HMIWI Questions and Answers

STATE PLAN REQUIREMENTS

1. Must the State Plan be revised if--

A. . . an existing source that has ceased operations wants to re-open before the compliance date[(1)]?

Answer: No, the State Plan does not need to be revised, provided the State Plan includes--and State procedure allows[(2)]

--a generic compliance schedule to apply to "all other applicable sources" not listed individually in the State Plan. The source must remain shut down until it demonstrates that it has caught up to the generic schedule, as well as met all applicable increments of progress.

In addition, before re-opening, the source must have a complete title V operating permit application in place by September 15, 2000. The source may also need to undergo review under the State's New Source Review procedures.

One might ask then, if the State Plan is not re-opened, when does the public have the opportunity to comment? Since both of these procedures require public review, the title V and/or NSR procedures will provide notice to the public and industry.

B. . .the State discovers an existing source after 2002?

No, there is no need to revise the State Plan to accommodate an existing source discovered after the final compliance deadline, assuming it has the generic applicability language discussed in question #1. The source must cease operations immediately and must remain closed until it can demonstrate compliance with the State Plan and that it has a title V permit . Since a longer compliance schedule with increments of progress is no longer an option for sources discovered after the statutory backstop final compliance deadline in the year 2002, there is no reason to revise the State Plan.

2. What if a State which believes they do not have any sources--and thus sends in a letter of negative declaration--subsequently discovers an existing source? Must the State submit a State Plan?

Answer: Yes, the State must submit a State Plan because section 129(b)(2) of the amended Clean Air Act says, "each State in which units are operating shall submit a State Plan." If the source were discovered before the statutory compliance deadline (~2002), then the source is subject to the default compliance schedule discussed above, which is 1 year from State Plan approval. Be aware that the source must still be in compliance no later than 5 years from promulgation of the EG -- regardless of when the State Plan is finally approved.

As discussed in question #1, an existing source discovered after the compliance deadline must cease operations immediately. It cannot reopen until it has demonstrated compliance with the approved State Plan and has a title V operating permit in place per sec. 129(e).

3. What happens if a State misses a source and it is not in the State Plan inventory? Is the source still subject to the standard?

Answer: All sources, whether they're on the state's list or not, are subject to the standard. Section 60.24(e) of 40 CFR Part 60, Subpart B says, "Emission standards shall apply to all designated facilities within the State." "Designated facilities" are all those facilities which meet the definition in the emission guidelines ("EG") or the State's definition (if as stringent as the EG), whether they're on the State's inventory or not.

The State could choose to revise the State Plan in order to establish a separate, but equally protective compliance schedule for the newly discovered source. But in order to avoid the need to revise the State Plan to add the newly discovered source(s), States should be advised to include language which says that sources that are subject to the standard "include, but are not limited to," the inventory in the State Plan. States should also include language such as, "Should another source be discovered subsequent to this notice, there will be no need to reopen the State Plan. Sources discovered after approval of the State Plan will be subject to these requirements. Therefore, the State Plan will not need to be reopened."

The State Plan should also contain a generic compliance schedule that "all other applicable sources" not listed individually in the State Plan must comply with. The newly discovered source would be bound to that generic compliance schedule. If the source were discovered well into the compliance schedule and had already missed several increments of progress, it would have to shut down and remain shut down until it had demonstrated to the State that it had "caught up" to the compliance schedule.

Other language that must be in the State Plan:

List in the enforcement section of the State Plan the consequences for sources not in compliance and the authority under which a State can shut down/close a source.

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

4. What are the timelines for submission and approval of State Plans following promulgation of Emission Guidelines for HMIWI?

Answer: States must submit Plans within 1 year of EPA promulgation of the Emission Guidelines. Since HMIWI Emission Guidelines were promulgated on September 15, 1997 (62 FR 48347), State Plans are due by September 15, 1998. The EPA must approve or disapprove the Plan within 6 months of submittal. If a Plan is disapproved, specific reasons will be given. The State is encouraged to address the concerns and resubmit the Plan. If a State does not have an approvable Plan in place by September 15, 1999, a Federal Plan will go into effect on that date.

5. Under Section 129(b)(2) of the Clean Air Act, will EPA's approval or disapproval of a State Plan be a letter, Federal Register notice, or both?

Answer: The EPA's approval or disapproval will be published in the *Federal Register*. If the Plan is not approved, the notice will include reasons for disapproval.

6. What are the consequences to a State if they do not file their State Plan by September 15, 1998?

Answer: State Plans are due by September 15, 1998. The EPA is required to review and approve or disapprove State Plans within 6 months of submittal. For States which do not have an approvable State Plan in place by September 15, 1999, a Federal Plan go into effect on that date (September 15, 1999). States benefit from developing State Plans rather than receiving a Federal Plan because States have the opportunity to tailor the compliance schedule to individual sources and to develop a State rule more stringent than the Emission Guidelines.

7. Is there a reason why a State which has no medical waste incinerators and only MWC's which are exempt should adopt the HMIWI EG?

Answer: Be aware that a State which has only co-fired combustors (burn 10 percent or less hospital/medical/infectious waste) or incinerators that burn low-level radioactive, chemotherapeutic or pathological waste must still submit a State Plan in order to compel those sources to meet

the record keeping and reporting requirements of section 60.32e of the HMIWI rule.

If a State has no sources subject to the EG, then it is not required to submit a State Plan. However, the State may want to submit a State Plan in order to address the contingency that a source is discovered and the State wants the source to be subject to the specifics of a State Plan rather than deferring to the Federal Plan.

8. Are public hearings required prior to submittal of a State Plan?

Answer: Yes, adequate opportunity for public hearings is required. 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 two 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.

If after adequate notice, no one requests a hearing, the hearing is not required.

9. Can a State incorporate by reference the EG?

Answer: No, because the EG is not written as direct requirements on the source but rather, as requirements for the State to ensure that their source requirements are at least as protective as the EG. The State may incorporate sections of the EG into their state rule such as the emission limits, operator training requirements, and record keeping requirements, and they may use the EG as a template for the State rule, but the EG cannot be simply incorporated by reference as a whole without changes or supplemental language to make it applicable to their sources.

The State can incorporate by reference the NSPS in its entirety because it is a Federal rule that is directly applicable to sources.

10. If the State has its own rule (e.g., CA, FL, NJ, NY, IL, NC) and the State rule is as protective as the Federal EG, does the State still have to submit a State Plan?

Answer: Yes, the State still needs to submit an approvable State Plan so that the public, EPA, and industry will be clear that the State is complying with the requirements of sections 129 and 111(d). In particular, the State must show that its State rule is at least as protective as the EG and how the State will ensure that the sources meet the applicable requirements. Also, the State Plan must include an inventory of all the affected sources in the state and satisfy the requirements for public review. In this case, where the State's existing rule would provide the legal authority, preparation of the State Plan should not require much effort beyond what the State has already done to promulgate their State rule.

11. How does a State demonstrate that its State rule is at least "as protective as" the EG? Is the burden of proof on EPA?

Answer: The burden of proof is on the State to show in the State Plan how the requirements in its State rule are at least as protective as the EG, including the increments of progress in the EG. The State must demonstrate this for each requirement that is different from the EG.

12. If a State has only "small" MWC's that need only keep records and report to the Administrator, must the State submit a State Plan or is a letter of negative declaration sufficient?

Answer: Per sec. 60.32e(e), only incinerators subject to the MWC rule for large MWC (Subparts Cb, Ea, or Eb) are exempt from the HMIWI rule.

Smaller MWC's exempt from the MWC rule by virtue of their size (less than 250 tons/day) and burning 10 percent or less hospital/medical/infectious waste need only notify the EPA Administrator of an exemption claim and keep records of wastes burned, per sec. 60.32e(c). These units burning 10 percent or less hospital waste and medical/infectious waste are called "co-fired combustors." Although co-combustors are not subject to the emission limits, a State Plan is necessary in order for the public to be aware of their existence and for States to ensure compliance with these record keeping/notification requirements.

13. There are approximately six HMIWI in operation in rural counties of one State. If all HMIWI burn 10 percent or less medical/infectious waste and burn the remaining 90 percent in trash (hospital waste) would these facilities be exempt from the Emission Guidelines? If it is documented that all sources stay within these parameters would the State Plan still need to be written? If the State does not write a Plan would the EPA step in and write a Federal Plan to regulate these six sources?

Answer: The "10 percent or less" criteria applies to both hospital waste and medical/infectious waste. That is, sources burning 10 percent or less hospital waste and medical/infectious waste are considered to be co-fired combustors. The units mentioned in the question above are not co-fired combustors. They are HMIWI because they burn 100 percent hospital waste and medical/infectious waste. Therefore, these facilities are subject to all the requirements of the Emission Guidelines, including the emission limits, and the State must submit a State Plan to cover these sources.

