make separate pyrolysis regulations unwieldy to implement at this time. The commenters requested that EPA modify the HMIWI regulations to provide flexibility if a specific operator training, siting, performance verification, compliance verification, monitoring, recordkeeping or reporting requirement does not directly apply to a pyrolysis system.

Other commenters stated that pyrolysis units are similar to conventional incinerators and requested that they be included under the HMIWI regulations. The commenters stated that, if EPA regulates pyrolysis units separately, that MACT floor levels should be based on available test data, and the pyrolysis regulation should be issued concurrently with the final HMIWI regulations.

The various arguments for and against developing separate regulations for pyrolysis units lead to three options for developing regulations for pyrolysis units: (1) Regulate pyrolysis under the standards and guidelines being promulgated today; (2) exempt pyrolysis units from the HMIWI regulations and simultaneously promulgate separate regulations for pyrolysis units; and (3) exempt pyrolysis units from the HMIWI regulation and defer the development of separate regulations.

Pyrolysis technology is different from conventional incineration. Because air is generally not used in the pyrolysis treatment process, the volume of exhaust gas produced from pyrolysis treatment is likely to be far less than the volume of gas produced from the burning of waste in an HMIWI. Although conventional combustion does not occur during pyrolysis treatment, there are some emissions from the pyrolysis process.

As discussed in the 1996 re-proposal, the EPA developed a draft regulation for pyrolysis units. The 1996 re-proposal pointed out that the draft regulatory text was incomplete and it included placeholders and requests for information where such information was lacking. The EPA requested

comments to help fill in the missing information.

Following the 1996 re-proposal, the EPA received information for use in developing the separate pyrolysis regulation from vendors of pyrolysis technology. As pointed out by one commenter and supported by the information received from pyrolysis vendors, there are variations in the operating characteristics among pyrolysis technologies that would make separate regulations for pyrolysis units very difficult to implement at this time. As a result, the EPA has concluded that sufficient information is not available to develop a separate and uniform regulation for pyrolysis technology that would contain requirements that are technically feasible for all pyrolysis units.

Because separate regulations for pyrolysis technology cannot be developed at this time, the EPA considered modifying the HMIWI regulations to include pyrolysis units. However, nearly all aspects of the HMIWI regulations would have to be altered to accommodate pyrolysis units including the format of the emission limits, the operator training requirements, siting requirements, the testing and monitoring requirements, and the reporting and recordkeeping requirements. Furthermore, the HMIWI subcategories and MACT floors would not be appropriate for pyrolysis units. Due to variations in the operating characteristics of pyrolysis technologies and the differences between HMIWI and pyrolysis technologies, it is unclear how the HMIWI regulations could be modified to feasibly cover pyrolysis technologies as well as HMIWI.

Section 129 requires EPA to develop NSPS and EG for ''solid waste incineration units * * * combusting hospital waste, medical waste, and infectious waste.'' As discussed above, pyrolysis and conventional incineration are not the same. Because regulations developed for HMIWI are not appropriate for pyrolysis technologies, pyrolysis treatment technologies have specifically been excluded from coverage under the final HMIWI standards and guidelines. The EPA may consider these devices in future regulatory development.

*C. Waste Management Plans*

During the public comment period following the 1996 re-proposal, several commenters stated that the EPA standards for HMIWI are reliant on pollution control and give little attention to pollution prevention. The commenters stated that recycling and pollution prevention measures could yield greater reductions in emissions than add-on controls alone. Some commenters stated that Congress intended for EPA to use process changes or substitution of materials to help eliminate emissions. Some commenters stated that dioxin/furan, HCl, and Hg emissions could be controlled through a pollution prevention program that reduces or eliminates incineration of chlorinated materials and batteries. One commenter requested that EPA suggest pollution prevention measures for controlling Hg as well as other pollutant precursors (i.e., lead, cadmium, chlorine, nitrogen, fluorine, and sulfur). The commenter maintained that the economic impact of the HMIWI regulations could be reduced significantly if EPA required medical facilities to institute pollution prevention techniques.

The types of materials sent to an HMIWI vary from facility to facility depending on facility operating practices, which are defined by purchasing decisions, waste handling procedures, and other practices that affect the types of materials incinerated.

In the February 1995 proposal, the EPA stated that it had no data to indicate the effects of waste handling practices on emissions of various pollutants and requested comments on the extent to which operating practices could influence emissions. To evaluate the effectiveness of waste segregation programs, the EPA specifically solicited detailed descriptions of programs and results of performance tests conducted to demonstrate pollutant emission levels from the HMIWI prior to implementation of the program and subsequent to implementation of the program. In addition, the EPA solicited comments on how such a program could be incorporated into the HMIWI regulations.

Following the 1995 proposal, the EPA received no data to conclusively indicate the effectiveness of waste segregation programs in reducing emissions from HMIWI. Therefore, the final HMIWI standards and guidelines are primarily based on air pollution controls rather than pollution prevention. However, as discussed in the 1996 re-proposal, EPA has included pollution prevention measurements in setting the Hg emission limit for good combustion. To ensure that emissions of Hg from facilities with good combustion controls meet the final emission guidelines for Hg, EPA is requiring that these facilities conduct a Hg emission test. If the facility fails the emission test, the facility will need to implement Hg pollution prevention measures or install an APCD to meet the emission limits.

The EPA has investigated the impacts on emissions of shifting the waste composition from chlorinated plastics to non-chlorinated polymers. However, the outcome of this investigation is inconclusive. A number of studies have concluded that the chlorine content of the waste is directly related to dioxin/furan emissions, while other studies suggest there is no relationship between the chlorine content of the waste and dioxin/furan emissions. At this point, the effectiveness of a pollution prevention program directed at reducing dioxin/furan emissions through shifting the waste composition from chlorinated plastics to nonchlorinated polymers would be questionable.

A number of health care facilities have implemented waste management measures to reduce the overall volume of waste. However, it should be stressed that each health care facility is unique and site-specific strategies must be developed that achieve the most efficient results. Through the development of individual waste management programs, health care facilities can achieve significant reductions in their waste stream, reduce the volume of waste to be incinerated, and thereby reduce the amount of air pollution emissions associated with that waste. Therefore, the final HMIWI standards and guidelines require that health care facilities which operate incinerators develop and implement a waste management plan.

The waste management plan would 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. The waste management plan may include elements such as paper, cardboard, plastics, glass, battery, or metal recycling; or 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 emission reductions expected to be achieved, and any other environmental or energy impacts they might have. A copy of the waste management plan would be submitted to EPA along with the results of the initial performance test demonstrating compliance with the emission limits. In addition, the waste

management plan may be reviewed by the Joint Commission on Accreditation of Health Care Organizations during the accreditation process.

Health care facilities are encouraged to review and incorporate into their waste management plans the waste minimization techniques discussed in ''An Ounce of Prevention: Waste Reduction Strategies for Health Care Facilities,'' which is published by the American Society for Health Care Environmental Services of the American Hospital Association. This document may be obtained by contacting AHA Services, Inc., P.O. Box 92683, Chicago, Illinois 60675–2683, or by calling 800–242–2626. The cost of the document is $50.00 plus $10.95 for shipping and handling. The document is available for public inspection at EPA's Air and Radiation Docket and Information Center (Docket A–91–61, item IV–J–124). See the ADDRESSES section at the beginning of this preamble for the location of the Docket. Note that because of copyright law, this document may not be copied. This document was approved for incorporation by reference by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

*D. Testing, Monitoring, and Inspection*

Section 129(c) of the CAA requires the EPA to include emissions monitoring and testing requirements in the regulation. The purpose of these requirements is to allow the EPA to determine whether a source is operating in compliance with the regulations.

In the 1996 re-proposal, the EPA stated that it was inclined to adopt requirements that EPA test methods be followed when performing any emission testing required to determine compliance with the HMIWI regulations. In most cases, three test runs of about 1 hour each would be necessary to determine compliance. The EPA also stated in the 1996 re-proposal that it was inclined to include in-house inspection and maintenance requirements wherever annual stack testing was not required. To minimize costs, the EPA stated that it was inclined to include requirements for monitoring of operating parameters and routine Method 9 (stack opacity) testing in the final regulations instead of CO and opacity continuous emissions monitoring systems (CEMS) for onsite HMIWI. Where the regulations are based on wet and/or dry scrubbing systems, the EPA stated that it was inclined to require initial and repeat stack testing (annual/skip testing where annual testing is required for the first 3 years and, if these tests show compliance, subsequent testing would be done every third year). Where the regulations are based, in part, on the use of good combustion alone, the EPA stated that it was inclined to require initial stack testing and routine inspections. The EPA solicited public comment on all of the testing and monitoring inclinations presented in the 1996 re-proposal. In addition, because some CEMS vendors questioned the CEMS and parameter monitoring costs developed by EPA, the EPA solicited public comment on the costs of CEMS and monitoring of operating parameters.

Several comments concerning the EPA's inclinations for monitoring and testing were received following the 1996 re-proposal. One commenter requested that EPA require CEMS for CO, HCl, $SO_2$, $NO_X$, Hg, and PM. The commenter contended that CEMS for CO, HCl, $SO_2$, $NO_X$, Hg, and PM would eliminate the need for stack testing. The commenter stated that the only way to ensure compliance at all times, as mandated by the CAA, is through the continuous use of CEMS. One commenter stated that EPA should require continuous monitoring of CO emissions from all HMIWI, continuous opacity monitoring at large incinerators, and continuous monitoring of HCl emissions from very large (>1000 lb/hr) incinerators. The commenter indicated that continuous monitoring of CO and $O_2$ is the only way to ensure that good combustion is occurring. The commenter concluded that CO and $O_2$ ''process'' monitors should be sufficient for HMIWI with capacities less than 500 lb/hr. The commenter stated that EPA's inclination not to require continuous monitoring is based on inaccurate CEMS costs.

A number of commenters supported EPA's inclination to determine compliance using parameter monitoring and routine inspection and maintenance rather than CEMS. One of the commenters supported monitoring of operating parameters and routine Method 9 testing combined with initial stack testing and annual inspections to ensure compliance with the rule. Another commenter stated that an initial stack test for the primary pollutants and regular inspection, maintenance, and daily recording of operating parameters would be appropriate. One commenter stated that monitoring of operating parameters with no CEMS and substitute stack testing with annual inspections would provide an excellent means to attain low emissions for minimal costs for small HMIWI. Other commenters recommended monitoring operating parameters and routine Method 9 testing with initial stack testing and no repeat testing. Another commenter suggested that an initial performance test and monitoring is sufficient and that additional tests are not necessary especially given operator training, inspections, and monitoring.

The most direct means of ensuring compliance with emission 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 emission limits. Other options are considered only when CEMS are not available or when the impacts of including such requirements are considered unreasonable. 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.

For the 1996 re-proposal, testing and monitoring costs were developed for a range of options, and the Agency concluded that the cost of CEMS were unreasonably high relative to the cost of the incinerators and air pollution control systems needed for compliance. Based on comments and information received as a result of the 1996 re-proposal, the cost estimates for CEMS and parameter monitoring have been revised. While the cost estimates for CEMS have been significantly reduced and additional costs have been included for parameter monitoring, it appears that the annual costs of monitoring requirements which include CEMS are still quite high compared to the cost of the incinerator and air pollution control device required to meet the emission limits.

A large HMIWI costs approximately $120,000/yr to operate, while an add-on APCD can cost from $150,000 to $300,000/yr to operate. The most comprehensive monitoring option including CEMS for HCl and CO costs about $95,000/yr. This option costs nearly as much to operate as the incinerator itself and could represent as much as half the cost of the APCD. In addition, the only emissions that are directly measured are HCl and CO. Consequently, the most comprehensive

monitoring option that could be selected for large HMIWI is considered unreasonable.

There are no direct measurements of dioxin/furan or toxic metals. Particulate matter and Hg CEMS are currently under development but have not been demonstrated in the United States to be capable of accurately and reliably measuring PM or Hg emissions for use in determining compliance with PM or Hg emission limits at this time. With regard to $SO_2$ and $NO_X$, the emission limits in the final regulations reflect uncontrolled emissions. Therefore, it is unreasonable to impose a cost (of monitoring) where no emission reduction benefit will be gained.

Looking at other options for large HMIWI, the only CEMS available are $CO/O_2$ and opacity. For a large HMIWI equipped with a sophisticated APCD like a wet scrubber, dry scrubber, or combined dry/wet scrubber, these CEMS provide very little information regarding the pollutants that are of most concern to the public (i.e., dioxin/furan and toxic metals). Consequently, because the APCD already represents a substantial increase in the cost of incineration and because the more comprehensive monitoring options do not provide much information regarding the pollutants of most concern, the final monitoring and testing requirements for HMIWI equipped with APCD reflect routine stack testing coupled with continuous monitoring of operating parameters.

Where incinerators are not equipped with add-on air pollution control (i.e., units utilizing good combustion alone), EPA agrees with commenters that CO provides the best measure of good combustion. However, regulations based on good combustion alone only apply to small existing HMIWI meeting certain ''remote'' criteria (see section V.B). For these small existing HMIWI using only good combustion, the incinerator costs about $35,000/yr to operate and the air pollution control costs about $10,000/yr to operate. Monitoring options including CO CEMS for compliance are clearly unreasonable at about $54,000/yr (five times the cost of the air pollution control). The monitoring option which includes a CO ''process'' monitor costs about $17,000/yr while the option that relies on operating parameters costs about $10,000/yr. The EPA does not believe that the CO ''process'' monitor provides enough additional information to justify the $7,000/yr additional cost, especially considering that the air pollution control only costs $10,000/yr. Consequently, where the regulations are based on good combustion alone, the monitoring requirements consist of an initial stack test coupled with continuous monitoring of operating parameters and annual inspections.

The specific values for operating parameters are chosen by the owner or operator and are established during the initial performance test demonstrating compliance with the emission limits. After the performance test, monitoring of the operating parameters is the only way to determine, on a continuous basis, whether the source is operating in compliance. Operation outside the bounds of an established operating parameter is a violation of an operating parameter limit. In addition, under certain conditions, operation outside the bounds of one or more parameter limits constitutes a violation of a specific emission limit. This latter provision was included in the 1995 proposed regulations and is retained in the final regulations. The owner or operator has the flexibility to choose the values for the operating parameters and may conduct repeated performance tests to ''fine tune'' the operating parameter limits, if desired.

With regard to the testing requirements, annual testing is required for the first 3 years. If these tests show that the facility is in compliance each of these 3 years, then subsequent testing would be done every third year. Initial testing includes testing for the following pollutants: PM, CO, HCl, dioxin/furan, Pb, Cd, Hg, and opacity. The annual/skip or ''repeat'' testing only includes testing for PM, CO, HCl, and opacity. Where good combustion alone serves as the basis for the emission limits, the Agency only requires facilities to perform an initial compliance test for PM, CO, dioxin/furan, Hg, and opacity, annual incinerator inspections, annual opacity testing, and parameter monitoring (charge rate and secondary chamber temperature). Minimum sampling times of 1 hour (4 hours for dioxin/furan) have been included in the final regulations for all HMIWI.

The ''repeat'' testing requirements will ensure, on an ongoing basis, that the APCD is operating properly, that no deterioration in performance has occurred, and that no changes have been made to the operating system or the type of waste burned. Where ''repeat'' testing is not required, annual inspections, annual opacity testing, and parameter monitoring will ensure that the HMIWI is in good working order. However, cost considerations were the only reason for excluding the repeat testing for units with good combustion alone. Good combustion alone with its associated monitoring are provided in order to minimize costs for a small number of incinerators in remote areas where alternatives to incineration might be unavailable. Initial testing for good combustion units includes testing for PM, CO, dioxin/furan, Hg, and opacity. The Hg testing is required to ensure that units are segregating Hg bearing wastes and meeting the Hg emission limit.

Rather than require third-party inspections, which could be burdensome for small remote facilities, the final guidelines allow for in-house equipment inspections. However, EPA plans to work with States to give higher priority to these small remote facilities in terms of enforcement inspections. Either the EPA or the State will inspect these small remote facilities annually for the first three years after the State plan is approved. Following the three-year period, these sources will be placed on the regular enforcement inspection schedule.

### *E. Operator Training and Qualification*

The final operator training and qualification requirements are almost identical to those described in the 1996 re-proposal. The final requirements provide flexibility by allowing State-approved training and qualification programs. Where there are no State-approved programs, the final regulations include minimum requirements for training and qualification. The EPA has a training manual available through its Air Pollution Training Institute (APTI). For further information, contact APTI at (919) 541–2497. In addition, EPA plans to work with the American Hospital Association to develop a correspondence course for those facilities that may not have access to adequate training. As discussed above, EPA plans to work with States to give higher priority to the small remote units in terms of enforcement inspections, including a review of operator training.

## IV. Standards of Performance for New Sources

This section presents a summary of the final standards, including identification of the source category and pollutants being regulated, and presentation of the final emission limits and their associated performance testing, monitoring, recordkeeping and reporting requirements. This section discusses the most significant changes to the standards presented in the June 20, 1996 **Federal Register** document. Also discussed in this section is the rationale for the selection of MACT and a summary of the impacts of the final standards.

### *A. Summary of the Standards*

The final standards (subpart Ec) apply to each new HMIWI for which

construction commenced after June 20, 1996 or to an existing HMIWI for which modification commenced after March 16, 1998. Hospital/medical/infectious waste incinerators for which construction commenced on or before June 20, 1996 are not covered under the subpart Ec standards; they are considered existing sources and are subject to the guidelines under subpart Ce (see section V of this notice).

A HMIWI is defined as any device that combusts any amount of medical/ infectious waste or hospital waste. The terms medical/ infectious waste and hospital waste are discussed in section III.A and defined in § 60.51c. An incinerator is not subject to subpart Ec during periods when only pathological, low-level radioactive, or chemotherapeutic waste (all defined in § 60.51c) is burned provided that the owner or operator keeps records of the periods of time when only pathological, low-level radioactive, and/or chemotherapeutic waste is burned. Any combustor required to have a permit under section 3005 of the SWDA is exempt from subpart Ec as are incinerators subject to subpart Cb, Ea, or Eb. New incinerators, processing operations, or boilers that co-fire medical/infectious waste or hospital waste with other fuels or wastes and that combust 10 percent or less medical/ infectious waste and hospital waste by weight (on a calendar quarter basis) are not subject to the emission limits under subpart Ec, but must keep records of the amount of each fuel and waste fired.

