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Office of Air Quality Planning and Standards
Research Triangle Park, NC 27711

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November, 1997

Air

HOSPITAL/MEDICAL/INFECTIOUS WASTE INCINERATOR EMISSION GUIDELINES: SUMMARY OF THE REQUIREMENTS FOR SECTION 111(d)/ 129 STATE PLANS

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Hospital/Medical/Infectious Waste Incinerator Emission Guidelines: Summary of the Requirements for Section 111(d)/129 State Plans (EPA-456/R-97-007)

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Hospital/Medical/Infectious Waste Incinerator Emission Guidelines: Summary of the Requirements for Section 111(d)/129 State Plans (EPA-456/R-97-007)

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Hospital/Medical/Infectious Waste Incinerator Emission Guidelines: Summary of the Requirements for Section 111(d)/129 State Plans (EPA-456/R-97-007)

Office of Air Quality Planning and Standards
U. S. Environmental Protection Agency
Research Triangle Park, North Carolina 27711

November 26, 1997

Disclaimer

This document does not establish any new requirements. Rather, it summarizes existing regulations and provides guidance to States pertaining to State Plan development under Section 129 of the Clean Air Act as amended in 1990.

HOSPITAL/MEDICAL/INFECTIOUS WASTE INCINERATOR EMISSION GUIDELINES
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Executive Summary

Air pollution emissions from the incineration of hospital waste and medical/infectious waste are regulated by Federal rules promulgated to implement the Clean Air Act as amended in 1990. This document addresses the regulations that have been developed for hospital/medical/infectious waste incinerator(s) (HMIWI) under sections 111 and 129 of the Clean Air Act. Section 111 of the Clean Air Act addresses Standards of Performance for Stationary Sources. Section 129 addresses Solid Waste Combustion.

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

(1) Emission Guidelines and Compliance Times for Hospital/Medical/Infectious Waste Incinerators [40 CFR Part 60, subpart Ce] (The Emission Guidelines apply to existing HMIWI that commenced construction on or before June 20, 1996);

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

(3) Standards of Performance for Hospital/Medical/Infectious Waste Incinerators for Which Construction is Commenced After June 20, 1996 [40 CFR Part 60 subpart Ec].

Unlike the subpart Ec New Source Performance Standards, which apply directly to new sources, States are to develop a State Plan in order to compel existing sources to meet the Emission Guidelines. Together, subpart B and subpart Ce specify the State Plan content and the general rules for adopting and submitting State Plans. Working with EPA Regional Offices and States, the EPA Office of Air Quality Planning and Standards has produced this guidance document to assist States in ensuring

submitting State Plans; and section 3 discusses the required elements of a State Plan. The appendices to this document contain reference and explanatory materials, including: (1) frequently asked questions and answers; (2) copies of the HMIWI NSPS and Emission Guidelines; (3) a fact sheet on the Emission Guidelines; (4) clarifications of the requirements and applicability of the Emission Guidelines; (5) contacts for further information; (6) emission factors for calculating HMIWI air pollutant emissions; and (7) references on health effects of pollutants.

On September 15, 1997 the EPA adopted (1) Emission Guidelines for existing HMIWI and (2) New Source Performance Standards for new HMIWI. The Clean Air Act requires that State regulatory agencies implement the Emission Guidelines according to a State Plan developed under sections 111(d) and 129 of the Clean Air Act, and that they submit the State Plan to EPA within 1 year after EPA's promulgation of the Emission Guidelines (i.e., by September 15, 1998).

State Plans must contain specific information and the legal mechanisms necessary to implement the Emission Guidelines. The minimum requirements are listed below.

1. A demonstration of the State's legal authority to carry out the section 111(d)/129 State Plan and identification of enforceable mechanisms, including:

    - a list in the enforcement section of the State Plan indicating the consequences for sources not in compliance and the authority under which a State can shut down/close a source, and

    - a reference to section 129(f)(3) (“PROHIBITION”) which prohibits a plant from operating if it does not comply with the standard.

    - adequate authority to enforce the recordkeeping and notification requirements

- a statement preceding the inventory which says that sources subject to the standard “includes but are not limited to” the inventory in the State Plan, and

- an additional statement that says, “should another source be discovered subsequent to this notice, there will be no need to reopen the State Plan.”

3. An inventory of emissions from HMIWI operating in the State.

4. Emission limitations for HMIWI that are at least as protective as those in the Emission Guidelines.

5. Compliance schedules (including increments of progress for compliance schedules which extend beyond 1 year after State Plan approval).

6. Testing, monitoring, and inspection requirements at least as protective as those in the Emission Guidelines.

7. Reporting and recordkeeping requirements at least as protective as those in the Emission Guidelines.

8. Operator training and qualification requirements at least as protective as those in the Emission Guidelines.

9. Requirements for development of a Waste Management Plan at least as protective as those in the Emission Guidelines.

10. A record of public hearing(s) on the State Plan.

11. Provision for State progress reports to EPA.

12. Title V permit applications due date.

13. A final compliance date not later than 3 years after approval of the State Plan or September 15, 2002, whichever is earlier.[1]

Plan. Plan approval or disapproval will be published in the Federal Register. If a Plan is disapproved, EPA will state the reasons for disapproval in the Federal Register and give the State opportunity to respond to EPA's concerns and submit a revised Plan. A Federal Plan will be developed for each State that does not have an approved Plan in place by September 15, 1999.

Based on the EPA's 1995 inventory of HMIWI subject to the Emission Guidelines, the total combustion capacity of the HMIWI subject to the Emission Guidelines is approximately 846,000 tons per year. According to the inventory, 26 percent of the HMIWI (which represent 67 percent of the U.S. HMIWI combustion capacity) employ some kind of add-on air pollution control device (APCD). An additional 42 percent of the HMIWI population (which constitute approximately 22 percent of the U.S. HMIWI combustion capacity) are believed to have good combustion.[2] Most of these units will require retrofit of an APCD to meet the Emission Guidelines. The remaining 32 percent of existing HMIWI (11 percent of the U.S. HMIWI combustion capacity) is likely to require retrofit of good combustion and an APCD in order to meet the emission limits. The table below presents the approximate number of HMIWI in each State. The figure below shows the location of the HMIWI.

Approximate Number of Hospital/Medical/Infectious Waste Incinerators in Each State

EPA Region	State	Approximate Number of HMIWI[a]
I	Connecticut	25
	Massachusetts	109
	Maine	36
	New Hampshire	17
	Rhode Island	11
	Vermont	3
II	New York	18
	New Jersey	61
	Puerto Rico	b
	Virgin Islands	b
III	Virginia	65
	Delaware	8
	District of Columbia	3
	Maryland	82
	Pennsylvania	72
	West Virginia	14
IV	Florida	44
	Georgia	103
	North Carolina	90
	Alabama	54
	Kentucky	37
	Mississippi	21

Approximate Number of Hospital/Medical/Infectious Waste Incinerators in Each State, Continued

EPA Region	State	Approximate Number of HMIWI[a]
V	Minnesota	119
	Wisconsin	10
	Illinois	108
	Indiana	92
	Michigan	287
	Ohio	126
VI	Arkansas	39
	Louisiana	92
	New Mexico	b
	Oklahoma	32
	Texas	63
VII	Iowa	34
	Kansas	114
	Missouri	59
	Nebraska	33
VIII	Colorado	39
	Montana	5
	North Dakota	76
	South Dakota	b
	Utah	2
	Wyoming	7

