EPA-456/R-00-003

HOSPITAL/MEDICAL/INFECTIOUS WASTE INCINERATORS: BACKGROUND INFORMATION FOR FEDERAL PLAN

DRAFT SUMMARY OF PUBLIC COMMENTS AND RESPONSES

U. S. Environmental Protection Agency
Office of Air and Radiation
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1.0 OVERVIEW

Under the authority of sections 111 and 129 of the Clean Air Act (CAA), the U.S. Environmental Protection Agency (EPA) promulgated Emission Guidelines for existing hospital/medical/infectious waste incinerators (HMIWI) on September 15, 1997. States with existing HMIWI subject to the Emission Guidelines were required by the CAA to submit, within one year following promulgation of the Emission Guidelines, a State plan that implements and enforces the Emission Guidelines. Indian tribes could also submit Tribal plans to implement and enforce the Emission Guidelines in Indian country. If a State or Tribe with existing HMIWI does not submit an approvable plan within two years after promulgation of the Emission Guidelines, EPA is required to develop, implement, and enforce a Federal plan for HMIWI in that State or Tribal area.

The EPA proposed Federal plan for HMIWI was published in the Federal Register on July 6, 1999. In the proposal notice, EPA requested comments from all interested parties on the Federal plan. The purpose of this document is to summarize and respond to the comments EPA received. The summary of comments and responses presented in this document serves as the basis for any revisions made to the HMIWI Federal plan between proposal and promulgation of the Federal plan.

2.0 LIST OF COMMENTERS

The public comment period on the proposed Federal plan lasted from July 6, 1999 to September 7, 1999. A total of six letters commenting on the proposed Federal plan were received. These comments have been placed in the docket for the Federal plan (Docket A-98-24) under categories IV-D and IV-G. Table 2-1 lists all persons who submitted written comments, their affiliations, and the recorded docket item number assigned to their correspondence.

TABLE 2-1. LIST OF COMMENTERS ON THE PROPOSED FEDERAL PLAN

Docket Item No.	Commenter and Affiliation
IV-D-01	D. K. Chamberlain Pennsylvania Department of Environmental Protection
IV-D-02	K. Michaels Arkansas Department of Environmental Quality
IV-D-03	R. Fritz Wisconsin Department of Natural Resources
IV-D-04	A. P. Jacobsohn Environmental Industry Associations
IV-G-01	D. G. Hawkins Natural Resources Defense Council
IV-G-02	B. Mathur Illinois Environmental Protection Agency

3.0 COMMENTS AND RESPONSES

3.1 APPLICABILITY OF THE FEDERAL PLAN

Comment: Commenter IV-G-02 believes there is an unnecessary overlap between the applicability of the Federal plan and State plans. The Federal plan applies to any existing HMIWI that is not covered by a State or Tribal plan; in addition, the Federal plan also applies to any existing HMIWI that is located in a State or Tribal area with an approved and effective plan, if the HMIWI is not covered by such plan. The commenter believes that all HMIWI within a State with an approved and effective plan should be subject to the State plan rather than some facilities being subject to the Federal plan. The commenter requested that the overlap in the Federal plan be eliminated.

Response: The EPA acknowledges that States, such as the Illinois plan, have gone to great lengths to identify operating HMIWI in their respective States and include them in their State plans or have drafted sufficiently broad language to include all facilities in their respective State. However, EPA recognizes that not all plans may be as thorough as the Illinois plan and there may be circumstances where State plans have inadvertently excluded facilities in their plans or not written their plan sufficiently broad enough to include all facilities operating in their State. In these circumstances, EPA believes that it is necessary for those facilities to be covered by the Federal plan. Therefore, EPA included language in the proposal to ensure that all facilities are either covered by a State plan or the Federal plan. The Agency has retained the applicability language of the proposal in the final Federal plan.

Comment: Commenter IV-D-01 stated that the discussion in Section III(A) of the preamble pertaining to “Inoperable Units” should be revised to be consistent with EPA’s

(2) stack/by-pass stack removed; and (3) combustion air blowers removed.

Response: The Agency has revised the preamble to clarify the criteria for rendering an incinerator inoperable.

3.2 STATE PLAN INFORMATION

Comment: Commenter IV-G-02 requested that EPA include Illinois in its list of States with an approved State plan in the final Federal plan.

Response: The EPA has revised the list of States with approved plans and has included Illinois in the list of States with approved plans.