The HMIWI source category is divided into three subcategories based on waste burning capacity: Small (≤200 lb/hr), medium (>200 to 500 lb/hr), and large (>500 lb/hr). Waste burning capacity is determined either by the maximum design capacity or by the ''maximum charge rate'' established during the most recent performance test. In other words, a source may change its size designation by establishing a ''maximum charge rate'' lower than its design capacity. For example, a ''medium'' unit with a design capacity of 250 lb/hr may establish a maximum charge rate of 200 lb/hr and be considered a ''small'' unit for purposes of the standards. Separate emission standards apply to each subcategory of new HMIWI. A summary of the final emission limits for new or modified HMIWI is presented in Table 3.

TABLE 3.—SUMMARY OF PROMULGATED EMISSION LIMITS FOR NEW HMIWI

| Pollutant (test method) | Emission limits | | |
|---|---|---|---|
| | Small HMIWI | Medium HMIWI | Large HMIWI |
| Particulate matter (EPA Method 5 or Method 29). | 69 mg/dscm (0.03 gr/dscf) | 34 mg/dscm (0.015 gr/dscf) | 34 mg/dscm (0.015 gr/dscf). |
| Carbon monoxide (EPA Method 10 or Method 10B). | 40 ppmv | 40 ppmv | 40 ppmv. |
| Dioxins/furans (EPA Method 23) | 125 ng/dscm total CDD/CDF (55 gr/$10^9$ dscf) or 2.3 ng/dscm TEQ (1.0 gr/$10^9$ dscf). | 25 ng/dscm total CDD/CDF (11 gr/$10^9$ dscf) or 0.6 ng/dscm TEQ (0.26 gr/$10^9$ dscf). | 25 ng/dscm total CDD/CDF (11 gr/$10^9$ dscf) or 0.6 ng/dscm TEQ (0.26 gr/$10^9$ dscf). |
| Hydrogen chloride (EPA Method 26). | 15 ppmv or 99% reduction | 15 ppmv or 99% reduction | 15 ppmv or 99% reduction. |
| Sulfur dioxide (testing not required). | 55 ppmv | 55 ppmv | 55 ppmv. |
| Nitrogen oxides (testing not required). | 250 ppmv | 250 ppmv | 250 ppmv. |
| Lead (EPA Method 29) | 1.2 mg/dscm (0.52 gr/$10^3$ dscf) or 70% reduction. | 0.07 mg/dscm (0.03 gr/$10^3$ dscf) or 98% reduction. | 0.07 mg/dscm (0.03 gr/$10^3$ dscf) or 98% reduction. |
| Cadmium (EPA Method 29) | 0.16 mg/dscm (0.07 gr/$10^3$ dscf) or 65% reduction. | 0.04 mg/dscm (0.02 gr/$10^3$ dscf) or 90% reduction. | 0.04 mg/dscm (0.02 gr/$10^3$ dscf) or 90% reduction. |
| Mercury (EPA Method 29) | 0.55 mg/dscm (0.24 gr/$10^3$ dscf) or 85% reduction. | 0.55 mg/dscm (0.24 gr/$10^3$ dscf) or 85% reduction. | 0.55 mg/dscm (0.24 gr/$10^3$ dscf) or 85% reduction. |

In addition to the emission limits, new or modified large HMIWI are subject to a 5 percent visible emission limit for fugitive emissions generated during ash handling and all new or modified HMIWI are subject to a 10 percent stack opacity limit. Performance tests for fugitive emissions from ash handling must be conducted using EPA Reference Method 22. Stack opacity must be determined using EPA Reference Method 9.

Table 4 summarizes the additional requirements for new or modified HMIWI under the NSPS, including the operator training and qualification requirements, siting requirements, compliance and performance testing requirements, monitoring requirements, and reporting and recordkeeping requirements. A summary of dates for compliance with the promulgated standards for new HMIWI is presented in Table 5. These dates apply to all new or modified HMIWI.

TABLE 4.—SUMMARY OF ADDITIONAL REQUIREMENTS UNDER THE NSPS FOR NEW HMIWI

| Additional requirements |
|---|
| Operator Training and Qualification Requirements: |
| • Complete HMIWI operator training course. |
| • Qualify operators. |
| • Maintain information regarding HMIWI operating procedures and review annually. |
| Siting Requirements: |
| • Prepare a siting analysis that considers air pollution control alternatives that minimize, on a site-specific basis and to the maximum extent practicable, potential risks to public health and the environment. |

TABLE 4.—SUMMARY OF ADDITIONAL REQUIREMENTS UNDER THE NSPS FOR NEW HMIWI—Continued

| Additional requirements |
|---|
| Waste Management Plan:<br>• Prepare a waste management plan that identifies the feasibility and approach to separate certain components of a health care waste stream.<br>Compliance and Performance Testing Requirements:<br>• Conduct an initial performance test to determine compliance with the PM, CO, CDD/CDF, HCl, Pb, Cd, and Hg emission limits and opacity limit, and establish operating parameters.<br>• Conduct annual performance tests to determine compliance with the PM, CO, and HCl emission limits and opacity limit.<br>• Facilities may conduct performance tests for PM, CO, and HCl every third year if the previous three HMIWI performance tests demonstrate that the facility is in compliance with the emission limits for PM, CO, or HCl.<br>• Perform annual fugitive testing (large HMIWI only).<br>Monitoring Requirements:<br>• Install and maintain equipment to continuously monitor operating parameters including secondary chamber temperature, waste feed rate, bypass stack, and APCD operating parameters as appropriate.<br>• Obtain monitoring data at all times during HMIWI operation.<br>Reporting and Recordkeeping Requirements:<br>• Maintain for 5 years records of results from initial performance test and all subsequent performance tests, operating parameters, any maintenance, the siting analysis, and operator training and qualification.<br>• Submit the results of the initial performance test and all subsequent performance tests.<br>• Submit reports on emission rates or operating parameters that have not been recorded or that exceeded applicable limits.<br>• Provide notification of intent to construct, construction commencement date, planned initial start-up date, planned waste type(s) to be combusted, the waste management plan, and documentation resulting from the siting analysis. |

NOTE: This table depicts major provisions of the NSPS and does not attempt to show all requirements. The regulatory text of Subpart Ec should be relied upon for a full and comprehensive statement of the requirements of the NSPS.

TABLE 5.—COMPLIANCE TIMES UNDER THE NSPS FOR NEW HMIWI

| Requirement | Compliance time |
|---|---|
| Effective date | 6 months after promulgation of NSPS. |
| Operator training and qualification requirements. | On effective date or upon initial start up, whichever is later. |
| Initial compliance test | On effective date or within 180 days of initial start up, whichever is later. |
| Performance test | Within 12 months following initial compliance test and annually thereafter. Facilities may conduct performance tests every third year if the previous three performance tests demonstrate compliance with the emission limits. |
| Operator parameter monitoring | Continuously, upon completion of initial compliance test. |
| Recordkeeping | Continuously, upon completion of initial compliance test. |
| Reporting | Annually, upon completion of initial compliance test; semiannually, if noncompliance. |

NOTE: This table depicts major provisions of the NSPS and does not attempt to show all requirements. The regulatory text of Subpart Ec should be relied upon for a full and comprehensive statement of the requirements of the NSPS.

*B. Significant Issues and Changes*

The most significant changes to the standards made following the June 20, 1996 **Federal Register** document are discussed below. Further discussion of these changes as well as other comments and responses regarding the NSPS are provided in ''Hospital/ Medical/ Infectious Waste Incinerators: Background Information for Promulgated Standards and Guidelines—Summary of Public Comments and Responses'' (EPA–453/ R–97–006b).

1. Combined Dry/Wet Scrubbers

As discussed in the 1996 re-proposal, the MACT floor for medium and large HMIWI was based on emission limits achievable with good combustion and a dry injection/fabric filter (DI/FF) combined with a high efficiency wet scrubber (combined dry/wet system).

During the public comment period following the 1996 re-proposal, several commenters questioned the basis for the MACT floors for new medium and large HMIWI. The commenters contended that the revised MACT floor emission levels were based on invalid test data and invalid assumptions as to the applicability and technical feasibility of combination dry/wet scrubbing systems. The commenters stated that the combined dry/wet system is not proven technology. Some commenters stated that the pollutant-by-pollutant approach used to determine the MACT floor for new medium and large units resulted in a MACT floor that can not be accomplished with any type of economic feasibility. Other commenters stated that the costs of requiring a wet scrubber in addition to a dry scrubber far outweigh the air pollution control benefits.

The EPA recognizes 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. For example, the pollutant-by-pollutant approach for the HMIWI regulation results in a MACT floor for HCl based on a high efficiency wet scrubber, while the MACT floor for other pollutants reflects the performance of a dry scrubber. Compared to the dry scrubber alone, the addition of the wet scrubber adds considerable cost to the regulation while achieving a relatively small additional reduction in HCl. However, as mentioned later in this notice, a spray dryer/fabric filter system with carbon injection could be used instead of a combined dry/wet scrubber to achieve all of the emission limits at a lower cost than the combined system. On the other hand, EPA interprets section 129 of the CAA to require that the MACT floor be determined in this manner, and EPA believes that Congress did in fact intend that sources subject to regulations developed under section 129 meet emission limits that are achieved by the

best controlled unit for each pollutant as long as the control systems are compatible with each other. To EPA's knowledge, there is no technical reason why these two air pollution control systems cannot be combined (discussed later).

Section 129(a)(2) of the CAA specifies that ''the degree of reduction in emissions that is deemed achievable for new units in a category shall not be less stringent than the emissions control achieved in practice by the best controlled similar unit, as determined by the Administrator.'' This requirement identifies the least stringent emissions standards that the EPA may adopt for new HMIWI (i.e., the MACT floor).

At least one existing HMIWI in the medium subcategory is controlled with a high efficiency wet scrubber and another is equipped with a DI/FF system without carbon. The MACT floor for new medium HMIWI was based on both of these technologies (i.e., a combined dry/wet scrubber system) because the wet scrubber achieves the lowest dioxin, HCl, and Hg emissions, but the DI/FF without carbon injection achieves the lowest Pb and Cd emissions (note: as discussed elsewhere, the DI/FF system with carbon injection achieves the same or lower dioxin and Hg emissions as a wet scrubber). While no combined dry/wet scrubber systems were identified on medium HMIWI, these systems are currently in operation on large HMIWI. As discussed later, test data appear to indicate that combining the two systems is technically feasible. Similarly, the MACT floor for new large HMIWI was based on the emission levels that are achievable with good combustion and a combined dry/wet system with activated carbon.

The EPA does not agree that the MACT floors are to be based upon one overall unit. Rather, the EPA believes that section 129 supports its interpretation that it is legally permissible to set the MACT floor pollutant-by-pollutant, as long as the various MACT floors do not result in standards that are not achievable.

Section 129(a)(2) requires the EPA to establish technology based emission standards that ''reflect the maximum degree of reduction in emission of air pollutants listed under section (a)(4) that the Administrator, taking into consideration the cost of achieving such emission reduction and any nonair quality health and environmental impacts and energy requirements, determines is achievable . . .'' Congress further specified in section 129(a)(2) the minimum reduction that could satisfy this requirement (i.e., the MACT floor) for new sources as ''the emission control that is achieved in practice by the best controlled similar unit, as determined by the Administrator.'' This language does not expressly address whether the floor may be established pollutant-by-pollutant. The ''emission control achieved by the best controlled similar unit'' can be read either to mean emission control as to a particular pollutant, or emission control that is achieved by the unit as a whole. Nevertheless, the MACT floor reflects the least stringent emission 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 dioxin/furan 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.

A more detailed discussion of the legal basis for this pollutant-by-pollutant approach is contained in section 3.4.2 of ''Hospital/Medical/Infectious Waste Incinerators: Background Information for Promulgated Standards and Guidelines—Summary of Public Comments and Responses'' (EPA–453/R–97–006b). Quantitative information about the costs and air pollution control performance of both wet scrubbers and dry scrubbers is summarized in the 1996 re-proposal (61 FR 31743). As discussed in the 1996 re-proposal, detailed descriptions of costs and air pollution control performance of these systems are available in Docket A–91–61, items IV–B–30, IV–B–32, IV–B–48, and IV–B–49. See the **ADDRESSES** section of this preamble for the location and telephone number for the docket.

The EPA also notes that it followed this approach of setting the MACT floors and MACT standards pollutant-by-pollutant in the proposed MWC rules that were published on September 20, 1994 pursuant to section 129 and codified in 40 CFR part 60, Subparts Eb and Cb. Commenters on that rule also expressed concerns about the achievability of the resulting standards. The EPA notes that large MWC units (more than 250 tons/day capacity) are achieving the promulgated standards (in fact, several combined systems were in operation at the time of promulgation); thus, the approach of proposing MACT standards pollutant-by-pollutant did not lead to unachievable or economically infeasible standards in this case.

In response to commenters' concerns regarding the technical feasibility of combined dry/wet systems, a review of the available data documenting the performance of combined dry/wet scrubber systems was conducted. Although limited emissions data are available for HMIWI with combined dry/wet control systems, the available data indicate that the MACT floor emission levels for new HMIWI are achievable and technically feasible. The performance of dry scrubbers with activated carbon injection and the performance of wet scrubbers is 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. Finally, as mentioned in the 1996 re-proposal, one existing HMIWI equipped with a spray dryer/fabric filter system with carbon injection was tested during the EPA testing program, and this test demonstrated that this scrubbing technology could be used instead of a combined dry/wet scrubber to achieve all of the emission limits.

2. Siting Analysis

Section 129 of the CAA states that performance standards for new HMIWI must incorporate siting requirements that minimize, on a site-specific basis and to the maximum extent practicable, potential risks to public health or the environment. The Agency is directed by the CAA to promulgate siting requirements that meet the minimum criteria outlined in the CAA. In the 1995 proposal, the siting requirements were patterned after the Prevention of Significant Deterioration (PSD) requirements within the New Source Review (NSR) program. Additionally, the originally proposed siting requirements included provisions for a public meeting and the preparation of a comment/response document that would be made available to the public.

Following the 1996 re-proposal, commenters requested that EPA do away with the siting requirements because they will be costly and will impede the permitting process. Other commenters requested that EPA adopt siting requirements that are consistent with those that have been developed and enacted by most of the State environmental agencies. The commenters noted that States are equally concerned with minimizing potential risks to the environment, and that most have taken appropriate steps

in the development of their own siting criteria. The commenters indicated that requiring siting analyses in addition to those required by States and under the National Environmental Policy Act would be duplicative and would not enhance environmental protection. Other commenters supported the EPA's 1995 proposal to require an opportunity for public comments and a hearing on siting decisions.

In reviewing the 1995 proposed siting requirements and the comments received, the Agency is promulgating siting requirements as outlined in the CAA. The siting requirements promulgated today require the potential owner of an affected facility to prepare an analysis of the impacts of the affected facility. The analysis must consider air pollution control alternatives that minimize, on a site-specific basis, to the maximum extent practicable, potential risks to public health or the environment. In considering such alternatives, the analysis may consider costs, energy impacts, non-air environmental impacts, or any other factors related to the practicability of the alternatives. Analyses of facility impacts prepared to comply with State, local, or other Federal regulatory requirements may be used to satisfy the requirements of this section, as long as they include the consideration of air pollution control alternatives specified above. The owner or operator of the affected facility must complete and submit the siting requirements to EPA.

*C. Selection of MACT*

The EPA considered three regulatory options for adoption as the final standard for new HMIWI. These regulatory options are discussed in Appendix A of ''Hospital/Medical/Infectious Waste Incinerators: Background Information for Promulgated Standards and Guidelines—Summary of Public Comments and Responses'' (EPA–453/R–97–006b). As required by section 129(a)(2) of the CAA, the Administrator reviewed the emissions reductions achievable with each regulatory option and the cost, nonair quality environmental, and energy impacts of the regulatory options. Based on this review, the Administrator determined that the most cost-effective and achievable emission standards for promulgation are based on emission limits achievable with good combustion and a moderate efficiency wet scrubber for new small HMIWI, and good combustion and a combined dry/wet control system with carbon for new medium and large HMIWI. These final emissions standards reflect the MACT floor emission levels for new small and large HMIWI, but are more stringent than the MACT floor for new medium HMIWI.

The MACT floor for new small HMIWI was based on emission limits achievable through use of good combustion and a moderate efficiency wet scrubber. Consideration of the impact of this MACT floor indicates that few new small HMIWI are likely to be constructed due to the substantial increase in the cost of a new small HMIWI as a result of the moderate efficiency wet scrubber and the availability of alternative means of medical waste disposal.

One regulatory option more stringent than this MACT floor would reflect the use of good combustion and a high efficiency wet scrubber. Consideration of this option indicates that the nationwide impacts would be negligible, primarily because few new small HMIWI would be constructed (i.e., because of switching to alternative means of medical waste disposal). Where a typical new small HMIWI was constructed, however, the high efficiency wet scrubber would only reduce PM emissions by a small amount and would increase air pollution control costs by about 15 percent. As a result, the EPA established the MACT emission limitations for small new HMIWI based on the use of good combustion and a moderate efficiency wet scrubber (i.e., the MACT floor).

The MACT floor for new medium HMIWI was based on emission limits achievable through the use of good combustion and a combined dry/wet control system without activated carbon. On a national basis, because of switching to the use of alternative means of medical waste disposal, the addition of activated carbon to the combined dry/wet system results in negligible cost increase. For a typical new medium HMIWI, the addition of carbon would reduce emissions of dioxin significantly and would increase air pollution control costs by less than 4 percent. As a result, the EPA established the MACT emission limitations for new medium HMIWI based on good combustion and a combined dry/wet scrubber system with activated carbon.

The MACT floor for new large HMIWI was based on emission limits achievable through use of good combustion and a combined dry/wet scrubber with activated carbon. There is no air pollution control technology which could achieve lower emissions than this system. Consequently, EPA established the MACT emission limitations for new large HMIWI based on good combustion and a combined dry/wet scrubber system with activated carbon (i.e., the MACT floor).

