FREQUENTLY ASKED QUESTIONS
REGARDING THE NEW SOURCE PERFORMANCE STANDARDS, EMISSIONS GUIDELINES, AND STATE PLAN PROCESS FOR HOSPITAL/MEDICAL/INFECTIOUS WASTE INCINERATORS

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Note: *This document does not establish any new requirements and is not binding or enforceable. It does not constitute final agency action under Clean Air Act section 307(b)(1), 42 U.S.C. 7607(b)(1). While these questions and answers constitute the best available information at this time, EPA recommends that you consult your state or local air pollution control agency for any final determinations. State and local agencies may implement provisions that are more stringent than those contained in the revised NSPS and Emissions Guidelines.*

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List of Acronyms and Abbreviations

AHA	American Hospital Association
APCD	Air Pollution Control Device
Btu	British thermal unit(s)
CAA	Clean Air Act
Cd	Cadmium
CEMS	Continuous Emissions Monitoring System
CFR	*Code of Federal Regulations*
CISWI	Commercial/Industrial Solid Waste Incinerator(s)
CO	Carbon Monoxide
d	Day(s)
Dioxins/furans	Tetra- through octa- chlorinated dibenzo-p-dioxins and dibenzofurans
EG	Emissions Guidelines
EPA	U.S. Environmental Protection Agency
EPCRA	Emergency Planning and Community Right-to-Know Act
FR	*Federal Register*
HMIWI	Hospital/Medical/Infectious Waste Incinerator(s)
HCl	Hydrogen Chloride
Hg	Mercury
hr	Hour(s)
IWI	Institutional Waste Incinerator(s)
lb	Pound(s)
MSA	Metropolitan Statistical Area
MWC	Municipal Waste Combustor
NO_X	Nitrogen Oxides
NSPS	New Source Performance Standard
NSR	New Source Review
OMB	Office of Management and Budget
OSWI	Other Solid Waste Incinerator(s)
Pb	Lead
PM	Particulate Matter
QA	Quality Assurance
SIP	State Implementation Plan
SMSA	Standard Metropolitan Statistical Area, as referenced in OMB Bulletin No. 93-17, dated June 30, 1993
SO_2	Sulfur Dioxide
SSM	Startup/Shutdown/Malfunction
TDRMW	Treated and Destroyed Regulated Medical Waste
tpd	Ton(s) per day
TRI	Toxics Release Inventory
TRMW	Treated Regulated Medical Waste
wk	Week(s)
WMP	Waste Management Plan

1.0 State Plan Requirements

1.1 Revision and Approval of State Plans

1. Would a State Plan need to 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 would 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 should remain shut down until it demonstrates that it has caught up to the generic schedule, as well as met all applicable increments of progress. [See the *Code of Federal Regulations* (CFR), specifically 40 CFR 62.14472, for procedures included in the Federal Plan.]

B. . . .the state discovers an existing source after 2014?

Answer: No, there should be 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 1A above. The source should cease operations immediately and remain closed until it can demonstrate compliance with the State Plan. Since a longer compliance schedule with increments of progress would no longer be an option for sources discovered after the statutory backstop final compliance deadline in the year 2014, there would be no reason to revise the State Plan.

2. What happens if a state misses a source and it is not in the State Plan inventory? Would the source still be subject to the standard?

Answer: All sources, whether they're on the state's list or not, would be subject to the standard. Section 60.24(b)(3) 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 Emissions Guidelines (EG) [40 CFR 60.32e(a)] or the state's definition (if as stringent as the EG), whether they're on the state's inventory or not.

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[1] Under section 129(b)(2), all sources should be in compliance as expeditiously as practicable, and no later than 3 years after State Plan approval or 5 years after promulgation of the Emissions Guidelines, whichever is earlier.

[2] The exception to this response would be a state which relies on an underlying authority other than a state rule. In this case, the State Plan would need to be revised if the underlying authority does not allow a generic compliance schedule. See Section 3.2 (Enforceable Mechanisms) of the October 2010 document *Hospital/Medical/Infectious Waste Incinerators: Summary of Requirements for Revised or New Section 111(d)/129 State Plans Following Amendments to the Emission Guidelines* (EPA-453/B-10-001, available at http://www.epa.gov/ttn/atw/129/hmiwi/rihmiwi.html).

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 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 with which "all other applicable sources" not listed individually in the State Plan should comply. 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 need 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 should 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 could shut down/close a source. [40 CFR 60.26(a)]
- Reference to Clean Air Act (CAA) section 129(f)(3) ("PROHIBITION") which prohibits a plant from operating if it does not comply with the standard.

3. What are the timelines for submission and approval of revised or new State Plans following promulgation of the amended EG for hospital/medical/infectious waste incinerators (HMIWI)? What would the consequences to a state be if they do not file their revised or new State Plan by the prescribed date?

Answer: States should submit revised or new State Plans within 1 year of promulgation of the amended EG. [CAA section 129(b)(2) and 40 CFR 60.39e(a)] Since the amended HMIWI EG were promulgated on October 6, 2009 [74 FR 51368, October 6, 2009], revised or new State Plans would be due by October 6, 2010. [40 CFR 60.39e(a)(2)] The U.S. Environmental Protection Agency (EPA) should approve or disapprove the Plan within 6 months of submittal. [CAA section 129(b)(2)] If a Plan is disapproved, specific reasons would be given. [CAA section 129(b)(2)] The state would be encouraged to address the concerns and resubmit the Plan. [CAA section 129(b)(2)] If a state does not have an approvable Plan or revision in place by October 6, 2011, the Federal Plan revision would become effective 30 days after its promulgation on that date in the *Federal Register* (FR). [CAA section 129(b)(3) and 40 CFR 60.39e(f)]

If a state filed their revised or new State Plan after October 6, 2010, there may be insufficient time for EPA to review and approve or disapprove the plan in time for the state to meet the October 6, 2011 deadline. 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 EG.

4. Under section 129(b)(2) of the CAA, would EPA's approval or disapproval of a revised or new State Plan be a letter, FR notice, or both?

Answer: The EPA's approval or disapproval would be published in the FR. If the Plan is not approved, the notice would include reasons for disapproval. [CAA section 129(b)(2) and 40 CFR 62.02(e) and 62.04]

5. Would the implementation plans filed by the state go to a central repository where they could be reviewed by the public at the same time that EPA is reviewing them?

Answer: The public would be given the opportunity to comment on the State Plans before they are submitted to EPA for review. Under EPA's rules, states would need 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. [40 CFR 60.23(c) and (d)] State Plans are to be submitted to the appropriate EPA Regional Office. [CAA section 129(b)(2) and 40 CFR 60.23(a)(1), 60.39e(a), and 62.10] The State Plans would not go to any central location where they may be reviewed by the public while EPA is reviewing the Plans, but they would be made publicly available upon request. [40 CFR 62.12] Following its review, EPA would then publish a notice in the FR indicating whether a State Plan has been approved or disapproved. [40 CFR 62.02(e) and 62.04] If a Plan has not been approved, the EPA would state the reasons for disapproval in the FR. [CAA section 129(b)(2) and 40 CFR 62.02(e) and 62.04]

6. Could a state develop a site-specific State Plan rather than a generic HMIWI State Plan?

Answer: The State Plan may include site-specific emissions limits and compliance schedules, as long as the limits and schedules are as protective as the EG. [CAA section 129(b)(2) and 40 CFR 60.24(a)-(c) and (e)(1), 60.33e(a), and 60.39e(a)-(c)]

1.2 Public Hearings

1. Would public hearings be required prior to submittal of a revised or new State Plan?

Answer: Yes, adequate opportunity for public hearings would be required by EPA's rules. Under 40 CFR Part 60, 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. [40 CFR 60.23(d)]

2. One or more public hearing(s) on the revised or new CAA section 111(d)/129 State Plan conducted at location(s) within the state, if requested. [40 CFR 60.23(c)(1)]

3. Date, time, and place of hearing(s) prominently advertised in each region affected. [40 CFR 60.23(d)(1)]

4. Availability of draft revised or new CAA section 111(d)/129 State Plan for public inspection in at least one location in each region to which it would apply. [40 CFR 60.23(d)(2)]

5. Notice of hearing provided to:
   a. EPA Regional Administrator
   b. Local affected agencies
   c. Other states affected
   [40 CFR 60.23(d)(3)-(5)]

6. Certification that the public hearing was conducted in accordance with subpart B and state procedures. [40 CFR 60.23(g)]

7. Retention of hearing records (e.g., list of commenters, their affiliation, summary of each presentation and/or comments submitted, and the state's responses to those comments) for a minimum of two years. [40 CFR 60.23(e)]

If after adequate notice, no one requests a hearing, the hearing would not be required, consistent with the public hearing provisions in §60.23 of subpart B.

2. Would a public hearing be required for a state's negative declaration?

Answer: Consistent with past practice for CAA section 111/129 negative declarations, no state hearing would be required, provided EPA publishes a notice of approval/disapproval with opportunity to challenge the state's determination.

1.3 Need for State Plan

1. What if a state believes they do not have any sources, sends in a letter of negative declaration, and subsequently discovers an existing source? Should the state submit a State Plan?