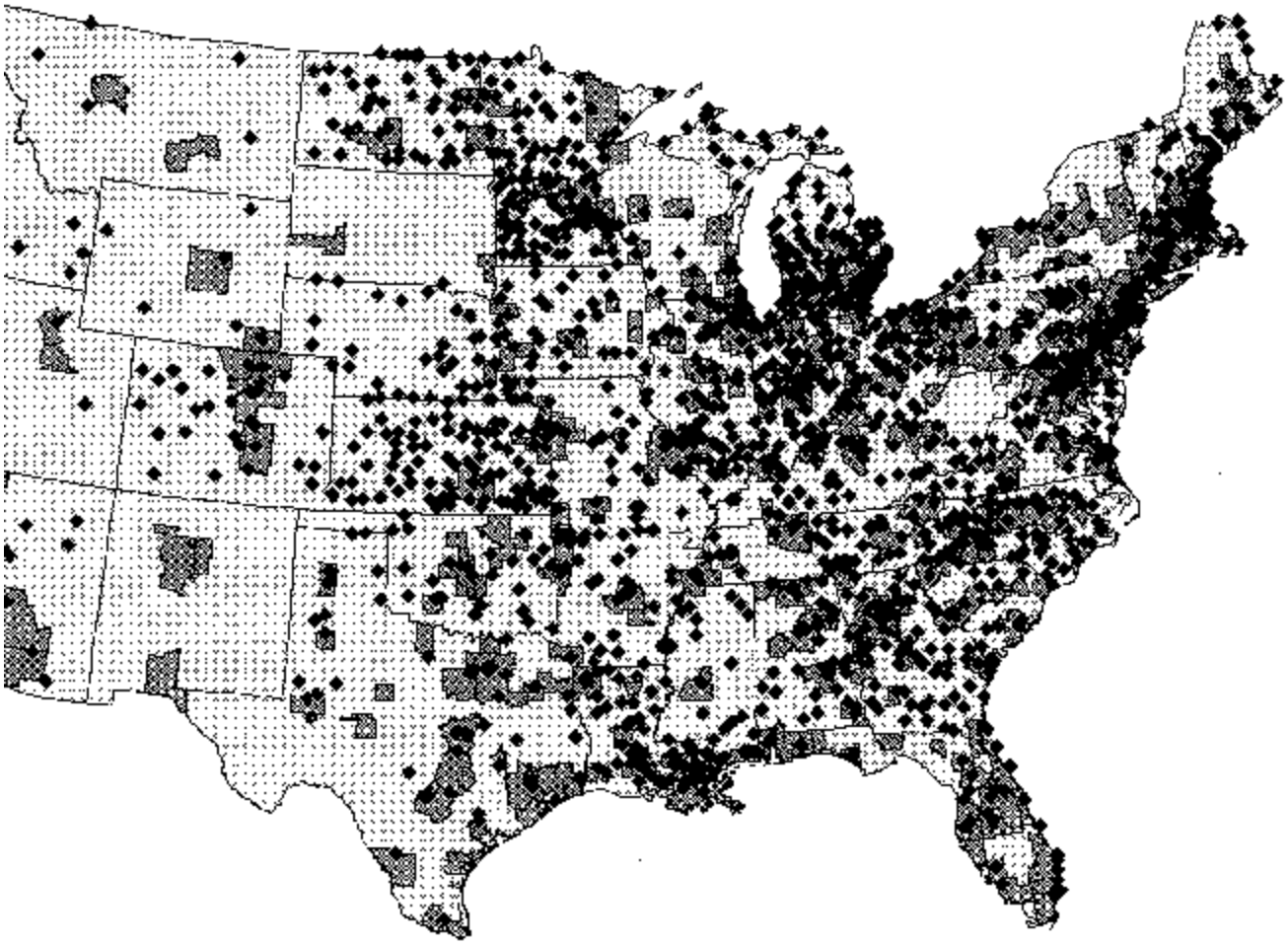
Approximate Number of Hospital/Medical/Infectious Waste Incinerators in Each State, Continued

EPA Region	State	Approximate Number of HMIWI[a]
IX	Arizona	14
	California	23
	Hawaii	b
	Nevada	b
X	Alaska	b
	Idaho	12
	Oregon	b
	Washington	31
Total		2,373

[a] The approximate number of HMIWI is based on data gathered in 1995. The number of HMIWI in each State may have changed since development of the 1995 inventory.

[b] Not known at present.

Inventory of Existing Medical Waste Incinerators (1995).



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List of Acronyms and Abbreviations

AFS	Aerometric Emissions Information Retrieval System Facility Subsystem
AHA	American Hospital Association
APCD	Air Pollution Control Device
CAA	Clean Air Act (of 1990)
Cd	Cadmium
CFR	Code of Federal Regulations
CO	Carbon Monoxide
Dioxin/furan	Tetra- through octa- chlorinated dibenzo-p-dioxins and dibenzofurans
EG	Emission Guidelines
EPA	U.S. Environmental Protection Agency
FR	Federal Register
HMIWI	Hospital/Medical/Infectious Waste Incinerator(s)
HCl	Hydrogen Chloride
Hg	Mercury
lb/hr	pounds per hour
MWC	Municipal Waste Combustor
NAAQS	National Ambient Air Quality Standards
NEDS	National Emissions Data System
NESHAP	National Emission Standards for Hazardous Air Pollutants
NO_x	Nitrogen Oxides
NSPS	New Source Performance Standard

TEQ	Toxic Equivalent Quantity

1.0 Introduction

The purpose of this document is to assist the State air regulatory agencies in developing State Plans which will implement regulations controlling air pollutant emissions from hospital/medical/ infectious waste incinerator(s) (HMIWI). Under the Clean Air Act as amended in 1990, the United States Environmental Protection Agency (EPA) is required to develop regulations to control air pollutant emissions from HMIWI. Emissions from new HMIWI are addressed by standards of performance for new sources (New Source Performance Standards [NSPS]), and emissions from existing HMIWI are addressed by guidelines for existing sources (Emission Guidelines). The EPA promulgated the NSPS (subpart Ec) and Emission Guidelines (subpart Ce) for HMIWI on September 15, 1997. States are to develop State Plans to implement the Emission Guidelines for existing sources and submit the State Plans to EPA by September 15, 1998. This document provides State agencies information on the required content of these State Plans.

1.1 Organization of this Document

This document brings together the information on the relevant parts of the various regulations that affect existing HMIWI constructed on or before June 20, 1996. These regulations were developed under section 111(d) and section 129 of the Clean Air Act. The regulations are codified in title 40 of the Code of Federal Regulations (CFR) Part 60. The CFR rules include (1) Adoption and Submittal of State Plans for Designated Facilities (subpart B) and (2) the Emission Guidelines for existing HMIWI (subpart Ce).

Table 1-1. Appendices to This Document

Appendix	Title
A	Answers to Questions About the Emission Guidelines and State Plan Process
B	Key Elements of an Acceptable Section 111(d)/129 State Plan
C	Emission Guideline Fact Sheet (40 CFR 60 Subpart Ce)
D	Applicability of the HMIWI Emission Guidelines
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F	EPA Regional and State/Local Agency Contacts
G	HMIWI Emission Inventory
H	References on Health Effects
I	NSR Permit Requirements for HMIWI
J	Clean Air Act Section 111(d)
K	Clean Air Act Section 129
L	40 CFR 60 Subpart B
M	40 CFR 60 Subparts Ce (EG) and Ec (NSPS)
N	Example Exemption Claim Forms

1.2 Clean Air Act Requirements

Section 111(d) has been included in the Clean Air Act since the 1970's and requires EPA to establish procedures for submission of State Plans for implementing Emission Guidelines. The first Emission Guideline adopted was for sulfuric acid plants in 1977. Other Emission Guidelines have been adopted since that time. The State Plans implement and provide mechanisms for enforcing the

Municipal Waste Combustors (MWC) similarly address both section 111(d) and section 129 requirements.)

Detailed procedures for submitting and approving State Plans under section 111(d) were promulgated by EPA in 1975 as 40 CFR Part 60, subpart B and amended in 1979, 1989, and 1995. The 1995 amendments to subpart B were adopted on December 19, 1995 in the same action that promulgated the subpart Cb Emission Guidelines for MWC. The revisions to subpart B address differences between sections 129 and 111(d) of the Clean Air Act. In particular, section 129 requires that State Plans for HMIWI be submitted to EPA within 1 year after promulgation of the Emission Guidelines, whereas the subpart B procedures developed to implement section 111(d) Plans have a different schedule. Also, section 129 requires section 111(d)/129 State Plans to be "at least as protective as the guidelines;" whereas section 111(d) allows States flexibility to consider the remaining useful life of the source and other factors in developing State Plans and standards. Where section 129 conflicts with section 111(d), the December 19, 1995 revisions supersede otherwise applicable requirements of subpart B. (See Appendices J, K, and L for the full text of section 111(d), section 129, and subpart B.) Figure 1-1 demonstrates the relationship between sections 111(d), section 129, and subpart B.

1.3 Emission Guidelines

The Emission Guidelines for HMIWI were promulgated on September 15, 1997 (62 FR 48347), and codified in 40 CFR Part 60, subpart Ce. An outline of the Emission Guidelines is presented in Table 1-2. The Emission Guidelines apply to existing HMIWI that commenced

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

Statues	Rules, Regulations, and Procedures
CAA	40 CFR Part 60
Section 111(b) (new sources)	NSPS----->General provisions --> subpart A Source category NSPS --> subpart D-ZZZ
Section 111(d) (existing sources)	EG------> Procedures (State Plan) --> subpart B - amended to allow additional directions specified in section 129 Source category EG -->subpart Cb (MWC), Ce (HMIWI), . . .
Section 129[3]	Provides more specific directions above sections 111(b) and 111(d) for those solid waste combustors listed in section 129.