*D. Impacts of the Standards*

There are a number of alternatives to onsite incineration of hospital waste and medical/infectious waste, including recycling or direct landfilling of non-infectious waste, and off-site commercial waste disposal or any of several waste disinfection technologies (e.g., steam autoclaving, microwave irradiation, macrowave irradiation, chemical treatment, thermal treatment, and biological treatment) for infectious waste. Many facilities that may have purchased an HMIWI in the absence of the HMIWI standards may find it more cost effective to dispose of their waste using one of these alternatives. As discussed in the June 1996 re-proposal, while further study is warranted, there appears to be no significant or substantial adverse economic, environmental, or health and safety issues associated with the increased use of the alternative waste treatment technologies.

In some cases, facilities that ''switch'' to alternative methods of waste disposal may further decrease their waste disposal costs by segregating their waste into infectious and noninfectious portions, and recycling or landfilling (rather than treating) their noninfectious waste. To account for facilities switching to alternative methods of waste disposal, the impacts of the standards were developed based on three compliance scenarios: no switching (scenario A), switching with waste segregation (scenario B), and switching without waste segregation (scenario C).

In the absence of the new standards, EPA projects that 85 new small HMIWI, 90 new medium HMIWI, 60 new large HMIWI, and 10 new commercial HMIWI would have been installed over the next five years. Scenario A preserves this assumption and estimates the costs of the additional control measures that would be required for these 245 new facilities to meet the standards at $36.2 million annually. The EPA believes that Scenario A is unrealistic and grossly overstates the national costs associated with the standards. Under Scenarios B and C, no new small or medium HMIWI are projected to be installed. Facilities that would have installed these units are assumed to find alternate methods of waste disposal. Under Scenario B, no new large HMIWI (other than commercial units) are projected to be installed either. The EPA believes that the total costs of the final standards for new sources in the fifth year after

implementation will fall somewhere between the $12.1 million/yr estimate for Scenario B and the $26.2 million/yr estimate for Scenario C.

Table 6 presents baseline emissions (i.e., emissions in the absence of the MACT emission standards) and the emissions that are expected to occur under the final MACT standard. A range of emissions is presented in Table 6 to account for the emissions that could occur under switching scenarios B and C as a result of the NSPS. Table 6 also presents the percent reduction in emissions achieved under the final MACT standard for new HMIWI.

TABLE 6.—BASELINE EMISSIONS, EMISSIONS IN THE FIFTH YEAR AFTER IMPLEMENTATION OF THE FINAL NSPS, AND EMISSIONS REDUCTION

[Metric Units]

| Pollutant, units | Baseline | Emissions under the final NSPS | Emissions reduction, percent |
|---|---|---|---|
| PM, Mg/yr | 28 | 2.1 to 4.1 | 85 to 92. |
| CO, Mg/yr | 14 | 6.5 to 14 | 0 to 52. |
| CDD/CDF, g/yr | 47 | 5.9 to 12 | 74 to 87. |
| TEQ CDD/CDF, g/yr | 1.1 | 0.14 to 0.28 | 74 to 87. |
| HCl, Mg/yr | 64 | 1.5 to 3.1 | 95 to 98. |
| $SO_2$, Mg/yr | 28 | 14 to 28 | 0 to 52. |
| $NO_X$, Mg/yr | 130 | 65 to 130 | 0 to 52. |
| Pb, Mg/yr | 0.39 | 0.031 to 0.06 | 85 to 92. |
| Cd, Mg/yr | 0.051 | $4.6\times10^{-3}$ to $8.9\times10^{-3}$ | 83 to 91. |
| Hg, Mg/yr | 0.21 | 0.056 to 0.12 | 45 to 74. |

To convert Mg/yr to ton/yr, multiply by 1.1. To convert g/yr to lb/yr, divide by 453.6.

As discussed further in Appendix A of ''Hospital/Medical/Infectious Waste Incinerators: Background Information for Promulgated Standards and Guidelines—Summary of Public Comments and Responses'' (EPA–453/R–97–006b), the EPA is not able to calculate a monetized value for most of these emission reductions. However, using ''Benefit-Cost Analysis of Selected NSPS for Particulate Matter'' as a basis, EPA has calculated a monetized value for reductions in PM emissions using an estimate of $6,075 (1993 dollars) per ton of PM. This yields annualized benefits of PM reductions for the standards ranging from $157,300 to $170,000 (1993 dollars).

As a result of the MACT standards for new HMIWI, industries that generate hospital waste and/or medical/infectious waste (i.e., hospitals, nursing homes, etc.) are expected to experience average price increases in the range of 0.00 to 0.16 percent, depending on the industry. These industries are expected to experience output and employment impacts in the range of 0.00 to 0.21 percent. In addition, the revenue impacts for these industries are expected to range from an increase of 0.05 percent to a decrease of 0.05 percent as a result of the standards. For hospitals, 0.03 percent is estimated as the price increase necessary to recover annual control costs. The expected average price increase for each hospital patient-day is expected to be less than 35 cents. The average price impact for the commercial medical waste incinerator industry is approximately a 4.1 percent increase in price.

Facilities with onsite HMIWI that are currently uncontrolled may experience impacts ranging from 0.03 to 1.70 percent, depending on the industry. For many of these facilities, the economic impacts of switching to an alternative method of waste disposal are much lower than the economic impacts of choosing to install emission control equipment. The decision to switch to an alternative method of waste disposal should preclude facilities from experiencing a significant economic impact. The impacts that would be incurred by medical/infectious waste generators that currently use an offsite waste incineration service range from 0.00 to 0.02 percent and are considered negligible impacts.

The option of switching to an alternative method of waste disposal will be an attractive option for many facilities that are considering the purchase of a new HMIWI and should preclude facilities from experiencing a significant economic impact. However, two types of HMIWI operators may not be able to switch to an alternative: commercial HMIWI operators, because their line of business is commercial incineration; and onsite HMIWI that burn a small amount of waste and are located far away from an urban area, because they may not have access to other methods of waste disposal. However only a few, if any, of the projected 10 new commercial HMIWI over the next 5 years, and at the most, only a few of the projected 85 new small onsite HMIWI over the next 5 years are likely to be significantly impacted by the regulation (under all three regulatory options). A ''significant impact'' does not necessarily imply a facility closure or the need to cancel plans to open up or expand a facility. For example, operators of small, remote onsite HMIWI may still have switching opportunities. As the commercial incineration industry continues to grow (with additional impetus being provided by the EG and NSPS), it is possible that services will be extended to remote, isolated areas that are currently not served. Onsite autoclaving is another possible treatment alternative. If a facility had planned to invest in a new HMIWI, it stands to reason that an onsite alternative technology of comparable cost would be affordable.

The economic impact analysis examines possible economic impacts that may occur in industries that will be directly affected by this regulation. Therefore, the analysis includes an examination of industries that generate hospital waste or medical/infectious waste or dispose of such waste. Secondary impacts such as subsequent impacts on APCD vendors and HMIWI vendors are not estimated due to data limitations. Air pollution control device vendors are expected to experience an increase in demand for their products due to the regulation. This regulation is also expected to increase demand for commercial HMIWI services. However, due to economies of scale, this regulation is expected to shift demand from smaller incinerators to larger incinerators. Therefore, small HMIWI vendors potentially may be adversely affected by the regulation. Lack of data on the above effects prevent

quantification of the economic impacts on these secondary sectors.

No increase in the total national usage of natural gas for combustion controls is expected to result from the final HMIWI standards. The total national usage of electrical energy for the operation of add-on control devices as a result of the final MACT standards is expected to increase by less than 9,800 megawatt hours per year (MW-hr/yr) (33.4 billion British thermal units per year [$10^9$ Btu/yr]). As discussed in the 1996 re-proposal, compared to the amount of energy used by health care facilities such as hospitals (approximately 2,460 $MMm^3$/yr of natural gas and 23.2 million MW-hr/yr of electricity), the increase in energy usage that results from implementation of the HMIWI emission standards is insignificant.

Less than 43,600 Mg/yr (48,000 tons/yr) of additional solid waste is expected to result from the adoption of the final MACT standards. As discussed in the 1996 re-proposal, compared to municipal waste, which is disposed in landfills at an annual rate of over 91 million Mg/yr (100 million tons/yr), the increase in solid waste from the implementation of the final HMIWI standards is insignificant.

Less than 3.3 million gallons of additional wastewater would be generated in the fifth year by HMIWI as a result of the final NSPS. This amount is the equivalent of wastewater produced annually by one small hospital. Therefore, when considering the wastewater produced annually at health care facilities nationwide, the increase in wastewater resulting from the implementation of the MACT emission standards for new HMIWI is insignificant.

## V. Emission Guidelines for Existing Sources

This section presents a summary of the final emission guidelines, including identification of the source category and pollutants being regulated, and presentation of the final emission limits and their associated performance testing, monitoring, recordkeeping and reporting requirements. This section discusses the most significant changes to the guidelines presented in the June 20, 1996 **Federal Register** document. Also discussed in this section is the rationale for the selection of MACT and a summary of the impacts of the final guidelines.

### *A. Summary of the Guidelines*

The final guidelines (subpart Ce) apply to each existing HMIWI for which construction commenced on or before June 20, 1996. Hospital/medical/infectious waste incinerators for which construction commenced after June 20, 1996 or modification commenced after March 16, 1998 are not subject to the final subpart Ce guidelines; they are considered new sources and are subject to the standards under subpart Ec (see section IV of this document).

A HMIWI is defined as any device that combusts any amount of medical/infectious waste or hospital waste. The terms ''medical/ infectious waste'' and ''hospital waste'' are discussed in section III.A and defined in § 60.51c. An incinerator is not subject to subpart Ce during periods when only pathological, low-level radioactive, or chemotherapeutic waste (all defined in § 60.51c) is burned provided that the owner or operator keeps records of the periods of time when only pathological, low-level radioactive, or chemotherapeutic waste is burned. Any unit required to have a permit under section 3005 of the Solid Waste Disposal Act is exempt from subpart Ce as are incinerators subject to subpart Cb, Ea, or Eb. Existing incinerators, processing operations, or boilers that co-fire hospital waste and/or medical/infectious waste with other fuels or wastes and combust 10 percent or less medical/infectious waste and hospital waste by weight (on a calendar quarter basis) are not subject to the emission limitations but must keep records of the amounts of each fuel and waste burned.

The HMIWI source category is divided into three subcategories based on waste burning capacity: small (≤200 lb/hr), medium (>200 to 500 lb/hr), and large (>500 lb/hr). Waste burning capacity is determined either by the maximum design capacity or by the ''maximum charge rate'' established during the most recent performance test. In other words, a source may change its size designation by establishing a ''maximum charge rate'' lower than its design capacity. For example, a ''medium'' unit with a design capacity of 250 lb/hr may establish a maximum charge rate of 200 lb/hr and be considered a ''small'' unit for purposes of the emission guidelines. Separate emission guidelines apply to each subcategory of existing HMIWI. A summary of the final emission limits for existing HMIWI is presented in Table 7. In addition to the emission limits presented in Table 7, all HMIWI are subject to a 10 percent stack opacity limitation. Stack opacity will be determined using EPA Reference Method 9.

TABLE 7.—SUMMARY OF PROMULGATED EMISSION LIMITS FOR EXISTING HMIWI

| Pollutant (test method) | Emission limits | | |
|---|---|---|---|
| | Small HMIWI | Medium HMIWI | Large HMIWI |
| Particulate matter (EPA Method 5 or Method 29). | 115 mg/dscm (0.05 gr/dscf) ..... | 69 mg/dscm (0.03 gr/dscf) ..... | 34 mg/dscm (0.015 gr/dscf). |
| Carbon monoxide (EPA Method 10 or Method 10B). | 40 ppmv ..... | 40 ppmv ..... | 40 ppmv. |
| Dioxins/furans (EPA Method 23) .. | 125 ng/dscm total CDD/CDF (55 gr/$10^9$ dscf) or 2.3 ng/dscm TEQ (1.0 gr/$10^9$ dscf). | 125 ng/dscm total CDD/CDF (55 gr/$10^9$ dscf) or 2.3 ng/dscm TEQ (1.0 gr/$10^9$ dscf). | 125 ng/dscm total CDD/CDF (55 gr/$10^9$ dscf). or 2.3 ng/dscm TEQ (1.0 gr/$10^9$ dscf). |
| Hydrogen chloride (EPA Method 26). | 100 ppmv or 93% reduction ..... | 100 ppmv or 93% reduction ..... | 100 ppmv or 93% reduction |
| Sulfur dioxide (testing not required). | 55 ppmv ..... | 55 ppmv ..... | 55 ppmv. |
| Nitrogen oxides (testing not required). | 250 ppmv ..... | 250 ppmv ..... | 250 ppmv. |
| Lead (EPA Method 29) ..... | 1.2 mg/dscm (0.52 gr/$10^3$ dscf) or 70% reduction. | 1.2 mg/dscm (0.52 gr/$10^3$ dscf) or 70% reduction. | 1.2 mg/dscm (0.52 gr/$10^3$ dscf) or 70% reduction. |
| Cadmium (EPA Method 29) ..... | 0.16 mg/dscm (0.07 gr/$10^3$ dscf) or 65% reduction. | 0.16 mg/dscm (0.07 gr/$10^3$ dscf) or 65% reduction. | 0.16 mg/dscm (0.07 gr/$10^3$ dscf) or 65% reduction. |

TABLE 7.—SUMMARY OF PROMULGATED EMISSION LIMITS FOR EXISTING HMIWI—Continued

| Pollutant (test method) | Emission limits | | |
|---|---|---|---|
| | Small HMIWI | Medium HMIWI | Large HMIWI |
| Mercury (EPA Method 29) ..... | 0.55 mg/dscm (0.24 gr/$10^3$ dscf) or 85% reduction. | 0.55 mg/dscm (0.24 gr/$10^3$ dscf) or 85% reduction. | 0.55 mg/dscm (0.24 gr/$10^3$ dscf) or 85% reduction. |

The emission limits for small existing HMIWI presented in Table 7 are more stringent than the MACT floor emission limits for small existing HMIWI. However, the final HMIWI guidelines contain alternative emission limits which are based on the MACT floor for small existing HMIWI that meet certain ''rural criteria.'' The ''rural criteria'' stipulates that an HMIWI is allowed to meet alternative emission limits if it is located at least 50 miles from the nearest Standard Metropolitan Statistical Area (SMSA) boundary and burns no more than 2,000 pounds of hospital waste and medical/infectious waste per week. The SMSA is defined by the Office of Management and Budget (OMB). For purposes of these emission guidelines, the list of areas comprising each SMSA as of June 30, 1993 will be used to determine whether a small HMIWI meets the ''rural criteria.'' The list of areas comprising each SMSA is presented in OMB Bulletin No. 93–17 entitled ''Revised Statistical Definitions for Metropolitan Areas.'' This document may be obtained by contacting the National Technical Information Services, 5285 Port Royal Road, Springfield, Virginia 22161, or by calling (703) 487–4650 and requesting document No. PB 93–192–664. This document is available for public inspection and copying at EPA's Air and Radiation Docket and Information Center (Docket A–91–61, item IV–J–125). See the **ADDRESSES** section at the beginning of this preamble for the telephone number and location of the Docket. This document has been approved for incorporation by reference by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The emission limits that correspond with these alternative guidelines for rural HMIWI are presented in Table 8. For further discussion of the ''rural criteria'' and rationale for the alternative emission limits for small existing HMIWI in rural areas, see section V.B ''Significant Issues and Changes'' (below).

TABLE 8.—SUMMARY OF ALTERNATIVE EMISSION LIMITS FOR SMALL EXISTING HMIWI THAT MEET THE RURAL CRITERIA

| Pollutant (Performance test method) | Emission limits |
|---|---|
| Particulate matter (EPA Method 5) ..... | 197 mg/dscm (0.086 gr/dscf). |
| Carbon monoxide (EPA Method 10 of 10B) ..... | 40 ppmv. |
| Dioxins/furans (EPA Method 23) ..... | 800 ng/dscm total CDD/CDF (350 gr/$10^9$ dscf) or 15 ng/dscm TEQ (6.6 gr/$10^9$ dscf). |
| Hydrogen chloride (testing not required) ..... | 3,100 ppmv. |
| Sulfur dioxide (testing not required) ..... | 55 ppmv. |
| Nitrogen oxides (testing not required) ..... | 250 ppmv. |
| Lead (testing not required) ..... | 10 mg/dscm (4.4 gr/$10^3$ dscf). |
| Cadmium (testing not required) ..... | 4 mg/dscm (1.7 gr/$10^3$ dscf). |
| Mercury (EPA Method 29) ..... | 7.5 mg/dscm (3.3 gr/$10^3$ dscf). |

Table 9 summarizes the additional requirements for existing HMIWI under the emission guidelines, including the operator training and qualification requirements, inspection requirements, compliance and performance testing requirements, monitoring requirements, and reporting and recordkeeping requirements. Table 10 summarizes the additional requirements under the emission guidelines for small existing HMIWI that meet the rural criteria. With the exception of the compliance and performance testing requirements and the inspection requirements, existing HMIWI that meet the small rural criteria are to comply with the same additional requirements as all other existing HMIWI. A summary of dates for compliance with the promulgated guidelines for existing HMIWI is presented in Table 11. These dates apply to all existing HMIWI.

TABLE 9.—SUMMARY OF ADDITIONAL REQUIREMENTS UNDER THE EMISSION GUIDELINES FOR EXISTING HMIWI

| Additional requirements |
|---|
| Operator Training and Qualification Requirements: |
| • Complete HMIWI operator training course. |
| • Qualify operators. |
| • Maintain information regarding HMIWI operating procedures and review annually. |
| Waste Management Plan: |
| • Prepare a waste management plan that identifies the feasibility and approach to separate certain components of a health care waste stream. |
| Compliance and Performance Testing Requirements: |
| • Conduct an initial performance test to determine compliance with the PM, CO, CDD/CDF, HCl, Pb, Cd, and Hg emission limits and opacity limit, and establish operating parameters. |
| • Conduct annual performance tests to determine compliance with the PM, CO, and HCl emission limits and opacity limit. |
| • Facilities may conduct performance tests for PM, CO, and HCl every third year if the previous three performance tests demonstrate that the facility is in compliance with the emission limits for PM, CO, and HCl. |

TABLE 9.—SUMMARY OF ADDITIONAL REQUIREMENTS UNDER THE EMISSION GUIDELINES FOR EXISTING HMIWI—Continued

| Additional requirements |
|---|
| Monitoring Requirements:<br>• Install and maintain equipment to continuously monitor operating parameters including secondary chamber temperature, waste feed rate, bypass stack, and APCD operating parameters as appropriate.<br>• Obtain monitoring data at all times during HMIWI operation.<br>Reporting and Recordkeeping Requirements:<br>• Maintain for 5 years records of results from the initial performance test and all subsequent performance tests, operating parameters, and operator training and qualification.<br>• Submit the results of the initial performance test and all subsequent performance tests.<br>• Submit reports on emission rates or operating parameters that have not been recorded or which exceeded applicable limits. |

NOTE: This table depicts the major provisions of the emission guidelines and does not attempt to show all requirements. The regulatory text of Subpart Ce should be relied upon for a full and comprehensive statement of the requirements of the final guidelines.