Answer: Unless the state prefers to accept delegation of the Federal Plan, the state should submit a State Plan because section 129(b)(2) of the amended CAA says, "each State in which units…are operating shall submit [a State Plan]." If the source were discovered before the statutory compliance deadline, then the source would be subject to the default compliance schedule discussed above, which would be 1 year from State Plan approval. [40 CFR 60.39e(b)] Be aware that the source should still be in compliance no later than 5 years from promulgation of

the EG—regardless of when the State Plan would finally be approved. [CAA section 129(b)(2) and (f)(2) and 40 CFR 60.39e(c)]

As discussed in question 1B under section 1.1 of this document, an existing source discovered after the compliance deadline should cease operations immediately. It should not reopen until it has demonstrated compliance with the approved State Plan, including the generic compliance schedule and all applicable increments of progress.

2. Is there a reason why a state which has no HMIWI and only "large" municipal waste combustors (MWCs), which are exempt, should adopt the HMIWI EG?

Answer: Per §60.32e(e), only incinerators subject to the MWC rule for large MWCs (subparts Cb, Ea, or Eb) would be exempt from the HMIWI rule. If a state has no sources subject to the amended EG, then it would not need to submit a State Plan. However, the state may want to submit a State Plan in order to address the contingency that a source would be discovered and the state wants the source to be subject to the specifics of a State Plan rather than deferring to the Federal Plan.

3. If a state has only "small" MWCs that need only keep records and report to the Administrator, should the state submit a State Plan, or would a letter of negative declaration be sufficient?

Answer: Smaller MWCs exempt from the large MWC rule by virtue of their size (burning less than 250 tons per day [tpd]) would be subject to other subparts of Part 60. Specifically, "Small MWCs" (burning between 35 and 250 tpd) would be subject to subpart AAAA (New Source Performance Standards [NSPS]) or subpart BBBB (EG). "Very Small MWCs" (burning less than 35 tpd) would be subject, along with "Institutional Waste Incinerators (IWI)," to subpart EEEE (NSPS) or subpart FFFF (EG)—the regulations for "Other Solid Waste Incinerators (OSWI)."

Those MWCs subject to subparts AAAA, BBBB, EEEE, or FFFF and burning 10 percent or less hospital/medical/infectious waste would only need to notify the EPA Administrator of an exemption claim and keep records of wastes burned, per §60.32e(c). Those units burning 10 percent or less hospital waste and medical/infectious waste are called "co-fired combustors." Although co-fired combustors would not be subject to the emissions limits, an HMIWI State Plan would be necessary in order for the public to be aware of their existence and for states to ensure compliance with these recordkeeping/notification requirements of §60.32e.

4. If all HMIWI in a state 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 EG? 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 sources?

Answer: The "10 percent or less" criterion 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. [40 CFR 60.31e and 60.51c] 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 would be subject to all the requirements of the EG, including the emissions limits, and the state should submit a State Plan to cover these sources.

If a state only had co-fired combustors, then the state would still need to submit a State Plan to include the sources on their inventory and enforce the notification and recordkeeping requirements of the EG for co-fired combustors. [40 CFR 60.25(a) and 60.26(a)] Under the EG, co-fired combustors would be required to notify the Administrator of an exemption claim and keep records of the amounts of each type of waste and/or fuel burned. [40 CFR 60.32e(c)] A State Plan would be necessary to compel co-fired combustors to comply with the notification and recordkeeping 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 2 under section 1.1 of this document.

If a State Plan is not submitted to cover such sources, a Federal Plan would become effective in that state 30 days after its promulgation on October 6, 2011 in the FR. [CAA section 129(b)(3) and 40 CFR 60.39e(f)]

5. For many states, it would take 1.5 to 2 years to develop a state rule. Therefore, many states in the process of developing a state rule would 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 would be the same?

Answer: For states that have failed to submit a timely and approvable plan, section 129(b)(3) of the CAA requires the EPA to develop, implement, and enforce a Federal Plan within 2 years (October 6, 2011) after the date on which the Administrator promulgated the HMIWI EG. The timing of deadlines established by section 129 shows that Congress thought it appropriate to give states the first opportunity in implementing EG, and to require a Federal Plan only where a state fails to submit an approvable State Plan. [CAA section 129(b)(2), (b)(3), and (f)(2)] The Federal Plan only acts as a "place holder" and applies until a state receives EPA approval of a revised State Plan. [CAA section 129(b)(2) and 40 CFR 60.28(c)] States should be aware that a State Plan provides more flexibility than a Federal Plan because of a greater level of public participation in the Plan development process. For example, a State Plan gives the state and its citizens the opportunity to (1) tailor their compliance schedule to individual sources [40 CFR 60.39e(c)], (2) develop a state rule more stringent than the EG in order to provide further emissions reductions of section 129 pollutants and thus achieve greater reductions in environmental and health risks to citizens [CAA section 129(h)(1)], and (3) provide for more stringent facility monitoring requirements [CAA section 129(h)(1)]. Furthermore, it is likely that a State Plan would result in a more detailed source and emissions inventory for designated facilities. [40 CFR 60.25(a)] However, states also have the option to simply accept delegation of

the Federal Plan and not prepare a State Plan. [40 CFR 62.14495; 65 FR 49873-4 and 49876-7, August 15, 2000]

6. Could a state incorporate by reference (IBR), in whole or part, emission guideline (EG) provisions into a proposed state section 111(d)/129 rule and plan?

Answer: [to be added]

7. If the state has its own rule (e.g., CA, FL, NJ, NY, IL, NC) and the state rule would be as protective as the federal EG, should the state still submit a State Plan?

Answer: Yes, the state still would need to submit an approvable State Plan so that the public, EPA, and industry would be clear that the state is complying with the requirements of sections 129 and 111(d). In particular, the state should show that its state rule is at least as protective as the EG and how the state would ensure that the sources meet the applicable requirements. [CAA section 129(b)(2) and 40 CFR 60.26(a)] Also, the State Plan should include an inventory of all the affected sources in the state and satisfy the requirements for public review. [40 CFR 60.25(a)] 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.

1.4 Stringency of State Plan

1. How would a state demonstrate that its state rule would be at least "as protective as" the EG? Would the burden of proof be on EPA?

Answer: The burden of proof would be 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. [CAA section 129(b)(2)] The state should demonstrate this for each requirement that is different from the EG. For example, if a State Plan includes emissions limitations in a regulatory format (e.g., emissions rates or ambient air concentrations) other than that used in the EG (i.e., stack concentrations), the state should show how the format correlates to the format in the EG and demonstrate that the emissions limitations are at least as protective as those in the EG.

2. On a case-by-case basis, under the CAA section 111(d) requirement in §60.24(f) (subpart B), states have the flexibility to submit State Plans that contain less stringent emissions standards or longer compliance times than those specified under the applicable EG. Would the provision in section 129(b)(2) of the CAA requiring State Plans to be "at least as protective as the EG" supersede the State Plan flexibility provided under §60.24(f)?

Answer: Yes. The provisions of subpart B were developed to implement section 111(d) of the CAA. State Plans for HMIWI are section 111(d)/129 plans and have additional requirements beyond those for State Plans developed under only section 111(d). The "at least as

protective" language in section 129 of the CAA applies to HMIWI, and §60.24(f) of subpart B would be superseded. Section 60.24(f) of subpart B was revised on December 19, 1995 [60 FR 65414, December 19, 1995] to allow subpart Ce to specify that states could not allow less stringent limits or longer compliance times than specified in subpart Ce.

3. If there are conflicting requirements under sections 111(d) and 129, which requirements would take precedence?

Answer: If there are conflicting requirements, CAA section 129 would take precedence over CAA 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 October 2010 EPA document *Hospital/Medical/Infectious Waste Incinerators: Summary of the Requirements for Revised or New Section 111(d)/129 State Plans Following Amendments to the Emission Guidelines* (Document No. EPA-453/B-10-001, available at http://www.epa.gov/ttn/atw/129/hmiwi/rihmiwi.html), which presents a table showing the portions of subpart B that apply to HMIWI and the portions that are revised by section 129.

4. Would emissions limits in the State Plan need to be the same as the emissions limits in the subpart Ce EG?

Answer: The emissions limits in the State Plan should be "at least as protective" as the EG [CAA section 129(b)(2) and 40 CFR 60.24(a)-(c) and 60.33e(a)], and EPA recommends that the limits be presented in the same regulatory format as the EG, (i.e., concentration limits). If a regulatory format other than that used in the EG is used in a State Plan, then the state should show how the format correlates to the format in the EG and demonstrate that it would be at least as protective as the EG.

5. Could a State Plan identify only air pollution control equipment to be retrofitted, or should it include emissions limits?

Answer: A State Plan needs to include emissions limits at least as protective as the EG [40 CFR 60.24(a)-(c) and 60.33e(a)], and those limits would need to apply to each HMIWI, for EPA to be able to approve it. Equipment specification would not be required, and, alone, would not be acceptable.

1.5 Reporting Requirements

1. Would reporting requirements in State Plans apply to HMIWI operators or just state agencies?

Answer: The requirements should apply to both. The state has responsibilities to develop the State Plan and to report implementation progress to EPA. [CAA section 129(b)(2) and 40 CFR 60.23(a), 60.25(e) and (f), and 60.39e(a)] The HMIWI owner should 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 limits or thresholds, as specified in subpart Ce and the related State Plan under 40 CFR Part 62, and the source's title V permit.