If a State only had co-fired combustors, then the State would still need to submit an abbreviated State Plan to include the sources on their inventory and to enforce the notification and record keeping

requirements of the Emission Guidelines for co-fired combustors. Under the Emission Guidelines, co-fired combustors are required to notify the Administrator of an exemption claim and to keep records of the amounts of each type of waste and/or fuel burned. A State Plan is necessary to compel co-fired combustors to comply with the notification and record keeping requirements. In addition, if the co-fired combustors began burning more than 10 percent hospital waste and medical/infectious waste, then the State could have the authority under the State Plan to require the sources to comply with the State Plan provided it contained the generic language discussed in the answer to question #3, above.

If a State Plan is not submitted to cover such sources, a Federal Plan would become effective in that State on September 15, 1999.

14. When implementation plans are filed by the State, will they go to some central repository where they can be reviewed by the public at the same time when EPA is reviewing them?

Answer: The public will be given the opportunity to comment on the State Plans before they are submitted to EPA for review. States are required to provide opportunity for a public hearing to discuss the State Plan and to make copies of the State Plan available for public review prior to submittal to EPA. State Plans are to be submitted to the appropriate EPA Regional Office. The State Plans will not go to any central location where they may be reviewed by the public while EPA is reviewing the Plans. The EPA will publish a notice in the *Federal Register* regarding whether a State Plan has been approved or disapproved. If a Plan is not approved, the EPA will state the reasons for disapproval in the *Federal Register*.

15. On a case-by-case basis, under Section 111(d) plan requirement [40 CFR Subpart B Section 60.24(f)], States have the flexibility to submit Plans that contain the application of less stringent emission standards or longer compliance times than required under the applicable Emission Guidelines. Does the "at least as protective as the EG" requirement of Section 129 of the Clean Air Act now eliminate the Plan flexibility provided under 40 CFR Section 60.24(f)?

Answer: Yes. State Plans for HMIWI are Section 111(d)/129 plans and have additional requirements than State Plans developed under only Section 111(d). The "at least as protective" language in Section 129 of the Clean Air Act applies to HMIWI, and Section 60.24(f) of Subpart B is superseded. Section 60.24(f) of Subpart B was revised on December 19, 1995 (see 60 FR 65414) to allow Subpart Ce to specify that States could not allow less stringent limits or longer compliance times than specified in Subpart Ce.

16. Can a State develop a site-specific Plan rather than a generic HMIWI Plan?

Answer: The State must submit a State Plan. The Plan may include site-specific emission limits and compliance schedules, as long as the limits and schedules are as protective as the Emission Guidelines.

17. If there are conflicting requirements under Sections 111(d) and 129, what requirements take precedence?

Answer: If there are conflicting requirements, section 129 takes precedence over section 111(d) and the Subpart B rules developed to implement section 111(d). For more information on specific section 111(d) and 129 requirements, refer to chapter 1 of the HMIWI Summary Document which presents a table showing the portions of Subpart B that apply to HMIWI and the portions that are revised by section 129 of the Clean Air Act.

18. Do emission limits in the State Plan need to be the same as the emission limits in the Subpart Ce Guidelines?

Answer: The emission limits in the State Plan must be "at least as protective" as the Emission Guidelines, and EPA recommends that the limits be presented in the same regulatory format as the Emission Guidelines, (e.g. concentration limits or percent reductions). If a regulatory format other than that used in the Emission Guidelines is used in a State Plan, then the State must show how the format correlates to the format in the Emission Guidelines and demonstrate that it is at least as protective as the Emission Guidelines.

19. Can a State Plan identify only air pollution control equipment to be retrofitted or must it include emission limits?

Answer: A State Plan must include emission limits at least as protective as the Emission Guidelines, and those limits must apply to each HMIWI. Equipment specification is not required, and alone, is unacceptable.

20. Do reporting requirements in State Plans apply to HMIWI operators or just State agencies?

Answer: The requirements apply to both. The State has responsibilities to develop the State Plan and to report implementation progress to EPA. The HMIWI owner must show expeditious progress on achieving compliance by the dates set and then show continuing compliance with the standard by annual compliance tests for various pollutants and operating parameter data, as specified in Subpart Ce.

21. Can the States incorporate the HMIWI progress reports into their 40 CFR section 51.321 annual report for SIPs?

Answer: Yes, provided that the HMIWI progress report satisfies the requirements of 40 CFR Section 51.321, HMIWI progress reports can be used to satisfy the SIP requirement. States are encouraged to coordinate their efforts in order to minimize duplication of reporting requirements to ensure the most productive compliance and enforcement activities.

COMPLIANCE SCHEDULE AND INCREMENTS OF PROGRESS

22. When setting compliance schedules, can a State allow a source longer than 1 year from State Plan approval to comply without any increments of progress?

Answer: No, a source cannot be allowed to operate beyond 1 year after State Plan approval unless the State Plan provides for enforceable increments of progress that are identical to or "at least as protective as" the five increments of progress listed in section 60.21(h) of Subpart B.

In addition, State Plans that allow sources planning to shut down (not to retrofit) longer than 1 year to comply must require that such facilities provide documentation to support their request, as described in section 60.39e(d)(1)(i-ii). Such sources must also have, at a minimum, the five increments of progress from Subpart B. Since these sources are shutting down, not retrofitting, the increments would need to be revised. In keeping with the intent of the required increments of progress of Subpart B, EPA suggests the following six increments for such sources:

1. Source's plan for shut down
2. Contract with the vendor (off-site hauler or alternative waste treatment equipment)
3. Begin construction of alternative waste treatment equipment (if applicable)
4. Complete installation of alternative (if applicable)

5. Shut down incinerator
6. Dismantle incinerator

23. Can the State set the same compliance schedule for all sources in the State?

Answer: Yes, the State Plan could require all sources to be in compliance within 1 year of State Plan approval. It could also require sources of specified circumstances that meet the criteria additional time[3] to comply, provided the State Plan includes enforceable increments of progress at least as protective as the EG and there is a clear link between each source and a compliance schedule.

Even if a State chooses to prescribe individual compliance schedules for each of its currently known sources, EPA recommends that it still include in its State Plan a generic compliance schedule applicable to sources discovered after submittal of the State Plan directed to "all other applicable sources" that the inventory may miss.

24. Are increments of progress for the individual sources requesting extensions under sec. 60.39e(d) submitted with the State Plan or are they negotiated later - after approval by EPA.

Answer: Section 60.39e(d) provides States with the option, through the State Plan, of allowing designated facilities to petition the State for extensions beyond 1 year from State Plan approval to comply. This is the one allowable situation in which compliance schedules, including increments of progress, are determined after EPA approval of the State Plan.

25. Do sources requesting an extension beyond 1 year from promulgation need to provide the documentation in 60.39e(d) to the State prior to submittal of the State Plan?

Answer: No. The rule only States that sources requesting an extension submit the documentation listed in 60.39e(d)(1)(i-ii) "in time to allow the State adequate time to grant or deny the extension within 1 year after EPA approval of the State Plan."

26. What rule determines whether a facility has only 1 year from State Plan approval to comply, or 3 years with the 5-increment compliance schedule?

Answer: This is a site-specific question that each State must address. The EPA expects that most sources will come into compliance with the State Plan within 1 year after EPA approval. The Emission Guidelines allow States to include compliance schedules for facilities planning to retrofit that extend beyond 1 year after State Plan approval, provided that the State Plan includes enforceable increments of progress for the facility and that the final compliance date is not later than 3 years following State Plan approval or September 15, 2002, whichever is earlier. There is no specific criteria in the Emission Guidelines that determines whether a facility has only 1 year from State Plan approval to comply, or 3 years with the 5-increment compliance schedule. States are to use their judgement and the information provided to the State by the source to determine if the source should be allowed more than 1 year after State Plan approval to comply.

27. If the EPA disapproves the State Plan, how does this affect the source's compliance time?

Answer: If a State submits and receives approval of a State Plan prior to September 15, 1999, sources are to comply with the State Plan within 1 year after EPA approval of the State Plan. Thus, States which submit State Plans that are disapproved have until September 15, 1999 to resubmit an approvable State Plan. In cases where the State does not receive approval of their State Plan by September 15, 1999, a Federal Plan will go into effect in that State. Sources will then have 1 year after September 15, 1999 to come into compliance unless they meet the increments of progress specified in the Federal Plan, in which case, they would have until September 15, 2002 to comply.

28. Under the Emission Guidelines, existing sources have 3 years from EPA approval of the State Plan to comply. Is this the compliance date in all cases?