TABLE 10.—SUMMARY OF ADDITIONAL REQUIREMENTS UNDER THE EMISSION GUIDELINES FOR EXISTING HMIWI THAT MEET THE RURAL CRITERIA

| Additional requirements |
|---|
| Operator Training and Qualification Requirements:<br>• Complete HMIWI operator training course.<br>• Qualify operators.<br>• Maintain information regarding HMIWI operating procedures and review annually.<br>Inspection Requirements:<br>• Provide for an annual equipment inspection of the designated facility.<br>Waste Management Plan:<br>• Prepare a waste management plan that identifies the feasibility and approach to separate certain components of a health care waste stream.<br>Compliance and Performance Testing Requirements:<br>• Conduct an initial performance test to determine compliance with the PM, CO, CDD/CDF, and Hg emission limits and opacity limit, and establish operating parameters.<br>• Conduct annual tests to determine compliance with the opacity limit.<br>Monitoring Requirements:<br>• Install and maintain equipment to continuously monitor operating parameters including secondary chamber temperature, waste feed rate, bypass stack, and APCD operating parameters as appropriate.<br>• Obtain monitoring data at all times during HMIWI operation.<br>Reporting and Recordkeeping Requirements:<br>• Maintain for 5 years records of results from the initial performance test and all subsequent performance tests, operating parameters, inspections, any maintenance, and operator training and qualification.<br>• Submit the results of the initial performance test and all subsequent performance tests.<br>• Submit reports on emission rates or operating parameters that have not been recorded or which exceeded applicable limits. |

NOTE: This table depicts the major provisions of the emission guidelines and does not attempt to show all requirements. The regulatory text of Subpart Ce should be relied upon for a full and comprehensive statement of the requirements of the final guidelines.

TABLE 11.—COMPLIANCE TIMES UNDER THE EMISSION GUIDELINES FOR EXISTING HMIWI

| Requirement | Compliance time |
|---|---|
| State Plan submittal | Within 1 year after promulgation of EPA emission guidelines. |
| Operator training and qualification requirements. | Within 1 year after EPA approval of State Plan. |
| Inspection requirements | Within 1 year after EPA approval of State Plan. |
| Initial compliance test | Within 1 year after EPA approval of State plan or up to 3 years after EPA approval of State plan if the source is granted an extension. |
| Repeat performance test | Within 12 months following initial compliance test and annually thereafter. |
| Parameter monitoring | Continuously, upon completion of initial compliance test. |
| Recordkeeping | Continuously, upon completion of initial compliance test. |
| Reporting | Annually, upon completion of initial compliance test; semiannually, if noncompliance. |

*B. Significant Issues and Changes*

This section discusses the most significant changes to the guidelines made following the June 20, 1996 **Federal Register** document. Further discussion of these changes as well as other comments and responses regarding the emission guidelines are provided in ''Hospital/Medical/Infectious Waste Incinerators: Background Information for Promulgated Standards and Guidelines—Summary of Public Comments and Responses'' (EPA–453/R–97–006b).

As discussed in the 1996 re-proposal, the MACT floor for small existing HMIWI was based on emission limits achievable through use of good combustion alone (i.e., without add-on control). The EPA presented regulatory options more stringent than the MACT floor for small existing HMIWI in the 1996 re-proposal and stated that it had no inclination as to which regulatory

option might be selected for the final emission guidelines for small HMIWI. The EPA solicited public comment on the available regulatory options for the guidelines for small existing HMIWI.

During the public comment period, the EPA received several comments containing suggestions for the final emission guidelines for small existing HMIWI. A number of commenters requested that the emission guidelines for small existing HMIWI be based on the MACT floor. Other commenters requested that the guidelines for small HMIWI require small HMIWI in urban locations to meet emission guidelines more stringent than the MACT floor and allow small HMIWI in rural locations to meet the MACT floor emission limits. These commenters noted that cost-effective alternatives to onsite incineration may not be available to facilities operating small HMIWI in rural locations and that emission limits based on wet scrubbers would cause these facilities financial hardship. Other commenters contended that emission limits for small incinerators consistent with no more than good combustion would result in largely uncontrolled emissions, and would encourage medium-sized units to change their size designation to small by burning less waste per hour while operating more hours per day. These commenters stated that there are cost-effective alternatives to incineration and requested that small existing HMIWI be subject to emission limits consistent with wet scrubbers.

Guidelines for small existing HMIWI based on the use of good combustion and low efficiency wet scrubbing could cause the cost of waste disposal to more than double for facilities that install the equipment necessary to meet the emission guidelines. Even guidelines based on the MACT floor (good combustion alone) would cause a significant increase in costs for such facilities. The EPA's cost projections show that the costs of retrofitting small existing HMIWI to meet the MACT floor would be about $18 million annually, while the cost of going beyond the floor (guidelines based on low efficiency wet scrubbers) for the estimated 1,025 small HMIWI that do not meet the ''remote'' criteria (discussed later) would be an additional $47 million. However, as noted by commenters and observed by States that have implemented stringent HMIWI regulations, there are a number of cost-effective alternatives to onsite incineration for most facilities that operate small HMIWI. Therefore, many health care facilities operating small HMIWI could switch to alternative means of waste disposal if the emission guidelines are based on the use of good combustion and low efficiency wet scrubbing. In fact, EPA's modeling projects that most existing facilities, except those meeting the ''remote'' criteria, would find it more economical to switch to alternative means of waste disposal than to retrofit their small incinerators even to meet the MACT floor, and virtually all such facilities would switch rather than retrofit small incinerators with low efficiency wet scrubbers. Under the switching scenario, the costs for non-''remote'' small facilities range from $6 to $13 million for guidelines based on the MACT floor, and from $6 to $20 million for guidelines based on low efficiency wet scrubbers. In addition, by making the guidelines for small existing HMIWI only slightly less stringent than those for medium existing HMIWI (the guidelines for small existing HMIWI are based on good combustion and low efficiency wet scrubbers, while those for medium existing HMIWI are based on good combustion and moderate efficiency wet scrubbers), the selected option removes any strong incentive for medium existing facilities to reclassify themselves as small in order to escape more stringent guidelines. The result is that, under the selected option, most medium existing facilities will also switch to alternative means of waste disposal. Unlike the small facilities, most of these medium HMIWI would have found it economical to continue operating if they could have reclassified themselves as small and been required to meet emission limits based on good combustion alone. Thus, most of the emission reduction benefits from going beyond the MACT floor for small existing HMIWI actually come from these medium HMIWI that switch to alternative waste disposal rather than operating as small units subject to emission limits based on good combustion alone (the MACT floor). The additional costs to this group under the switching scenario of going beyond the floor range from $4 to $30 million annually.

While EPA's objective is to adopt MACT emission guidelines that fulfill the requirements of section 129 of the CAA, and not to cause the shutdown of most existing small and medium HMIWI, the EPA believes that the replacement of poorly controlled incinerators with cost effective alternatives that significantly reduce toxic emissions is an appropriate outcome. From a national perspective, guidelines for small existing HMIWI based on good combustion and low efficiency wet scrubbing (and the switching to alternative waste disposal options that EPA believes will result) will minimize emissions of PM, dioxin, acid gases, and metals from small and medium existing HMIWI at a relatively low cost due to the availability of alternative means of waste treatment. As a result, the final emission guidelines for small HMIWI are based on emission limits achievable through the use of good combustion and low efficiency wet scrubbers. These emission limits are more stringent than the MACT floor for small HMIWI.

As some commenters have pointed out, alternative means of medical waste treatment may not be available at a reasonable cost to some facilities that operate small HMIWI in rural or remote locations. Facilities that operate small HMIWI in remote locations could be faced with adverse impacts if required to meet emission limits associated with good combustion and low efficiency wet scrubbing. Therefore, the final emission guidelines subcategorize facilities for purposes of establishing MACT standards based on the location of the facility and the amount of waste burned. The EPA established MACT standards at the respective MACT floors for facilities that meet certain ''rural criteria;'' which are achievable through the use of good combustion alone. The EPA set MACT standards for all other small HMIWI more stringent than the MACT floors.

The basis for this subcategorization approach is found in section 129(a)(2), which states: ''The Administrator may distinguish among classes, types * * * and sizes of units within a category in establishing such standards.'' This language gives EPA broad discretion to distinguish among units in a category in establishing subcategories, including establishing subcategories based on a unit's location. See *Davis County Solid Waste Management & Energy Recovery Special Services District* v. *EPA*, 101 F.3d 1395, 1405 n.11 (D.C. Cir. 1996), *amended* 108 F.3d 1454 (D.C. Cir. 1997). As discussed above, the EPA believed it was appropriate to subcategorize for purposes of establishing MACT standards, where all MACT standards were at least as stringent as the respective MACT floors.

In the 1996 re-proposal, the EPA discussed the option of adopting emission guidelines with criteria for small existing HMIWI located in rural areas to meet requirements—on a case by case basis—based on the use of good combustion alone. The EPA solicited public comment on this option and on what criteria could be associated with this option to determine if a facility may be faced with cost impacts that warrant special consideration with regard to the emission guidelines.

Following the 1996 re-proposal, the EPA received several comments regarding possible ''rural criteria'' that may be used if the final guidelines allow rural HMIWI to meet less stringent emission limits. Some commenters suggested that rural criteria be based on distance from a SMSA or population density. Other commenters recommended a weekly limit on amount of waste burned in the small HMIWI and a requirement that no more than 10 percent of the waste burned in the small HMIWI is from an outside facility. Other commenters suggested that facilities operating small rural HMIWI should be required to demonstrate that no alternatives to onsite incineration are available at a reasonable cost. Finally, other commenters suggested considering ambient air quality, good engineering practice stack height, and risk analysis as part of the rural criteria.

The purpose of the rural criteria is to further define those facilities operating small HMIWI in remote areas that may have fewer cost-effective options for waste disposal; in which case, emission guidelines based on wet scrubbers could cause financial hardship. It is difficult to determine precisely which HMIWI have limited waste disposal options, and it is difficult to establish a universal set of criteria that could quantify ''hardship.'' All of the suggestions submitted by commenters with regard to the rural criteria for small HMIWI were considered. However, many of the suggestions would be very difficult to define or implement. Consequently, the rural criteria examined focused on (1) distance from a SMSA, and (2) amount of waste burned per week. The combination of small size, distance from an SMSA, and small amount of waste burned are the most likely indications that commercial services are not available for a reasonable cost.

Distance criteria ranging from 25 to 150 miles from an SMSA in conjunction with weekly waste burning limits ranging from 500 to 3,300 lb/wk were examined to determine the appropriate rural criteria. The final ''rural criteria'' selected for small existing HMIWI stipulates that: (1) The facility must be located at least 50 miles from the nearest SMSA boundary and (2) the HMIWI operated by the facility may not be used to burn more than 2,000 lb/wk. The 2,000 pound per week criterion was suggested by commenters; focuses the option for less stringent requirements on the smallest HMIWI; and reflects a sufficient quantity of waste to ensure that commercial services are available. The 50 mile criterion added to the 2,000 lb/wk criterion provides the less stringent requirements for less than 10 percent of small HMIWI (over 90 percent of small HMIWI would remain subject to guidelines based on wet scrubbers). It is very likely that commercial services are available within 50 miles of an SMSA, regardless of the amount of waste to be picked up.

Small units with good combustion alone are not left ''uncontrolled.'' Good combustion reduces emissions of PM, CO, and dioxin/furan, and these units remain subject to operator training requirements. Small HMIWI operating with good combustion alone are also required to reduce Hg emissions through pollution prevention. The guidelines also include requirements for routine inspection and maintenance to ensure good combustion. Based on EPA's assessment of costs and other impacts, these less stringent requirements will, themselves, raise the cost of incineration such that alternatives, if available, are likely to be less expensive. In other words, where alternatives are available, guidelines based on good combustion alone are likely to result in switching. Under the MACT guidelines, less than one percent of the waste burned in existing HMIWI will be burned in small rural HMIWI with good combustion controls alone. The final guidelines result in substantial reductions in emissions from the HMIWI source category as a whole. The promulgated emission guidelines for small HMIWI are consistent with section 129 because they reflect the maximum degree of reduction in emissions that can be achieved by small existing HMIWI while avoiding detrimental cost impacts to facilities operating small ''remote'' HMIWI.

### *C. Selection of MACT*

The EPA considered six regulatory options for adoption as the final guidelines for existing HMIWI. These regulatory options are discussed in Appendix B of ''Hospital/Medical/Infectious Waste Incinerators: Background Information for Promulgated Standards and Guidelines—Summary of Public Comments and Responses'' (EPA–453/R–97–006b). As required by section 129(a)(2) of the CAA, the Administrator reviewed the emissions reductions achievable with each regulatory option and the cost, nonair quality environmental, and energy impacts of the regulatory options. Based on this review, the Administrator determined that the most cost effective and achievable emission guidelines for promulgation are based on emission levels achievable with good combustion and a low efficiency wet scrubber for most small existing HMIWI; good combustion and a moderate efficiency wet scrubber for medium existing HMIWI; and good combustion and a high efficiency wet scrubber for large existing HMIWI. The promulgated emission guidelines allow small HMIWI that meet certain ''rural criteria'' to meet emission limits achievable with good combustion alone.

The EPA concluded that MACT for most small units should reflect emission limits achievable with good combustion and a low efficiency wet scrubber because the reductions in emissions are substantial, while the cost and economic impacts for most small HMIWI appear minimal. Compared to emission limits achievable with good combustion and low efficiency wet scrubbers, emission limits based on the use of good combustion and moderate or high efficiency wet scrubbers would increase the capital control costs for facilities operating small HMIWI by 15 to 42 percent and would only slightly decrease the emissions of PM from small HMIWI. As a result, good combustion and moderate or high efficiency wet scrubbers were not further considered in the selection of MACT for small HMIWI.

The MACT floor for medium existing HMIWI appears to require the use of good combustion and a moderate efficiency wet scrubber. One regulatory option more stringent than this MACT floor would reflect the use of good combustion and a high efficiency wet scrubber. On a nationwide basis, while this more stringent option would result in a relatively small cost increase, it would also result in only a small decrease in PM emissions. For a typical facility operating a medium HMIWI that installed or upgraded an existing wet scrubber to a high efficiency wet scrubber, air pollution control costs would increase by about 15 to 25 percent. As a result, EPA concluded that the MACT emission limitations for medium existing HMIWI based on the use of good combustion and a moderate efficiency wet scrubber (i.e., the MACT floor) are the most cost effective and achievable. These emission limitations could also be achieved using a dry scrubber with activated carbon.

The MACT floor for large existing HMIWI appears to require the use of good combustion and a high efficiency wet scrubber. Regulatory options more stringent than this MACT floor were not considered for large HMIWI for the reasons discussed below. As a result, EPA concluded that MACT emission limitations for large existing HMIWI based on the use of good combustion and a high efficiency wet scrubber (i.e., the MACT floor) are the most cost

effective and achievable. These emission limitations could also be achieved using a dry scrubber with activated carbon.

The MACT emission limitations for medium and large existing HMIWI were structured so that either a dry scrubber or a wet scrubber could be used to achieve the emission limits. The emission limitations were not based on the use of dry scrubbers exclusively or wet scrubbers exclusively because a dry scrubber typically costs much more than a wet scrubber, and a dry scrubber with activated carbon would result in only a very small additional reduction in dioxin, Pb, and Cd emissions. Furthermore, for existing HMIWI already equipped with wet scrubbers, replacing a wet scrubber with a dry scrubber would be extremely expensive. Similarly, for existing HMIWI already equipped with dry scrubbers, replacing the dry scrubber with a wet scrubber would be extremely expensive. Guidelines based on the use of combined dry/wet scrubbing systems were not considered for medium and large existing HMIWI because such control systems are very expensive and result in only small additional reductions in emissions.

*D. Impacts of the Guidelines*

There are a number of alternatives to onsite incineration of hospital waste and medical/infectious waste, including recycling or direct landfilling of non-infectious waste, and off-site commercial waste disposal or any of several waste disinfection technologies (e.g., steam autoclaving, microwave irradiation, macrowave irradiation, chemical treatment, thermal treatment, and biological treatment) for infectious waste. Many facilities that currently operate onsite HMIWI may find it more cost effective to dispose of their waste using one of these alternatives. As discussed in the June 1996 re-proposal, while further study is warranted, there appears to be no significant or substantial adverse economic, environmental, or health and safety issues associated with the increased use of the alternative waste treatment technologies.

In some cases, facilities that ''switch'' to alternative methods of waste disposal may further decrease their waste disposal costs by segregating their waste into infectious and noninfectious portions, and recycling or landfilling (rather than treating) their noninfectious waste. To account for facilities switching to alternative methods of waste disposal, the impacts of the guidelines were developed based on three compliance scenarios: no switching (scenario A), switching with waste segregation (scenario B), and switching without waste segregation (scenario C).

The EPA estimates that there are approximately 1,139 existing small HMIWI, 692 existing medium HMIWI, 463 existing large HMIWI, and 79 existing commercial HMIWI in operation today. Scenario A preserves this assumption and estimates the costs of the additional control measures that would be required for these 2,373 existing facilities to meet the guidelines at $172 million annually. The EPA believes that Scenario A is unrealistic and grossly overstates the national costs associated with the guidelines. Under Scenarios B and C, 93 to 100 percent of existing small ''non-remote'' HMIWI, 60 to 95 percent of existing medium HMIWI, and as many as 35 percent of existing large HMIWI are expected to cease operation. All 79 commercial units and 114 small units meeting the ''remote'' criteria are assumed to remain in operation. Facilities that cease operation are assumed to find alternate methods of waste disposal. The EPA believes that the total costs of the final guidelines for existing sources will fall somewhere between the $59 million/yr estimate for Scenario B and the $120 million/yr estimate for Scenario C.