2. Could the states incorporate the HMIWI progress reports into their §51.321 annual report for State Implementation Plans (SIPs)?

Answer: Yes, provided that the HMIWI progress report satisfies the requirements of §51.321, HMIWI progress reports could 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.

2.0 Compliance Schedule and Increments of Progress

2.1 Setting the Compliance Schedule

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

Answer: No, a source could not 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 §60.21(h) of subpart B. [40 CFR 60.24(a) and (e)(1) and 60.39e(b) and (c)]

In addition, State Plans that allow sources planning to shut down (not to retrofit) longer than 1 year to comply should require that such facilities provide documentation to support their request, as described in §60.39e(d)(1)(i)-(ii) of subpart Ce. Such sources should 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, based on the increments listed in §62.14471(b)(1)(ii) of the August 15, 2000 Federal Plan:

1. Source's plan for shutdown;
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 waste treatment equipment (if applicable);
5. Shut down incinerator; and
6. Dismantle incinerator.

2. Could 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. [CAA section 129(b)(2) and 60.39e(b)] It could also require sources of specified circumstances that meet the criteria for 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. [40 CFR 60.39e(c) and (d)]

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.

[3] Up to 3 years following State Plan approval or October 6, 2014, whichever is earlier. [CAA section 129(b)(2) and (f)(2) and 40 CFR 60.39e(c)]

3. Could 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 would be no later than 3 years after State Plan approval or October 6, 2014 (5 years after publication of amended EG), whichever is earlier. [CAA section 129(b)(2) and (f)(2) and 40 CFR 60.39e(c)]

4. Should increments of progress for the individual sources requesting extensions under §60.39e(d) be submitted with the State Plan or negotiated later--after approval by EPA?

Answer: As a practical and legal matter, increments of progress for individual and/or generic sources should be included in the state enforceable mechanism and submittal of the revised or new State Plan. Most State Plans would contain generic measurable and enforceable increments of progress for designated facilities whose owner/operator may decide to petition the state for a final compliance date that extends beyond 1 year from State Plan approval, but no later than the statutory compliance date, 3 years after EPA approval of the revised or new State Plan, or October 6, 2014, whichever date is earlier. [CAA section 129(b)(2) and (f)(2) and 40 CFR 60.39e(c)]

If an individual source owner/operator, under the provisions of §60.24(e)(2), seeks state approval or formulation of increments of progress after State Plan approval, the final compliance date, as stated above, could be no later than the statutory date(s) noted above. If the revised or new State Plan does not provide for compliance date extensions and related increments of progress, the individual source owner/operator could still request a compliance date extension. [40 CFR 60.39e(d)] However, the extension request would require the opportunity for a public hearing, as specified under §60.23, and the submittal of the proposed increments of progress in an enforceable mechanism as a State plan revision, as specified under §60.28(a) and (c).

5. 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 should address. The EPA hopes that most sources would come into compliance with a revised or new State Plan (by completing retrofit or ceasing operation) within 1 year after EPA approval of the State Plan. [CAA section 129(b)(2) and 40 CFR 60.39e(b)] The EG 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 October 6, 2014, whichever is earlier. [40 CFR 60.39e(c)] The State Plan may tailor the various compliance dates associated with the increments of progress. 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, e.g., minor new source review (NSR) permits.

There are no specific criteria in the EG that determine whether a facility has only 1 year from State Plan approval to comply, or 3 years with the 5-increment compliance schedule. However, CAA section 129 (f)(2) and §60.24(c) require compliance as expeditious as practicable. States could use their judgment 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 in an expeditious manner.

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

Answer: Under EPA's rules, all sources would need to be in compliance within 1 year of State Plan approval, unless the state has provided increments of progress, in which case sources could be provided up to 3 years from State Plan approval to comply or October 6, 2014, whichever is earlier. [CAA section 129(b)(2) and (f)(2) and 40 CFR 60.39e(b) and (c)] If the state chooses to give sources longer than 1 year, the State Plan would need to include the five enforceable increments of progress for each HMIWI as required by subpart B. [40 CFR 60.24(e)(1)] The required increments are:

1. Submit a final control plan;
2. Award contracts for controls;
3. Initiate on-site construction or installation of controls;
4. Complete on-site construction or installation of controls; and
5. Final compliance.

[40 CFR 60.21(h)]

Additional increments of progress could also be included in the Plan. [40 CFR 60.24(e)(1) and 60.39e(c)] The State Plan should include binding and enforceable compliance dates for the five increments. [40 CFR 60.21(g)] The first four increments could be fixed calendar dates or floating dates set a certain time from State Plan approval or issuance of a specific permit necessary for retrofit activities, e.g., a minor NSR permit. If such a permit is cited in the State Plan as the significant date from which the increments would be referenced, the specific permit should be identified, and, for purposes of 111(d)/129 plan implementation, the increments of progress and final compliance date in the permit should continue to be enforceable even after the permit expiration date, if applicable. The fifth increment, final compliance, could be set only from State Plan approval and may not, under the CAA, extend beyond 3 years from State Plan approval or October 6, 2014, whichever is earlier. [CAA section 129(b)(2) and (f)(2) and 40 CFR 60.39e(c)] Those sources which the State Plan requires to cease operations by October 6, 2014, could reopen after the final compliance deadline (i.e., October 6, 2014), but

only to demonstrate full compliance within 180 days of restarting. [40 CFR 60.8(a)] If full compliance is not demonstrated during the test, the unit would need to immediately shut down and not reopen until authorized by the state for the purpose of demonstrating compliance. [40 CFR 60.26(a)].

The schedules in the State Plan would be enforceable, but the State Plans could be revised, provided they meet the requirements above and the public was given adequate notice of an opportunity for public comment. [40 CFR 60.23(c) and (d), 60.26(a), and 60.28] (See question 4 under this section.) That is, if the state and HMIWI agree that more time would be 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 a State Plan revision specified in 40 CFR Part 60, subpart B. [40 CFR 60.28(a)] The final retrofit date or cease operation date, however, would still need to be within 3 years of State Plan approval or October 6, 2014, whichever is earlier. [CAA section 129(b)(2) and (f)(2) and 40 CFR 60.39e(c)]

The state and HMIWI would need to review the emissions limits in the amended subpart Ce EG (promulgated October 6, 2009) and the draft state standards being developed to implement the EG and make judgments about the likely retrofit requirements in order to include an expeditious compliance schedule in the State Plan. Except for those states that may already have more stringent standards or broader coverage, most states are expected to match the EG requirements.

2.2 Meeting the Compliance Schedule

1. Would 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: Not necessarily, but timing may affect a state's ability to act. 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."

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

Answer: If a state submits and receives approval of a revised or new State Plan prior to October 6, 2011, EPA's rules provide that sources are to comply with the State Plan within 1 year after EPA approval of the State Plan. [40 CFR 60.39e(b)] If a state submits a revised or new State Plan that is disapproved, the state would have until October 6, 2011 to resubmit an approvable State Plan, which is the date a Federal Plan would be promulgated for states that have not submitted an approvable State Plan. [CAA section 129(b)(3) and 40 CFR 60.39e(f)] Sources would then be covered under the Federal Plan and would have 1 year after October 6, 2011 to come into compliance with the Federal Plan, unless they meet the increments of progress

specified in the Federal Plan, in which case they would have until October 6, 2014 to comply. [CAA section 129(b)(3) and 40 CFR 60.39e(f)]

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

Answer: Yes. The State Plan should specify a deadline for an HMIWI to complete retrofit or to cease operations. [40 CFR 60.24(a) and (e)(1) and 60.39e] If a State Plan specified that an HMIWI would cease operations by a given date, and the HMIWI owner later decided to retrofit controls, the state should modify the State Plan to include a new compliance date for the HMIWI (including meeting all requisite notice-and-comment requirements and five increments of progress). [40 CFR 60.28(a)] The State Plan revision would need to be approved by the EPA. [40 CFR 60.28(c)] If an HMIWI owner already knows the cease operations agreement would be an interim step toward retrofit and restart of the unit, the requirement to cease operation could 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 need to cease operation on or before October 6, 2014 and would need to complete its retrofit before restarting operations. [40 CFR 60.39e(c)] Within 180 days of restarting, the unit would need to complete the required performance test and demonstrate full compliance; if not, the unit would need to immediately shut down. [40 CFR 60.8(a) and 60.26(a)].

4. If a facility plans to close down their HMIWI rather than comply with the amended EG, should the facility close down by the date 1 year after State Plan approval, or could the facility continue operating without complying with increments of progress?

Answer: The facility should close down by the date 1 year after approval of the new or revised State Plan, unless the facility is granted an extension by the state. [40 CFR 60.39e(b); see also 40 CFR 62.14471 of the August 15, 2000 HMIWI Federal Plan as an example] In order for a state to grant such an extension, the State Plan should include the provisions listed in §60.39e(d) of subpart Ce, as amended.

5. If a unit fails to meet an increment of progress established by the state, should the unit shut down until the increment of progress is met?