Answer: No, States can require compliance sooner. All HMIWI covered by a State Plan must complete retrofit or cease operation by the date 1 year after State Plan approval. Sources planning to retrofit may have until the date 3 years after State Plan approval or until September 15, 2002, whichever is earlier, provided that the State Plan contains increments of progress. The State Plan may tailor the various compliance dates provided the sources meet the September 15, 2002 deadline. The State may elect to tie the enforceable increments of progress to (1) fixed calendar dates, (2) "float" dates from EPA approval of the State Plan, or (3) with the exception of increment 5 (final compliance), "float" dates from issuance of permits necessary for retrofit activities.

29. Can a facility submit a closure agreement as an alternative compliance plan, and decide later to retrofit controls?

Answer: Yes. The State Plan must specify a deadline for an HMIWI to complete retrofit or to cease operations. If a State Plan specified that

an HMIWI would cease operations by a given date, and the HMIWI owner later decides to retrofit controls, the State must modify the State Plan to include a new compliance date for the HMIWI (including meeting all requisite notice-and-comment requirements and the five increments of progress. The Emission Guideline revision would need to be approved by the EPA. If an HMIWI owner already knows the cease operations agreement is an interim step toward retrofit and restart of the unit, the requirement to cease operation can be added to the five required increments of progress toward compliance with the State Plan. By adding the cease operation requirement to the State Plan, the State would eliminate the need to modify the State Plan in order to allow the unit to retrofit and resume operation. The unit would have to cease operation on or before September 15, 2002 and would have to complete its retrofit before restarting operations.

30. Some sources will wait until the standards are finally adopted by the State before deciding whether to retrofit or shut down. How will States be able to determine compliance schedules in the State Plan for sources which have not yet even begun the bidding/contracting process at time of State Plan submittal? How binding are the compliance schedules? Can the compliance schedules be a "best guess"?

Answer: All sources must be in compliance within 1 year of State Plan approval, unless the State has provided increments of progress, in which case sources would have up to 3 years from State Plan approval to comply or September 15, 2002, whichever is earlier. If the State chooses to give sources longer than 1 year, the State Plan must include at a minimum, the five enforceable increments of progress for each HMIWI as required by Subpart B. The required increments are:

submit a final control plan,

award contracts for controls,

initiate on-site construction or installation of controls,

complete on-site construction or installation of controls, and

final compliance.

Additional increments of progress may also be included in the Plan. The State Plan must include binding and enforceable compliance dates for the five increments. The first four increments can be calendar dates or floating dates set a certain time from State Plan approval or issuance of a specific permit. But the fifth increment, final compliance, can be set only from State Plan approval and cannot extend beyond 3 years from State Plan approval or September 15, 2002, whichever is earlier. Sources which the Plan requires to cease operations by September 15, 2002, can reopen after the final compliance deadline (i.e., September 15, 2002), but in order to do so the sources must demonstrate that they are in full compliance before reopening.

The schedules in the State Plan are enforceable but the State Plans can be revised provided they meet the requirements above and the public is given adequate notice of an opportunity for public comment. That is, if the State and HMIWI agree that more time is necessary for an increment of progress after the State Plan has been approved, the State could submit a State Plan revision to EPA for approval after following the procedures for Plan revision specified in 40 CFR Part 60, Subpart B. The final retrofit date or cease operation date, however, would still need to be within 3 years of State Plan approval and no later than September 15, 2002.

The State and HMIWI will need to review the emission limits in the Subpart Ce Emission Guidelines (September 15, 1997, 62 FR 48348) and draft State standards being developed to implement the Guidelines and make judgments about the likely retrofit requirements in order to include a schedule in the State Plan. Except for those few States that already have more stringent standards or broader coverage, most States will propose to match the Emission Guidelines requirements.

31. Can a State tie the compliance date for the HMIWI to the date of State adoption of the rule?

Answer: Yes, as long as there is the backstop compliance date (retrofit completed or cease operation) which is no later than three years after State Plan approval or September 15, 2002 (5 years after Emission Guidelines promulgation), whichever is earlier.

32. For many States, it takes 1.5 to 2 years to develop a State rule. Therefore, many States in the process of developing a State rule will receive a Federal Plan. Why doesn't EPA just apply a Federal Plan across the board saving States the trouble of developing a State rule since the end result will be the same?

Answer: The EPA does not have the authority to implement a Federal Plan until 2 years after the promulgation date. The Federal Plan only applies until a State develops an approvable State Plan. By developing a State Plan, States have the opportunity to tailor the compliance schedule to individual sources and to develop a State rule more stringent than the Emission Guidelines. States should be aware that a State Plan provides more flexibility than a Federal Plan. For example, a State Plan gives the State the opportunity to tailor their compliance schedule to sources. It also allows the State to be more stringent than the EG. In addition, it is likely that a State Plan would result in a more detailed source inventory.

33. Are fixed calendar dates required in increments of progress?

Answer: Yes and no. There are five mandatory increments of progress. These are: 1) submittal of a final control plan; 2) awarding of contracts; 3) initiation of on-site construction; 4) completion of on-site construction, and 5) final compliance. Either calendar dates or floating dates can be used for these increments of progress, as long as final compliance does not go beyond 3 years from State Plan approval or September 15, 2002.

The State may submit a compliance schedule that uses either all calendar dates or a mix of calendar and floating dates, or, a State could submit a schedule with dates that all float. For the first four increments of progress, dates may float from date of State Plan approval or date of issuance of a permit. If a permit is cited in the State Plan as the significant date from which the increments will be referenced, the specific permit must be identified.

34. If a facility plans to close down their HMIWI rather than comply with the Emission Guidelines, must the facility close down by the date 1 year after State Plan approval or can the facility continue operating without complying with increments of progress?

Answer: The facility must close down by the date 1 year after State Plan approval, unless the facility is granted an extension by the State. In order for a State to grant such an extension, the State Plan must include the provisions listed in section 60.39e(d) of Subpart Ce.

35. What are the consequences for a unit which fails to meet an increment of progress established in the State Plan?

Answer: Once EPA approves the State Plan, the increments of progress become Federally enforceable. If a source misses an increment of progress, that source is operating out of compliance and risks enforcement action.

STANDARD METROPOLITAN STATISTICAL AREA (SMSA)

36. How are metropolitan areas defined in the Emission Guidelines?

Answer: The Emission Guidelines define Standard Metropolitan Statistical Areas (SMSA) as areas listed in OMB Bulletin No. 93-17 entitled "Revised Statistical Definitions for Metropolitan Areas" dated June 30, 1993. See answer to #37, below, for information on how to obtain a copy of the 1993 SMSA listing.

37. Where can States access OMB Bulletin No. 93-17 (for SMSA boundaries)?

Answer: OMB Bulletin No. 93-17 is item No. IV J 125 in docket No. A-91-61. The docket phone number is 202-260-7548.

A listing of the Standard Metropolitan Statistical Areas (SMSA's), as defined by the OMB on 6/30/93 is at http://www.census.gov/population/estimates/metro-city/93mfips.txt on the Internet.

38. Are we bound by the HMIWI regulations to use only the 1993 SMSA publication, or is it correct to use the most current publication of statistical data?

Answer: The definition of Standard Metropolitan Statistical Area in the Emission Guidelines is based on the 1993 SMSA definitions. The Emission Guidelines specify that the 1993 SMSA definitions be used to ensure that the rural criteria is applied uniformly and consistently for small HMIWI. Therefore, States are required by the Emission Guidelines to use the 1993 SMSA definitions for determining applicability of the rural criteria to HMIWI.

39. Regarding the 50-mile limit from an SMSA, is this from the edge of an urbanized area or the edge of the county? In other words, for counties which are part of the SMSA but have only a small urbanized area in the corner, is the 50 miles measured from the county line or the city limit line?

Answer: The 50-mile limit from an SMSA is measured from the edge of the SMSA. In most cases this is a county line. In some cases, it is the city or township boundary.

LEGAL AUTHORITY

40. What is the difference between "legal authority" and "enforcement mechanism"?

Answer: Legal authority is a general term described in 40 CFR sec. 60.26 that means the power that a State has to require a source to do something--be it meet certain emission limits or put on certain control devices. The manner in which a State uses its legal authority to enforce requirements is called the enforcement mechanism. Examples of enforcement mechanisms that could be used to give a State legal authority over a source are: a State rule, an Administrative Order, a Compliance Order, or a Federally enforceable State operating permit.

41. If a State already has a State rule in place, can the State submit the rule as the legal authority?

Answer: Yes, the existing State rule would be the State's legal authority.

42. If a State develops a State rule to adopt the Emission Guidelines, must this rule be passed by the State legislature within 1 year after promulgation or is it sufficient to have submitted the rule to the State legislature for review by 1 year after promulgation?

Answer: The State rule must be passed by the State legislature by September 15, 1998.

43. If a State uses a SIP regulation as a basis for the legal authority in a State Plan, does the State need to demonstrate legal authority?