Table 12 presents baseline emissions (i.e., emissions in the absence of the MACT emission guidelines) and the range of emissions that are expected to occur under the final MACT guidelines. A range of emissions is presented in Table 12 to account for the emissions that could occur under switching scenarios B and C as a result of the guidelines. Table 12 also presents the percent reduction in emissions achieved under the final MACT guidelines for existing HMIWI.

TABLE 12.—BASELINE EMISSIONS, EMISSIONS AFTER IMPLEMENTATION OF THE FINAL EMISSION GUIDELINES, AND EMISSIONS REDUCTION

[Metric Units]

| Pollutant, units | Baseline | Emissions under the final emission guidelines | Emissions reduction, percent |
|---|---|---|---|
| PM, Mg/yr | 940 | 72 to 120 | 88 to 92. |
| CO, Mg/yr | 460 | 82 to 120 | 75 to 82. |
| CDD/CDF, g/yr | 7,200 | 210 to 310 | 96 to 97. |
| TEQ CDD/CDF, g/yr | 150 | 5 to 7 | 95 to 97. |
| HCl, Mg/yr | 5,700 | 130 to 140 | 98. |
| $SO_2$, Mg/yr | 250 | 170 to 250 | 0 to 30. |
| $NO_X$, Mg/yr | 1,200 | 810 to 1,200 | 0 to 30. |
| Pb, Mg/yr | 11 | 1.4 to 2.2 | 80 to 87. |
| Cd, Mg/yr | 1.2 | 0.19 to 0.30 | 75 to 84. |
| Hg, Mg/yr | 15 | 0.8 to 1.1 | 93 to 95. |

To convert Mg/yr to ton/yr, multiply by 1.1. To convert g/yr to lb/yr, divide by 453.6.

As discussed further in Appendix B of ''Hospital/Medical/Infectious Waste Incinerators: Background Information for Promulgated Standards and Guidelines—Summary of Public Comments and Responses'' (EPA–453/R–97–006b), the EPA is not able to calculate a monetized value for most of these emission reductions. However, using ''Benefit-Cost Analysis of Selected NSPS for Particulate Matter'' as a basis, EPA has calculated a monetized value for reductions in PM emissions using an estimate of $6,075 (1993 dollars) per ton of PM. This yields annualized benefits of PM reductions for the guidelines ranging from $5.5 million to $5.8 million (1993 dollars).

As a result of the MACT guidelines for existing HMIWI, industries that generate hospital waste and/or medical/infectious waste (i.e., hospitals, nursing homes, etc.) are expected to experience average price increases in the range of 0.00 to 0.14 percent, depending on the

industry. These industries are expected to experience output and employment impacts in the range of 0.00 to 0.18 percent. In addition, the revenue impacts for these industries are expected to range from an increase of 0.05 percent to a decrease of 0.04 percent as a result of the guidelines. For hospitals, 0.03 percent is the estimated price increase necessary to recover annual control costs. The expected average price increase for each hospital patient-day is expected to be less than 30 cents. The average price impact for the commercial HMIWI industry is approximately a 2.6 percent increase in price.

Facilities with onsite HMIWI that are currently uncontrolled may experience impacts ranging from 0.03 to 1.83 percent, depending on the industry. For many of these facilities, the economic impacts of switching to an alternative method of waste disposal are much lower than the economic impacts of choosing to install emission control equipment. The decision to switch to an alternative method of waste disposal should preclude any facilities from experiencing a significant economic impact. The impacts that would be incurred by medical/infectious waste generators that currently use an offsite waste incineration service range from 0.00 to 0.02 percent and are considered negligible impacts.

The option of switching to an alternative method of waste disposal will be an attractive option for many facilities that currently operate onsite HMIWI and should preclude most facilities from experiencing a significant economic impact. However, two types of HMIWI operators may not be able to switch to an alternative: commercial HMIWI operators, because their line of business is commercial incineration; and small, rural, remote HMIWI, which may not have access to alternative waste disposal methods. For commercial HMIWI operators, only three of the 59 facilities operating the 79 commercial HMIWI in the HMIWI inventory were found to be significantly impacted by the regulation. As discussed in ''Hospital/Medical/Infectious Waste Incinerators: Background Information for Promulgated Standards and Guidelines—Analysis of Economic Impacts for Existing Sources'' (EPA–453/R–97–007b), commercial HMIWI are considered to be significantly impacted if the price impact (i.e., the price increase that would be necessary to recover compliance costs) on an individual facility exceeds the market price increase (2.62 percent) by more than 2 percentage points (i.e., above 4.6 percent). Price increases at these three facilities are calculated as 9.58 percent, 11.13 percent, and 18.36 percent. These facilities may not have to raise their prices this much to remain profitable, since they are completely uncontrolled in the baseline and therefore may currently enjoy a cost advantage over their competitors (most of which are at least partially controlled in the baseline). Also, demand may increase as a result of switching away from onsite incineration. In this latter case, increased revenues (which could offset control costs) may result in one of two ways: either by allowing a larger increase in price, or by providing an increase in the amount of waste coming to the facility (i.e., increased capacity utilization). Impacts are not significant for small, rural, remote HMIWI operators because the final guidelines allow good combustion alone where alternatives to onsite incineration might be unavailable.

The economic impact analysis examines possible economic impacts that may occur in industries that will be directly affected by this regulation. Therefore, the analysis includes an examination of industries that generate hospital waste or medical/infectious waste or dispose of such waste. Secondary impacts such as subsequent impacts on air pollution device vendors and HMIWI vendors are not estimated due to data limitations. Air pollution control device vendors are expected to experience an increase in demand for their products due to the regulation. This regulation is also expected to increase demand for commercial HMIWI services. However, due to economies of scale, this regulation is expected to shift demand from smaller incinerators to larger incinerators. Therefore, small HMIWI vendors potentially may be adversely affected by the regulation. Lack of data on the above effects prevent quantification of the economic impacts on these secondary sectors.

The total national usage of natural gas for HMIWI combustion controls is expected to increase by less than 16.6 million cubic meters per year ($MMm^3$/yr) (586 million cubic feet per year [$10^6$ $ft^3$/yr]). The total national usage of electrical energy for the operation of add-on control devices as a result of the final MACT guidelines is expected to increase by less than 259,000 megawatt hours per year (MW-hr/yr) (883 billion British thermal units per year [$10^9$ Btu/yr]). As discussed in the 1996 re-proposal, compared to the amount of energy used by health care facilities such as hospitals (approximately 2,460 $MMm^3$/yr of natural gas and 23.2 million MW-hr/yr of electricity) the increase in energy usage that results from implementation of the HMIWI emission guidelines is insignificant.

Less than 211,000 Mg/yr (233,000 tons/yr) of additional solid waste is expected to result from the adoption of the final MACT guidelines. As discussed in the 1996 re-proposal, compared to municipal waste, which is disposed in landfills at an annual rate of over 91 million Mg/yr (100 million tons/yr), the increase in solid waste from the implementation of the final HMIWI guidelines is insignificant.

Less than 198 million gallons of additional wastewater would be generated by HMIWI as a result of the final emission guidelines. This amount is the equivalent of wastewater produced annually by four large hospitals. Therefore, when considering the wastewater produced annually at health care facilities nationwide, the increase in wastewater resulting from the implementation of the MACT emission guidelines for existing HMIWI is insignificant.

## VI. Administrative Requirements

This section addresses the following administrative requirements: Docket, Paperwork Reduction Act, Executive Orders 12866 and 12875, Unfunded Mandates Reform Act, Regulatory Flexibility Act, Small Business Regulatory Enforcement Fairness Act, and Clean Air Act Procedural Requirements.

### *A. Docket*

The docket is an organized and complete file of all the information considered in the development of this rulemaking. The principal purposes of the docket are: (1) To allow interested parties to identify and locate documents so that they can effectively participate in the rulemaking process; and (2) to serve as the record in case of judicial review, except for interagency review material. The docket number for this rulemaking is A–91–61. Information on how to obtain documents from the docket was provided in the **ADDRESSES** section at the beginning of this preamble.

### *B. Paperwork Reduction Act*

The information collection requirements in this rule have been submitted for approval to OMB under the Paperwork Reduction Act. An Information Collection Request (ICR) document has been prepared by EPA (ICR No. 1730.02) and a copy may be obtained from Sandy Farmer, OPPE Regulatory Information Division; U. S. Environmental Protection Agency (2136); 401 M St., S.W.; Washington, DC 20460 or by calling (202) 260–2740.

This ICR document is also available electronically via the Internet. See the **SUPPLEMENTARY INFORMATION** section of this preamble for information on accessing this document via the Internet.

The information required to be collected by this rule is necessary to identify the regulated entities who are subject to the rule and to ensure their compliance with the rule. The recordkeeping and reporting requirements are mandatory and are being established under authority of sections 114 and 129(c) of the CAA. All information submitted as part of a report to the Agency for which a claim of confidentiality is made will be safeguarded according to the Agency policies set forth in Title 40, Chapter 1, part 2, subpart B—Confidentiality of Business Information (see 40 CFR Part 2; 41 FR 36902, September 1, 1976, amended by 43 FR 39999, September 28, 1978; 43 FR 42251, September 28, 1978; 44 FR 17674, March 23, 1979).

The Agency predicts that somewhere between 2 and 14 new HMIWI will be constructed each year after implementation of the NSPS. The total annual reporting and recordkeeping burden summarized in the ICR document for this collection averaged over the first 3 years of the NSPS application to new HMIWI is estimated to be about 14,106 person hours per year if 14 new HMIWI are constructed each year. This burden estimate includes the time needed to review instructions, search existing data sources, gather and maintain the data needed, and complete and review the collection of information. Efforts were made to reduce the burden on facilities installing new HMIWI by allowing them to: (1) Monitor operating parameters rather than continuously monitor emissions using CEMS; (2) test emissions once every 3 years instead of annually if they demonstrate that they consistently meet the emissions requirements; (3) retest emissions of PM, CO, and HCl rather than emissions of all pollutants; and (4) submit reports semiannually (or annually if no exceedances occur) rather than quarterly as was originally proposed.

Comments on the ICR document are requested, including the Agency's need for the information presented in this ICR document, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden. Send comments on the ICR to the Director, OPE Regulatory Information Division; U. S. Environmental Protection Agency (2136); 401 M St. S.W.; Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th St. N.W.; Washington, DC 20503; marked ''Attention: Desk Officer for EPA.'' Include the ICR number in any correspondence. Since the OMB is required to make a decision concerning the ICR between 30 and 60 days after today's request for comment, a comment to OMB is best assured of having its full effect if OMB receives it by October 15, 1997. The EPA will publish a response to OMB and public comments on the information collection requirements contained in this document in a subsequent **Federal Register** document.

*C. Executive Order 12866*

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the EPA must determine whether a regulatory action is ''significant,'' and therefore, subject to OMB review and the requirements of the Executive Order. The Order defines ''significant'' regulatory action as one that is likely to lead to a rule that may:

1. Have an annual effect on the economy of $100 million or more, or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or Tribal governments or communities;

2. Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

3. Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

4. Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Pursuant to the terms of Executive Order 12866, the EPA considers these promulgated standards and guidelines to be ''significant.'' As such, this action was submitted to OMB for review. Changes made in response to OMB suggestions or recommendations are documented in the public docket for this rulemaking.

Also, in accordance with the provisions of the Executive Order regarding ''significant regulatory actions,'' EPA has prepared assessments of the costs and benefits of the rule and of ''potentially effective and reasonably feasible alternatives.'' These assessments are contained in four documents: ''Hospital/Medical/Infectious Waste Incinerators: Background Information for Promulgated Standards and Guidelines—Analysis of Economic Impacts for Existing Sources'' (EPA–453/R–97–007b), ''Hospital/Medical/Infectious Waste Incinerators: Background Information for Promulgated Standards and Guidelines—Analysis of Economic Impacts for New Sources'' (EPA–453/R–97–008b), ''Hospital/Medical/Infectious Waste Incinerators: Background Information for Promulgated Standards and Guidelines—Regulatory Impact Analysis for New and Existing Sources'' (EPA–453/R–07-009b), and Appendices A and B of ''Hospital/Medical/Infectious Waste Incinerators: Background Information for Promulgated Standards and Guidelines—Summary of Public Comments and Responses'' (EPA–453/R–970–006b). The selected options for both the New Source Performance Standards and the Emissions Guidelines are identified as regulatory option 2 in these documents. Several other options, both more and less stringent than the selections options, are also analyzed. A summary of these analyses is included below in Section VI.D.2 of this preamble.

*D. Unfunded Mandates Reform Act*

Under section 202 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), signed into law on March 22, 1995, the EPA must prepare a statement to accompany any rule where the estimated costs to State, local, or Tribal governments, or to the private sector, will be $100 million or more in any 1 year. Section 203 requires the EPA to establish a plan for informing and advising any small governments that may be significantly impacted by the rule. Under section 205(a), the EPA must select the ''least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule'' and is consistent with statutory requirements. The EPA has complied with section 205 of the Unfunded Mandates Act, by promulgating a rule that is the most cost-effective alternative for regulation of these sources that meets the statutory requirements under the Clean Air Act.

The unfunded mandates statement under section 202 must include: (1) A citation of the statutory authority under which the rule is proposed, (2) an assessment of the costs and benefits of the rule including the effect of the mandate on health, safety and the environment, and the Federal resources available to defray the costs, (3) where feasible, estimates of future compliance costs and disproportionate impacts upon particular geographic or social segments of the nation or industry, (4) where relevant, an estimate of the effect on the national economy, and (5) a description of the EPA's consultation with State, local, and Tribal officials.

Since this rule is estimated to impose costs to the private sector and government entities in excess of $100 million per year, it is considered a significant regulatory action. Therefore, EPA has prepared the following statement with respect to Sections 202 through 205 of the Unfunded Mandates Act.

1. Statutory Authority

This rule establishes emission guidelines for existing HMIWI and standards of performance for new HMIWI pursuant to sections 111 and 129 of the CAA. Section 129(a)(2) requires the Administrator to promulgate standards for new solid waste incinerator units and emission guidelines for existing units that ''reflect the maximum degree of reduction in emissions of air pollutants listed under section (a)(4) that the Administrator, taking into consideration the cost of achieving such emission reduction, and any non-air quality health and environmental impacts and energy requirements, determines is achievable for new or existing units in each category. The Administrator may distinguish among classes, types, and sizes of units within a category in establishing such standards . . .'' This is commonly referred to as maximum achievable control technology, or MACT. Section 129(a)(2) further defines a minimum level of stringency that can be considered for MACT standards—commonly referred to as the MACT floor—which for new units, is the level of control achieved by the best controlled similar unit, and for existing units, is the level of control achieved by the average of the best performing 12 percent of units in the category.

Control technologies and their performance are discussed in the June 1996 re-proposal (61 FR 31736, June 20, 1996). For the promulgated standards and guidelines, EPA divided the HMIWI population into three size categories which reflect technical differences in HMIWI design: small (≤200 lb/hr), medium (>200 to ≤500 lb/hr), and large (>500 lb/hr). The EPA considered emission reduction, costs, and energy impacts, as required by the statutory language of section 111 of the CAA, in selecting the promulgated MACT standards and guidelines. The promulgated standards and guidelines achieve a significant reduction in HMIWI emissions as outlined in sections IV.D and V.D and in section 2 ''Social Costs and Benefits'' (below). The cost impacts of the standards and guidelines are presented in section 2 ''Social Costs and Benefits'' (below). Consultations with the public entities and affected industries as required by the Unfunded Mandates Act are described in section 4, ''Consultation with Government Officials'' (below). The energy impacts are discussed in sections IV.D and V.D of this notice. Regarding EPA's compliance with section 205(a), the EPA considered a reasonable number of alternatives which are discussed in section 2.b, ''Regulatory Alternatives Considered'' (below).

2. Social Costs and Benefits

This assessment of the costs and benefits to State, local, and Tribal governments of the NSPS and guidelines is based on the regulatory impact analysis (EPA–453/R–97–009b). Measuring the social costs of the rule requires identification of the affected entities by ownership (public or private), consideration of regulatory alternatives, calculation of the regulatory compliance costs for each affected entity, and assessment of the market implications of the additional pollution control costs. Calculating the social benefits of the NSPS and guidelines requires estimating the anticipated reductions in emissions at HMIWI due to regulation, identification of the harmful effects of exposure to HMIWI emissions, and valuing the expected reductions in these damages to society.

a. *Affected Entities.* Approximately 2,400 HMIWI are estimated to be in operation in this country, and this inventory estimate was used to estimate the cost of the EG to affected entities. While the inventory distinguishes the size of HMIWI and indicates whether the HMIWI are located at commercial waste disposal facilities, other information is not precisely known such as the types of entities (hospitals, laboratories, nursing homes, and other) and ownership characteristics (public versus private) of entities operating onsite HMIWI. However, the majority of directly affected entities are not likely to be owned or operated by State, local, or Tribal governments. This statement is based upon the ownership characteristics of these industries rather than the ownership characteristics of the portion of these industries operating HMIWI. Approximately 26.5 percent of the 6,500 hospitals operating in this country are designated to have affiliations with State and local governments. The remaining 73.5 percent have private ownership; are designated nongovernment, not-for-profit; or have Federal government affiliations. Nearly 20,900 nursing homes and 4,200 commercial research labs operate in the United States. Of these nursing homes and research labs, approximately 28.4 and 8.2 percent, respectively are tax exempt and may have government affiliations or be nonprofit organizations. Finally, 59 commercial HMIWI operate in this country, and these facilities are predominately privately owned. Since the number of HMIWI operating is only a fraction of the total number of hospitals, laboratories, nursing homes, and other entities in existence in this country, only a fraction of these entities will be directly impacted by the HMIWI regulations. Other firms generating hospital, medical, and infectious waste and sending the waste offsite for disposal will be indirectly affected by the regulation to the extent waste disposal fees increase. The above affected entity information is equally relevant to the NSPS since no additional information is known about the types of entities or ownership characteristics expected for new HMIWI.

b. *Regulatory Alternatives Considered.* Under section 205 of the Unfunded Mandates Act, the EPA must identify and consider a reasonable number of regulatory options before promulgating a rule for which a budgetary impact statement must be prepared. The Agency must select from those alternatives the least costly, most cost-effective, or least burdensome alternative that achieves the objectives of the rule, unless the EPA explains why this alternative is not selected or the selection of this alternative is inconsistent with the law.