Answer: Yes, unless the source promptly submits to the state air agency (1) the reason or reasons for missing the increment of progress, and (2) a revised expeditious compliance schedule that requires the unit to meet the original final compliance date under the approved State Plan. [40 CFR 60.39e(d)] If the source fails to meet the final compliance date, it should immediately cease operation. [40 CFR 60.26(a)]

3.0 Standard Metropolitan Statistical Area (SMSA)

1. How are metropolitan areas defined in the EG?

Answer: The EG define Standard Metropolitan Statistical Areas (SMSAs) as areas listed in OMB Bulletin No. 93-17 entitled "Revised Statistical Definitions for Metropolitan Areas," dated June 30, 1993. [40 CFR 60.31e] See below for information on how to obtain a copy of the 1993 SMSA listing. Note: Such areas are more currently referred to as "Metropolitan Statistical Areas (MSAs)."

2. Where could states access OMB Bulletin No. 93-17 (for SMSA boundaries)?

Answer: OMB Bulletin No. 93-17 is Item No. IV-J-143, in Legacy Docket No. A-91-61. The telephone number for the EPA Docket Center is (202) 566-1742. A listing of the SMSAs, as defined by the Office of Management and Budget (OMB) on June 30, 1993, is available on the Internet at the following address: http://www.census.gov/population/estimates/metro-city/93mfips.txt.

3. Would states be bound by the HMIWI regulations to use only the 1993 SMSA publication, or would it be correct to use the most current publication of statistical data?

Answer: The definition of "Standard Metropolitan Statistical Area" in the EG is based on the 1993 SMSA definitions. [40 CFR 60.31e] This definition of "Standard Metropolitan Statistical Area" was not revised in the October 6, 2009 amendments to the EG. The EG specify that the 1993 SMSA definitions be used to ensure that the rural criteria are applied uniformly and consistently for small HMIWI. Therefore, states should use the 1993 SMSA definitions for determining applicability of the rural criteria to HMIWI.

4. Regarding the 50-mile limit from an SMSA, should this be 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, should the 50 miles be measured from the county line or the city limit line?

Answer: The 50-mile limit from an SMSA should be measured from the edge of the SMSA. [40 CFR 60.33e(b)] In most cases, this is a county line. In some cases, it is the city or township boundary.

4.0 Legal Authority

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

Answer: Legal authority is a general term described in §60.26, which means the power that a state has to require a source to do something--be it meeting certain emissions limits or putting 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.

2. If a state already has a state rule in place, could the state submit the rule as the legal authority?

Answer: Yes, the existing state rule would be the state's legal authority. [40 CFR 60.26(b)]

3. If a state develops a state rule to adopt the EG, should this rule be passed by the state legislature within 1 year after promulgation, or would it be sufficient to submit the rule to the state legislature for review by 1 year after promulgation?

Answer: The state rule should be passed by the state legislature by October 6, 2010. [CAA section 129(b)(2) and 40 CFR 60.39e(a)(2)]

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

Answer: A state could select from a range of enforcement mechanisms, provided the state shows it has adequate legal authority. A demonstration of legal authority would be needed in all cases, except for state rules. [40 CFR 60.26(b)] If a SIP rule is used, citations, rather than copies of actual state legal authority, should be adequate. However, it is unlikely the SIP would address all of the CAA section 129 pollutants. [CAA section 129(a)(4) and (b)(1) and 40 CFR 60.26(b)]

For all other enforcement mechanisms, a demonstration of authority would be needed. [40 CFR 60.26(b)] The EPA strongly recommends that states include an opinion from their State Attorney General for such a demonstration, if a mechanism other than a state regulation is used. If the state relies on a mechanism other than a state rule to implement the amended EG, the state needs to document in the State Plan how the selected mechanism ensures that the HMIWI will meet the requirements of the amended EG and attach a copy of the enforceable mechanism. [CAA section 114(b)(1), 40 CFR 60.26(b)] To ensure that the selected mechanism meets all of the requirements of the EG, the state would need to legally certify (preferably in an Attorney General's Opinion, as discussed above) that the selected mechanism can be used to create enforceable requirements in the state 111(d)/129 plan or revision. Given that a process

other than a rulemaking is being used to create federally-enforceable requirements, the state would also need to explain how the public has had an opportunity to participate in the development of the 111(d)/129 plan requirements, how the mechanism is permanent, and how the public will have access to the underlying documents which contain the limits and requirements. The selected enforcement mechanism should not be title V permits, because (1) title V permits could not be used to create applicable federal requirements from the EG, (2) title V permits are not permanent, and (3) the public participation process under the EG is distinct from title V public notice requirements. Additionally, it is important to note that Attorneys General's Opinions submitted as part of title V program submittals would not be able to address the issues resulting from a state selecting an enforceable mechanism other than a rule to implement the EG.

5.0 Source/Emissions Inventory

1. If a former HMIWI is now only burning municipal waste and the hospital is gone, would they still meet the definition of "fully or partially dismantled," and, thus, should 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. [40 CFR 60.25(a)] 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. [see 65 FR 49876, August 15, 2000] If the answer is "yes" to at least one of the questions below, then the incinerator would not need 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, since the incinerator is still operating, the state would also look at the possibility that the unit could accept waste from another hospital, or be moved to a hospital or other location where it may again accept hospital and/or medical/infectious waste. If the state determines that the incinerator is permanently shut down for purposes of accepting hospital and/or medical/infectious waste, then it would not need to be included on the state's inventory [40 CFR 60.25(a); see also 65 FR 49876, August 15, 2000]

2. Should a "small" MWC that is (1) not subject the large MWC rule, (2) burning 10 percent or less hospital/medical/infectious waste, and (3) only required to keep records, be included on the State Plan inventory?

Answer: Per §60.32e(e), incinerators subject to the large MWC rule would be exempt from the HMIWI rule's standards and, as such, would not need to be included on the state's inventory of HMIWI.

Smaller MWCs not subject to the MWC rule and burning 10 percent or less hospital/medical/infectious waste would only need to notify the EPA Administrator of an exemption claim and keep records of wastes burned, per §60.32e(c). Those units burning 10 percent or less hospital waste and medical/infectious waste are called "co-fired combustors." [40 CFR 60.31e] Although co-fired combustors would not be subject to the emissions limits, in order for the public to be aware of their existence and for states to ensure compliance with these recordkeeping/notification requirements, such units should be included in the State Plan inventory. [40 CFR 60.25(a), 60.26(a), and 60.32e(c)] Applicable sources not included in the State Plan inventory would still be subject to the recordkeeping/notification requirements of §60.32e(c).

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

Answer: Crematoria would not be subject to any part of the HMIWI regulations as long as they burn only human remains. Therefore, there would be no need to include human crematoria in the state's inventory. However, if the crematory incinerator were used to burn any hospital waste or medical/infectious waste, it would be subject to certain recordkeeping and notification requirements at §60.32e(c) and should be included in the inventory. [40 CFR 60.25(a)]

4. Where in the CAA or HMIWI regulation is the requirement for the state to submit an inventory? What should be included in the inventory?

Answer: Section 60.25(a) of subpart B specifies that states should submit an inventory of sources, as well as an inventory of the emissions from the designated facilities (HMIWI) in the state. Subpart B implements CAA section 111(d), which, along with CAA section 129, provides the authority for the development of State Plans for HMIWI under subpart Ce. 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. [40 CFR 60.25(a)] Co-fired combustors and incinerators of low-level radioactive, chemotherapeutic, and pathological waste should be included in the source inventory, but would be exempt from the State Plan emissions inventory. [40 CFR 60.25(a) and 60.32e(b) and (c)]

5. Where are the emissions factors for use in creating the emissions inventory located?

Answer: EPA believes that, where available, actual and reliable results from facility-specific continuous emissions monitoring systems (CEMS) and stack sampling should be used in place of emissions factors. [AP-42, Fifth Edition, Volume I, Introduction] However, if a state needs to estimate emissions when developing its emissions inventory, there are three options it could consider. One, the state could use the state's own emissions factors. Two, the state could use the Medical Waste Incineration emissions factors in section 2.3 of the AP-42, which is available at http://www.epa.gov/ttn/chief/ap42/ch02/index.html. Three, the state could use the emissions factors developed from emissions data used in the amended HMIWI rulemaking process. Those emissions factors are included in Appendix F of the October 2010 EPA document *Hospital/Medical/Infectious Waste Incinerators: Summary of the Requirements for Revised or New Section 111(d)/129 State Plans Following Amendments to the Emission Guidelines,* Document No. EPA-453/B-10-001, which is available at http://www.epa.gov/ttn/atw/129/hmiwi/rihmiwi.html. The memorandum which documents the emissions data is available in the docket at http://www.regulations.gov [Item No. EPA-HQ-OAR-2006-0534-0318]. The title of the memorandum is "Documentation of HMIWI Test Data Database."

6. Will the AP-42 emissions factors be updated for HMIWI?

Answer: No, there are no plans to do so in the near future. The AP-42 section on "Medical Waste Incineration" (July 1993) is located at http://www.epa.gov/ttn/chief/ap42/ch02/index.html.