Answer: A State can select from a range of legal mechanisms provided that the State can show it has adequate legal authority. A demonstration of legal authority is required in all cases except for State rules. If a SIP rule is used, citations, rather than copies of actual State legal authority is adequate. It is unlikely the SIP will address all of the HAPs (see Section 60.26[b]).

For all other legal instruments, a demonstration of authority is required. The EPA strongly recommends that States include a certification letter from the State Attorney General for such a demonstration if a mechanism other than a State regulation is used. (Several States have originally thought they could avoid a rule by using a title V permit as their enforcement mechanism, for example. But their Attorney General's opinion was that the State did not have the authority to incorporate applicable requirements into a title V permit.)

SOURCE/EMISSIONS INVENTORY

44. If a former HMIWI is now only burning municipal waste and the hospital is gone, do they still meet the definition of "fully or partially dismantled," thus must be included on the State's inventory?

Answer: States are encouraged to make a reasonable attempt to include in their inventory all incinerators in the State that have the potential to restart. As guidance, States may use the following questions to help determine whether an incinerator that is shut down should be included in the inventory or not. If the answer is "yes" to at least one of the questions below, then the incinerator would not to be included in the inventory:

- Are the charge doors welded shut?
- Is the main stack and/or bypass stack removed?
- Have the blowers been removed?
- Have the burners and/or fuel supply been removed?

In the case cited above, it is unlikely that the incinerator in question would ever be used again to burn hospital waste or medical/infectious waste. Thus, it need not be included on the State's inventory because it is not an HMIWI.

However, if the incinerator started taking any hospital waste or medical/infectious waste, it would then become subject to the regulations.

45. Must a "small" MWC not subject the MWC rule (burning 10 percent or less hospital/medical/infectious waste) and only required to keep records be included on the State Plan inventory?

Answer: "Smaller" MWC's exempt from the MWC rule by virtue of their size (less than 250 tons/day) and burning 10 percent or less hospital/medical/infectious waste need only notify the EPA Administrator of an exemption claim and keep records of wastes burned, per sec. 60.32e(c). These units burning 10 percent or less hospital waste and medical/infectious waste are called "co-fired combustors." Although co-combustors are not subject to the emission limits, in order for the public to be aware of their existence and for States to ensure compliance with these record keeping/notification requirements, such units must be included in the State Plan inventory.

Note: Per sec. 60.32e(e), HMIWI's subject to the MWC rule are exempt from the HMIWI rule, and as such, would not need to be included on the State's inventory of HMIWI.

46. Have sample inventory questionnaires been developed?

Answer: A sample inventory questionnaire is contained in the HMIWI Implementation Summary document as Appendix G.

47. Are crematoria, etc., required to be included in the inventory, even if they are "exempt"?

Answer: Crematoria are not subject to any part of the HMIWI regulations as long as they burn only human remains. Therefore, there is no need to include crematoria in the State's inventory. However, if the crematory incinerator is used to burn any hospital waste or medical/infectious waste, it is subject to at least some portion of the HMIWI regulation and must be included on the State's inventory.

48. Where in the Act or Regulation is the requirement for the State to submit an inventory? What must be included in the inventory?

Answer: Section 60.25(a) of Subpart B says that States are to submit an inventory of sources as well as an inventory of the emissions from the HMIWI in the State. The inventory should include a list of applicable sources, including HMIWI, co-fired combustors, and incinerators burning only pathological waste, low-level radioactive waste, and chemotherapeutic waste. Co-fired combustors and incinerators of low-level radioactive, chemotherapeutic, and pathological waste must be included in the source inventory but are exempt from the State Plan emissions inventory.

49. Where are the emission factors which supported rule development published?

Answer: The emission factors developed during the HMIWI rulemaking process are contained in the appendices of the HMIWI Summary Document. The memorandum which documents the emission factors is available at the Air and Radiation Docket and Information Center in Docket No. A-91-61, Item No. IV-B-42. The title of the memorandum is "Emission Factors for Medical Waste incinerators." The phone number for the EPA Docket Office is (202) 260-7548.

50. Other than the name, location, owner/operator, etc., are States also expected to update the Charge Rate, APCD and Type sections of the inventory list EPA presently has? If so, States would like a legend or key to what the codes stand for under MWI Type. Also, are States supposed to know what APCD number each site is, or does EPA have a key for those, too?

Answer: An inventory of designated facilities will be needed in each 111(d)/129 State Plan, as required by Section 60.25 of Subpart B of 40 CFR 60. Section 60.25 also requires an estimate of emissions from each source. The EPA inventory sent to the States was used by EPA to conduct analyses for the HMIWI rulemaking. It is not necessarily precise, but we thought it would be a good starting point for States to begin developing a list of sources. Consequently, the State can use as much or as little of the EPA 1995 inventory as they wish, keeping in mind they must develop their own list and an emissions estimate.

With that in mind, following is a short description of each column.

"Charge Rate" reflects the design waste burning capacity of each unit in the EPA inventory. For many units, the charge rate was assumed based on the number of beds at the hospital. For purposes of determining size (and corresponding emission limits in the guideline) and estimating emissions, it would probably be a good idea for States to try to determine the actual design waste charge rate for each unit and the actual waste burned per hour (or day, or year) for each unit.

"APCD Number" reflects the type of air pollution control on the facility. Again, many are assumed based on permit limits and on State regulations for particulate matter. EPA can provide a key for the APCD numbers, but it would probably be better to try to find out what (or whether) APCD is actually in place. This could also help in estimating emissions.

"MWI Type" means the design of the incinerator. "B" stands for "batch," "C" stands for "continuous," and "I" stands for "intermittent."

51. Will the AP-42 emission factors be updated for HMIWI's?

Answer: No, at least there are no plans to do so in the near future. Actual emissions are always better, but if a State must estimate emission when developing emissions inventory, there are three options.

One, the State can use the State's own emission factors. Two, the State can use the emission factors used to support the rule (contained in the appendix of the HMIWI Summary Document and the docket). Or three, the State can use the emission factors from AP-42.

APPLICABILITY

52. Are MWC's subject to Cb, Ea or Eb exempt from the HMIWI rule or are they only exempt from one subpart and thus, still subject to other parts?

Answer: There are three terms that must be kept straight. All of these regulations are under "Part" 60 of the Code of Federal Regulations. Each of the regulations is a "Subpart" of Part 60 (i.e., Subpart Cb, Subpart Ce, Subpart Ea, Subpart Eb, etc.). Each Subpart is broken to "Sections" (e.g., Section 60.32e(e)). Combustors subject to Subparts Cb, Ea, or Eb are not subject to Subparts Ce or Ec. That is, they are exempt from the entire HMIWI rule.

53. Are MWC's exempt regardless of the amount of medical waste they burn?

Answer: Any MWC subject to Subpart Cb, Ea, or Eb is exempt from Subparts Ce and Ec, regardless of the amount of hospital waste or medical/infectious waste burned. However, not all MWC's are subject to Subparts Cb, Ea, or Eb because these subparts only affect MWC larger than 250 tons/day. An MWC which is smaller than 250 tons/day and burns more than 10 percent hospital waste and medical/infectious waste is subject to Subpart Ce or Ec. An MWC which is smaller than 250 tons/day and burns 10 percent or less hospital waste and medical/infectious waste is exempt from most of the provisions of Subparts Ce and Ec, but must notify the Administrator of an exemption claim and keep records of wastes burned. These units burning 10 percent or less hospital waste and medical/infectious waste are called "co-fired combustors."

54. Are the HMIWI regulations applicable to crematorium and animal waste incinerators? The definition of medical/infectious waste in the Emission Guidelines seems to include animal waste.

Answer: Human corpses, remains, and anatomical parts intended for interment or cremation are not considered medical/infectious waste or hospital waste for the purposes of this rule. Consequently, human crematoria that burn only human remains are not subject to the HMIWI regulations. However, if the crematory incinerator is used at any time to burn hospital waste or medical/infectious waste, it is subject to the HMIWI regulations. Animal remains can sometimes meet the defintion of medical/infectious waste. If

the animal remains meet the definition of medical/infectious waste, then the incinerator burning the medical/infectious animal remains is subject to the HMIWI regulations. However, if the incinerator burns exclusively animal remains, containers used to collect and transport the remains, and animal bedding, then the incinerator is exempt from most provisions of the HMIWI regulations and is subject only to notification and recordkeeping requirements. If the incinerator burns 10 percent or less of hospital waste and medical/infectious waste, it is a co-fired combustor subject only to notification and recordkeeping requirements. If the incinerator burns more than 10 percent hospital waste and medical/infectious waste, it is subject to all of the requirements of the regulation.

55. Please define "commence construction." We have a building which put in building footing. They have not built the building or purchased equipment.