Comment: Commenter IV-D-01 believes that the Agency incorrectly stated that it has received a "draft plan" from Pennsylvania. The EPA Region III has stated that the Pennsylvania State plan is not approvable until Pennsylvania submits federally enforceable State operating permits containing enforceable increments of progress and compliance schedules, as a plan revision. The commenter stated that Pennsylvania has completed public participation for their permit program and will submit a revised program no later than September 10, 1999.

Response: As discussed above, EPA has revised the list of States with approved plans and has revised that list to include the appropriate status of Pennsylvania.

3.3 COMPLIANCE SCHEDULE

3.3.1 Suspension of Compliance Schedule.

U. S. Court of Appeals decision has resulted in uncertainties for the final emission limits for existing HMIWI. The resulting uncertainties make compliance with the emission limits in the Federal plan difficult because the commenter believes the final standards will be lower than those presented in the proposed Federal plan. Therefore, the commenter requested that facilities not be required to comply with the standards until such time as the Federal court is satisfied with the emission limits for existing HMIWI.

Response: On March 2, 1999, the United States Court of Appeals for the District of Columbia Circuit ruled on the case of Sierra Club and Natural Resources Defense Council (NRDC) versus the United States Environmental Protection Agency. The petitioners, the Sierra Club and NRDC, challenged EPA's rule establishing HMIWI standards, complaining principally that EPA failed to comply with the specifications of the maximum achievable control technology (MACT) floors for new and existing HMIWI. Although the court rejected the petitioners' statutory construction challenge, the court did conclude that there are serious doubts about the reasonableness of EPA's treatment of the floor requirements, and remanded the rule for further explanation. The court decided not to vacate the standard. Rather, the current regulation remains in place as requested by Sierra Club and NRDC. In light of the court decision, EPA is obligated to adhere to the compliance schedule set out in the Emission Guidelines. Therefore, the EPA will promulgate the final Federal plan as scheduled.

3.3.2 Definition of Final Compliance

Comment: Commenter IV-G-02 believes that the definition of "final compliance" in the Federal plan should be revised to match the definition of "final compliance" in the Emission Guidelines. The commenter stated that EPA's definition of "final compliance" in the proposed Federal plan does not

compliance deadline should be required to conduct an initial performance test by September 15, 2000, as required by the Emission Guidelines, rather than be in "final compliance" as the Federal plan requires. The commenter requested that the final compliance dates in the Federal plan be revised to match those in the Emission Guidelines.

Response: The Agency disagrees that there is a discrepancy between the definition of final compliance in the Emission Guidelines and the Federal plan. The EPA asserts that if a facility has retrofitted all air pollution control equipment and the equipment is operating as designed, then the facility has reached compliance and should meet all emission limits. As defined in § 62.14470 of subpart HHH, by the final compliance date, a facility must have incorporated all process changes or completed retrofit construction as designed in the final control plan. The EPA maintains that facilities meeting this definition will produce emissions below the emission limits in the Federal plan. Consistent with section 129(b)(2) of the Clean Air Act, the HMIWI Federal plan requires final compliance by September 15, 2002, which is five years after promulgation of the Emission Guidelines.

The final Federal plan allows a facility up to180 days after installation of equipment to complete performance testing. The EPA contends that it is appropriate to allow a facility up to 180 days to conduct performance testing after installation of equipment. This is consistent with New Source Performance Standards and the National Emission Standards for Hazardous Air Pollutants. The 180 days allows a facility to make final adjustments and tune the newly installed control equipment, reach stable operation, and perform a stack test. If the initial compliance test submitted to EPA shows the facility failed to attain the emission limits or if an initial compliance test is not submitted within the required 180 days, then EPA can take appropriate enforcement action. A State may require the performance test earlier in their State plan.

However, the commenter stated that the Federal plan is missing one element in the increments of progress that was included in the Emission Guidelines. The commenter stated that under § 60.39e(d)(1)(i) of the Emission Guidelines, State plans that allow a facility to petition for an extension of time beyond one year after plan approval must "include an evaluation of the option to transport the waste off-site to a commercial medical waste treatment and disposal facility on a temporary or permanent basis." The commenter stated that under § 62.14470(b) of the proposed Federal plan for facilities that plan to comply later than one year after Federal plan promulgation, there is no requirement to provide an evaluation of the off–site option. The commenter also stated that the same element is missing under § 62.14472 in the proposed Federal plan for facilities that plan to shut down and then restart their incinerators.