6.0 Applicability

6.1 Exemptions

1. Would MWCs subject to 40 CFR Part 60, subpart Cb, Ea, or Eb be exempt from the HMIWI rule?

Answer: Yes. Per §§60.32e(e) and 60.50c(e), combustors that meet the applicability of subparts Cb, Ea, or Eb would be exempt from subpart Ce or Ec, respectively.

2. Would MWCs be exempt regardless of the amount of medical waste they burn? What if the wastes have been autoclaved before being received at the MWC?

Answer: No. Any MWC subject to subparts Ea or Eb, or to the subpart Cb EG under a related large MWC State Plan would be exempt from subparts Ce and Ec. [40 CFR 60.32e(e) and 60.50c(e)] However, MWCs that burn more than 70 percent non-municipal waste (including hospital waste) could be exempted from these MWC subparts under the co-fired combustor provisions for these subparts. Also, not all MWCs would be subject to subparts Ea, Eb, or a Part 62 Plan (applicable state subpart) because these subparts only affect MWC units with a combustion capacity greater than 250 tpd. An MWC which is 250 tpd or smaller and burns hospital waste and medical/infectious waste would be subject to subpart Ce or Ec. [40 CFR 60.32e(e) and 60.50c(e)] If the 250 tpd or smaller MWC burns 10 percent or less hospital waste and medical/infectious waste, it would be exempt from most of the provisions of subparts Ce and Ec, but should 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. [40 CFR 60.32e(c) and 60.50c(c)] These units burning 10 percent or less hospital waste and medical/infectious waste are called "co-fired combustors." [40 CFR 60.31e and 60.51c]

There is no distinction in the HMIWI rule between treated and untreated waste. Even if the waste were already treated, there would still be emissions from the combustion of the waste (e.g., metals released, dioxins/furans created).

3. Would the HMIWI regulations apply to crematoria and animal waste incinerators? How would the remains from human stillborn births fit under the HMIWI regulations?

Answer: Human corpses, remains, and anatomical parts intended for interment or cremation would not be considered medical/infectious waste or hospital waste for the purposes of this rule. [40 CFR 60.31e and 60.51c] The remains of human stillborn births intended for cremation would be included under the exemption in the hospital waste definition in subparts Ce and Ec. [40 CFR 60.31e and 60.51c] Consequently, human crematoria that burn only human remains would not be subject to the HMIWI regulations. However, if the crematory incinerator were used at any time to burn hospital waste and/or medical/infectious waste, it would be subject

to the HMIWI regulations. [40 CFR 60.32e(a) and 60.50c(a)] Animal remains could sometimes meet the definition of medical/infectious waste, for example, if exposed to infectious, biological, or pharmaceutical agents during research. [40 CFR 60.31e and 60.51c] If the animal remains meet the definition of medical/infectious waste, then the incinerator burning the medical/infectious animal remains would be subject to the HMIWI regulations. [40 CFR 60.32e(a) and 60.50c(a)] However, during periods of time that the incinerator burns exclusively animal remains that are not medical/infectious waste, containers used to collect and transport the remains, and/or animal bedding (or other defined pathological waste), the incinerator would be exempt from most provisions of the HMIWI regulations and would be subject only to certain notification and recordkeeping requirements. [40 CFR 60.32e(b) and 60.52c(b)]

4. Would the following be 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? Suppose a state has crematory rules under which the above sources should keep records. Under this scenario, could the state submit a negative declaration?

Answer: Applicability would not be 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 and/or medical/infectious waste, they would not be subject to the regulations and would not need to be included in a State Plan. [40 CFR 60.31e and 60.51c] Other state rules affecting the source category would not change this. If there are no incinerators in the state burning any hospital waste and/or medical/infectious waste, then the state should submit a negative declaration. [40 CFR 62.06]

If any of the facilities listed burn any amount of hospital waste or medical/infectious waste at any time, they would be subject to, at a minimum, the reporting and recordkeeping requirements of §§60.32e and 60.50c. The only exemptions would be 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). [40 CFR 60.32e(d)-(g) and 60.50c(d)-(g)]

5. Would the HMIWI rule apply to a 2-year-old uncontrolled incinerator with a maximum capacity of 600 pounds per hour (lb/hr) located at a diagnostic lab (veterinary-animal disease investigations), which derates burn at 200 lb/hr? About 90 percent of the material burned in the incinerator is pathological waste (carcasses, tissues). The facility is 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 would be considered co-fired combustors. [40 CFR 60.31e and 60.51c] Co-fired combustors would only be required to notify the Administrator of an exemption claim and then keep quarterly records of the amount and type of wastes burned. [40 CFR 60.32e(c) and 60.51c(c)] Because the facility in the question is a laboratory, it is not likely to burn any hospital waste. For purposes of determining applicability of a co-fired combustor, the pathological waste

would not be included in the determination of the amount of medical/infectious waste burned. [40 CFR 60.31e and 60.51c] Therefore, if the facility burns 10 percent or less medical/infectious waste, then it would be considered a co-fired combustor. [40 CFR 60.31e and 60.51c]

6. Would an incinerator located at a hospital that burns only pathological, chemotherapeutic, and low-level radioactive waste generated at the hospital be subject to the HMIWI rule? If not, would it be regulated under another standard?

Answer: Incinerators used to combust only pathological waste, chemotherapeutic waste, and low-level radioactive waste alone or in combination would not be subject to subparts Ce and Ec. However, the owner or operator should 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. [40 CFR 60.32e(b) and 60.50c(b)] The incinerator currently is not subject to a federal regulation, but EPA intends to include it as an affected facility in the revisions to the Other Solid Waste Incinerator (OSWI) rule.

7. What would the notification and recordkeeping requirements be for facilities burning only pathological waste in their HMIWI?

Answer: Facilities burning only pathological waste that otherwise meet the applicability of subpart Ce or subpart Ec would need to notify the Administrator of an exemption claim and keep records of the time periods when only pathological waste is burned. [40 CFR 60.32e(b) and 60.50c(b)] These records would need to be maintained onsite by the facility. [40 CFR 60.7(f)] Reporting would not be needed for facilities burning only pathological waste.

8. Suppose a pharmaceutical facility combusts about 65 percent returned pharmaceuticals and 35 percent laboratory animal waste (which meets the definition of medical/infectious waste). If the amount of medical waste is reduced to 10 percent or less, would the facility then not be subject to the EG or the NSPS?

Answer: There are three possibilities. In all three cases, the returned pharmaceuticals do not meet the definition of medical/infectious waste and would not be considered hospital waste, because the definition of hospital waste specifically excludes unused items returned to the manufacturer. [40 CFR 60.31e and 60.51c] The three possibilities arise from what is meant by "laboratory animal waste."

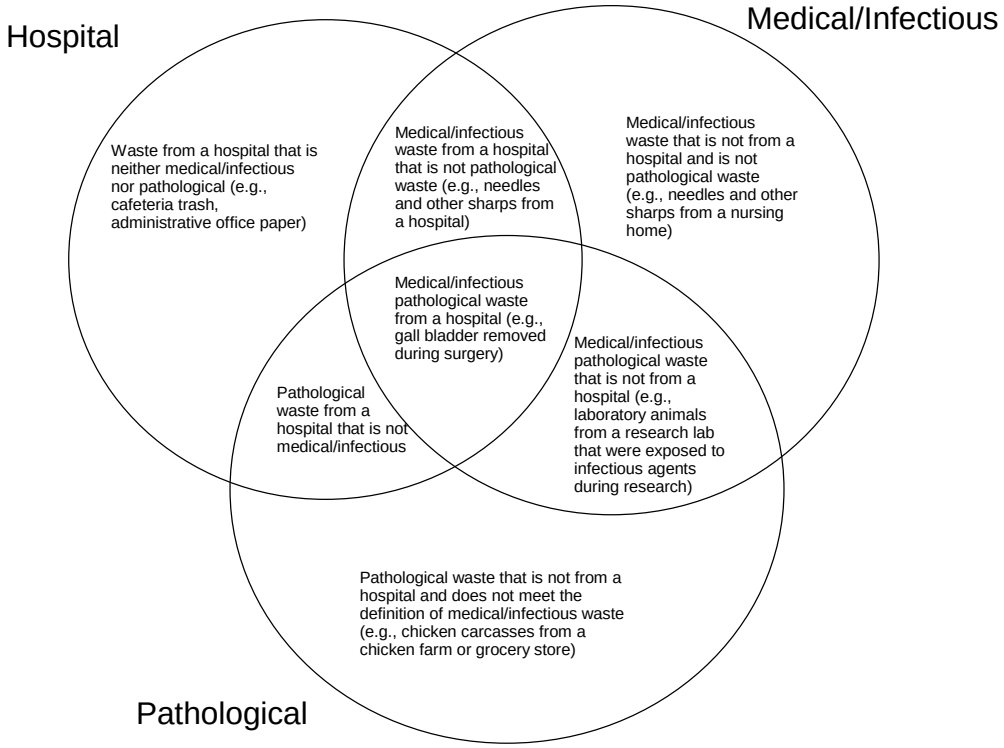
First, if the laboratory animal waste consists only of animal tissue, containers used to collect and transport the tissue, and/or animal bedding, then the laboratory animal waste would be considered pathological waste. [40 CFR 60.31e and 60.51c] In this case, the incinerator is burning no hospital waste 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 (e.g., laboratory animal waste exposed to infectious, biological, or pharmaceutical agents during research). [40 CFR 60.31e and 60.51c] Under these conditions, this incinerator would be a co-fired combustor

already, and reducing the amount of medical/infectious waste would not alter the applicability. It would be exempt from most of the provisions of the regulations, but should notify the Administrator of its existence and keep records of fuels and wastes burned. [40 CFR 60.32e(c) and 60.50c(c)]