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

- State rule must be at least as protective as the EG.
- Deletes opportunity for sources to have a longer compliance schedule than what the EG specifies.
- Allows States a longer time for submittal of their State Plan (i.e., 12 months instead of 9 months).

Table 1-2. Outline of the Emission Guidelines for HMIWI (40 CFR Part 60, Subpart Ce)

Section	Contents
60.30e	Scope
60.31e	Definitions
60.32e	Designated facilities
60.33e	Emission guidelines
60.34e	Operator training and qualification guidelines
60.35e	Waste Management Plan
60.36e	Inspection guidelines
60.37e	Compliance, performance testing, and monitoring guidelines

1.4 Requirements for State Plans

States are to develop section 111(d)/129 State Plans to implement the HMIWI Emission Guidelines and to submit their Plans to the appropriate EPA Regional Office for approval. The first step for meeting the State Plan requirement is to identify and prepare a list of sources operating in the State that are subject to the Emission Guidelines. If there are no sources affected by the Emission Guidelines in the State, then the State need only submit a letter of certification called a negative declaration to their EPA Regional Administrator, and no Plan is submitted.[4]

All sources, whether they are on the State's list or not, are subject to the State Plan and must be in compliance no later than 3 years following State Plan approval or by September 15, 2002, whichever is earlier. In order to cover sources that might be discovered after submittal of the State Plan, States should include certain language in the State Plan. Although a State could choose to revise the State Plan in order to establish a separate, but equally protective compliance schedule for the newly discovered source, it is not necessary, provided the State Plan includes the following:

1. A statement preceding the inventory which says that sources subject to the standard "include, but are not limited to" the inventory in the State Plan; and

2. In additional statement that says, "Should another source be discovered subsequent to this notice, there will be no need to reopen the State Plan."

The EPA also advises States to include in their State Plan a generic compliance schedule with which "all other applicable sources" not listed individually in the State Plan must comply. Any newly discovered source would be bound to that generic compliance schedule.

It is possible that HMIWI that are not operating at the time of State Plan submittal could reopen as an existing unit in the future. Such a unit would be considered an existing HMIWI, assuming it was constructed prior to June 20, 1996.[5] Therefore, States should make a reasonable effort to include sources in the inventory which have shut down but have the potential to reopen.

In order for an HMIWI that shut down to reopen, the State must submit a State Plan to require retrofit of the necessary air pollution controls before the HMIWI reopens. The revised Plan for the non-operating unit must contain a final compliance date and legal authority to ensure that the HMIWI would complete retrofit before reopening. As discussed above, the State does not need to revise the State Plan in order to require newly discovered sources to retrofit, but rather, need only refer them to the generic compliance schedule contained in the State Plan. If a source were discovered well into the compliance time and had already missed several increments of progress, it would need to shut down immediately and remain closed until it had caught up with the increments. Of course, the State always has the option of assigning a separate compliance schedule to that newly discovered source, but in order to do so, the State would need to revise the State Plan.

States which have HMIWI are required to submit a section 111(d)/129 State Plan. At a minimum, the State Plan must include the elements listed below.

1. A demonstration of the State's legal authority to carry out the section 111(d)/129 State Plan and identification of enforceable mechanisms, including:

    - a list in the enforcement section of the State Plan indicating the consequences for sources not in compliance and the authority under

- a reference to section 129(f)(3) ("PROHIBITION") which prohibits a plant from operating if it does not comply with the standard.

- adequate authority to enforce the recordkeeping and notification requirements for co-fired combustors and incinerators burning only pathological, low-level radioactive, and chemotherapeutic waste (see section 60.32e of subpart(e)).

2. An inventory of sources in the State affected by the Emission Guidelines, including to the best of the State's knowledge, HMIWI that have shut down and are capable of restarting, and including:

   - a statement preceding the inventory which says that sources subject to the standard "includes but are not limited to" the inventory in the State Plan, and

   - an additional statement that says, "should another source be discovered subsequent to this notice, there will be no need to reopen the State Plan."

3. An inventory of emissions from HMIWI operating in the State.

4. Emission limitations for HMIWI that are at least as protective as those in the Emission Guidelines.

5. Compliance schedules (including increments of progress for compliance schedules which extend beyond 1 year after State Plan approval).

6. Testing, monitoring, and inspection requirements at least as protective as those in the Emission Guidelines.

7. Reporting and recordkeeping requirements at least as protective as those in the Emission Guidelines.

8. Operator training and qualification requirements at least as protective as those

12. Title V permit applications due date.

13. A final compliance date not later than 3 years after approval of the State Plan or September 15, 2002, whichever is earlier. [6]

The State Plans are due to EPA by September 15, 1998. Table 1-3 is a cross check of subpart B requirements and of whether or not each section applies to HMIWI. Table 1-3 also indicates where the HMIWI Emission Guidelines (subpart Ce) and section 129 of the Clean Air Act override specific provisions of subpart B. The EPA published policy guidance for subpart B in 1977. That guidance applies to the HMIWI Emission Guidelines except where overridden by the changes introduced in section 129 of the Clean Air Act of 1990 and subpart Ce.

Table 1-3. Regulations for Adopting and Submitting State Plans (40 CFR 60 Subpart B)

Section Number and Title	General Contents	Does the section Apply to HMIWI ?
60.20 "Applicability"	Subpart B applies when final Guidelines are promulgated (i.e., subpart Ce).	Yes, final HMIWI Guidelines (subpart Ce) were published September 15, 1997 so subpart B now applies to HMIWI.
60.21 "Definitions"	Definitions of key terms.	Definition of "designated pollutant" in subpart B does not apply to HMIWI. Subpart Ce lists nine HMIWI pollutants that are covered. Definition of "designated facility" in subpart B is defined in subpart Ce as each HMIWI for which construction commenced on or before June 20, 1996.
60.22 "Publication of guideline documents, Emission Guidelines, and final compliance times"	Descriptions of contents of Emission Guidelines to be developed by EPA.	Yes. Guidelines for HMIWI (subpart Ce) have been developed and published as required (September 15, 1997 [62 FR 48347]).
60.23 "Adoption and submittal of State Plans, public hearings"	Schedules and procedures for States to follow in developing and submitting State Plans. Requirements for public hearings on State Plans.	Yes, except for 60.23(a). Section 129 specifies that State Plans for HMIWI be submitted 1 year after publication of subpart Ce (i.e., September 15, 1998).
60.24 "Emission standards[7] and compliance schedules"	State Plans must include emission standards and compliance schedules. State Plans may be more or less stringent than the Guidelines.	Yes, except 60.24(f) does not apply. Subpart Ce and Section 129 specify that State Plans must be "at least as protective" as the Guidelines.
60.25 "Emission inventories, source surveillance, reports"	Plans must include a plant inventory and an emissions inventory and provisions for monitoring compliance. States must submit progress reports to EPA.	Yes.
60.26 "Legal authority"	Plans must demonstrate that the State has legal authority to carry out the Plan as submitted.	Yes.

Table 1-3. Continued

Section Number and Title	General Contents	Does the section Apply to HMIWI ?
60.27 "Actions by the Administrator"	Procedures for EPA review and approval or disapproval of Plans. Federal Plans will be developed if States have not submitted approvable Plans.	The schedules in 60.27 do not apply. For HMIWI, section 129(b)(2) of the Clean Air Act allows 6 months for EPA to approve or disapprove State Plans. The EPA will implement a Federal Plan per section 129(b) for all States (with affected sources) which do not have an EPA approved State Plan in place by September 15, 1999 (2 years after promulgation).
60.28 "Plan revisions by the State"	Procedures for revision of Plans.	Yes.
60.29 "Plan revisions by the Administrator"	Procedures for revision of Plans.	Yes.

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

The State Plans for implementing the HMIWI Emission Guidelines are different from State Implementation Plans (SIP) required by sections 110 or 172 of the Clean Air Act. The State Plan and the SIP are programs for State implementation of Federal requirements, and for both, the administrative procedures, particularly the public hearing process, are similar. Both programs are designed to achieve emission reductions at sources by identifying the pollutant to be controlled, establishing the emission limits for the source, and establishing procedures to ensure that emission limits are met.

However, the States and EPA fulfill different responsibilities under the two programs. The goal of section 111(d) State Plans is to control the emissions of designated pollutants[8] by

EPA on a national level. States are responsible for developing and implementing a program to achieve compliance with these technologically-based standards.

The goal of the SIPs, on the other hand, is to attain and maintain National Ambient Air Quality Standards (NAAQS) or ambient concentrations for certain criteria pollutants (Pb, SO_2, PM_{10}, NO_2, CO, and ozone) in a given area. Hence, in the SIP program, the State establishes emission limitations or standards based on the sources' contributions to local air quality and other local factors. The emission control requirements for a regulated source category under a SIP may vary from plant to plant based on local factors.