The commenter indicated that the evaluation of the off-site disposal option is significant because it forces facilities to perform a more thorough evaluation of their waste disposal options when developing their waste management plans. In addition, it forces facilities to avoid waiting until the last minute to take action in response to the HMIWI rule. The commenter noted that many facilities are unaware of the time necessary to develop an effective waste management plan that considers the many factors that go into a decision about waste disposal methods (e.g., cost of waste disposal options, facility image, etc.). The commenter asserted that facilities should only be allotted extra time to comply when they have a legitimate reason for needing the time, and not because they waited too long to take action.

Response: Sections 60.39e(c) and (d) of the Emission Guidelines allow State plans to provide facilities with additional time beyond the 1-year compliance date. Section 60.39e(c) allows facilities installing the appropriate pollution control beyond 1 year to comply with the Emission Guidelines provided they meet certain measurable and enforceable activities. Section 60.39e(d) allows facilities

off-site to a commercial medical waste treatment facility. 40 CFR § 62.14470(b) parallels § 60.39e(c) of the Emission Guidelines which does not require facilities to perform an analysis of the option to transport waste off-site to a commercial medical waste treatment facility. The Agency does agree with the commenter that a requirement for facilities who are planning to shut down beyond the 1-year compliance date and re-start operations after September 15, 2002 will need to perform an evaluation of the option to transport waste off-site to a commercial medial waste treatment facility. Section 62.14472 of the final regulation has been modified to accommodate this change.

3.4 INSPECTIONS AND REPAIRS

Comment: Commenter IV-G-02 stated that § 62.14443 of the proposed Federal plan is inconsistent with the requirements for inspections in the Emission Guidelines. The commenter stated that § 62.14443 of the Federal plan provides that any necessary repairs must be completed within 10 operating days of the inspection while the Emission Guidelines require that any repairs must be made within10 days. The commenter recommended deletion of the term "operating" in the Federal plan.

Response: Under § 60.36e(a)(2) of the Emission Guidelines, the owner or operator is required to complete repairs within 10 operating days following an equipment inspection. The word "operating" was inadvertently omitted from § 60.38e(b)(1) of the Emission Guidelines. Therefore, § 6214460(b)(13) of the Federal Plan has been revised to accurately capture the intent of the Emission Guidelines, requiring repairs to be completed within 10 operating days.

3.5 TITLE V PERMITTING REQUIREMENTS

interpretation of title V applicability conflicts with the requirements of both section 502(a) and section 129(e) of the CAA. The commenter noted that section 502(a) requires sources subject to standards under section 111 to obtain title V permits. In addition, section 129(e) requires that "Beginning (1) 36 months after the promulgation of a performance standard ...each unit in the category shall operate pursuant to a permit issued under this subsection and
Title V." The commenter interpreted EPA's position as follows: If co-fired combustors (as defined in 40 CFR 62.14490) and HMIWI combusting only pathological waste, low-level radioactive waste, and/or chemotherapeutic waste (also defined in 40 CFR 62.14490) comply with their recordkeeping obligations, they need not obtain a Title V permit. However, if they fail to keep the required records, they must obtain a Title V permit. The commenter mentioned that general title V permits could be crafted to reduce the burden of title V permitting for these exempt sources.

Commenter IV-G-01 pointed out that under EPA's proposal not to require title V permits for these sources, control agencies and the public will not be able to determine whether the sources are keeping the proper records; records which are the basis for creating and continuing the exemption from title V permitting. The commenter stated that nothing in the proposed rule requires sources to submit summaries of the required records or to certify that they are keeping the records. The commenter noted that if a title V permit were required, sources would be required to certify that they are conducting the required recordkeeping. The commenter requested that EPA either require sources to obtain title V permits or adopt an equally enforceable and transparent mechanism to require sources to certify that they are conducting the required recordkeeping and to ensure that citizens can access information relevant to the obligation to keep such records. The commenter noted that if these records are maintained onsite at a source, then the relevant agency may take the position that the records are not subject to disclosure under "freedom of information" laws. Therefore, the commenter requested

Another commenter, IV-D-04, disagreed with EPA's assessment that reporting and recordkeeping requirements are not substantive elements of the HMIWI rule for purposes of Title V even though pathological, low-level radioactive, and chemotherapeutic wastes are being considered under the Industrial Combustion Coordinated Rulemaking (ICCR). The commenter noted that recordkeeping and reporting supplies the agency with vital information to ensure that rules are functioning as intended and helps to supply data needed to develop new rules such as the ICCR. In addition, recordkeeping and reporting require a significant amount of employee time and facility dollars.