Answer: "Commence construction" is defined by definitions in 40 CFR 60 Subpart A - General Provisions. "Commenced" is defined with respect to the definition of new source as, that an owner or operator has undertaken a continuous program of construction or modification or that an owner or operator has entered into a contractual obligation to undertake and complete, within a reasonable time, a continuous program of construction or modification. "Construction" is defined as fabrication, erection, or installation of an affected facility.

For purposes of determining what is a new HMIWI, Subpart Ec refers to HMIWI which commenced construction after June 20, 1996. Thus, if the HMIWI was or is to be constructed after June 20, 1996, then the HMIWI is a new unit regardless of when the building is constructed. However, if the facility went under contractual obligation with a company to construct an HMIWI prior to June 20, 1996, then the unit may be considered as an existing unit. Without more specific information than is provided in the question above, it is difficult to determine if the facility has or is constructing a new or existing HMIWI.

56. With respect to applicability, please discuss alternatives to onsite incineration (i.e., autoclaves, microwave, etc.).

Answer: The HMIWI regulations are not "medical waste disposal" regulations. The HMIWI Emission Guidelines apply to hospital/medical/infectious waste incinerators which are defined as "any device that combusts any amount of hospital waste and/or medical/infectious waste." Alternatives to onsite incineration such as autoclaves and microwaves do not combust waste and therefore do not meet the definition of "hospital/medical/infectious waste incinerator" in the Emission Guidelines. Therefore, the Emission Guidelines do not apply or contain any requirements for the autoclave, microwave, or to any other alternative to onsite incineration which does not combust hospital waste or medical/infectious waste.

57. Does the small "rural" unit count for medium and large units in rural areas that are derated?

Answer: Under the small rural criteria, the HMIWI would have to burn less than 2,000 pounds of waste per week and be located more than 50 miles from an SMSA . Most medium and large HMIWI have the capacity to burn much more than 2,000 lbs/wk and would have to undergo drastic measures to derate their capacity to less than 2,000 lb/wk. It is not anticipated that it will be very cost efficient for facilities operating medium and large HMIWI to severely derate their capacities in order to burn less than 2,000 lbs/wk. Medium or large HMIWI that derate their capacity in order to fall in the small subcategory may be considered as small "remote" units if they meet the small rural criteria.

58. A hospital in NC has a permit to construct awarded prior to June 1996. Bidding on the air pollution control device occurred after June 1996. The incinerator was constructed prior to June 1996, but the APC device has not been installed yet since the permit has lapsed. Would the unit, (i.e., the incinerator and scrubber) be considered a new or existing unit? If existing, does it have to meet the current North Carolina standards or the new EPA emission standards on existing units?

Answer: Hospital/medical/infectious waste incinerators which commenced construction on or before June 20, 1996 are considered to be existing sources subject to the HMIWI Emission Guidelines. Hospital/medical/infectious waste incinerators commenced construction after June 20, 1996 are considered to be new sources subject to the HMIWI New Source Performance Standards. The answer to the above questions involves the definition of "commenced construction." The General Provisions (40 CFR 60 Subpart A) define "commence" and "construction." The applicability date for the HMIWI Emission Guidelines depends on the date when the HMIWI is constructed, not when the APCD is installed. Thus, the unit discussed in the question would be an existing HMIWI because the HMIWI was constructed on or before June 20, 1996.

The Emission Guidelines do not apply directly to existing HMIWI and they do not override or negate any State regulations. Rather, States are to develop State Plans to implement the Guidelines. The HMIWI in question would be subject to the State Plan once it is approved by EPA. In the meantime, the HMIWI remains subject to current State regulations. Once the State Plan is approved by EPA, the HMIWI will be subject to any applicable State regulations and the State Plan. It is likely that the State will combine current State regulations with the State Plan so that the HMIWI will be subject to just one requirement by the State.

59. Say a facility uses a batch incinerator with a charging rate of 100 pounds per batch. The incinerator is loaded 5 times per day. Total daily loading is 500 pounds per day. Would this fall under a small incinerator? (i.e., [500 lb/day] / [24 hr/day] = 20 lb/hr ==> small in size). Is this the correct calculation in determining incinerator size?

Answer: Batch HMIWI are typically loaded with waste, started and allowed to burn the waste, and cooled down so the ash may be removed. The entire batch process usually takes the majority of a day. The unit in question does not sound like a typical batch unit, because a batch unit could not be loaded 5 times per day. Nevertheless, small batch units as defined in the HMIWI rule, burn less than 1,600 lbs/day. If the unit is indeed a batch unit, then it would be considered a small HMIWI because it only burns 500 lbs/day. If the unit were something else (e.g., an intermittent unit) then the unit would still be small provided that it does not charge more than 200 pounds of waste per hour.

Methods for calculating HMIWI size for purposes of the HMIWI regulations are provided in section 60.51c of Subpart Ec under the definitions of "maximum charge rate" and/or "maximum design waste burning capacity." The size cutoffs for each subcategory are provided in the definitions of small, medium, and large HMIWI.

60. Our facility burns on average 2,200 pounds per week, of which 200 pounds is pathological. Would the 200 pounds be subtracted from the total and make this a small rural unit?

Answer: Co-fired combustors are units which burn 10 percent or less hospital waste and medical/infectious waste. The only time the amount of pathological waste would be subtracted from the total waste burned is for purposes of determining applicability of a co-fired combustor. If the unit in question is burning hospital waste and/or infectious waste, the only way it may be considered a small rural unit is if: (1) the facility reduces the amount of waste burned (including the pathological waste) to less than 2,000 pounds per week, (2) the unit is a small unit as defined in section 60.51c of Subpart Ec, and (3) the unit is located more than 50 miles from the nearest SMSA.

61. Can an enforceable permit condition limiting charge rate (pounds per hour) below the specific applicability size threshold be used to change the size category from large to medium or from medium to small incinerator?

Answer: Yes. States may allow units which burn less than their design capacity to base their size determination on the "maximum charge rate," as defined in section 60.51c of the HMIWI rule.

62. What if the source does change its size category through a permit condition and then violates that condition by operating in the next larger category? Does the source then become subject to the requirements in that next larger category?

Answer: No, size is determined by the maximum charge rate which was defined earlier (performance test or permit condition). Thus, the source doesn't automatically become subject the requirements of the next larger category. Nevertheless, in this case, the source would be in violation of the regulation and/or the permit condition.

63. Are the following exempt from the HMIWI rule: funeral homes, pet crematories (at zoos and veterinaries), teaching hospitals (which burn carcasses from anatomy class and animals from research), or university labs? Our State has crematory rules under which the above sources must keep records. Under this scenario, could our State submit a negative declaration?

Answer: Applicability is not determined by where the incinerator is located, but rather, by what the incinerator is burning. If the facilities listed burn only materials that do not meet EPA's definition of hospital waste or medical/infectious waste, they are not subject to the regulations and need not be included in a State Plan. If a State is confident that there are no incinerators in the State burning any hospital waste or medical/infectious waste, then the State should submit a negative declaration. Note that human corpses, remains, and anatomical parts intended for interment or cremation are not considered medical/infectious waste or hospital waste for purposes of this rule.

If any of the facilities listed burn any amount of hospital waste or medical/infectious waste at any time, they are subject to, at a minimum, the reporting and recordkeeping requirements of section 60.32e. The only exemptions are for any combustor required to have a permit under Section 3005 of the Solid Waste Disposal Act; any pyrolysis unit; any cement kiln; or any combustor subject to Subpart Cb, Ea, or Eb (standards and guidelines for certain municipal waste combustors). If the incinerator burns only pathological, low-level radioactive, and/or chemotherapeutic waste, it is subject only to notification and recordkeeping requirements and should be included in the State Plan inventory. If the incinerator burns 10 percent or less of hospital waste and medical/infectious waste, it is a co-fired combustor subject only to notification and recordkeeping requirements and should be included in the State Plan inventory. If the incinerator burns more than 10 percent hospital waste and medical/infectious waste, it is subject to all of the requirements of the regulation.

64. Is a pyrolysis furnace that is used to clean metallic filters classified as an incinerator? The furnace is rated at three million Btu/hr and uses only natural gas. Is the operator training requirements applicable? No material containing toxic metal or halides are burned in the furnace.

Answer: No. Pyrolysis units are not subject to any part of the HMIWI regulations.

65. We have a 2-year-old incinerator with a maximum capacity of 600 lbs/hr. We derate burn at 200 lbs/hr. We are a diagnostic lab (veterinary-animal disease investigations). We believe that 90 percent of our material is pathological waste (carcasses, tissues). What do you

see for the future of exempted pathological waste? We do not have a scrubber. We are 55 miles from a city of 100,000 (city limits) and 32 miles from the SMSA border of the county line, for that area.