The States are responsible for implementing both section 111(d)/129 State Plans and SIP programs, and both programs complement each other. Where the SIP requirements are adequate to meet the 111(d)/129 standard, the State may elect to submit a section 111(d)/129 State Plan that relies on the requirements of the SIP (section 110) to meet the section 111(d)/129 emission standard. In addition, where the section 111(d)/129 requirements protect the NAAQS, the State may elect to rely on these requirements in the SIP control strategy.

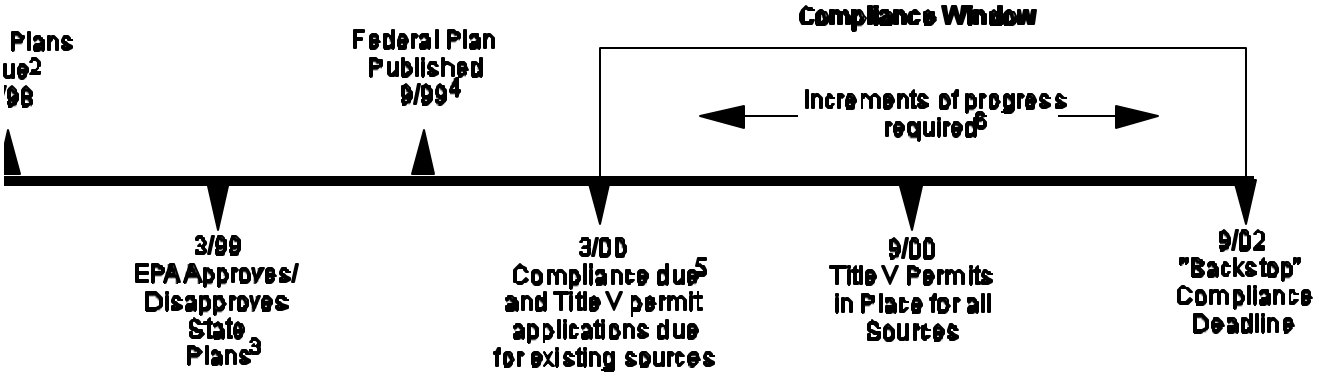
2.0 Schedule and Responsibilities

Sections 111(d) and 129 of the Clean Air Act require each State to adopt and submit Plans that implement the HMIWI Emission Guidelines within 1 year after EPA publication of the final Emission Guidelines. Emission Guidelines for HMIWI (40 CFR Part 60, subpart Ce) were published on September 15, 1997 (62 FR 48347) and State Plans must be submitted to EPA on or before September 15, 1998. Figure 2-1 is a timeline which shows how implementation of the Emission Guidelines might proceed if the maximum time allowed is used for each event.

2.1 State Plan Schedule

In order to submit the section 111(d)/129 State Plan by September 15, 1998, States need to develop the section 111(d)/129 State Plan as soon as possible and complete the required public hearings. The steps that are necessary for States to develop and submit the State Plans are listed in Table 2-1, along with an example schedule.

After the State Plan is submitted, EPA is required to approve or disapprove the Plan no later than 6 months of State Plan submittal. The EPA's decision to approve or disapprove each State Plan will be published in the Federal Register (FR). Final decisions will be codified in 40 CFR Part 62, "Approval and Promulgation of State Plans for Designated Facilities and Pollutants." If a State Plan is not approvable, EPA will attempt to discuss its concerns about the State Plan with the State prior to official disapproval. If the Plan is not approved, the basis for disapproval will be discussed in the FR notice and the State would have to opportunity to submit a revised Plan addressing EPA’s concerns. If



State Plans be submitted not later than one year after promulgation of the rule.
EPA to approve or disapprove a State Plan within 180 days of submission.
EPA to develop a Federal Plan within 2 years of rule promulgation (if necessary).
'A approval of State Plan under sec. 60.39e of subpart Ce unless the State has granted an extension to a source
oval of State Plan but not less than 5 years after promulgation).
part B requires legally enforceable increments of progress for any compliance schedule extending beyond
lan approval. Sec. 60.39e(c)(1)-(9) of subpart Ce and Sec. 60.21 of subpart B list suggested increments of progress
art B contains five required increments of progress.
ources have 36 months from promulgation to get a complete permit application into the permitting agency.

equirements for all 111(d) State Plans. Amended 12/19/95 to allow subsequent subparts (Ce and Ec) to supersede

IIWI's.
HMIWI's.
/C's.
MWC's.

Figure 2-1. HMIWI Implementation Timeline

Section 111(d)/129 State Plans must include a compliance schedule for all existing HMIWI located in the State. The compliance schedule can allow up to 3 years from State Plan approval for HMIWI to comply provided the Plan includes enforceable increments of progress. In all cases, all applicable sources must be in compliance no later than 3 years after State Plan approval by EPA or September 15, 2002, whichever is earlier. Compliance can be achieved by either completing retrofit of air pollution controls or by shutdown. States may establish compliance schedules that are shorter than the times allowed by the Emission Guidelines, but they may not establish compliance schedules that are longer than allowed by the Emission Guidelines.

For purposes of the Emission Guidelines, the HMIWI population has been divided into three subcategories which are based on HMIWI pound per hour (lb/hr) capacity to burn hospital waste and medical/infectious waste. The "small" subcategory consists of HMIWI that burn less than or equal to 200 lb/hr. State Plans may further divide the small subcategory to allow some small HMIWI located in rural areas the option of meeting less stringent Emission Guidelines. The "rural criteria" to be used in determining which small HMIWI could be allowed to meet the less stringent Emission Guidelines is discussed in Appendix D. The "medium" subcategory includes HMIWI that burn between 200 and 500 lb/hr, and the "large" subcategory consists of HMIWI which burn more than 500 lb/hr. Hospital/medical/infectious waste incinerator capacity is to be determined using the methods presented in §60.51c of subpart Ec and in Appendix D of this document. The emission limits in the Emission Guidelines are slightly different for each of the three HMIWI subcategories. However, the compliance schedules are the same for all HMIWI, regardless of the subcategory. The Emission Guidelines give HMIWI up to 3 years after section 111(d)/129 State Plan approval by EPA to complete retrofits, or until September 15, 2002, whichever is earlier. If the compliance schedule for an HMIWI extends

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

Action	Date
Begin source inventory	Immediately
Emission Guidelines promulgated by EPA	September 15, 1997
EPA issues summary document on section 111(d)/129 State Plans	November 1997
Decide what State authority to use	October 1997
Start State rulemaking or other procedure needed to ensure State authority	November 1997
Start drafting State Plan	November 1997
Notice of public hearings	January 1998 (30 days before hearing)
Complete State rulemaking or other procedure needed	May 1998
Complete public hearing on State Plan	May 1998
State Plans due to EPA Regional Office	September 15, 1998
Respond to any clarifications requested by EPA	During the 180 day period following September 15, 1998
EPA approval/disapproval of the State Plan	No later than 6 months after State Plan submittal
If disapproved, submit revised approvable State Plan	September 15, 1999
Permit applications due	September 15, 2000

In order to avoid a Federal Plan, the approved State Plan must be in the Federal Register prior to September 15, 1999.

2.2.1 EPA Responsibilities

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

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

Federal Plan. The EPA anticipates that all States will develop approvable section 111(d)/129 State Plans. However, in the event an approvable State Plan is not submitted, EPA will develop and implement a Federal Plan.

The EPA encourages Tribes to develop Tribal Plans for their HMIWI and EPA will

Title V Permit. Section 129 requires sources to have a complete title V permit applications submitted to the permitting agency no later than 36 months after the promulgation date for the Emission Guidelines (i.e., September 15, 2000). The EPA reviews and comments on State development of title V operating permits. The individual title V permits are not a required component of State Plan submittal, nor are they required for EPA approval of the State Plan, unless a State demonstrates that it has the ability under State law to utilize title V permits as its legally enforceable mechanism.

2.2.2 State Responsibilities

Developing a State Plan. The State develops and submits a State Plan that meets the criteria presented in sections 111(d) and 129, the Emissions Guidelines, and this document. This document outlines how States can meet this responsibility.