Commenter IV-D-04 stated that the CAA requires specific reasons for a decision by EPA that a source should not be required to file a title V permit. The commenter noted that section 502(a) of the CAA states that EPA may exempt a source in one or more source categories if EPA finds that "compliance with such requirements is impracticable, infeasible, or unnecessarily burdensome on such categories..." However, the law does not state that EPA may exempt a source category when only recordkeeping and reporting are required. The commenter noted that requiring co-fired combustors and HMIWI combusting only pathological waste, low-level radioactive waste, and/or chemotherapeutic waste to file a title V permit application may not be practicable at this time because EPA may develop a rule with specific emission limits for these sources in the near future. However, the commenter stated that offering these types of sources several years of additional time to come into compliance without requiring that they take some action towards understanding their obligations under the CAA is inappropriate.

Response: The EPA disagrees with both commenters' views concerning this Federal plan. The Federal plan requires owners or operators of HMIWI combusting only pathological waste, low-level radioactive waste, and/or chemotherapeutic waste and co-fired combustors to fulfill certain recordkeeping and reporting requirements to demonstrate that they are exempt from the emission

recordkeeping requirements related to the applicability of the Federal plan and necessary for these sources to demonstrate exemption.

The reporting and recordkeeping requirements that these sources must fulfill (in section 62.14400 [Applicability] of subpart HHH) differ from the emission control- related reporting and recordkeeping requirements (in sections 62.14460 through 62.14465 [Reporting and Recordkeeping] of subpart HHH) of the Federal plan. Section 62.14400 requires owners or operators of HMIWI that combust only pathological waste, low-level radioactive waste, and/or chemotherapeutic waste and owners or operators of co-fired combustors to submit a one-time notification of an exemption claim. In addition to this exemption claim, owners or operators of HMIWI that combust only pathological waste, low-level radioactive waste, and/or chemotherapeutic waste must keep records on a calendar quarter basis of the periods of time when these types of waste are the only types of waste combusted. Owners or operators of co-fired combustors must keep records on a calendar quarter basis of the weight of hospital waste and medical/infectious waste combusted and the weight of all other fuels and wastes combusted. The emission control-related reporting and recordkeeping requirements for HMIWI include notifications, records, and reports pertaining to waste management, parameter monitoring, operator training, inspections, and performance testing.

The EPA interprets CAA section 502(a) and 40 CFR 70.3(a)(2) and 71.3(a)(2) to mean that sources subject to this exemption (combusting only pathological waste, low-level radioactive waste, and/or chemotherapeutic waste, and co-fired combustors) are “not subject to standards or regulations under section 111" for purposes of title V permitting. The Agency believes that the recordkeeping and reporting requirements with which these facilities must comply if they are to attain and maintain their exemptions are not the type of requirements that make them “subject to” a standard or regulation under section 111 within the meaning of the first sentence of section 502(a). In EPA’s view, facilities in this

operators of these sources that do not comply with the recordkeeping and reporting requirements necessary to attain and maintain exemption from the Federal plan will become subject to the emission control-related requirements and will have to obtain title V permits. While HMIWI combusting pathological, low-level radioactive, and/or chemotherapeutic waste and co-fired combustors subject to this exemption need not obtain title V permits now, they are not prohibited from applying for title V permits.

As Commenter IV-D-04 stated, section 502(a) of the Act also provides a mechanism for the Administrator to "promulgate regulations to exempt" one or more source categories from title V permitting requirements, if EPA finds that compliance with such requirements is "impracticable, infeasible, or unnecessarily burdensome on such categories, except that the Administrator may not exempt any major source from such regulations." The EPA is not invoking this mechanism to justify its conclusion that facilities subject to exemptions from emissions-control related requirements are not required to obtain title V permits. These facilities have not been "exempted" from title V within the meaning of the last sentence of section 502(a), and the Agency has not made or does not purport to have made the statutory showing of impracticability, infeasibility or unnecessary burden for these sources. Rather, as stated earlier, the Agency believes that the recordkeeping and reporting requirements with which these facilities must comply are not the type that would make them "subject to" a standard under section 111 or 502(a) of the Act. These reporting and recordkeeping requirements are simply conditions for exemption from the emission control-related requirements of the Federal plan.