Answer: Facilities which burn 10 percent or less hospital waste and/or medical/infectious waste are considered to be co-fired combustors. Co-fired combustors are only required to notify the Administrator of an exemption claim and keep quarterly records of the amount and type of wastes burned. Because the facility in the question is a laboratory, it is not likely to burn any hospital waste. The 90 percent pathological waste is not included in the determination of the amount of medical/infectious waste burned. Therefore, if the facility burns 10 percent or less medical/infectious waste, then it would be considered a co-fired combustor.

Regulations for these types of incinerators are under development, but it is too early to know what the requirements will be.

66. What are specific de-commissioning requirements: (1) complete dismantlement, or (2) disconnect fuel supply for control power to unit?

Answer: There are no specific de-commissioning requirements. States are to use their best judgement to determine which HMIWI that have ceased operation are capable of reopening. For those HMIWI which have ceased operation, but are capable of reopening, then the State should include in its State Plan some mechanism by which to require such facilities to comply with the State Plan.

As a suggestion, criteria for determining whether an HMIWI is inoperable could include but not be limited to, one or more of the following conditions:

- Waste charge door welded shut;
- Stack/by-pass stack removed;
- combustion air blowers removed; and/or
- burners or fuel supply removed.

67. Our facility currently combusts about 65 percent returned pharmaceuticals and 35 percent laboratory animal waste (which meets the definition of medical waste). If we reduce the amount of medical waste to 10 percent or less, are we then not subject to the Guidelines?

Answer: There are three possibilities. In all three cases, the returned pharmaceuticals do not meet the definition of medical/infectious waste and are not considered hospital waste because the definition of

hospital waste specifically excludes unused items returned to the manufacturer. The three possibilities arise from what is meant by "laboratory animal waste."

First, if the laboratory animal waste consists only of animal tissue, containers used to collect and transport the tissue, and/or animal bedding, the laboratory animal waste is considered pathological waste. In this case, the incinerator is burning no hospital waste and is burning some medical/infectious waste, all of which is pathological. The definition of co-fired combustor states that pathological waste should be considered as "other" waste when calculating the percentage of medical/infectious waste, even if the pathological waste meets the definition of medical/infectious waste. Under these conditions, this incinerator is a co-fired combustor already, and reducing the amount of medical/infectious waste would not alter the applicability. It is exempt from most of the provisions of the regulations, but must notify the Administrator of its existence and keep records of fuels and wastes burned.

Second, if some of the laboratory animal waste is medical/infectious waste that is not animal tissue, containers, and/or bedding (i.e., some of the laboratory animal waste is non-pathological medical/infectious waste), but this non-pathological medical/infectious waste accounts for 10 percent or less of the total waste burned, then this incinerator is also a co-fired combustor subject to the same requirements described above.

Finally, if some of the laboratory animal waste is medical/infectious waste that is not animal tissue, containers, and/or bedding (i.e., some of the laboratory animal waste is non-pathological medical/infectious waste), and this non-pathological medical/infectious waste accounts for more than 10 percent of the total waste burned, then this incinerator is subject to all of the requirements in the regulations.

68. Does the applicability date mean the date of initial construction, initial startup, or when the HMIWI finally reaches full operation?

Answer: The applicability date is the date construction is commenced. For example, the Subpart Ce applies to units for which construction is commenced on or before June 20, 1996. "Commenced" is defined in the NSPS General Provisions in 40 CFR Part 60 Subpart A, Section 60.2. As defined under Section 60.2, commenced means that an owner or operator has undertaken a continuous program of construction or modification or that an owner or operator has entered into a contractual obligation to undertake and complete, within a reasonable time, a continuous program of construction or modification.

69. Are units which commenced construction between the February 1995 proposal and promulgation of the HMIWI rule (September 15, 1997) required to meet the emission limits in the NSPS?

Answer: The EPA first proposed the medical waste incinerator Emission Guidelines in February 1995. In response to comments received following

this proposal, the EPA published a supplemental *Federal Register* notice on June 20, 1996. This supplemental notice had most of the elements of a proposal and is now considered to be a reproposal of the medical waste regulation. Units which commenced construction prior to June 20, 1996 are considered to be existing HMIWI and are required to meet emission limits in the State Plan. Facilities which commenced construction after June 20, 1996 are considered to be new units and are subject to the New Source Performance Standards.

70. Is an incinerator located at a hospital that burns only noninfectious trash from the hospital covered?

Answer: Yes, because the incinerator is burning more than 10 percent by weight hospital waste.

71. Is an incinerator located at a hospital that is used to burn only pathological waste covered?

Answer: Incinerators used for the sole purpose of combusting human or animal remains and pathological waste are exempt from most provisions of the EG. The hospital operating the incinerator must notify the Administrator of an exemption claim and keep quarterly records of the time periods when only pathological waste is combusted.

72. Is an incinerator burning waste from a nursing home covered?

Answer: Nursing homes are not considered to be hospitals and thus, not generators of "hospital" waste under the Emission Guidelines. However, most nursing homes generate "medical/infectious" waste and thus, would be covered by the EG to the extent that any other incinerator burning medical/infectious waste would be covered.

73. Incinerators used to burn pathological waste, low-level radioactive waste, and chemotherapy waste are not covered under the Emission Guidelines. Does EPA plan to regulate these incinerators under another standard?

Answer: Yes. Incinerators burning pathological waste, chemotherapeutic waste, and low-level radioactive waste will be covered under the Industrial Combustion Coordinated Rulemaking.

74. Is notification and record keeping required for facilities operating pathological incinerators?

Answer: Facilities operating pathological incinerators are required to notify the Administrator of an exemption claim and keep records of the time periods when only pathological waste is burned. These records are to be maintained onsite by the facility. Reporting is not required for facilities operating pathological incinerators.

75. According to the Emission Guidelines, HMIWI capacity may be determined by either the maximum charge rate or the maximum design waste burning capacity. What if the maximum design waste burning capacity places the HMIWI in one subcategory and the maximum charge rate places the same HMIWI in another subcategory?

Answer: In the scenario stated above, the maximum charge rate would be used to determine the HMIWI subcategory. Maximum charge rate, as defined in Subpart Ec, is 110 percent of the lowest 3-hour average charge rate measured during the most recent performance test. The maximum design waste burning capacity is calculated based on primary chamber volume and heat release rate. A formula for this calculation is included in Subpart Ec. Because the maximum design waste burning capacity is based on the design capacity of the incinerator, it is fixed, and cannot be changed. The maximum charge rate, on the other hand, is based on the amount of waste that a facility actually burns in the incinerator. In some cases the maximum charge rate will be lower than the maximum design waste burning capacity. For enforcement purposes, the HMIWI would be bound by the maximum charge rate.

76. Is an MWC covered by the HMIWI rule if it burns hospital waste and/or medical/infectious waste and is not subject to Subparts Cb, Ea, or Eb?

Answer: Maybe. If the MWC burns more than 10 percent by weight hospital waste and/or medical/infectious waste, it is covered. If the MWC burns some hospital waste or medical/infectious waste, but 10 percent or less, it is considered a co-fired combustor for purposes of the HMIWI Emission Guidelines and the facility must notify the Administrator of an exemption claim and keep quarterly records of the weight of hospital waste, medical/infectious waste, and other fuels combusted on a calendar quarter basis.

77. If an incinerator owned and operated by a pharmaceutical company is used to burn drugs, noninfectious trash, infectious waste, pathological waste, and low-level radioactive waste, is it covered?

Answer: Drugs are not considered to be medical/infectious waste. Drugs are also not considered to be hospital waste if returned to a pharmaceutical company from a hospital because the definition of hospital waste in the Emission Guidelines excludes items returned to the manufacturer. Because the incinerator in this case is used to burn some infectious waste, it is covered by the EG. If the infectious waste accounts for 10 percent or less of the total waste burned, the incinerator is considered a co-fired combustor and the facility must notify the Administrator of an exemption claim and keep quarterly records of the weight of medical/infectious waste and other fuels combusted. The incinerator is covered by all of the provisions of the EG if it is used to burn more than 10 percent by weight of items considered to be hospital waste and/or medical/infectious waste. The portions of pathological and low-level radioactive waste that could be considered medical/infectious under the medical/infectious waste definition in the Emission Guidelines are not included in the 10 percent determination.

78. Is an incinerator located at a hospital that burns only pathological, chemotherapeutic, and low-level radioactive waste generated at the hospital covered by the HMIWI rule?

Answer: Incinerators used to combust pathological waste, chemotherapeutic waste, and low-level radioactive waste alone or in combination are exempt from most provisions of the EG. The hospital operating the incinerator must notify the Administrator of an exemption claim, and keep quarterly records of the periods of time when only pathological waste, chemotherapeutic waste, and low-level radioactive waste is combusted.

79. If a facility operates two HMIWI, must the facility combine the capacity of both units to determine overall HMIWI size?