Second, if some of the laboratory animal waste is medical/infectious waste that is not animal remains, anatomical parts, and/or tissue, the bags/containers used to collect and transport the waste material, and/or animal 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 would also be a co-fired combustor subject to the same requirements described above. [40 CFR 60.31e and 60.51c]

Finally, if some of the laboratory animal waste is medical/infectious waste that is not animal remains, anatomical parts, and/or tissue, the bags/containers used to collect and transport the waste material, and animal 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 would be subject to all of the requirements in the HMIWI regulations. [40 CFR 60.31e and 60.51c]

The following Venn diagram illustrates the overlap of the definitions for hospital waste, medical/infectious waste, and pathological waste:



Source: U.S. Environmental Protection Agency. *Hospital/Medical/Infectious Waste Incinerators: Summary of Requirements for Revised or New Section 111(d)/129 State Plans Following Amendments to the Emission Guidelines.* Document No. EPA-453/B-10-001. October 2010. Available at http://www.epa.gov/ttn/atw/129/hmiwi/rihmiwi.html.

9. Would an incinerator, owned and operated by a pharmaceutical company and used to burn drugs, noninfectious trash, infectious waste, pathological waste, and low-level radioactive waste, be subject to the HMIWI rule?

Answer: Yes. However, drugs are not medical/infectious waste. [40 CFR 60.31e and 60.51c] Drugs also are not hospital waste if returned to the pharmaceutical manufacturer from a hospital, because the definition of hospital waste in subparts Ce and Ec excludes items returned to the manufacturer. [40 CFR 60.31e and 60.51c] However, because the example incinerator is used to burn some infectious waste, it would be subject to subpart Ce or Ec. If the infectious waste accounts for 10 percent or less of the total waste burned, the incinerator would be considered a co-fired combustor, and the facility should notify the Administrator of an exemption claim and keep quarterly records of the weight of medical/infectious waste and other fuels combusted, but no other requirements apply. [40 CFR 60.31e, 60.32e(c), 60.50c(c), and 60.51c] The incinerator would be subject to all of the provisions of subparts Ce and Ec if it is used to burn more than 10 percent by weight (on a quarterly basis) of infectious waste. [40 CFR 60.31e and 60.51c] The pathological waste and low-level radioactive waste that are medical/infectious under the medical/infectious waste definition would be considered "other" waste when calculating the percentage of medical/infectious waste combusted. [40 CFR 60.31e and 60.51c]

10. Would an incinerator that combusts 'offspec' or 'out-of-date' drugs be subject to the HMIWI regulations?

Answer: Pharmaceutical wastes such as "offspec" or "out-of-date" drugs would not be considered medical/infectious waste as defined in the final HMIWI regulations. [40 CFR 60.31e and 60.51c] Also, pharmaceutical wastes would not be considered hospital waste unless generated at a hospital and disposed with the hospital's waste; in the HMIWI regulations, "hospital waste" is defined as discards generated at a hospital, excluding human remains and unused items returned to the manufacturer. [40 CFR 60.31e and 60.51c] Thus, "out-of-date" drugs returned by a hospital to a pharmaceutical company for disposal would not be considered hospital waste. Waste pharmaceuticals are viewed the same as other fuels and wastes (e.g., municipal waste, coal, etc.) under the HMIWI regulations. Therefore, incinerators that combust waste pharmaceuticals, and combust 10 percent or less hospital waste and medical/infectious waste (by weight) would not be subject to the HMIWI regulations. [40 CFR 60.31e and 60.51c] However, any incinerator that combusts waste pharmaceuticals along with more than 10 percent hospital waste and medical/infectious waste would be subject to the HMIWI regulations. [40 CFR 60.31e and 60.51c; 62 FR 48357, September 15, 1997]

11. Would an incinerator located at a hospital that burns only noninfectious trash from the hospital be subject to the HMIWI rule?

Answer: Yes, because the incinerator is burning more than 10 percent by weight hospital waste. Per the definition of hospital waste in §§60.31e and 60.51c, hospital waste includes discards, such as general, noninfectious waste, generated at a hospital.

12. Would an incinerator burning waste from a nursing home be subject to the HMIWI rule?

Answer: Maybe. Nursing homes are not considered to be hospitals and, thus, would not be generators of "hospital" waste under the EG. [40 CFR 60.31e and 60.51c] However, most nursing homes generate "medical/infectious" waste and, thus, would have potential applicability under either subpart Ce or subpart Ec. [40 CFR 60.31e and 60.51c]

13. Would a pyrolysis furnace that is used to clean metallic filters be classified as an incinerator? The furnace is rated at three million British thermal units per hour (Btu/hr) and uses only natural gas. Would the operator training requirements be applicable? No material containing toxic metal or halides is burned in the furnace.

Answer: No. Pyrolysis units would not be subject to any part of the HMIWI regulations, per §§60.32e(f) and 60.50c(f).

14. Would portable units burning hospital/medical/infectious waste, which could be moved from location to location and otherwise meet the applicability, be subject to the HMIWI rule?

Answer: Yes. There are no exemptions for portable units, unless they otherwise meet one of the exemptions below: [40 CFR 60.32e(b)-(g) and 60.50c(b)-(g)]

1. HMIWI that combusts only pathological waste, low-level radioactive waste, and/or chemotherapeutic waste.
2. Co-fired combustor.
3. Combustor required to have permit under section 3005 of Solid Waste Disposal Act (hazardous waste combustor).
4. Combustor which meets the applicability requirements of 40 CFR Part 60, subpart Cb, Ea, or Eb (standards or guidelines for certain municipal waste combustors).
5. Pyrolysis unit processing hospital waste and/or medical/infectious waste.
6. Cement kiln firing hospital waste and/or medical/infectious waste.

15. Would tattoo waste, such as the sharps (needles) used in the procedure or other associated wastes, be considered medical/infectious waste under the HMIWI regulations?

Answer: Yes. Sharps and other items contaminated with blood, generated as tattoo waste, would be considered medical/infectious waste if burned in an HMIWI. [40 CFR 60.31e and 60.51c]

6.2 Applicability Dates

1. Would the applicable date be the date of initial construction, initial startup, or when the HMIWI finally reaches full operation?

Answer: Per §§60.32e(a) and 60.50c(a), the applicable date would be the date construction is commenced. For example, the amended subpart Ce applies to units for which construction is commenced on or before December 1, 2008. "Commenced" is defined in the NSPS General Provisions in §60.2. As defined under §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."

2. Please define "commenced" and "construction" in the context of having put in building footing but not yet built the building nor purchased the equipment.

Answer: "Commenced" and "construction," as used in CAA section 111, are defined by 40 CFR Part 60, subpart A (General Provisions). [40 CFR 60.2] With respect to the definition of new source, "commenced" is defined to mean 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."

Subpart Ec, as amended, would be applicable to each HMIWI which commenced construction after December 1, 2008. [40 CFR 60.50c(a)(3)] An HMIWI is defined in the NSPS as any device that combusts any amount of hospital waste and/or medical/infectious waste. [40 CFR 60.51c] Thus, if the HMIWI was constructed after December 1, 2008, then the HMIWI would be a new unit regardless of when the building was constructed, since the HMIWI is the affected facility, not the building. However, if the owner or operator was under a contractual obligation, prior to December 1, 2008, to construct an HMIWI, then the unit may be an existing unit. [40 CFR 60.2] Specific determinations for "commenced" and "construction" should be taken up with the appropriate delegated authority under §60.5.

3. Would units which commenced construction between the December 1, 2008 re-proposal and October 6, 2009 promulgation of the HMIWI rule be required to meet the emissions limits in the amended NSPS?

Answer: Yes. The EPA re-proposed the amended HMIWI EG and NSPS on December 1, 2008. Per §60.50c(a), facilities which commenced construction after December 1, 2008 would be considered to be new units and would be subject to the amended NSPS subpart Ec. The

emissions limits for these subpart Ec facilities are provided in Table 1B of the NSPS, as amended.

4. Would units which commenced construction after June 20, 1996 but no later than December 1, 2008 (i.e., original 1997 NSPS sources) be required to meet the emissions limits in the amended State Plan?