Under the Federal plan sources are not required to routinely submit to EPA the records they are required to maintain onsite to support their exemption from the section 129 standard. However, we are adding two provisions to the regulation to facilitate public access to those records. First, the regulation requires in sections 62.14400(b)(1) and (b)(2) that these sources must submit these records

records from sources following receipt of a citizen request under applicable freedom of information laws (comparable to the Freedom of Information Act) and make such information available to the requestor.

Additionally, to clarify what the records maintained by co-fired combustors must contain in order for an exemption from subpart HHH and title V permitting to be allowed, we have added language to section 62.14400(b)(2). Language in this section states that the records maintained by the owner or operator of a co-fired combustor must reflect that the source continues to meet the definition of co-fired combustor in section 62.14490. Language has been added to section 62.14400(c) stating that the records required by paragraphs (b)(1) and (b)(2) of section 62.14400 must be maintained by the relevant sources for a period of at least 5 years. Language has also been added to section 62.14400(c) stating that the notifications of exemption claims also required by paragraphs (b)(1) and (b)(2) of section 62.14400 must be maintained by the EPA or delegated enforcement authority for a period of at least 5 years. Such notifications are to be made available upon request.

3.6 TRANSFERRING OF AUTHORITY

Comment: Commenter IV-D-03 raised the question of whether the authority to implement the Federal Plan could be transferred to States and local agencies through the title V operating permits program. The commenter noted that part IV of the preamble to the proposed Federal plan (in section C on page 36432) describes two mechanisms for transferring authority to State and local agencies and that part V of the preamble discusses title V operating permits programs. These two mechanisms as described on page 36432 of the proposed Federal plan are (1) the approval of a State plan after the Federal plan is in effect; and (2) if a State does not submit or obtain approval of its own plan, EPA

must include the requirements of the Federal plan. Thus, title V permitting authorities already have implementation responsibility for the Federal plan through the title V permits program, regardless of whether the authority to implement the Federal plan is delegated to the State or local agency. The commenter stated that the authority to implement the Federal plan would be most useful before a title V permit is issued. The commenter stated that the time required for a State to request and obtain authority to implement the Federal plan through delegation is similar to the lead time required in the Federal plan for submitting title V permit applications. The commenter requested an explanation of why delegation of the Federal plan is necessary if a title V program is in place.

Response: There are legal and practical reasons why incorporating a standard into a permit without formal delegation is not equivalent to taking formal delegation and then issuing a part 70 permit containing the standard. The Act and part 70 require States, local agencies or Tribes, wishing to adopt a part 70 permitting program to have the legal authority to place all applicable requirements (including HMIWI standards) in permits and to implement and enforce them in that context. However, this requirement is not legally equivalent to formal delegation, nor does it take the place of formal delegation. When a State takes formal delegation, EPA allows the State to implement and enforce a standard independent of a title V permit. This is significant because a title V source may be allowed to operate without a title V permit for a number of years in some cases between the time it first triggers the requirement to apply for a permit and the issuance of the permit. Prior to the issuance of a part 70 permit and absent formal delegation, the State may not implement and enforce the requirements of a standard. Moreover, a source with a title V permit with a permit term less than 3 years is not required by part 70 to reopen the permit to include new applicable requirements, such as the HMIWI standard. See 40 CFR section 70.7(f)(1)(i). However, the source must still comply with that standard. Delegation enables a State to implement and enforce the standard outside of the permit until permit

enforcement after delegation, should be qualified to reflect State and local enforcement responsibility after a title V permit is issued. The commenter questioned whether EPA or the State and local title V permitting authorities would have enforcement responsibilities for the Federal plan after a title V permit is issued to a source.

Response: The EPA first notes that the language in the proposal preamble to which the commenter refers was errant and has been deleted from the preamble to the final rule. Rather, EPA's position on this issue is accurately reflected in the same part of the proposal preamble (part IV) that the commenter references under the section titled "Delegation of the Federal Plan and Retained Authorities": "The EPA will continue to hold enforcement authority along with the State or Tribe even when a State or Tribe has received delegation of the Federal plan." Moreover, the retained authorities discussion immediately following this sentence in the proposal preamble does not address enforcement of the Federal plan, and section 62.14495 of the proposed and final rules does not include enforcement of the Federal plan as an authority retained by the EPA Administrator. In fact, both State and local permitting authorities that have taken delegation, as well as the EPA, will have responsibility for bringing enforcement actions against sources violating Federal plan requirements. Prior to delegation, only the EPA will have enforcement authority. In neither instance does the title V permit status of a source affect the enforcement responsibility of EPA or the State and local permitting authorities.