The two broad categories of regulatory standards available include design standards and emission standards. Design standards specify the type of control equipment polluters must install, whereas emission standards specify the maximum quantity of a given pollutant that any one polluter may release.

Design standards offer the least flexible approach considered in this analysis. Owners of HMIWI would have to install the specified control equipment regardless of the additional emission reductions achieved or the relative cost of alternative means of emission reductions.

Emission standards allow greater flexibility in the methods used to reduce emissions. Owners of HMIWI are free to meet the emission limit in the manner that is least costly to them. Consequently, for a given level of emission reductions, emission standards are generally less costly than design standards. Furthermore, emission standards give owners of HMIWI an incentive to develop more effective means of controlling emissions. In addition, the CAA requires the

Administrator to promulgate emission standards unless such standards are not feasible. Since emission standards for HMIWI are feasible, the EPA is barred from promulgating design standards for HMIWI.

Even though emission standards generally result in a more efficient allocation of costs than design standards, uniform emission standards can be more costly than necessary. Uniform emission standards require the same level of emission control of every discharger. Because marginal control costs differ for plants of different sizes, different technologies, different levels of product recovery (i.e., in the chemical industry), and different levels of baseline control, an effective solution can be reached if standards are carefully tailored to the special characteristics of each discharger. This type of standard is referred to as a differentiated standard.

In formulating the regulatory options for HMIWI, EPA divided the HMIWI population into three size categories: small (≤200 lb/hr), medium (>200 to ≤500 lb/hr), and large (>500 lb/hr). A number of regulatory options were considered for each size classification. The regulatory options for the three selected size classifications did not specify a particular control technology; rather, they specified emission limits that facilities would be required to meet.

A detailed discussion of the regulatory options considered for the final standards and guidelines is presented in Appendices A and B of ''Hospital/Medical/Infectious Waste Incinerators: Background Information for Promulgated Standards and Guidelines—Summary of Public Comments and Responses'' (EPA–453/R–97–006b). For the most part, the final standards and guidelines reflect the MACT floor, the least stringent regulatory option EPA may adopt for the final rule. In two cases (medium new units and small existing units), MACT was selected at a level more stringent than the MACT floor. A description of EPA's decision regarding medium new units is presented in section IV.C of this notice, and a description of EPA's decision regarding small existing units is presented in sections V.B and V.C of this notice. The EPA believes that the final standards and guidelines reflect the least costly, most cost-effective, and least burdensome regulatory option that achieves the objectives of the rule.

c. *Social Cost and Benefits.* The regulatory impact analysis, including the Agency's assessment of costs and environmental benefits, is detailed in the ''Medical Waste Incinerators—Background Information for Proposed Standards and Guidelines: Regulatory Impact Analysis for New and Existing Facilities,'' (EPA 453/R–94–063a). The regulatory impact assessment document has been updated for the final rule and is entitled ''Hospital/Medical/Infectious Waste Incinerators: Background Information for Promulgated Standards and Guidelines—Regulatory Impact Analysis for New and Existing Facilities'' (EPA–453/R–97–009b). Estimates of the costs and benefits of the various regulatory options considered are discussed in the revised regulatory impact analysis document and in Appendices A and B of ''Hospital/Medical/Infectious Waste Incinerators: Background Information for Promulgated Standards and Guidelines—Summary of Public Comments and Responses'' (EPA–453/R–97–006b). Quantitative estimates of the costs, impacts, and benefits associated with the final NSPS and EG are presented in sections IV.D and V.D of this notice. These estimates are summarized below.

Total costs for the selected options are estimated to range from $71 million per year under Scenario B, which assumes switching and substantial additional waste segregations, to $146 million per year under Scenario C, which assumes switching but little opportunity for additional waste segregations. As a point of reference, EPA also calculated the costs under Scenario A, in which all existing HMIWI install retrofit technology and all new HMIWI projected to be built over the next 5 years install control technology to comply with the guidelines and standards. Under Scenario A, the total costs are estimated to be $210 million per year. The EPA does not believe Scenario A represents a realistic outcome, given the availability of alternative waste disposal options that would be cheaper than installing control technology for many facilities. Thus, EPA believes the actual costs will fall within the range estimated for Scenarios B and C.

Implementation of the NSPS and EG for HMIWI is expected to reduce emissions of HAP, dioxin/furan, and criteria air pollutants. Reduction in a variety of HAP including Cd, HCl, Pb, and Hg is expected as a result of the regulation. Dioxin/furan emissions are also expected to be reduced. In addition, decreases in the following criteria air pollutants are anticipated: PM, $SO_2$, CO, and $NO_X$. Table 6 in section IV.D gives a quantitative estimate of the emissions reductions expected from the NSPS, and Table 12 in section V.D gives a quantitative estimate of the emissions reductions expected from the EG. Air quality benefits resulting from the air quality improvements resulting from this regulation include a reduction in adverse health effects associated with inhalation of the above pollutants as well as improved welfare effects such as improved visibility and crop yields.

While the Agency believes that the health and environmental benefits of this rule are quite significant, the EPA is not currently able to quantitatively evaluate all human and environmental benefits associated with the rule's air quality improvements, and is even more limited in its ability to assign monetary values to these benefit categories. Categories that are not evaluated include several health and welfare endpoints (categories), as well as entire pollutant categories. Consequently, the discussion of benefits included in the Regulatory Impact Analysis and summarized here is primarily qualitative.

However, monetized benefits were calculated for PM emissions reductions. These benefits were estimated using a valuation of $6075/ton, based on analyses of PM emissions reductions benefits from other rules that are discussed in the EPA document, ''Benefit-Cost Analysis of Selected NSPS for Particulate Matter.'' Total PM emissions reduction benefits from this rule are estimated to range from $5.5 million under Scenario B to $5.8 million under Scenario C. Thus *net* monetized costs (after subtracting out monetized benefits) are estimated to range from $65 million under Scenario B to $140 million under Scenario C. Although the monetized benefits associated with PM emission reductions are compared to the estimated annualized emission control costs of the regulation, EPA notes that, because most categories of emissions reductions cannot be monetized, the monetized benefits and therefore the net benefits are understated (in this case annualized costs exceed the monetized benefits so net costs are overstated) for the regulation.

A qualitative discussion of the pollutants that do not have a monetary benefit value shows the significance of other benefits achieved by the rule. Emission reductions of Cd, Pb, HCl, and Hg are expected to occur as a result of the HMIWI rule. Health effects associated with exposures to Cd and Pb include probable carcinogenic effects. Respiratory effects are associated with exposure to Cd, HCl, and Hg. The HAP emitted from HMIWI facilities have also been associated with effects on the central nervous system, neurological system, gastrointestinal system, mucous membranes, and kidneys.

Reduction in emission of dioxin/furan are expected as a result of the HMIWI

rule. Exposure to dioxin/furan has been linked to reproductive and developmental effects, changes in hormone levels, and chloracne. Toxic Equivalent Quantity, or TEQ, has been developed as a measure of the toxicity of dioxin/furan. The TEQ measures the more chlorinated compounds of dioxin/furan and thus provides a better indicator of the part of dioxin/furan that has been linked to the toxic effects associated with dioxin/furan. Unfortunately, quantitative relationships between the toxic effects and exposure to dioxin/furan have not been developed. Therefore, quantitative estimates of the health effects of dioxin/furan emission reductions are not estimated.

Emission reductions are also anticipated for criteria air pollutants. The health effects associated with exposure to PM include premature mortality as well as morbidity. The morbidity effects of PM exposure have been measured in terms of increased hospital and emergency room visits, days of restricted activity or work loss, increased respiratory symptoms, and reductions in lung function. The welfare effects of PM exposure include increased soiling and visibility degradation. Sulfur dioxide has been associated with respiratory symptoms and pulmonary function changes in exercising asthmatics and may also be associated with respiratory symptoms in nonasthmatics. In addition to the effects on human health, $SO_2$ has also been linked to adverse welfare effects, such as materials damage, visibility degradation, and crop and forestry damage. Carbon monoxide affects the oxygen-carrying capacity of hemoglobin and, at current ambient concentrations, has been related to adverse health effects among persons with cardiovascular and chronic respiratory disease. Both congestive heart failure and angina pectoris have been related to CO exposure. Nitrogen oxides have also been shown to have an adverse impact on both human health and welfare. The effects associated with $NO_X$ include respiratory illness, damages to materials, crops, and forests, and visibility degradation.

3. Effects on the National Economy

The Unfunded Mandates Act requires that the EPA estimate ''the effect'' of this rule

On the national economy, such as the effect on productivity, economic growth, full employment, creation of productive jobs, and international competitiveness of the U.S. goods and services, if and to the extent that the EPA in its sole discretion determines that accurate estimates are reasonably feasible and that such effect is relevant and material.

As stated in the Unfunded Mandates Act, such macroeconomic effects tend to be measurable, in nationwide econometric models, only if the economic impact of the regulation reaches 0.25 to 0.5 percent of gross domestic product (in the range of $15 billion to $30 billion). A regulation with a smaller aggregate effect is highly unlikely to have any measurable impact in macroeconomic terms unless it is highly focused on a particular geographic region or economic sector. Because the economic impact of the HMIWI regulation is less than $1.5 billion, no estimate of this rule's effect on the national economy has been conducted.

4. Consultation with Government Officials

The Unfunded Mandates Act requires that the EPA describe the extent of the EPA's consultation with affected State, local, and Tribal officials, summarize the officials' comments or concerns, and summarize the EPA's response to those comments or concerns. In addition, section 203 of the Unfunded Mandates Act requires that the EPA develop a plan for informing and advising small governments that may be significantly or uniquely impacted by a proposal.

Throughout the development of these rules (pre-proposal through pre-promulgation phases), the EPA consulted with representatives of affected State and local governments, including the U.S. Conference of Mayors, the National Governors Association, the National League of Cities, and the National Association of Counties, to inform them of the 1995 proposed rule and determine their concerns. The EPA also consulted with representatives from other entities affected by the 1995 proposed rule, such as the National Association of Public Hospitals, the American Hospital Association, the Sierra Club, and the Natural Resources Defense Council.

As part of EPA's consultation efforts in this rulemaking, the EPA mailed a copy of the draft regulatory package for the February 1995 proposed HMIWI standards and guidelines to each of the associations mentioned above and to several State and local governments. The EPA also mailed a copy of the February 1995 draft regulatory package to many other associations and stakeholders. At least 60 draft regulatory packages were delivered to government agencies, associations, and stakeholders. Interested parties who were not sent a draft regulatory package were mailed an announcement of the 1995 proposed HMIWI regulations, information on where to obtain a copy of the proposal, and notice of a public meeting held to discuss the proposal and answer any questions to allow stakeholders to better formulate their written comments.

Following the 1995 proposal and prior to the June 1996 re-proposal, the EPA held several public meetings to discuss changes in the HMIWI regulations and to allow opportunity for additional public input. Prior to each meeting, a notice of the meeting and the topics to be discussed was delivered to over 300 stakeholders and government officials. Additionally, many meetings were held with smaller expert groups (e.g., environmental groups, STAPPA/ALAPCO, NAPH, etc.) to discuss specific issues and allow for additional comment. With these efforts, the EPA believes that every affected State and local government, association, and stakeholder, was made aware of the HMIWI rulemaking, provided with the necessary information, and given ample opportunity for input.

Following the 1995 proposal and the 1996 re-proposal, comment letters were received from State, local, and Tribal governments. Additional comments were expressed by State, local, and Tribal governments in meetings held during the course of the rulemaking. Many of the commenters suggested that EPA consider ''tiering'' the standards and guidelines using HMIWI size categories most often used by State environmental agencies. For the most part, these commenters supported the size categories presented in the 1996 re-proposal. Other commenters expressed concern about the lack of medical waste disposal options for facilities in rural locations and suggested that the Agency consider location when developing the standards and guidelines. Many of the commenters requested that the originally proposed broad definition of medical waste be narrowed for the final HMIWI regulations. Some commenters requested that the EPA exclude crematories and incinerators used solely to burn pathological waste from the HMIWI regulations. Also, several commenters requested that the EPA revise the 1995 proposed operator training requirements to allow State-approved programs and onsite operator training.

The EPA has incorporated the suggestions of State, local, and Tribal governments as well as suggestions from other stakeholders into the standards and guidelines being promulgated today. As a result of consultations with affected entities, the final HMIWI standards and guidelines: (1) Subcategorize HMIWI based on the size

categories and technical distinctions most often used by States; (2) allow existing facilities that meet certain rural criteria and operate small HMIWI (≤200 lb/hr) to meet less stringent emission limits; (3) define HMIWI through use of a narrow definition of medical waste which recognizes that most hospital waste is not infectious and can be recycled or disposed of as municipal-type waste; (4) exclude crematories and pathological incinerators; (5) allow for HMIWI operator training and qualification to be obtained through a State-approved program, which may allow facilities to provide training onsite; and (6) focus the regulations on incineration units whose primary purpose is disposal of hospital waste and/or medical/infectious waste by providing an exemption for units burning 10 percent or less hospital waste and medical/infectious waste.

Documentation of the EPA's consideration of comments on the 1995 proposal is provided in the 1996 re-proposal notice. Documentation of EPA's consideration of comments on the 1996 re-proposal is provided in ''Hospital/Medical/Infectious Waste Incinerators: Background Information for Promulgated Standards and Guidelines—Summary of Public Comments and Responses'' (EPA–453/R–97–006b). Refer to the **SUPPLEMENTARY INFORMATION** and **ADDRESSES** sections of this preamble for information on how to acquire copies of these documents.

As discussed in section VI.F, the number of small entities that are significantly affected by the HMIWI regulation is not expected to be substantial. The full analysis of potential regulatory impacts on small organizations, small governments, and small businesses is included in the economic impact assessment in the docket and is listed at the beginning of today's document under **SUPPLEMENTARY INFORMATION.** Because the number of small entities that are likely to experience significant economic impacts as a result of the HMIWI regulation is not expected to be substantial, no plan to inform and advise small governments is required under section 203 of the Unfunded Mandates Act. However, as described above, the EPA has communicated and consulted with small governments and businesses that will be affected by the standards and guidelines, keeping them informed about the content of this promulgation.

*E. Executive Order 12875*

To reduce the burden of Federal regulations on States and small governments, the President issued Executive Order 12875 on October 26, 1993, entitled ''Enhancing the Intergovernmental Partnership.'' Under Executive Order 12875, the EPA is required to consult with representatives of affected State, local, and Tribal governments, and keep these affected parties informed about the content and effect of the promulgated standards and emission guidelines. Section II.F of this notice provides a brief account of the actions that the EPA has taken to communicate and consult with the affected parties. Because this regulatory action imposes costs to the private sector and government entities in excess of $100 million per year, the EPA pursued consultations, the preparation of an unfunded mandates statement, and other requirements of the Unfunded Mandates Reform Act. The requirements of the Unfunded Mandates Reform Act were met for this rulemaking as presented under VI.D of this notice and also fulfill the requirements of Executive Order 12875.

*F. Regulatory Flexibility Act (RFA) and Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA)*

Section 605 of the Regulatory Flexibility Act (RFA) requires Federal agencies to give special consideration to the impacts of regulations on small entities, which are small businesses, small organizations, and small governments. The major purpose of the RFA is to keep paperwork and regulatory requirements from getting out of proportion to the scale of the entities being regulated without compromising the objectives of, in this case, the CAA.

The President signed the Small Business Regulatory Enforcement Fairness Act (SBREFA) into law on March 29, 1996. The SBREFA amended the RFA to strengthen the RFA's analytical and procedural requirements. The SBREFA also made other changes to agency regulatory practices as they affect small entities.

Finally, SBREFA established a new mechanism for expedited Congressional review of virtually all agency rules.

EPA has determined that it is not necessary to prepare a regulatory flexibility analysis in connection with this final rule. The Administrator also has determined that the EG and NSPS for HMIWI will not have a significant economic impact on a substantial number of small entities.

The U.S. Small Business Administration (SBA) definitions pertaining to business size are either specified by number of employees or sales revenue. For analysis of the regulations being promulgated today, the EPA considers a small business or small organization to be one with gross annual revenue less than $5 million or one with less than 500 employees. The EPA considers a small government to be one that serves a population less than 50,000. Three types of small ''entities'' are impacted by the regulation: small businesses, small nonprofit organizations, and small governmental jurisdictions. Examples of impacted businesses include for-profit hospitals and tax-paying nursing homes. Examples of impacted nonprofit organizations include not-for-profit hospitals and, in many cases, tax-exempt nursing homes. Examples of impacted governmental jurisdictions include those (e.g., municipalities, counties, States) that operate hospitals and probably some tax-exempt nursing homes. For a description of EPA's outreach efforts to these small entities and the general public, see section II.F of this preamble.

In accordance with the RFA as amended by the SBREFA and current EPA Guidance, an analysis of impacts of the EG and NSPS on small ''entities'' '' including small businesses, small nonprofit organizations, and small governmental jurisdictions '' was performed. The economic impact analysis indicates that neither the EG nor the NSPS will have a ''significant economic impact on a substantial number of small entities'' under any regulatory option. Impacts are not significant for the vast majority of medical waste generators that send their waste offsite to be treated and disposed. Impacts are also not significant for the great majority of HMIWI operators that would have the opportunity to switch to an alternative method of medical waste treatment and disposal if control costs are prohibitive. Some significant impacts were found for commercial HMIWI operators and for small onsite HMIWI operators that are remote from an urban area. These facilities might not have the opportunity to switch to an alternative medical waste treatment and disposal method '' commercial HMIWI operators because medical waste incineration is their line of business, and small, remote HMIWI because they may not have access to commercial incineration services. However, the number of such facilities that are both significantly impacted under the regulatory option selected for promulgation and ''small'' would be, at the most, only a few, and would therefore not be substantial.

*G. Submission to Congress and the General Accounting Office*

Under 5 U.S.C. 801(a)(1)(A) of the Administrative Procedures Act, as added by the SBREFA of 1996, the EPA submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the General Accounting Office prior to publication of the rule in today's **Federal Register**. This rule is a ''major rule'' as defined by 5 U.S.C. 804(2).

*H. Clean Air Act Procedural Requirements*

The following procedural requirements of the CAA are addressed: Administrative listing, periodic review, external participation, and economic impact assessment.