Answer: No, HMIWI size is determined on an individual unit basis.

80. I am concerned that the definition of "medical waste" in the HMIWI rule, which is broader than our State definition, may put pressure on the State to change its definition. This would be a setback because under our mandatory waste reduction planning requirements, facilities are able to recycle items that by the definition in the Emission Guidelines would have to be treated as infectious waste.

Answer: There is a misconception that the EPA HMIWI rule somehow determines which items in a waste stream must be "treated" and which items need not be "treated." This is an incinerator regulation, not a waste management regulation. The only reason medical/infectious waste is defined at all is to determine whether or not an incinerator is covered by this regulation. For example, IV bags are considered "medical/infectious" waste under the EPA HMIWI regulation, even if they

are not infectious. If a hospital puts IV bags into an incinerator, that incinerator is covered by the regulation. If hospitals in a State routinely recycle IV bags, there is nothing in the EPA HMIWI rule that prohibits the hospital from continuing to recycle IV bags. There is no need for the State to change its definition of medical waste to coincide with EPA's definition.

81. Subpart Ce defines "hospital/medical/infectious waste incinerator," "HMIWI," and "HMIWI unit." However, reference is made numerous times to "designated facility" and "affected facility". The latter terms appear to identify the same entity. For clarity and consistency, is it acceptable to use the term "hospital/medical/infectious waste incinerator" in place of "designated facility" and "affected facility"?

Answer: Under the Subpart Ce guideline, the "designated facility" is each individual HMIWI for which construction was commenced on or before June 20, 1996. Under the Subpart Ec NSPS, the "affected facility" is each individual HMIWI for which construction is commenced after June 20, 1996 or for which modification is commenced after March 16, 1998. Consequently, "designated facility" and "HMIWI" can be used interchangeably with respect to existing units under the Emission Guidelines, while "affected facility" and "HMIWI" can be used interchangeably with respect to new units under the NSPS.

OPERATOR TRAINING AND QUALIFICATION

82. Please expand on the minimum elements required for operator training?

Answer: Operator training may be obtained through a State-approved program or by completing and passing a training course that satisfies the requirements listed in section 60.53c(c) through (g) of Subpart Ec. In general, the operator training course described in section 60.53c(c) through (g) of Subpart Ec requires (1) 24 hours of classroom instruction, (2) an exam designed and administered by the course instructor, and (3) reference material distributed to the attendees covering course topics. State-approved operator training programs do not necessarily have to meet all of the requirements specified in section 60.53c(c) through (g) of Subpart Ec; however, States must decide if a program provides adequate HMIWI operator training before granting approval of the program.

83. What must an exam for operator training consist of and what constitutes passing?

Answer: The examination is to be designed and administered by the course instructor. Typically the exam would cover the material presented during

the training course. Each operator training program that develops an examination is responsible for determining what grade is acceptable for HMIWI operators to pass the course.

84. Some HMIWI operators have been trained through a program developed in cooperation with the equipment manufacturer and owner/operator. In some cases, such training programs are probably more facility-specific and comprehensive than a State-approved program. Owner/operators may be more qualified to develop a training program. Will EPA recognize owner/operator developed program over a State-approved program? Is EPA approval required for privately run operator training?

Answer: Facilities are to obtain operator training through either an operator training program that meets the requirements specified in section 60.53c(c) through (g) of Subpart Ec or through a State-approved operator training program. Thus, privately run operator training programs are acceptable if they meet the requirements specified in section 60.53c(c) through (g) of Subpart Ec. Approval by EPA is not required for privately run operator training programs that meet the Subpart Ec requirements. Privately run operator training programs that differ from the Subpart Ec requirements must obtain approval from the State. If a State disapproves an operator training program, then the training program will not be valid in that State and the EPA will not step in and have the State approve the training program. If the State says nothing about the training program and the program meets the requirements of section 60.53c(c) through (g) of Subpart Ec, then the program may be used to train HMIWI operators in that State.

85. What do States have to do to have a State operator training program instead of the training requirements defined in Subpart Ec? If a State already has an operator training program, is it automatically approved?

Answer: State Plans must require training of HMIWI operators through the program which meets the requirements specified in Subpart Ec or by a State-approved program. A State may develop and implement a program in lieu of the training requirements specified in Subpart Ec. State training programs are only good within the State of issuance. The training requirements mentioned in Subpart Ec are acceptable nationally.

86. Are there specific requirements for a State-run operator training program?

Answer: No, the EPA does not have specific requirements for State operator training programs.

87. Does a trained and qualified operator have to be onsite at all times while the incinerator is in operation?

Answer: No. The trained and qualified operator may be the supervisor of another HMIWI operator and may be on call while the incinerator is in operation. However, the Emission Guidelines require the trained and qualified operator to be onsite within 1 hour from the time when a problem with the HMIWI occurs.

88. The Emission Guidelines require that facilities comply with the operator training requirements within 1 year after EPA approval of the State Plan. Must facilities that intend to shut down later than 1 year from State Plan approval comply with the operator training and qualification requirements of section 60.39e(e)?

Answer: In order to continue operating beyond 1 year from State Plan approval, a source must comply with the requirements of the EG, including the operator training and qualification requirements of section 60.39e(e). The source must also have increments of progress. Therefore, yes, a source which will shut down after 1 year from State Plan approval must comply with the operator training and qualification requirements. If a source plans to shut down within 1 year of State Plan approval, it does not have to meet the operator training and qualification requirements of section 60.39e(e).

COMPLIANCE, PERFORMANCE TESTING, MONITORING AND INSPECTIONS

89. What happens if a facility is in the process of retrofitting, but is not able to demonstrate compliance with the emission limits by the 5-year deadline?

Answer: The facility must cease operation until a performance test is conducted and the facility demonstrates compliance.

90. Will the Guideline allow previous stack test results to be reused to determine compliance after retrofit? Can the stack test be used as part of the three consecutive tests for HMIWI?

Answer: After retrofit, previous stack tests may not be used to determine compliance. If there is no retrofit, stack tests performed prior to the compliance date may be used as part of the three consecutive tests for compliance if the State determines that such tests

were conducted in accordance with the required test methods and procedures, and that operating parameter limits (e.g., minimum scrubber liquor flow rate) can be established based on test results.

91. Who is to conduct the initial and annual equipment inspections for facilities operating small HMIWI that meet the rural criteria?

Answer: The owner or operator of the small rural HMIWI is responsible for ensuring the initial and annual equipment inspections are conducted. The inspection may be conducted by an outside party or by the owner or operator. Minimum requirements for inspecting the HMIWI are included in the Emission Guidelines. The owner or operator is to ensure that any repairs are completed within 10 operating days following the equipment inspection unless written approval is obtained from the State establishing a date whereby the repairs must be completed. Facilities are required to keep records and submit annual reports of the equipment inspections.

92. If an annual stack test shows that an HMIWI is out of compliance with the emission limit for one pollutant, must the facility repeat stack testing for all pollutants for the next three years or for only the pollutant that was above the emission limit?

Answer: Annual stack tests are only required for PM, HCl, and CO. If an annual stack test shows that an HMIWI is out of compliance with the emission limit for one pollutant, the facility must only repeat stack testing for the pollutant that was above the emission limit.

93. According to what baseline should compliance with Subpart Ce be verified? For example, 100 ppmv or 93 percent reduction in HCl emissions. What is the 93 percent reduction measured from?

Answer: The format of the standard allows a unit to demonstrate compliance *either* by meeting the 100 ppmv emission limit *or* by showing that the air pollution control device reduces the flue gas HCl concentration by 93 percent before it exits the stack. The percent reduction is determined by the difference between the concentration at the inlet to the air pollution control device and the concentration at the outlet of the air pollution control device.

94. When are units required to perform initial testing in respect to the timeline for State Plans?

Answer: Units are required to perform initial performance test as scheduled in the State Plan but no later than 3 ½ years after approval of the State Plan or 180 days after September 15, 2002 (whichever is earlier).

95. Regarding the use of operating parameters to define violations of emission limits, are there specific parameter relationships defined in the rule?

Answer: Violation of a particular operating parameter does not necessarily indicate a violation of an emission limit. However, relationships between operating parameters and emission limits have been established for a number of pollutants. Therefore, being out of compliance with two or more operating parameters could indicate a violation of an applicable emission limit. These combinations of operating parameters are defined in the rule.

96. During initial testing, is there a wider emission standard that allows for experimentation?

Answer: Sources are given 180 days to complete the initial performance test. During this period, experimentation can be done to optimize the system. The formal initial performance test must demonstrate compliance with the emission limits. Following the initial performance test, the HMIWI must be operated in compliance with the emission limits at all times.