Establishing Compliance Schedules. The State Plan must include emission limits and compliance schedules for all HMIWI. When developing a workable section 111(d)/129 State Plan, States should contact HMIWI owners and operators to ensure that they understand the requirements of the Emission Guidelines. State Plans are to require facilities to come into compliance with the State Plan by either completing a retrofit of shutting down by the date 1 year after EPA approval of the State Plan. If the State Plan contains increments of progress, HMIWI may be allowed to extend their retrofit schedule beyond the 1-year compliance date. All HMIWI planning to retrofit must do so within 3 years of EPA approval of the State Plan, but no later than September 15, 2002. All HMIWI planning to shut down must do so within 1 year after EPA approval of the State Plan,

Ensuring Compliance. Plants must either comply (i.e., complete retrofits) or shut down by the dates established in the section 111(d)/129 State Plans. In order to prevent sources from restarting without proper controls, State Plans must demonstrate authority that would require HMIWI which shut down to maintain closure. States are advised to include a generic compliance schedule in their State Plans to cover facilities which have shut down but may reopen in the future. Units that shut down by the date 1 year after EPA approval of the State Plan, and restart prior to the September 15, 2002 deadline must complete all of the missed increments of progress in the State's generic compliance schedule before reopening. Units which restart after the September 15, 2002 compliance deadline must comply with the State Plan before resuming operation.

Hospital/medical/infectious waste incinerators that shut down can be divided into two groups. The first group is HMIWI that have shut down or will shut down and are not planning to restart. Once shut down, such sources cannot restart without a State Plan revision and retrofit of air pollution control equipment.

The second group is HMIWI that shut down as an element of their retrofit activities. For these HMIWI, schedules for shutdown and completion of retrofit activities would be included in the State Plan. For retrofitting plants, the State Plan must include the five enforceable increments of progress for retrofit activities (discussed in section 3.10.3), along with a sixth increment, a date for shutdown. Under the Plan, the HMIWI would shut down by the specified date and could not restart until the other increments of progress, including retrofit of controls, is complete.

Submitting Progress Reports. States must report annually to the EPA on the

title V operating permit requirements. This is a State responsibility and is not a required component of related section 111(d)/129 State Plans. Section 5.0 of this document discusses the title V permit requirements for HMIWI.

2.2.3 Source Responsibilities

Developing Compliance Plans and Schedules. Hospital/medical/infectious waste incinerator owners and operators must work with the State to develop a compliance Plan and retrofit schedule for the State Plan that are both workable and meet requirements established by the State to implement the Emission Guidelines. All HMIWI must either shut down within 1 year of EPA approval of the State Plan[1] or complete retrofits to comply with the emission limits not later than 3 years after section 111(d)/129 State Plan approval or by September 15, 2002, whichever is sooner. Critical information is needed about each HMIWI such as controls in place and extent of retrofit needed in order to support State Plan development and development of an emission inventory for all affected HMIWI as part of the public participation process (see section 3.4).

Upgrading or Retrofitting Facilities. Owners and operators must retrofit or upgrade their facilities to meet the emission limits on the compliance schedules established by the State.

Meeting Additional State Plan Requirements. In addition to completing the necessary retrofits, owners and operators are responsible for meeting other State Plan requirements. Facilities are required to comply with operator training and qualification requirements, inspection requirements (HMIWI meeting the small rural criteria only), and to develop a Waste Management Plan.

qualification requirements and the inspection requirements, which must be completed within 1 year after State Plan approval.

Related Section 129 Programs. Owners and operators must apply for a title V operating permit in accordance with their State's part 70 applications process. These permits would include all applicable Federal and State requirements pertaining to air emissions, including the applicable requirements of the section 111(d)/129 State Plan. Every source subject to the HMIWI rule must have a title V permit, unless the source is a co-fired combustor or an incinerator which burns only pathological, low-level radioactive, and/or chemotherapeutic waste. Title V permit applications are due to the permitting authority no later than 36 months after promulgation of the Emission Guidelines. Under section 503(c) of the CAA, the permitting authority has 18 months to deny or issue the permit. Title V operating permits are discussed in more detail in section 5.0.

3.0 Required Elements of an Acceptable State Plan

Section 1.4 and Appendix B of this document contain summaries of the required elements of a State Plan. States may find this summary helpful in preparing section 111(d)/129 State Plans, and EPA will use it in reviewing the Plans. Table 3-1 summarizes the elements of the State Plan for HMIWI, provides citations from subparts B and Ce, and identifies the sections of this chapter that discuss each element.

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

3.1 <u>Demonstration of Legal Authority</u>

The section 111(d)/129 State Plan must demonstrate that the State has the legal authority under current State law to adopt and implement the emission standards and compliance schedules in the State Plan. The legal authority must support the legal mechanism selected by the State to implement the emission limits for HMIWI. The legal authority must be available to the State at the time the State submits its section 111(d)/129 State Plan to EPA [40 CFR Part 60, subpart B,

A State may use existing demonstrations of legal authority to meet the requirements of subpart B. Which existing authorities the State uses to implement the section 111(d)/129 requirements depends on the legislative structure of the State. This

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

Required Item	Reference in 40 CFR Part 60, Subpart B or Ce	Section of this Document
Demonstration that State has legal authority to carry out Plan	60.26(a) of subpart B	3.1
Enforceable mechanisms selected by the State to implement the Guidelines	60.24(a) of subpart B	3.2
Inventory of HMIWI, their emissions and information related to their emissions	60.25(a) and 60.25(c) of subpart B	3.3 and 3.4
Allowable emissions	60.24(b)(1) of subpart B and 60.33e of subpart Ce	3.5
Test methods and procedures used for determining compliance with the emissions standards	60.24(b)(2) of subpart B and 60.37e of subpart Ce	3.6
Provisions for monitoring HMIWI compliance status, including: 1. Legally enforceable procedures for requiring the maintenance of records and periodic reporting to the State for the determination of compliance, 2. Periodic inspections and testing, and 3. Testing, monitoring, recordkeeping, and reporting requirements specified in subpart Ce.	60.25(b) of subpart B and 60.36e, 60.37e, and 60.38e of subpart Ce	3.6
Operator training and qualification	60.34e of subpart Ce	3.7
Inspections	60.36e of subpart Ce	3.8
Waste Management Plan	60.35e of subpart Ce	3.9
Compliance schedules and legally enforceable increments of progress for HMIWI to achieve compliance	60.24(a) and 60.24(e)(1) of subpart B and 60.39e of subpart Ce	3.10
Certification that a public hearing was held before the State Plan was adopted and list of the attendees at the hearing and their affiliation, with a summary of their presentations and handouts	60.23(f)(1) and (2) of subpart B	3.11
State progress reports	60.25(f) of subpart B	3.12

implementation guidance provides the minimum requirements of section 111(d) and 129 pertaining to HMIWI, and leaves the State flexibility to implement the requirements as long as provisions are enforceable under State law.

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

1. Adopt emission standards (including stack opacity) and enforceable conditions (see section 3.2) as well as compliance schedules applicable to the designated facilities and pollutants for which the section 111(d)/129 State Plan is submitted;

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

3. Obtain information necessary to determine compliance;

4. Require reporting and recordkeeping, operator training and qualification, equipment inspections, and testing;

5. Require the use of monitors and require emission reports of HMIWI owners/operators;

6. Make emission data available to the public; and

7. Require a Waste Management Plan.

Demonstrations of legal authority can take several forms. States that use a legal mechanism other than rulemaking to implement the Emission Guidelines should submit legal

State demonstrates that the State governmental agency has adequate authority [section 60.26(e)]. The State may authorize a local agency to implement a portion of the Section 111(d)/129 State Plan provided that the local agency demonstrates that it has adequate legal authority to implement that portion of the Plan and the State is not relieved of responsibility [section 60.26(e)].

3.2 Criteria for an Adequate Enforceable Mechanism

Many States that have HMIWI covered by the Guidelines will develop section 111(d)/129 State Plans that use State rules as the legal instrument to enforce the Emission Guidelines. However, States may use alternative mechanisms to implement the Emission Guidelines. An essential element of a section 111(d)/129 State Plan is the emission standards, which 40 CFR Part 60, subpart B section 60.20(f) defines as "a legally enforceable regulation setting forth an allowable rate of emissions into the atmosphere, or prescribing equipment specifications for control of air pollution emissions." For section 111(d)/129 State Plans, EPA interprets the term "regulation" in section 60.22(f) to include - in addition to a uniform State requirement or State rule - other mechanisms that are legally enforceable under State law. For example, depending on the applicable State law, enforceable mechanisms that might be used as the vehicle for implementing HMIWI Emission Guidelines may include a regulatory or administrative order, a compliance order, or a State operating permit.

A State may select other enforceable mechanisms provided that the State demonstrates that it has the underlying authority and demonstrates that the selected mechanism is State enforceable. In addition, a State may have the authority under its State law to incorporate the Emission Guidelines

Note that the pollutants that must be regulated under the HMIWI Emission Guidelines are a combination of criteria and hazardous air pollutants. Generally, States have adequate authority under their air pollution statutes to regulate both criteria pollutants and hazardous air pollutants through a variety of mechanisms. As mentioned earlier, the State legal authority must be in place and effective at the time of State Plan submittal.