Answer: Yes. Units which commenced construction no later than December 1, 2008 would be considered to be existing HMIWI and would be required to meet emissions limits in the amended State Plan. [40 CFR 60.32e(a)(1) and (2)] For those HMIWI which commenced construction no later than June 20, 1996 (original 1997 EG sources), the State Plan should include emissions limitations at least as protective as the emissions limitations in the amended 2009 EG. [40 CFR 60.32e(a)(1) and 60.33e(a)(2)] For those HMIWI which commenced construction after June 20, 1996 but no later than December 1, 2008 (original 1997 NSPS sources), the State Plan should include emissions limitations at least as protective as the more stringent emissions limitations listed in Table 1B of subpart Ce and Table 1A of subpart Ec, as amended on October 6, 2009. [40 CFR 60.32e(a)(2) and 60.33e(a)(3)]

5. Suppose a hospital has a permit to construct an HMIWI, which was awarded prior to December 1, 2008. Bidding on the air pollution control device occurred after December 1, 2008. The incinerator was constructed prior to December 1, 2008, but the air pollution control device was not installed until after December 1, 2008. Would the HMIWI be considered a new or existing source? If existing, would it need to meet the current state standards and State Plan or the amended EPA emissions standards on existing units?

Answer: The HMIWI in this example would be an existing source, using the definitions of "commenced" and "construction" from the General Provisions. [40 CFR 60.2] Each HMIWI which commenced construction after December 1, 2008 would be a new source subject to the amended HMIWI NSPS subpart Ec. [40 CFR 60.50c(a)(3)] Each HMIWI which commenced construction on or before June 20, 1996 would be an existing source subject to the amended HMIWI EG subpart Ce. [40 CFR 60.32e(a)(1)] Each HMIWI which commenced construction after June 20, 1996 but no later than December 1, 2008 (i.e., original 1997 NSPS sources) would also be an existing source, but would be subject to the more stringent of the emissions limitations from the original 1997 NSPS and the amended HMIWI EG, as described in subpart Ce. [40 CFR 60.32e(a)(2) and 60.33e(a)(3)]

The applicability date for the amended HMIWI EG and NSPS would depend on the date when the HMIWI (the affected or designated source) is constructed, not when the air pollution control device (APCD) is installed. [40 CFR 60.32e(a) and 60.50c(a)] Thus, the unit discussed in the question would be an existing HMIWI because the HMIWI was constructed on or before December 1, 2008.

The EG do not apply directly to existing HMIWI, and they do not override or negate any state regulations. Rather, states would need to develop State Plans to implement the EG. [CAA

section 129(b)(2)] The example HMIWI in the question would be subject to the revised State Plan once it is approved by EPA, as well as any applicable state regulations. In the meantime, the example HMIWI would remain subject to the current State Plan and applicable state regulations.

6.3 Size Categories

1. Would a batch incinerator that has a charging rate of 100 lb/batch, is loaded five times per day, and has a total daily loading of 500 lbs per day (lb/d) fall under the small HMIWI subcategory, i.e., (500 lb/d) / (24 hr/d) = 20 lb/hr → small HMIWI? Is this the correct calculation in determining incinerator size?

Answer: To meet the definition of "batch HMIWI," the units typically are loaded with waste, started, allowed to burn the waste, and cooled down, and the ash is removed. [40 CFR 60.31e and 60.51c] The entire batch process usually takes the majority of a day. The unit in question does not sound like a typical batch unit, because the example batch unit is loaded five times per day, which is more frequent than the expected cycle of a typical batch HMIWI. Nevertheless, small batch units, as defined in the HMIWI rule, burn less than 1,600 lb/d. [40 CFR 60.31e and 60.51c] If the example unit is indeed a batch unit, then it would be considered a small HMIWI because it only burns 500 lb/d. 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 lb/hr of waste. [40 CFR 60.31e and 60.51c]

Methods for calculating HMIWI size, for purposes of the HMIWI regulations, are provided in §§60.31e and 60.51c 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 HMIWI," "medium HMIWI," and "large HMIWI" in §§60.31e and 60.51c.

2. Could the small "rural" unit subcategory apply to derated medium and large units in rural areas?

Answer: Yes. Under the small rural criteria, the HMIWI would have to burn less than 2,000 pounds per week (lb/wk) of waste and be located more than 50 miles from an SMSA. [40 CFR 60.33e(b)] Most medium and large HMIWI have the capacity to burn much more than 2,000 lb/wk and likely would have to undergo drastic measures to derate their capacity to less than 2,000 lb/wk. It would not be very cost efficient for facilities operating medium and large HMIWI to derate their capacities in order to burn less than 2,000 lb/wk. However, medium or large HMIWI that derate their capacity in order to fall in the small subcategory may be considered small rural units if they meet the small rural criteria.

3. Suppose a facility burns on average 2,200 lb/wk, of which 200 lbs is pathological. Would the 200 lbs be subtracted from the total and make this a small rural unit?

Answer: No. The only time the amount of pathological waste would be subtracted from the total waste burned would be to determine applicability of a co-fired combustor. [40 CFR 60.31e, 60.32e(c), 60.50c(c), and 60.51c] Co-fired combustors are units which burn 10 percent or less of hospital waste and/or medical/infectious waste. [40 CFR 60.31e and 60.51c] If the unit in question is burning hospital waste and/or infectious waste, the only way it may be considered as a small rural unit is if: (1) the facility reduces the amount of all waste burned (including the pathological waste) to less than 2,000 lb/wk [40 CFR 60.33e(b)], (2) the unit is a small unit [40 CFR 60.31e and 60.51c], and (3) the unit is located more than 50 miles from the nearest SMSA [40 CFR 60.33e(b)].

4. According to the EG and NSPS, HMIWI capacity could 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: A source could change its size designation by establishing an enforceable "maximum charge rate" lower than its design capacity. [62 FR 48362 and 48367, September 15, 1997; 65 FR 49874, August 15, 2000] (Note: If a "maximum charge rate" lower than the source's design capacity is established, it needs to be established outside of the source's title V permit before being incorporated into it. [See 40 CFR 70.6(b).] The title V permit can then specifically reference the publicly-available document in which the "maximum charge rate" is contained.) "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. [40 CFR 60.31e and 60.51c] The maximum design waste burning capacity would be calculated based on primary chamber volume and heat release rate. A formula for this calculation is included in the definition for "maximum design waste burning capacity" in §60.51c (and referenced in §60.31e). Because the maximum design waste burning capacity would be calculated based on the design capacity of the incinerator, it would be fixed, and could not be changed. The maximum charge rate, on the other hand, would be calculated based on the amount of waste that a facility actually burns in the incinerator. In some cases, the maximum charge rate would be lower than the maximum design waste burning capacity. For enforcement purposes, the HMIWI would be bound by the maximum charge rate.

5. Could an enforceable permit condition limiting charge rate (lb/hr) below the specific applicability size threshold be used to change the HMIWI size category from large to medium or from medium to small?

Answer: Yes. States could allow units which burn less than their design capacity to base their size determination on the "maximum charge rate," as defined in §§60.31e and 60.51c. [62 FR 48362 and 48367, September 15, 1997; 65 FR 49874, August 15, 2000] The definitions for "large HMIWI," "medium HMIWI," and "small HMIWI" in §§60.31e and 60.51c provide the maximum charge rates for these subcategories. For example, a "large" unit with a design capacity of 600 lb/hr could have an enforceable maximum charge rate of 500 lb/hr and be considered a "medium" unit for purposes of the EG or NSPS. [40 CFR 60.31e and 60.51c] (As noted above, the enforceable "maximum charge rate" needs to be established outside of a title V

permit before being incorporated into it.) This issue is briefly discussed in the preamble to the September 15, 1997 rule. [62 FR 48367, September 15, 1997]

6. Would a source that lowers its maximum charge rate as described above and then exceeds that maximum charge rate by operating in the next larger category automatically become subject to the requirements in that next larger category?

Answer: No. Size is determined by the maximum charge rate, which would be determined through the performance test or permit condition. [40 CFR 60.31e, 60.37e(a)(2) and (c)(1), 60.51c, and 60.56c(h)(1)] If the source exceeds this rate, it does not *automatically* become subject to 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, and repeated exceedances could subject the HMIWI to the requirements for the larger unit. [40 CFR 60.37e(a)(2), (b)(2), and (c)(3); 60.56c(e)-(h)]

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

Answer: No. HMIWI size would be determined on an individual unit basis. [40 CFR 60.31e and 60.51c]

6.4 Definitions

1. If the definition of "medical waste" in the HMIWI rule is broader than the state definition, would this require the state to change its definition, for purposes of handling medical waste disposal?

Answer: No. Subparts Ce and Ec are regulations to ensure the proper operation and control of an HMIWI, but they are not waste management regulations. In other words, subparts Ce and Ec would not determine which items in a waste stream need to be "treated" and which items need not be "treated." Subparts Ce and Ec contain definitions of hospital waste and medical/infectious waste to determine whether or not an incinerator is covered by the regulations. [40 CFR 60.31e and 60.51c] For example, IV bags would be considered "medical/infectious" waste under the EPA HMIWI regulation, even if they are not infectious. [40 CFR 60.31e and 60.51c] If a hospital puts IV bags into an incinerator, that incinerator would be covered by the regulation. If hospitals in a state routinely recycle IV bags, there is nothing in the EPA HMIWI rule that would prohibit the hospital from continuing to recycle IV bags.

2. Subparts Ce and Ec define "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, would it be acceptable to use the term "hospital/ medical/infectious waste incinerator" in place of "designated facility" and "affected facility"?