97. Will testing be required for NO_x and SO_2?

Answer: The Emission Guidelines specify emission limits for NO_x and SO_2. State Plans are to contain NO_x and SO_2 emission limits at least as protective as those in the Emission Guidelines. The Emission Guidelines do not require that State Plans include requirements for testing of NO_x and SO_2. However, State Plans may include testing requirements for NO_x and SO_2, thereby becoming more stringent than the Emission Guidelines.

98. Is the 10-percent opacity standard a "shall-not-exceed-maximum-limit-for-more-than-3-minutes-in-any-hour" standard or is it a 6-minute block average?

Answer: The opacity limit cannot exceed 10-percent on a 6-minute block average.

99. If tests are not required, how can we, the regulators, know the compliance status?

Answer: For existing HMIWI, initial emissions testing is required for the following: CO, PM, HCl, CDD/CDF, Pb, Cd, Hg, and opacity. Repeat emissions testing is required for PM, CO, and HCl for the first 3 years following the initial test, and then every third year provided that the HMIWI demonstrates compliance with the emission limits during each test. Annual testing is required for opacity. For those small HMIWI that meet the "remote" criteria, initial testing is required for PM, CDD/CDF, CO, Hg, and opacity. Annual inspections are required instead of repeat stack tests for PM, HCl, and CO for small "rural" units. In addition to the testing requirements, all existing HMIWI are required to monitor operating parameters including secondary chamber temperature, waste feed rate, bypass stack temperature, and APCD operating parameters as appropriate at all times during HMIWI operation.

The purpose of the above testing and monitoring requirements is to provide information pertaining to facility compliance status. States may choose to include more extensive testing and monitoring requirements in their State Plans if the State would like additional information regarding facility compliance status.

100. If a facility has continuous emission monitors, can the emissions be averaged over a period of 24 hours?

Answer: No. For purposes of demonstrating compliance, State Plans are to require facilities using CEMS to use a 12-hour rolling average, calculated each hour as the average of the previous 12 operating hours (not including startup, shutdown, or malfunction) as indicated in §60.56c(c)(4)(I).

101. Can you give us a ballpark figure on what it will cost a facility to perform the initial stack/performance test? What is the difference in cost between that test for small, rural facilities and other HMIWI?

Answer: Initial performance testing will cost roughly $63,000 for most existing HMIWI. For small rural HMIWI, initial testing will cost approximately $42,000. Thus, there is a difference of about $21,000 in the costs of initial testing for most existing HMIWI and for small rural HMIWI.

WASTE MANAGEMENT PLANS

102. What must be included in the Waste Management Plan? By what date must facilities complete the Waste Management Plan? How will facilities demonstrate that the Waste Management Plan has been implemented?

Answer: State Plans are to require facilities to develop a Waste Management Plan that identifies opportunities for recycling or reduction of wastes such as paper, plastics, cardboard, glass, batteries, etc. The Plan may evaluate the approach, costs, feasibility, and impacts of additional waste management measures. The purpose of the Waste Management Plan is only to prompt facilities to seek opportunities for waste reduction and to identify wastes that could be recycled, rather than burned. State Plans are to require facilities to submit the Waste Management Plan no later than 60 days following the initial performance test. State Plans may include additional requirements by which facilities demonstrate implementation of their Waste Management Plans.

103. Are hospitals that are operating as de facto commercial treatment facilities required to account for receipt and handling of medical waste accepted from off-site generators in their Waste Management Plans?

Answer: Facilities operating commercial HMIWI have little control over the wastes that are accepted from offsite locations. This is one reason why the requirements for Waste Management Plans are somewhat open-ended. One thing that commercial facilities may be able to do in an attempt to control the types of waste that are sent the incinerator is to advertise to their customers what types of waste could be recycled and what types of waste should not be sent to the incinerator. Thus, a commercial facility could indicate its strategy for advertising in its Waste Management Plan.

104. What is the title of the AHA publication on waste reduction and where may copies be obtained?

Answer: The title of the AHA publication that health care facilities are encouraged to consider when developing waste management plans is "An Ounce of Prevention: Waste Reduction Strategies for Health Care Facilities." This document is published by the American Society for Health Care Environmental Services of the American Hospital Association, Chicago, Illinois, 1993. The AHA Catalog number is 057007. This document may be obtained by contacting AHA Services, Inc., P.O. Box 92683, Chicago, Illinois 60675, or by calling 800-242-2626. The cost of the document is $50.00 plus $10.95 for shipping and handling.

PERMITS

105. When is the title V permit application due?

Answer: All affected sources, both existing and new , must submit a complete title V permit application to the permitting authority no later than 36 months after promulgation, or, September 15, 2000.

The exception to this deadline is an HMIWI which is already a major source and the source already has a title V permit. In this case, if there are 3 or more years remaining on the permit term, then the permit needs to be revised to incorporate the applicable requirements for the HMIWI rule. If there are less than 3 years remaining on the permit term, then the permit does not need to be revised to include the applicable requirements until permit renewal--bearing in mind that sources are subject to the applicable requirements even though they are not yet contained in the permit.

106. Must a "small" MWC not subject the MWC rule (burning 10 percent or less hospital/medical/infectious waste) and only required to keep records have a title V permit?

Answer: As of this writing (11/97), OAQPS' interpretation of part 70 is that sources subject only to the recordkeeping and notification requirements under section 60.32e are exempt from title V.[4]

107. When should an HMIWI that is already a major source for other designated pollutants incorporate the NSPS or EG into their permit?

Answer: Sources that are subject to title V because they are subject to a section 129 standard and/or for reasons other than section 129 (e.g., they are a NOx major source) must follow the standard title V schedule. In this case, the 5-year permit review timeframe would determine when they incorporated the limits into their permit. See the answer to question #105.

108. Does the "maximum charge rate" need to be included in an operating permit?

Answer: According the Emission Guidelines, HMIWI size may be determined by either the "maximum charge rate" or the "maximum design waste burning capacity." In some cases the "maximum charge rate" may place a unit into a smaller subcategory than would the "maximum design waste burning capacity." For the HMIWI to be considered as a unit in the smaller

subcategory, then the State would need some mechanism to bind the HMIWI to the smaller subcategory. One way of doing this is to include the HMIWI "maximum charge rate" in an operating permit.

109. If a facility has multiple emission units and at least one emission units falls under HMIWI, how would the title V (total facility) emissions be handled? What if one of the emission units was a plasma type unit?

Answer: Plasma (pyrolysis) units are not subject to any part of the HMIWI rule and are not required to have a title V permit. Once facilities with multiple emission units are subject to title V, they are to develop a permit application listing all of the emission units, describing the emissions from those units, and including all applicable requirements. This could be a daunting task. However, EPA's first White Paper provides some relief in that facilities do not necessarily have to speciate HAP's or regulated air pollutants that are required to be listed. For multiple units of the same type, the facility may list the units generically. For instance, if a facility has six of the same unit, then the facility need only describe the unit once. Otherwise, multiple HMIWI would need to be listed in the permit application. There would only be applicable requirements for those subject to the rule. An easier way would be to refer to the White Paper. It is on the TTN under title V policy and guidance.

INDIAN COUNTRY

110. How do the Emission Guidelines affect facilities located within Indian country? Our State rules are not enforceable in Indian country.

Answer: As a general matter, State rules are not enforceable in Indian country, and States are not responsible for HMIWI implementation within Indian country. In most cases, implementing the HMIWI rule within Indian country will be covered under a Federal Plan.

111. Are Tribes required to submit Tribal Plans for their HMIWI within 2 years of the promulgation of the rule?

Answer: No, Tribes are not required to develop Tribal Plans for their HMIWI, though EPA encourages Tribes to do so, and EPA will work with those Tribes that choose to develop Tribal Plans. EPA recognizes that due to competing priorities for environmental staff and resource issues, most Tribes will be unable or will choose not to develop Tribal Plans. It is expected that most Tribes will rely on a Federal Plan that will be jointly implemented by the Tribe and the EPA Regional Office.

112. Is a Federal Plan the only way Tribes can enforce the EG for HMIWI's on their lands?

Answer: No. Tribes may submit their Plans to EPA for approval, and EPA will approve Tribal plans provided the approval criteria (which include adequate legal authority and capability of administering the program) have been met. However, most Indian Nations are expected to rely on joint EPA/Tribal implementation of a Federal Plan.

1. [1] Under sec. 129(b)(2), all sources must be in compliance by 3 years after State Plan approval or 5 years after promulgation of the EG, whichever is earlier.

2. [2] The exception to this response is a State which relies on an underlying authority other than a State rule. In this case, the State Plan will need to be revised if the underlying authority (e.g., administrative order, state operating permit) does not allow a generic compliance schedule.

3. [3] Up to 3 years following State Plan approval or September 15, 2002, whichever is earlier.

4. Bearing in mind that the source may still be subject to title V for a reason other than the HMIWI rule.