If the State relies on a mechanism that is not a State rule to implement the Emission Guidelines, such as a regulatory order, the State must document in the State Plan how the selected mechanism ensures that the HMIWI will meet the requirements of the EG and attach a copy of the enforceable mechanism. If a State rule is used, only citations from the overall rule and copies of the sections pertaining to HMIWI are required. The State does not have to submit a copy of the entire rule.

The State may submit a section 111(d)/129 State Plan that relies on the requirements in the SIP to meet the section 111(d)/129 emission standard for a particular pollutant, where they are found to be adequate. If the State relies on existing or revised SIP emission limits to implement the section 111(d)/129 HMIWI emission standards, the State Plan must cite the SIP and the date it became effective. The State must also document how the SIP assures that the requirements of 111(d)/129 are met. In all cases, the mechanism(s) must be in place at the time of Plan submittal.

A reduced demonstration of authority is allowed where all HMIWI in a State have already shut down or will shut down within 1 year of Plan approval. Such demonstration of legal authority does not need to point to an enforceable mechanism which orders a plant to shut down.

must give the State the requisite authority to enforce the emission limit using the legal mechanism identified by the State. Thus, a mechanism (e.g., a regulatory order) that is approvable for one State under its State law might not be approvable in another State under the law in that State.

3.3 Source Inventory

A complete source inventory of affected HMIWI in the State regulated by the Emission Guidelines must be submitted as part of the section 111(d)/129 State Plan [40 CFR Part 60, subpart B, section 60.25(a)]. Sources affected by the Emission Guidelines that must be included in the State's source inventory include: (1) HMIWI, (2) co-fired combustors, and (3) incinerators burning only pathological, low-level radioactive, and chemotherapeutic waste alone or in combination. Each of these three types of combustors are defined in section 60.51c of subpart Ec. The HMIWI are subject to all of the subpart Ce requirements. Co-fired combustors and incinerators burning pathological, low-level radioactive, and chemotherapeutic waste are only required to notify the Administrator of a exemption claim and to keep certain records. Nevertheless, these sources are affected by the Emission Guidelines and thus, must be included in the source inventory. In addition, States are encouraged to make a reasonable effort to include sources which have shut down their incinerator but, which still have the capability of resuming operation.

In cases where a facility has shut down its HMIWI and does not intend to resume operation, the HMIWI may be left off of the State's source inventory if the State determines that the HMIWI is inoperable. Criteria for determining whether an incinerator is inoperable could include, but are not limited to one or more of the following conditions:

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

3.4 Emission Inventory

An emission inventory, based on the HMIWI source inventory, for the pollutants regulated by the Emission Guidelines is required by 40 CFR Part 60, subpart B, section 60.25(a) and is to be included in the section 111(d)/129 State Plan. The emissions inventory, as well as the source inventory, must be made available to the public at the public hearing and presented with the applicable emission standards. The inventory data should include CEMS data, actual test data, or estimates of 1997 emissions where practicable. Means of estimating emissions from HMIWI are readily available and are discussed in section 3.4.1 below and in Appendix G. It may be more difficult to estimate emissions from co-fired combustors and incinerators burning only pathological, low-level radioactive, and chemotherapeutic waste due to the mixtures of wastes combusted. Unlike HMIWI, co-fired combustors and incinerators burning pathological, low-level radioactive, and chemotherapeutic waste are not required to be subject to the emission limits in the State Plan. Therefore, while States are encouraged to include these sources in their source inventories, States may elect to leave these units out of the emissions inventory. Likewise, States may choose to leave incinerators which have shut down out of their emissions inventory since these sources would have zero emissions.

3.4.1 Emission Estimation Methods

Estimates of emissions for the emission inventory can be derived from a variety of

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

3rd choice. Emission factors:

a. AP-42/FIRE[2] emission factors rated "A" through "D"--based on source tests performed at one or more facilities within an industry ("A" is the highest rating) or EPA emission factors generated from data used in the development of the HMIWI Emission Guidelines (presented in Appendix G).

b. State emission factors--possibly more optimized to local or regional conditions.

c. Industry emission factors.

d. AP-42/FIRE emission factors rated "E" and "U" ("E" is the lowest rating on the A through E scale, and "U" is unratable).

Emission factors that apply to HMIWI are included in Appendix G and can be used for developing the required emission inventory. These emission factors were generated based on data used for development of the Emission Guidelines and are appropriate for developing the emission inventory to be submitted in the section 111(d)/129 State Plans due September 15, 1998. States can also use their own emission factors or emission factors from AP-42.[3] Where emission factors are used, the AP-42 *Compilation of Air Pollutant Emission Factors*, provides preferred emission estimation methods. Example calculations for estimating emissions from emission factors are provided in AP-42. Where emissions data from actual testing are already available and are thought to be representative, the data should be used in place of emission factors. Additional testing is not required for the inventory in the State Plan where data are not available.

3.4.2 Required Emission Summary Reports

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

3.4.3 Annual Emission Reporting

In addition to the initial emission inventory required for the section 111(d)/129 State Plan, 40 CFR Part 60, subpart B section 60.25(e) also requires States to submit progress reports as part of the annual report to EPA submitted under 40 CFR Part 51, sections 51.321 through 51.323. These annual reports must update the emissions inventory for sources that achieve compliance, sources that are new or modified, sources that have shut down, and sources whose emissions have changed more than 5 percent from the most recently submitted emission data. If none of the above events occur, then the State only needs to change the year (i.e., the State can still use the data from the previous year).

3.4.4 Reporting to AFS

Emission data must be reported to the Aerometric Emissions Information Retrieval System Facility Subsystem (AFS) as specified in Appendix D to 40 CFR Part 60. The AFS is a repository of emission information for stationary sources that has now superseded the National

include emission limitations that are at least as protective as the Emission Guidelines and also must address non-operating HMIWI (unless the HMIWI is inoperable) and HMIWI that will shut down rather than retrofit air pollution control equipment.

Under section 129(b)(2), the section 111(d)/129 State Plans must include emission limits that are "at least as protective as" those in the HMIWI Emission Guidelines (40 CFR Part 60, subpart Ce). The emission limits for the nine HMIWI pollutants are found in subpart Ce (Appendix M) and the Fact Sheet (Appendix C).

The section 111(d)/129 State Plan must include limitations for all of the pollutants in subpart Ce. Section 60.33e of subpart Ce specifies emission limits for PM, CO, Cd, Pb, Hg, SO_2, HCl, dioxins/furans, and NO_x. All of these limits are in units of concentration. For example, the PM and metals limits are in units of milligrams per dry standard cubic meter exhaust. The metals limits are also expressed in terms of percent reduction across the air pollution control device (if applicable). The dioxin/furan limit is also a concentration limit (nanograms per dry standard cubic meter for total and toxic equivalent quantity [TEQ]). The HCl limits expressed as either a concentration (parts per million by volume) or a percent reduction across the pollution control device (if applicable). The SO_2, NO_x, and CO limits are concentration limits in parts per million by volume.

To be approvable, the section 111(d)/129 State Plan must include emission limits in dimensions identical to the Guidelines, or alternative formats demonstrated to be at least as protective as the concentration limits or percent reductions specified for each pollutant in subpart Ce. Other State programs and permits may include limitations in the form of emission rates (e.g., pounds per hour) or

In addition to emission limits for the nine pollutants regulated by the Emission Guidelines, section 111(d)/129 State Plans must also include, among other things, requirements for stack opacity [section 60.33e], operator training and qualification requirements [section 60.34e], requirements for equipment inspections (small rural HMIWI only) [section 60.36e], and requirements for development of a Waste Management Plan [section 60.35e].

3.6 Testing, Monitoring, Recordkeeping, Reporting and Other Source Requirements

The section 111(d)/129 State Plan must include requirements for the testing and monitoring, reporting and recordkeeping, operator training and qualification, Waste Management Plans, and the inspection provisions from the Emission Guidelines.

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

1. The performance testing methods listed in section 60.56c of subpart Ec [40 CFR Part 60, subpart Ce, section 60.37e],

2. The monitoring requirements listed in section 60.57c of subpart Ec [40 CFR part 60, subpart Ce, section 60.37e],

3. The reporting and recordkeeping provisions listed in section 60.58c of subpart Ec [40 CFR Part 60, subpart Ce, section 60.38e],

4. The operator training and qualification requirements listed in section 60.53c of subpart Ec [40 CFR Part 60, subpart Ce, section 60.34e],

parameters for 5 years. The facility must submit annual reports if it is in compliance and semiannual reports if it exceeds emission standards or operating parameter limits. Details of these requirements are contained in subpart Ce (Appendix M).