1. Administrator Listing—Sections 111 and 129 of the Clean Air Act

Section 129 of the 1990 Amendments to the CAA directs the Administrator to promulgate standards for new HMIWI and guidelines for existing HMIWI. Section 129(a) states that the standards and guidelines are promulgated under both sections 129 and 111 of the Clean Air Act.

2. Periodic Review—Sections 111 and 129 of the Clean Air Act

Sections 111 and 129 of the CAA require that the standards and guidelines be reviewed not later than 5 years following the initial promulgation. At that time and at 5-year intervals thereafter, the Administrator shall review the standards and guidelines and revise them if necessary. This review will include an assessment of such factors as the need for integration with other programs, the existence of alternative methods, enforceability, improvements in emission control technology, and reporting requirements.

3. External Participation

In accordance with section 117 of the CAA, publication of this promulgation was preceded by consultation with appropriate advisory committees, independent experts, and Federal departments and agencies. See section II.F of this preamble for a discussion of EPA's consultation efforts.

4. Economic Impact Assessment

Section 317A of the CAA requires the EPA to prepare an economic impact assessment for any standards or guidelines promulgated under section 111(b) of the CAA. An economic impact assessment was prepared for the promulgated standards and guidelines. In the manner described in the sections of this preamble regarding the impacts of and rationale for the promulgated standards and guidelines, the EPA considered all aspects of the economic impact assessment in promulgating the standards and guidelines. The economic impact assessment is included in the list of key technical documents at the beginning of today's notice under **SUPPLEMENTARY INFORMATION**.

**List of Subjects in 40 CFR Part 60**

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

Dated: August 15, 1997.

**Carol M. Browner,**

*Administrator.*

Part 60, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

## PART 60—STANDARDS OF PERFORMANCE FOR NEW STATIONARY SOURCES

1. The authority citation for part 60 is revised to read as follows:

**Authority:** 42 U.S.C. 7401, 7411, 7413, 7414, 7416, 7429, 7601 and 7602.

## Subpart A—[Amended]

2. Section 60.17. is amended by removing from paragraph (b)(1) the reference ''60.244(f)(2)''; and by adding new paragraphs (k) and (l) to read as follows:

### § 60.17 Incorporation by reference.

* * * * *

(k) This material is available for purchase from the American Hospital Association (AHA) Service, Inc., Post Office Box 92683, Chicago, Illinois 60675–2683. You may inspect a copy at EPA's Air and Radiation Docket and Information Center (Docket A–91–61, Item IV–J–124), Room M–1500, 401 M Street SW, Washington, DC.

(1) An Ounce of Prevention: Waste Reduction Strategies for Health Care Facilities. American Society for Health Care Environmental Services of the American Hospital Association. Chicago, Illinois. 1993. AHA Catalog No. 057007. ISBN 0–87258–673–5. IBR approved for § 60.35e and § 60.55c.

(l) This material is available for purchase from the National Technical Information Services, 5285 Port Royal Road, Springfield, Virginia 22161. You may inspect a copy at EPA's Air and Radiation Docket and Information Center (Docket A–91–61, Item IV–J–125), Room M–1500, 401 M Street SW, Washington, DC.

(1) OMB Bulletin No. 93–17: Revised Statistical Definitions for Metropolitan Areas. Office of Management and Budget, June 30, 1993. NTIS No. PB 93–192–664. IBR approved for § 60.31e.

3. Section 60.30 is revised to read as follows:

### § 60.30 Scope.

The following subparts contain emission guidelines and compliance times for the control of certain designated pollutants in accordance with section 111(d) and section 129 of the Clean Air Act and subpart B of this part.

(a) Subpart Ca—[Reserved]

(b) Subpart Cb—Municipal Waste Combustors.

(c) Subpart Cc—Municipal Solid Waste Landfills.

(d) Subpart Cd—Sulfuric Acid Production Plants.

(e) Subpart Ce—Hospital/Medical/Infectious Waste Incinerators.

4. Part 60 is amended by adding a new subpart Ce to read as follows:

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

Sec.



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

### § 60.30e Scope.

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

### § 60.31e Definitions.

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

*Standard Metropolitan Statistical Area* or *SMSA* means any areas listed in OMB Bulletin No. 93–17 entitled ''Revised Statistical Definitions for Metropolitan Areas'' dated June 30, 1993 (incorporated by reference, see § 60.17).

**§ 60.32e Designated facilities.**

(a) Except as provided in paragraphs (b) through (h) of this section, the designated facility to which the guidelines apply is each individual HMIWI for which construction was commenced on or before June 20, 1996.

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

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

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

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

(1) Notifies the Administrator of an exemption claim;

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

(3) Keeps records on a calendar quarter basis of the weight of hospital waste and medical/infectious waste combusted, and the weight of all other fuels and wastes combusted at the co-fired combustor.

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

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

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

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

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

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

**§ 60.33e Emission guidelines.**

(a) For approval, a State plan shall include the requirements for emission limits at least as protective as those requirements listed in Table 1 of this subpart, except as provided for in paragraph (b) of this section.

(b) For approval, a State plan shall include the requirements for emission limits at least as protective as those requirements listed in Table 2 of this subpart for any small HMIWI 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. The 2,000 lb/week limitation does not apply during performance tests.

(c) For approval, a State plan shall include the requirements for stack opacity at least as protective as § 60.52c(b) of subpart Ec of this part.

**§ 60.34e Operator training and qualification guidelines.**

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

**§ 60.35e Waste management guidelines.**

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

**§ 60.36e Inspection guidelines.**

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

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

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

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

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

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

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

(vi) Inspect motors for proper operation;

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

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

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

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

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

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

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

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

(xv) Inspect bypass stack components;

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

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

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

(b) For approval, a State plan shall require that each small HMIWI subject to the emission limits under § 60.33e(b) undergo an equipment inspection annually (no more than 12 months following the previous annual equipment inspection), as outlined in paragraphs (a)(1) and (a)(2) of this section.

**§ 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, excluding the fugitive emissions testing requirements under § 60.56c(b)(12) and (c)(3).

(b) For approval, a State plan shall require any small HMIWI subject to the emission limits under § 60.33e(b) to

meet the following compliance and performance testing requirements:

(1) Conduct the performance testing requirements in § 60.56c(a), (b)(1) through (b)(9), (b)(11) (Hg only), and (c)(1) of subpart Ec of this part. The 2,000 lb/week limitation under § 60.33e(b) does not apply during performance tests.

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

(3) 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 except during periods of startup, shutdown and malfunction. 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).

(4) Except as provided in paragraph (b)(5) 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 emission limits.

(5) 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 emission limit(s). Repeat performance tests conducted pursuant to this paragraph must be conducted using the identical operating parameters that indicated a violation under paragraph (b)(4) of this section.

(c) For approval, a State plan shall include the requirements for monitoring listed in § 60.57c of subpart Ec of this part, except as provided for under paragraph (d) of this section.

(d) For approval, a State plan shall include requirements for any small HMIWI subject to the emission limits under § 60.33e(b) to meet the following monitoring requirements:

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

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

(3) The owner or operator of a designated facility shall obtain monitoring data at all times during HMIWI operation except during periods of monitoring equipment malfunction, calibration, or repair. At a minimum, valid monitoring data shall be obtained for 75 percent of the operating hours per day and for 90 percent of the operating hours per calendar quarter that the designated facility is combusting hospital waste and/or medical/infectious waste.

**§ 60.38e Reporting and recordkeeping guidelines.**

(a) For approval, a State plan shall include the reporting and recordkeeping requirements listed in § 60.58c(b), (c), (d), (e), and (f) of subpart Ec of this part, excluding § 60.58c(b)(2)(ii) (fugitive emissions) and (b)(7) (siting).

(b) For approval, a State plan shall require the owner or operator of each small HMIWI subject to the emission limits under § 60.33e(b) to:

(1) Maintain records of the annual equipment inspections, any required maintenance, and any repairs not completed within 10 days of an inspection or the timeframe established by the State regulatory agency; and

(2) Submit an annual report containing information recorded under paragraph (b)(1) of this section no later than 60 days following the year in which data were collected. Subsequent reports shall be sent no later than 12 calendar months following the previous report (once the unit is subject to permitting requirements under Title V of the Act, the owner or operator must submit these reports semiannually). The report shall be signed by the facilities manager.

**§ 60.39e Compliance times.**

(a) Not later than September 15, 1998, each State in which a designated facility is operating shall submit to the Administrator a plan to implement and enforce the emission guidelines.

(b) Except as provided in paragraphs (c) and (d) of this section, State plans shall provide that designated facilities comply with all requirements of the State plan on or before the date 1 year after EPA approval of the State plan, regardless of whether a designated facility is identified in the State plan inventory required by § 60.25(a) of subpart B of this part.

(c) State plans that specify measurable and enforceable incremental steps of progress towards compliance for designated facilities planning to install the necessary air pollution control equipment may allow compliance on or before the date 3 years after EPA approval of the State plan (but not later than the September 16, 2002. 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(i) of subpart Ec of this part.

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

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

(4) Date for ordering the air pollution control device(s);

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

(6) Date for initiation of site preparation for installation of the air pollution control device(s);

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

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

(9) Date for initial compliance test(s) of the air pollution control device(s).

(d) State plans that include provisions allowing designated facilities to petition the State for extensions beyond the compliance times required in paragraph (b) of this section shall:

(1) Require that the designated facility requesting an extension submit the following information in time to allow the State adequate time to grant or deny the extension within 1 year after EPA approval of the State plan:

(i) Documentation of the analyses undertaken to support the need for an extension, including an explanation of why up to 3 years after EPA approval of the State plan is sufficient time to comply with the State plan while 1 year after EPA approval of the State plan is not sufficient. The documentation shall also include an evaluation of the option to transport the waste offsite to a commercial medical waste treatment and disposal facility on a temporary or permanent basis; and

(ii) Documentation of measurable and enforceable incremental steps of progress to be taken towards compliance with the emission guidelines.

(2) Include procedures for granting or denying the extension; and

(3) If an extension is granted, require compliance with the emission

guidelines on or before the date 3 years after EPA approval of the State plan (but not later than September 16, 2002.

(e) For approval, a State plan shall require compliance with § 60.34e—Operator training and qualification guidelines and § 60.36e—Inspection guidelines by the date 1 year after EPA approval of a State plan.

(f) The Administrator shall develop, implement, and enforce a plan for existing HMIWI located in any State that has not submitted an approvable plan within date 2 years after September 15, 1997. Such plans shall ensure that each designated facility is in compliance with the provisions of this subpart no later than date 5 years after September 15, 1997.

TABLE 1 TO SUBPART CE.—EMISSION LIMITS FOR SMALL, MEDIUM, AND LARGE HMIWI

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

TABLE 2 TO SUBPART CE.—EMISSIONS LIMITS FOR SMALL HMIWI WHICH MEET THE CRITERIA UNDER § 60.33E(B)

| Pollutant | Units (7 percent oxygen, dry basis) | HMIWI emission limits |
|---|---|---|
| Particulate matter | Milligrams per dry standard cubic meter (grains per dry standard cubic foot) | 197 (0.086). |
| Carbon monoxide | Parts per million by volume | 40. |
| Dioxins/furans | nanograms per dry standard cubic meter total dioxins/furans (grains per billion dry standard cubic feet) or nanograms per dry standard cubic meter TEQ (grains per billion dry standard cubic feet). | 800 (350) or 15 (6.6). |
| Hydrogen chloride | Parts per million by volume | 3100. |
| Sulfur dioxide | Parts per million by volume | 55. |
| Nitrogen oxides | Parts per million by volume | 250. |
| Lead | Milligrams per dry standard cubic meter (grains per thousand dry standard cubic feet). | 10 (4.4). |
| Cadmium | Milligrams per dry standard cubic meter (grains per thousand dry standard cubic feet). | 4 (1.7). |
| Mercury | Milligrams per dry standard cubic meter (grains per thousands dry standard cubic feet). | 7.5 (3.3). |

5. Part 60 is amended by adding a new subpart Ec to read as follows:

**Subpart Ec—Standards of Performance for Hospital/Medical/Infectious Waste Incinerators for Which Construction Is Commenced After June 20, 1996**



## Subpart Ec—Standards of Performance for Hospital/Medical/Infectious Waste Incinerators for Which Construction Is Commenced After June 20, 1996

### § 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) for which construction is

commenced after June 20, 1996 or for which modification is commenced after March 16, 1998.

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

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

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

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

(1) Notifies the Administrator of an exemption claim;

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

(3) Keeps records on a calendar quarter basis of the weight of hospital waste and medical/infectious waste combusted, and the weight of all other fuels and wastes combusted at the co-fired combustor.

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

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

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

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

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

(i) In delegating implementation and enforcement authority to a State under section 111(c) of the Clean Air Act, the following authorities shall be retained by the Administrator and not transferred to a State:

(1) The requirements of § 60.56c(i) establishing operating parameters when using controls other than those listed in § 60.56c(d).

(2) Alternative methods of demonstrating compliance under § 60.8.

(j) Affected facilities subject to this subpart are not subject to the requirements of 40 CFR part 64.

(k) The requirements of this subpart shall become effective March 16, 1998

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

**§ 60.51c Definitions.**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

*Hospital waste* means discards generated at a hospital, except unused items returned to the manufacturer. The definition of hospital waste does not include human corpses, remains, and anatomical parts that are intended for interment or cremation.

*Infectious agent* means any organism (such as a virus or bacteria) that is

capable of being communicated by invasion and multiplication in body tissues and capable of causing disease or adverse health impacts in humans.

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

*Large HMIWI* means:

(1) Except as provided in (2);

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

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

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

(2) The following are not large HMIWI:

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

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

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

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

*Maximum charge rate* means:

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

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

*Maximum design waste burning capacity* means:

(1) For intermittent and continuous HMIWI,

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

Where:

C=HMIWI capacity, lb/hr

$P_V$=primary chamber volume, $ft^3$

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

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

(2) For batch HMIWI,

$C=P_V \times 4.5/8$

Where:

C=HMIWI capacity, lb/hr

$P_V$=primary chamber volume, $ft^3$

4.5=waste density, $lb/ft^3$

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

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

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

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

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

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

(3) Human blood and blood products including:

(i) Liquid waste human blood;

(ii) Products of blood;

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

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

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

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

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

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

*Medium HMIWI* means:

(1) Except as provided in paragraph (2);

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

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

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

(2) The following are not medium HMIWI:

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

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

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

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

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

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

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

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

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

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

*Modification* or *Modified HMIWI* means any change to an HMIWI unit after the effective date of these standards such that:

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

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

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

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

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

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

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

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

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

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

*Small HMIWI* means:

(1) Except as provided in (2);

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

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

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

(2) The following are not small HMIWI:

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

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

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

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

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

### § 60.52c Emission limits.

(a) On and after the date on which the initial performance test is completed or is required to be completed under § 60.8, whichever date comes first, no owner or operator of an affected facility shall cause to be discharged into the atmosphere from that affected facility any gases that contain stack emissions in excess of the limits presented in Table 1 of 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 from the stack of that affected facility any gases that exhibit greater than 10 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 utilizing a large HMIWI 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, except as provided in paragraphs (d) and (e) of this section.

(d) The emission limit specified in paragraph (c) of this section does not cover visible emissions discharged inside buildings or enclosures of ash conveying systems; however, the emission limit does cover visible emissions discharged to the atmosphere from buildings or enclosures of ash conveying systems.

(e) The provisions specified in paragraph (c) of this section do not apply during maintenance and repair of ash conveying systems. Maintenance and/or repair shall not exceed 10 operating days per calendar quarter unless the owner or operator obtains written approval from the State agency establishing a date whereby all necessary maintenance and repairs of ash conveying systems shall be completed.

**§ 60.53c Operator training and qualification requirements.**

(a) No owner or operator of an affected facility shall allow the affected facility to operate at any time unless a fully trained and qualified HMIWI operator is accessible, either at the facility or available within 1 hour. The trained and qualified HMIWI operator may operate the HMIWI directly or be the direct supervisor of one or more HMIWI operators.

(b) Operator training and qualification shall be obtained through a State-approved program or by completing the requirements included in paragraphs (c) through (g) of this section.

(c) Training shall be obtained by completing an HMIWI operator training course that includes, at a minimum, the following provisions:

(1) 24 hours of training on the following subjects:

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

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

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

(iv) Combustion controls and monitoring;

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

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

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

(viii) Actions to correct malfunctions or conditions that may lead to malfunction;

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

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

(xi) Work safety procedures;

(xii) Pre-startup inspections; and

(xiii) Recordkeeping requirements.

(2) An examination designed and administered by the instructor.

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

(d) Qualification shall be obtained by:

(1) Completion of a training course that satisfies the criteria under paragraph (c) of this section; and

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

(e) Qualification is valid from the date on which the examination is passed or the completion of the required experience, whichever is later.

(f) To maintain qualification, the trained and qualified HMIWI operator shall complete and pass an annual review or refresher course of at least 4 hours covering, at a minimum, the following:

(1) Update of regulations;

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

(3) Inspection and maintenance;

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

(5) Discussion of operating problems encountered by attendees.

(g) A lapsed qualification shall be renewed by one of the following methods:

(1) For a lapse of less than 3 years, the HMIWI operator shall complete and pass a standard annual refresher course described in paragraph (f) of this section.

(2) For a lapse of 3 years or more, the HMIWI operator shall complete and pass a training course with the minimum criteria described in paragraph (c) of this section.

(h) The owner or operator of an affected facility shall maintain documentation at the facility that address the following:

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

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

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

(4) HMIWI startup, shutdown, and malfunction procedures;

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

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

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

(8) Procedures for monitoring HMIWI emissions;

(9) Reporting and recordkeeping procedures; and

(10) Procedures for handling ash.

(i) The owner or operator of an affected facility shall establish a program for reviewing the information listed in paragraph (h) of this section annually with each HMIWI operator (defined in § 60.51c).

(1) The initial review of the information listed in paragraph (h) of this section shall be conducted within 6 months after the effective date of this subpart or prior to assumption of responsibilities affecting HMIWI operation, whichever date is later.

(2) Subsequent reviews of the information listed in paragraph (h) of this section shall be conducted annually.

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

**§ 60.54c Siting requirements.**

(a) The owner or operator of an affected facility for which construction is commenced after September 15, 1997 shall prepare an analysis of the impacts of the affected facility. The analysis shall consider air pollution control alternatives that minimize, on a site-specific basis, to the maximum extent practicable, potential risks to public health or the environment. In considering such alternatives, the analysis may consider costs, energy impacts, non-air environmental impacts, or any other factors related to the practicability of the alternatives.