A State Plan that incorporates the testing, monitoring, reporting, and recordkeeping requirements specified in subpart Ce will be consistent with the State Plan

requirements in subpart B. Under section 60.25b of subpart B, State Plan requirements for monitoring compliance must include the following:

1. Legally enforceable requirements that require owners and operators to keep records of the nature and amount of emissions and any other information that may be necessary to enable the State to judge compliance. This information must be reported periodically to the State. (Subpart Ce requires such records and reports.)

2. Legally enforceable requirements that provide for periodic inspection and testing. (Subpart Ce requires periodic testing and monitoring of operating parameters.)

3. Provisions for making reports of emissions, correlated with the emission standards that apply available to the general public.

3.7 Operator Training and Qualification Requirements

As specified in section 60.34e of the subpart Ce Emission Guidelines, State Plans are to require that each facility have at least one trained and qualified operator on duty or on-call. The trained and qualified HMIWI operator must pass an HMIWI operator training course which is either State-approved or meets the requirements specified in the Guidelines. Also, State Plans are to require each facility to develop site-specific information regarding HMIWI operation. State Plans are to

State Plans must require facilities operating small existing HMIWI meeting the "rural" criteria to conduct annual equipment inspections. Section 60.36e of subpart Ce lists the components of the HMIWI which State Plans must require facilities operating small rural HMIWI to inspect. State Plans are to require an initial equipment inspection for small rural HMIWI within 1 year following EPA approval of the State Plan. From then on, State Plans are to require facilities operating small rural HMIWI to conduct annual equipment inspections. According to section 60.36e(a)(2) of subpart Ce, State Plans are to require such facilities to complete any necessary equipment repairs within 10 HMIWI operating days following an equipment inspection. State Plans may allow repairs to be completed after 10 operating days, provided that the State supplies the facility with written permission and a date by which all repairs are to be completed.

3.9 Waste Management Plan Requirements

Section 60.35e of subpart Ce requires State Plans to ensure that facilities develop a Waste Management Plan that identifies the feasibility and approach to separate certain components of the solid waste stream from the health care waste stream. The Waste Management Plan requirements in State Plans are to be at least as protective as the requirements for Waste Management Plans under section 60.55c of subpart Ec. State Plans are to require facilities to submit their Waste Management Plan within 60 days following their initial performance test.

When developing their Waste Management Plans, facilities are to consult “An Ounce of Prevention: Waste Reduction Strategies for Health Care Facilities,” a 1993 publication by the American Society for Health Care Environmental Services of the American Hospital Association, Chicago,

3.10 Compliance Schedules

To comply with the emission limits contained in the section 111(d)/129 State Plan, existing HMIWI may need to retrofit emission controls. The State Plan must contain schedules for retrofitting these HMIWI. The elements included in a compliance schedule are listed in Table 3-2.

The retrofit schedules for HMIWI are developed by the State air pollution control agency considering input from the public and input from the HMIWI owners and operators. The Emission Guidelines place certain restrictions on retrofit schedules. Retrofit schedules can extend up to 3 years after section 111(d)/129 State Plan approval, but no retrofit schedule can extend beyond September 15, 2002.

The section 111(d)/129 State Plan must also specify legally enforceable increments of progress toward compliance for HMIWI that have compliance or retrofit schedules that extend past 1 year beyond approval of the section 111(d)/129 State Plan. In some cases, HMIWI may shut down as of September 15, 2002 or 3 years after State approval, whichever is earlier, complete a retrofit, and then reopen when retrofits are completed.

3.10.1 Retrofit Required

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

The acid gas/PM scrubbing system is the more expensive control system. The acid gas/PM scrubbing system controls multiple pollutants including dioxin/furan, Pb, Cd, Hg, PM, and HCl. The Emission Guidelines are based on add-on control systems of varying PM-control efficiencies for all HMIWI except units that fall within the small rural criteria (discussed in section 2.1 and Appendix D). Units at facilities meeting the small rural criteria

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

Activity	Date
State Plan submittal	September 15, 1998
State Plan approval	March 15, 1999
If not in compliance by this date, need enforceable increments of progress for HMIWI	March 15, 2000
Submit a final control plan	A set date in State Plan
Award contracts for control system	A set date in State Plan
Initiate construction or installation of control system	A set date in State Plan
Complete construction or installation of control system	A set date in State Plan
Submit title V permit application	No later than September 15, 2000
Final compliance date for HMIWI	No later than 3 years from approval of State Plan[a] or September 15, 2002, whichever is earlier, or shut down by that date
Reports of periodic performance test data	Annually after compliance date, if in compliance. Semiannually after compliance date, if the emission limits or operating parameters are exceeded

[a] Section 129 does not preclude a State from requiring earlier compliance dates.

may elect to comply with emission limits based on the use of good combustion alone (i.e., without an acid gas/PM scrubbing system).

compliance schedules extending more than 1 year after State Plan approval. State Plans may allow units to shut down by the specified date and restart after completing the retrofit.

3.10.3 Increments of Progress

Compliance schedules for HMIWI with compliance dates that extend more than 1 year after State Plan approval must include legally enforceable increments of progress towards compliance as required by section 60.24(e) of subpart B. Each increment of progress from section 60.21(h) of subpart B must have an enforceable compliance date in the section 111(d)/129 State Plan. The State Plan may include such additional increments of progress as may be necessary for close and effective supervision of progress toward final compliance. Section 60.39e(c) of subpart Ce suggests nine other increments of progress which are discussed below.

The minimum five increments of progress required by section 60.21(h) of subpart B for each HMIWI within a State are as follows:

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

2. Awarding contracts for control systems or process modifications or orders for purchase of components;

3. Initiating on-site construction or installation of the air pollution control device(s)

All five increments of progress for HMIWI can be fixed calendar dates or set as floating dates. For increments one to four, the floating dates can be tied to either the date of the approval of the State Plan or the date of a local permit issuance. For example, the date for submitting a final control plan could be set as 3 months following approval of the State Plan. If an increment of progress is tied to the date of a permit issuance, the State Plan must identify the specific permit.

The fifth increment of progress, the date for final compliance, can be set as a calendar date or a floating date. As a floating date, it can be tied only to the date of the approval of the State Plan, not to the date of permit issuance, and must include the limitation that the date in no case can be later than 3 years from State Plan approval or September 15, 2002, whichever is earlier (unless the HMIWI will shut down).

Additional suggested increments of progress are listed in sections 60.39e(c)(1) through (9) of subpart Ce. Some of these suggested increments of progress are already required by subpart B. The remaining suggested increments of progress may be included in the section 111(d)/129 State Plan as enforceable increments of progress with compliance dates, as non-enforceable increments of progress with reporting requirements only, or they may be left out of the section 111(d)/129 State Plan entirely.

The additional suggested increments of progress from subpart Ce are:

1. Date for submitting a petition for site specific operating parameters;

2. Date for obtaining services of an architectural and engineering firm regarding 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).

The section 111(d)/129 State Plan may include one set of increments with compliance dates applicable to all HMIWI within the State or it may tailor compliance dates to individual HMIWI to address specific issues. In all cases, the enforceable increments of progress must be arranged chronologically, and the compliance dates must be set to ensure full compliance with the applicable requirements *as expeditiously as practicable* [section 60.24(c) of subpart B] but not later than 3 years after State Plan approval, or September 15, 2002, whichever is earlier. For example, a State Plan that requires an HMIWI to "submit a final control plan and to award contracts no later than the third year of the compliance schedule" will likely be disapproved because the increments are too close to the end of the compliance window, do not appear to ensure expeditious progress, and thus jeopardize timely compliance, unless the HMIWI plan to shut down. Although there may be HMIWI-specific reasons for other schedules, EPA would expect contracts to be awarded within the first year for HMIWI taking longer than 1 year to comply. Depending on the extent of the retrofit, EPA would expect on-site construction to be completed in the second or third year of the compliance schedule.

3.10.4 HMIWI Shutdowns

Hospital/medical/infectious waste incinerators that are planning shut down rather than

outlines the specific provisions State Plans must include in order to allow facilities more than 1 year to shut down.

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

Under such special circumstances States may allow facilities to petition the State after approval of a State Plan for additional time to come into compliance by shutting down their HMIWI. In order to allow facilities an extension, the State Plan must contain provisions for granting or denying petitions for an extension beyond the 1-year deadline. Section 60.39e(d) of subpart Ce requires that States have sources to submit the following information in time to allow the State adequate opportunity to grant or deny the extension before the 1-year compliance deadline:

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

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

When a petition for an extension is granted, States may allow sources planning to shut down up to 3 years after EPA approval of the State Plan to come into compliance with the Emission Guidelines by shutting down. However, States are to use their best judgement to determine if the source can shut down before the date 3 years after EPA approval of the State Plan. In cases where a source requesting an extension is able to shut down before the 3-year deadline, the State should require the source to shut down as soon after the 1-year compliance deadline as possible.

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

Sources planning to shut down which request an extension are also to provide the State with a plan that documents the incremental steps of progress that the facility intends to take to

increments of progress that sources requesting extensions to install onsite alternative treatment technologies may use to demonstrate to the State that they are in the process of shutting down their HMIWI:

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

The following are some suggested increments of progress that sources requesting extensions to contract with a commercial disposal company on a permanent basis may use to demonstrate to the State that they are in the process of shutting down their HMIWI:

1. Obtaining price quotes from commercial disposal services;
2. Going under contract with a commercial waste treatment and disposal facility;
3. Shutting down the existing HMIWI; and
4. Rendering the existing HMIWI inoperable.[5]

3.11 <u>Public Hearings</u>

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:

1. Reasonable notice of opportunity for one or more public hearing(s) at least 30 days before the hearing.

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

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

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

5. Notice of hearing provided to:

   a. EPA Regional Administrator
   b. Local affected agencies
   c. Other States affected

6. Certification that the public hearing was conducted in accordance with subpart B and State procedures.

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

3.12 State Progress Reports to EPA

operation, emission inventory information for sources that have started operation, updated emission inventory and compliance information, and copies of technical reports on all performance testing and monitoring, including concurrent process data.

States may want to include additional information on periodic inspection and testing activities, emission and parameter exceedances, QA/QC, outreach activities, title V or other permit condition compliance status, and compliance assistance activities.

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

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

Co-fired combustors are defined as units combusting 10 percent by weight or less hospital waste and/or medical/infectious waste with other fuels or wastes (e.g., coal, municipal solid waste). The Emission Guidelines exempt co-fired combustors and incinerators burning only pathological, low-level radioactive, and chemotherapeutic waste from most of the requirements under the Emission Guidelines. However, State Plans are to require these units to notify the Administrator of an exemption claim and to keep certain records per section 60.32e(b)(1-2) (pathological, low-level radioactive, and chemotherapeutic) and 60.32(i)(1-3) (co-fired) of the HMIWI rule.

Assuming an approved State Plan is in effect, exemption claims are to be sent to the head of the State air pollution control agency responsible for implementing the Emission Guidelines through the State Plan, with a carbon copy (cc) of the exemption claim to the appropriate EPA Regional Office. A list of State and Regional contacts is provided in Appendix F. Exemption claims must be received by the State agency and EPA Regional Office within 1 year following State Plan approval, providing adequate time for the State to determine if an exemption is in order. Appendix N1 contains an example exemption claim form for co-fired combustors. Appendix N2 contains an example exemption claim form for incinerators burning only pathological, low-level radioactive, and/or chemotherapeutic waste.

Facilities operating co-fired combustors must provide the State with an estimate of (1) the amount of hospital and medical/infectious waste combusted, and (2) the amount of other fuels and wastes being combusted. This information may be submitted to the State as part of the exemption

The Emission Guidelines do not require States that have facilities operating co-fired combustors to maintain records of each individual type of waste burned. Rather, the Emission Guidelines should be interpreted to mean that facilities must keep records of two categories of wastes: (1) the combined weight of hospital waste and medical/infectious waste, and (2) the combined weight of all other wastes and fuels burned at the co-fired incinerator.

Incinerators are not subject to subpart Ce during periods when only pathological, low-level radioactive, and/or chemotherapeutic waste are being incinerated, provided the facility submits an exemption claim and keeps certain records. Incinerators burning only pathological, low-level radioactive and/or chemotherapeutic waste must only keep records on a calendar quarter basis of periods of time when only pathological, low-level radioactive, and/or chemotherapeutic waste is burned.

As discussed in section 3.3, States must include co-fired combustors and incinerators burning only pathological, low-level radioactive and/or chemotherapeutic waste in their source inventory. However, these incinerators do not need to be included on the State's emissions inventory.

As of November 26, 1997, it is the EPA Office of Air Quality Planning and Standards interpretation of Part 70 that co-fired combustors and incinerators burning only pathological, low-level radioactive and/or chemotherapeutic waste are not required to obtain a title V permit as a result of the HMIWI Emission Guidelines because these units are exempt from the emission limits. Written confirmation from the Agency is pending at this time, and is expected in the next few weeks. States will be notified as soon as possible if there is a change in this interpretation. Otherwise, States should

5.0 Title V Requirements for HMIWI

Title V of the Clean Air Act provides for a nationwide operating permit program which applies to all major sources and to certain other sources. The title V permit brings together in one document all of the Clean Air Act requirements that apply to a source. Title V permit applications clarify which requirements apply to each source, describe how compliance with those requirements is to be maintained and demonstrated, and provide an administrative mechanism for reconciling conflicting or duplicated requirements. All of the regulations applicable to each HMIWI will ultimately be incorporated into the title V permit for the affected source.

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

Whether a State can use title V as its enforceable mechanism is a question of State law. However, few States, if any, are expected to have the authority under their State law to incorporate the Emission Guidelines directly into their title V permits because, unlike Federal standards such as the NSPS, the Emission Guidelines are only guidelines and are not Federal regulations.

HMIWI That Are Located With Major Sources. If the incinerator is located at a major source, then the permit application for that source should have already been submitted to the permitting authority. Moreover, the permit application should identify the incinerator as an emissions unit. If a permit has been issued and if there are 3 or more years remaining on the permit term, then the

HMIWI That Are Not Located With Major Sources. For those incinerators that are not located with major sources, but are subject to the applicable requirements of the HMIWI rule, a complete title V permit application is due to the permitting authority no later than 36 months after promulgation of the HMIWI rule. Owners and operators of incinerators should be aware that if they have complete applications prepared before the 36 month deadline and if the permitting authorities are ready to accept applications, then there is no need to delay submitting the applications. The EPA encourages owners and operators to proceed with their permitting processes as soon as possible.

Co-fired Combustors and Incinerators Burning Only Pathological, Low-Level Radioactive, and Chemotherapeutic Waste. Because these sources are exempt from the emission limits, they are not required to obtain a title V permit.[2] This means that owners and operators of these sources will not be required by the title V operating permit program to collect data upon which compliance certifications are to be made or to submit compliance certifications. Thus, in order to ensure that such sources comply with the recordkeeping and notification requirements of section 60.32e(b)(1)-(2) (pathological, low-level radioactive, chemotherapeutic) and 60.32(c)(1-3) (co-fired), EPA suggests that States include sufficient authority in their State Plans and include these sources on their source invnetory to ensure the requirements are enforceable by the State. States should also apprise owners and operators of such sources to include in their exemption claim that the incinerators are not subject to title V. Such a statement could look like this:

> "This incinerator is not subject to title V because it meets the definition of an incinerator which combusts only pathological, low-level radioactive, and/or chemotherapeutic, or the definition of a co-fired combustor."

Applications, issued July 10, 1995, not all of this information is necessary to determine whether a permit application complete enough to begin processing. Section II.D of the White Paper identifies four elements of an administratively complete permit application. These elements include a definition of applicable requirements and a description of source status (major or minor); a compliance certification for the applicable requirements; enough clarity concerning the individual emission units so that the permitting authority can determine the permit issuance schedule; and a certification of truth, accuracy, and completeness.

For purposes of the HMIWI rule, a permitting authority could accept the following statements as a complete permit application:

> "County Hospital owns and operates a small HMIWI subject to the approved State/Federal Plan submitted to meet subpart Ce. County Hospital will meet the requirements of subpart Ce on a timely basis. I certify that this information is true, accurate, and complete.
>
> Jim Johnson, Responsible Official."

Note that specific requirements concerning emission limits, testing, monitoring, reporting, and recordkeeping would be added after the determination of administrative completeness but before a draft permit would be given to the public.

The following is the anticipated schedule for compliance with the title V permit requirements.

Assumed State Plan Submitted -	Date-
Emission Guidelines promulgated	09/97
State Plan submitted to EPA w/in 1 year	09/98
EPA approval of Plan w/in 6 months	03/99
Complete title V permit application due to permitting authority	by 09/00
State issues title V permit	by 09/01[3]
HMIWI in compliance with the EG	
w/in 3 years of Plan approval	03/02
but no later than 5 years after promulgation	by 09/02

Assuming Federal Plan Required -	Date-
Federal Plan, if no State Plan submitted	by 09/99
Complete title V permit application due to permitting authority by	09/00
EPA issues title V permit	by 03/02
HMIWI in compliance with requirements of section 129 no	
later than 5 years after promulgation	by 09/02