(b) Analyses of facility impacts prepared to comply with State, local, or other Federal regulatory requirements may be used to satisfy the requirements of this section, as long as they include the consideration of air pollution control alternatives specified in paragraph (a) of this section.

(c) The owner or operator of the affected facility shall complete and submit the siting requirements of this section as required under § 60.58c(a)(1)(iii).

**§ 60.55c Waste management plan.**

The owner or operator of an affected facility shall prepare a waste management plan. The waste management plan shall identify both the feasibility and the approach to separate certain components of solid waste from the health care waste stream in order to reduce the amount of toxic emissions from incinerated waste. A waste management plan may include, but is not limited to, elements such as paper, cardboard, plastics, glass, battery, or metal recycling; or 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 emission 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.

**§ 60.56c Compliance and performance testing.**

(a) The emission limits under this subpart apply at all times except during periods of startup, shutdown, or malfunction, provided that no hospital waste or medical/infectious waste is charged to the affected facility during startup, shutdown, or malfunction.

(b) The owner or operator of an affected facility shall conduct an initial performance test as required under § 60.8 to determine compliance with the emission limits using the procedures and test methods listed in paragraphs (b)(1) through (b)(12) of this section. The use of the bypass stack during a performance test shall invalidate the performance test.

(1) All performance tests shall consist of a minimum of three test runs conducted under representative operating conditions.

(2) The minimum sample time shall be 1 hour per test run unless otherwise indicated.

(3) EPA Reference Method 1 of appendix A of this part shall be used to select the sampling location and number of traverse points.

(4) EPA Reference Method 3 or 3A of appendix A of this part shall be used for gas composition analysis, including measurement of oxygen concentration. EPA Reference Method 3 or 3A of appendix A of this part shall be used simultaneously with each reference method.

(5) The pollutant concentrations shall be adjusted to 7 percent oxygen using the following equation:

$C_{adj}=C_{meas}\ (20.9—7)/(20.9—\%O_2)$ where:

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

$C_{meas}$=pollutant concentration measured on a dry basis (20.9—7)=20.9 percent oxygen—7 percent oxygen (defined oxygen correction basis);

20.9=oxygen concentration in air, percent; and

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

(6) EPA Reference Method 5 or 29 of appendix A of this part shall be used to measure the particulate matter emissions.

(7) EPA Reference Method 9 of appendix A of this part shall be used to measure stack opacity.

(8) EPA Reference Method 10 or 10B of appendix A of this part shall be used to measure the CO emissions.

(9) EPA Reference Method 23 of appendix A of this part shall be used to measure total dioxin/furan emissions. The minimum sample time shall be 4 hours per test run. If the affected facility has selected the toxic equivalency standards for dioxin/furans, under § 60.52c, the following procedures shall be used to determine compliance:

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

(ii) For each dioxin/furan congener measured in accordance with paragraph (b)(9)(i) of this section, multiply the congener concentration by its corresponding toxic equivalency factor specified in Table 2 of this subpart.

(iii) Sum the products calculated in accordance with paragraph (b)(9)(ii) of this section to obtain the total concentration of dioxins/furans emitted in terms of toxic equivalency.

(10) EPA Reference Method 26 of appendix A of this part shall be used to measure HCl emissions. If the affected facility has selected the percentage reduction standards for HCl under § 60.52c, the percentage reduction in HCl emissions ($\%R_{HCl}$) is computed using the following formula:

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

Where:

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

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

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

(11) EPA Reference Method 29 of appendix A of this part shall be used to measure Pb, Cd, and Hg emissions. If the affected facility has selected the percentage reduction standards for metals under § 60.52c, the percentage reduction in emissions ($\%R_{metal}$) is computed using the following formula:

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

Where:

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

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

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

(12) The EPA Reference Method 22 of appendix A of this part shall be used to determine compliance with the fugitive ash emission limit under § 60.52c(c). The minimum observation time shall be a series of three 1-hour observations.

(c) Following the date on which the initial performance test is completed or is required to be completed under § 60.8, whichever date comes first, the owner or operator of an affected facility shall:

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

(2) Determine compliance with the PM, CO, and HCl emission limits by conducting an annual performance test (no more than 12 months following the previous performance test) using the applicable procedures and test methods listed in paragraph (b) of this section. If all three performance tests over a 3-year period indicate compliance with the emission 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 emission 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 emission 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 emission limit. The use of the bypass stack during a performance test shall invalidate the performance test.

(3) For large HMIWI, determine compliance with the visible emission limits for fugitive emissions from flyash/bottom ash storage and handling by conducting a performance test using EPA Reference Method 22 on an annual basis (no more than 12 months following the previous performance test).

(4) Facilities using a CEMS to demonstrate compliance with any of the emission limits under § 60.52c shall:

(i) Determine compliance with the appropriate emission limit(s) using a 12-hour rolling average, calculated each hour as the average of the previous 12 operating hours (not including startup, shutdown, or malfunction).

(ii) Operate all CEMS in accordance with the applicable procedures under appendices B and F of this part.

(d) The owner or operator of an affected facility equipped with a dry scrubber followed by a fabric filter, a wet scrubber, or a dry scrubber followed by a fabric filter and wet scrubber shall:

(1) Establish the appropriate maximum and minimum operating parameters, indicated in Table 3 of this subpart for each control system, as site specific operating parameters during the initial performance test to determine compliance with the emission limits; and

(2) Following the date on which the initial performance test is completed or is required to be completed under § 60.8, whichever date comes first, ensure that the affected facility does not operate above any of the applicable maximum operating parameters or below any of the applicable minimum operating parameters listed in Table 3 of this subpart and measured as 3-hour rolling averages (calculated each hour as the average of the previous 3 operating hours) at all times except during periods of startup, shutdown and malfunction. Operating parameter limits do not apply during performance tests. Operation above the established maximum or below the established minimum operating parameter(s) shall constitute a violation of established operating parameter(s).

(e) Except as provided in paragraph (h) of this section, for affected facilities equipped with a dry scrubber followed by a fabric filter:

(1) Operation of the affected facility above the maximum charge rate and below the minimum secondary chamber temperature (each measured on a 3-hour rolling average) simultaneously shall constitute a violation of the CO emission limit.

(2) Operation of the affected facility above the maximum fabric filter inlet temperature, above the maximum charge rate, and below the minimum dioxin/furan sorbent flow rate (each measured on a 3-hour rolling average) simultaneously shall constitute a violation of the dioxin/furan emission limit.

(3) Operation of the affected facility above the maximum charge rate and below the minimum HCl sorbent flow rate (each measured on a 3-hour rolling average) simultaneously shall constitute a violation of the HCl emission limit.

(4) Operation of the affected facility above the maximum charge rate and below the minimum Hg sorbent flow rate (each measured on a 3-hour rolling average) simultaneously shall constitute a violation of the Hg emission limit.

(5) Use of the bypass stack (except during startup, shutdown, or malfunction) shall constitute a violation of the PM, dioxin/furan, HCl, Pb, Cd and Hg emission limits.

(f) Except as provided in paragraph (h) of this section, for affected facilities equipped with a wet scrubber:

(1) Operation of the affected facility above the maximum charge rate and below the minimum pressure drop across the wet scrubber or below the minimum horsepower or amperage to the system (each measured on a 3-hour rolling average) simultaneously shall constitute a violation of the PM emission limit.

(2) Operation of the affected facility above the maximum charge rate and below the minimum secondary chamber temperature (each measured on a 3-hour rolling average) simultaneously shall constitute a violation of the CO emission limit.

(3) Operation of the affected facility above the maximum charge rate, below the minimum secondary chamber temperature, and below the minimum scrubber liquor flow rate (each measured on a 3-hour rolling average) simultaneously shall constitute a violation of the dioxin/furan emission limit.

(4) Operation of the affected facility above the maximum charge rate and below the minimum scrubber liquor pH (each measured on a 3-hour rolling average) simultaneously shall constitute a violation of the HCl emission limit.

(5) Operation of the affected facility above the maximum flue gas temperature and above the maximum charge rate (each measured on a 3-hour rolling average) simultaneously shall constitute a violation of the Hg emission limit.

(6) Use of the bypass stack (except during startup, shutdown, or malfunction) shall constitute a violation of the PM, dioxin/furan, HCl, Pb, Cd and Hg emission limits.

(g) Except as provided in paragraph (h) of this section, for affected facilities equipped with a dry scrubber followed by a fabric filter and a wet scrubber:

(1) Operation of the affected facility above the maximum charge rate and below the minimum secondary chamber temperature (each measured on a 3-hour rolling average) simultaneously shall constitute a violation of the CO emission limit.

(2) Operation of the affected facility above the maximum fabric filter inlet temperature, above the maximum charge rate, and below the minimum dioxin/furan sorbent flow rate (each measured on a 3-hour rolling average) simultaneously shall constitute a violation of the dioxin/furan emission limit.

(3) Operation of the affected facility above the maximum charge rate and below the minimum scrubber liquor pH (each measured on a 3-hour rolling average) simultaneously shall constitute a violation of the HCl emission limit.

(4) Operation of the affected facility above the maximum charge rate and below the minimum Hg sorbent flow rate (each measured on a 3-hour rolling average) simultaneously shall constitute a violation of the Hg emission limit.

(5) Use of the bypass stack (except during startup, shutdown, or malfunction) shall constitute a violation of the PM, dioxin/furan, HCl, Pb, Cd and Hg emission limits.

(h) 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 emission 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), or (g) of this section.

(i) 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, or a dry scrubber followed by a fabric filter and a wet scrubber to comply with the emission 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.

(j) The owner or operator of an affected facility may conduct a repeat performance test at any time to establish new values for the operating parameters. The Administrator may request a repeat performance test at any time.

**§ 60.57c Monitoring requirements.**

(a) 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 of this subpart 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 except during periods of startup and shutdown.

(b) The owner or operator of an affected facility shall install, calibrate (to manufacturers' specifications), maintain, and operate a device or method for measuring the use of the bypass stack including date, time, and duration.

(c) The owner or operator of an affected facility using something other than a dry scrubber followed by a fabric filter, a wet scrubber, or a dry scrubber followed by a fabric filter and a wet scrubber to comply with the emission limits under § 60.52c shall install, calibrate (to the manufacturers' specifications), maintain, and operate the equipment necessary to monitor the site-specific operating parameters developed pursuant to § 60.56c(i).

(d) 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 and for 90 percent of the operating days per calendar quarter that the affected facility is combusting hospital waste and/or medical/infectious waste.

**§ 60.58c Reporting and recordkeeping requirements.**

(a) The owner or operator of an affected facility shall submit notifications, as provided by § 60.7. In addition, the owner or operator shall submit the following information:

(1) Prior to commencement of construction;

(i) A statement of intent to construct;

(ii) The anticipated date of commencement of construction; and

(iii) All documentation produced as a result of the siting requirements of § 60.54c.

(2) Prior to initial startup;

(i) The type(s) of waste to be combusted;

(ii) The maximum design waste burning capacity;

(iii) The anticipated maximum charge rate; and

(iv) If applicable, the petition for site-specific operating parameters under § 60.56c(i).

(b) The owner or operator of an affected facility shall maintain the following information (as applicable) for a period of at least 5 years:

(1) Calendar date of each record;

(2) Records of the following data:

(i) Concentrations of any pollutant listed in § 60.52c or measurements of opacity as determined by the continuous emission monitoring system (if applicable);

(ii) Results of fugitive emissions (by EPA Reference Method 22) tests, if applicable;

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

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

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

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

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

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

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

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

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

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

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

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

(xv) For affected facilities complying with §§ 60.56c(i) and 60.57c(c), the owner or operator shall maintain all operating parameter data collected.

(3) Identification of calendar days for which data on emission rates or operating parameters specified under paragraph (b)(2) of this section have not been obtained, with an identification of the emission rates or operating parameters not measured, reasons for not obtaining the data, and a description of corrective actions taken.

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

(5) Identification of calendar days for which data on emission rates or operating parameters specified under paragraph (b)(2) of this section exceeded the applicable limits, with a description of the exceedances, reasons for such exceedances, and a description of corrective actions taken.

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

(7) All documentation produced as a result of the siting requirements of § 60.54c;

(8) Records showing the names of HMIWI operators who have completed review of the information in § 60.53c(h) as required by § 60.53c(i), including the date of the initial review and all subsequent annual reviews;

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

(10) Records showing the names of the HMIWI operators who have met the criteria for qualification under § 60.53c and the dates of their qualification; and

(11) Records of calibration of any monitoring devices as required under § 60.57c(a), (b), and (c).

(c) The owner or operator of an affected facility shall submit the information specified in paragraphs (c)(1) through (c)(3) 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)(12), as applicable.

(2) The values for the site-specific operating parameters established pursuant to § 60.56c(d) or (i), as applicable.

(3) The waste management plan as specified in § 60.55c.

(d) An annual report shall be submitted 1 year following the submission 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 (d)(8) of this section. All reports shall be signed by the facilities manager.

(1) The values for the site-specific operating parameters established pursuant to § 60.56c(d) or (i), 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 § 60.56c(d) or (i), as applicable.

(3) The highest maximum operating parameter and the lowest minimum operating parameter, as applicable for each operating parameter recorded pursuant to § 60.56c(d) or (i) for the calendar year preceding the year being reported, in order to provide the Administrator with a summary of the performance of the affected facility over a 2-year period.

(4) Any information recorded under paragraphs (b)(3) through (b)(5) of this section for the calendar year being reported.

(5) Any information recorded under paragraphs (b)(3) through (b)(5) of this section for the calendar year preceding the year being reported, in order to provide the Administrator with a summary of the performance of the affected facility over a 2-year period.

(6) If a performance test was conducted during the reporting period, the results of that test.

(7) If no exceedances or malfunctions were reported under paragraphs (b)(3) through (b)(5) of this section for the calendar year being reported, a statement that no exceedances occurred during the reporting period.

(8) Any use of the bypass stack, the duration, reason for malfunction, and corrective action taken.

(e) The owner or operator of an affected facility shall submit semiannual reports containing any information recorded under paragraphs (b)(3) through (b)(5) of this section no later than 60 days following the reporting period. The first semiannual reporting period ends 6 months following the submission of information in paragraph (c) of this section. Subsequent reports shall be submitted no later than 6 calendar months following the previous report. All reports shall be signed by the facilities manager.

(f) All records specified under paragraph (b) of this section shall be maintained onsite in either paper copy or computer-readable format, unless an alternative format is approved by the Administrator.

TABLE 1 TO SUBPART EC.—EMISSION LIMITS FOR SMALL, MEDIUM, AND LARGE HMIWI

| Pollutant | Units (7 percent oxygen, dry basis) | Emission limits | | |
|---|---|---|---|---|
| | | 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). |
| Carbon monoxide | Parts per million by volume | 40 | 40 | 40. |
| Dioxins/furans | Nanograms per dry standard cubic meter total dioxins/furans (grains per billion dry standard cubic feet) or nanograms per dry standard cubic meter total dioxins/furans 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). |
| Hydrogen chloride | Parts per million or percent reduction | 15 or 99% | 15 or 99% | 15 or 99%. |
| Sulfur dioxide | Parts per million by volume | 55 | 55 | 55. |
| Nitrogen oxides | Parts per million by volume | 250 | 250 | 250. |
| Lead | Milligrams per dry standard cubic meter (grains per thousand dry standard cubic feet) or percent reduction. | 1.2 (0.52) or 70% | 0.07 (0.03) or 98% | 0.07 (0.03) or 98%. |
| 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%. |
| 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%. |

TABLE 2 TO SUPBART EC.—TOXIC EQUIVALENCY FACTORS

| Dioxin/furan congener | Toxic equivalency factor |
|---|---|
| 2,3,7,8-tetrachlorinated dibenzo-p-dioxin | 1 |
| 1,2,3,7,8-pentachlorinated dibenzo-p-dioxin | 0.5 |
| 1,2,3,4,7,8-hexachlorinated dibenzo-p-dioxin | 0.1 |
| 1,2,3,7,8,9-hexachlorinated dibenzo-p-dioxin | 0.1 |
| 1,2,3,6,7,8-hexachlorinated dibenzo-p-dioxin | 0.1 |
| 1,2,3,4,6,7,8-heptachlorinated dibenzo-p-dioxin | 0.01 |
| octachlorinated dibenzo-p-dioxin | 0.001 |
| 2,3,7,8-tetrachlorinated dibenzofuran | 0.1 |
| 2,3,4,7,8-pentachlorinated dibenzofuran | 0.5 |
| 1,2,3,7,8-pentachlorinated dibenzofuran | 0.05 |

TABLE 2 TO SUPBART EC.—TOXIC EQUIVALENCY FACTORS—Continued

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

TABLE 3 TO SUBPART EC.—OPERATING PARAMETERS TO BE MONITORED AND MINIMUM MEASUREMENT AND RECORDING FREQUENCIES

| Operating parameters to be monitored | Minimum frequency | | Control system | | |
|---|---|---|---|---|---|
| | Data measurement | Data recording | Dry scrubber followed by fabric filter | Wet scrubber | Dry scrubber followed by fabric filter and wet scrubber |
| Maximum operating parameters: | | | | | |
| Maximum charge rate | Continuous | 1×hour | ✔ | ✔ | ✔ |
| Maximum fabric filter inlet temperature | Continuous | 1×minute | ✔ | | ✔ |
| Maximum flue gas temperature | Continuous | 1×minute | ✔ | ✔ | |
| Minimum operating parameters: | | | | | |
| Minimum secondary chamber temperature | Continuous | 1×minute | ✔ | ✔ | ✔ |
| Minimum dioxin/furan sorbent flow rate | Hourly | 1×hour | ✔ | | ✔ |
| Minimum HCl sorbent flow rate | Hourly | 1×hour | ✔ | | ✔ |
| Minimum mercury (Hg) sorbent flow rate | Hourly | 1×hour | ✔ | | ✔ |
| Minimum pressure drop across the wet scrubber or minimum horsepower or amperage to wet scrubber. | Continuous | 1×minute | | ✔ | ✔ |
| Minimum scrubber liquor flow rate | Continuous | 1×minute | | ✔ | ✔ |
| Minimum scrubber liquor pH | Continuous | 1×minute | | ✔ | ✔ |

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