Answer: Not without some qualifying factors. "Designated facility" and "affected facility" are terms of art under section 111 of the CAA. In the case of the subpart Ce EG, the "designated facility" would be each individual HMIWI for which construction was commenced on or before December 1, 2008. [40 CFR 60.32e(a)(1) and (2)] Under the subpart Ec NSPS, the "affected facility" would be each individual HMIWI for which construction is commenced after December 1, 2008 or for which modification is commenced after April 6, 2010. [40 CFR 60.50c(a)(3) and (4)] Therefore, substituting "HMIWI" or "HMIWI unit" for "designated facility" or "affected facility" would not be correct unless the other qualifying factors (e.g., type of regulation–NSPS or EG, construction or modification, applicable dates) are also included.

7.0 Operator Training and Qualification

1. What are the minimum elements required for operator training?

Answer: Operator training could be obtained through a state-approved program or by completing and passing a training course that satisfies the requirements listed in §60.53c(c) through (g) of subpart Ec (and referenced in §60.34e). In general, the operator training course described in §60.53c(c) through (g) of subpart Ec would include: (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 would not necessarily have to meet all of the requirements specified in §60.53c(c) through (g) of subpart Ec; however, states should decide if a program provides adequate HMIWI operator training before granting approval of the program.

2. What should an exam for operator training consist of and what would constitute passing?

Answer: The examination would need to be designed and administered by the course instructor. [40 CFR 60.34e and 60.53c(c)(2)] Typically, the exam would cover the material presented during the training course. Each operator training program that develops an examination would be responsible for determining what grade would be acceptable for HMIWI operators to pass the course.

3. 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 better qualified to develop a training program. Would EPA recognize an owner/operator-developed program over a state-approved program? Would EPA approval be required for privately run operator training?

Answer: Facilities would need to obtain operator training through either an operator training program that meets the requirements specified in §60.53c(c) through (g) of subpart Ec (referenced in §60.34e) or through a state-approved operator training program. Thus, privately-run operator training programs would be acceptable if they meet the requirements specified in §60.53c(c) through (g) of subpart Ec. Approval by EPA would not be 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 would need to obtain approval from the state. [CAA section 129(d) and 40 CFR 60.26(a)] If a state disapproves an operator training program, then the training program would not be valid in that state, and the EPA would not step in and have the state approve the training program. [CAA section 129(d) and 40 CFR 60.26(a)] If the state says nothing about the training program and the program meets the requirements of §60.53c(c) through (g) of subpart Ec, then the program could be used to train HMIWI operators in that state.

4. What would 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, would it be automatically approved? Are there specific requirements for a state operator training program?

Answer: State Plans should require training of HMIWI operators through the program which meets the requirements specified in subpart Ec (and referenced in subpart Ce) or by a state-approved program. [40 CFR 60.34e and 60.53c] A state could develop and implement its own program in lieu of the training requirements specified in subpart Ec. The EPA does not have specific requirements for state operator training programs. However, this does not preclude EPA from commenting on a proposed state operator training program.

Section 129(d) of the CAA specifies that the Administrator may authorize any state to implement a model program for operator training, if the state has adopted a program which is at least as effective as the model program developed by the Administrator. Section 60.34e of subpart Ce specifies that, for approval, a State Plan would need to include requirements for operator training and qualification at least as protective as those requirements listed in §60.53c of subpart Ec. State training programs would only be good within the state of issuance. The training requirements mentioned in subpart Ec would be acceptable nationally.

If the state air pollution control agency wants to enforce its own operator training requirements, in lieu of the requirements in §60.53c(c) through (g), then the applicable state operator training rule should be submitted as part of the revised or new State Plan, in order to ensure federal enforceability of the state operator training requirements, if necessary. This has already been done for several State Plans. If a state governmental agency other than the state air pollution control agency would be responsible for implementing and enforcing the operator training requirements, then they would need to meet the requirements in §60.26(d) of subpart B, demonstrating their legal authority to carry out these responsibilities.

5. Would a trained and qualified operator need to be onsite at all times while the incinerator is in operation?

Answer: No. The EG and NSPS specify that the trained and qualified operator should be onsite within 1 hour. The trained and qualified HMIWI operator could operate the HMIWI directly or be the direct supervisor of one or more HMIWI operators.

6. Section 62.14423(a)(2) of the HMIWI Federal Plan specifies that operators who do not participate in a state-approved training program should have (1) 6 months experience as an HMIWI operator, (2) 6 months experience as a direct supervisor of an HMIWI operator, or (3) completion of two burn cycles under the supervision of two qualified HMIWI operators, in order to be qualified. If the facility currently has no qualified HMIWI operators, would the facility need to hire two qualified HMIWI operators as contractors to observe and supervise the employees the facility want to use as operators once the employees complete the operating training

requirements under §62.14422? Or could each operator operate the unit after the training course, but the qualification would not be valid until each operator works for 6 months as an "operator-in-training," after which the operators would attain trained/qualified HMIWI operator status?

Answer: Qualification of a trained HMIWI operator can be satisfied by either scenario. Qualification under the first scenario (two burn cycles under supervision by two qualified HMIWI operators) can be achieved sooner than qualification under the second scenario (6 months experience as an HMIWI operator).

Under the first scenario, if the facility does not already employ a trained, qualified HMIWI operator, it could engage the services of two outside consultants who have each satisfied the training/qualification requirements in §60.53c of subpart Ec. The qualified contractors would need to "supervise" the trained HMIWI facility's operator for at least two burn cycles, after which time the facility's operator would be fully qualified as an operator.

Under the second scenario, a trained HMIWI operator would be "qualified" after 6 months experience. No supervision is required in this scenario.

8.0 Compliance, Performance Testing, Monitoring, and Inspections

8.1 Compliance

1. What would happen if a facility is in the process of retrofitting, but is not able to demonstrate compliance with the emissions limits by the compliance deadline?

Answer: The facility should cease operation until a performance test is conducted and the facility demonstrates compliance. [40 CFR 60.8 and 60.26(a)] (See question 6 under section 2.1 of this document and questions 3 and 5 under section 2.2.)

2. If emissions tests for every section 129 pollutant are not required on an annual basis, how could the regulators know the compliance status?

Answer: For new and existing HMIWI, initial emissions testing would be required for the nine pollutants and opacity listed under section 129. [CAA section 129(a)(4) and 40 CFR 60.37e(a)(2) and (b)(2) and 60.56c(b), as amended] Annual emissions testing would be required for three of these pollutants—particulate matter (PM), carbon monoxide (CO), and hydrogen chloride (HCl)—to gain a good indication that the incinerator and APCD are operating properly. The annual emissions tests would be required for the first 3 years following the initial test, and then every third year, provided that the HMIWI demonstrates compliance with the emissions limits during each test. [40 CFR 60.37e(a)(2) and (b)(2) and 60.56c(c)(2)] Annual testing would also be required for opacity, with no skip testing. [40 CFR 60.37e(a)(2) and (b)(2) and 60.56c(c)(1)] In addition to the testing requirements, owner/operators of all HMIWI would be 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, except during periods of monitoring equipment malfunction, calibration, or repair. [40 CFR 60.37e(d) and (e)(3) and 60.57c(e)] The owner/operators would also be required to conduct annual inspections of HMIWI equipment and control devices. [40 CFR 60.36e(b) and (d) and 60.57c(g)] The purpose of the above testing, monitoring, and inspection requirements is to provide information pertaining to facility compliance status. For HMIWI subject to the EG, states could choose to include more extensive testing, monitoring, and inspection requirements in their State Plans. [CAA section 129(h)(1)]

3. How are exceedances of operating parameters related to violations of emissions limits?

Answer: The rule states that operation above the established maximum or below the established minimum operating parameter(s) would constitute a violation of a established operating parameter(s). [40 CFR 60.37e(a)(2) and (c)(2) and 60.56c(d)(2)] Additionally, direct relationships between certain operating parameters and emissions limits have been established for a number of pollutants, and the rule provides specific scenarios which indicate a violation of

an applicable emissions limit. [40 CFR 60.37e(a)(2) and (c)(3) and 60.56c(e)-(h)] Monitored use of a bypass stack would constitute a violation of the PM, dioxin/furan, HCl, lead (Pb), cadmium (Cd), and mercury (Hg) emissions limits. [40 CFR 60.37e(a)(2) and (b)(2); 60.56c(e)(5), (f)(6), and (g)(5)]

4. What would the averaging period be for determining compliance with the new 6 percent opacity standard?

Answer: Under the amended regulations, the opacity limit cannot exceed 6 percent on a 6-minute block average. [40 CFR 60.33e(c)(2) and 60.52c(b)(2)]

8.2 Performance Testing

1. When would units need to perform initial testing with respect to the timeline for revised or new State Plans?

Answer: Units would need to perform initial performance test as scheduled in the revised or new State Plan, but no later than 3 years and 180 days after approval of the revised or new State Plan or 180 days after October 6, 2014 (whichever is earlier). [40 CFR 60.8(a)]

2. Would the amended EG allow previous stack test results to be reused to determine compliance after retrofit?

Answer: Sources could use results of their previous emissions tests to demonstrate initial compliance with the amended emissions limits, provided the source demonstrates to the state or Administrator (or delegated authority) that the previous test results are representative of current operations. [40 CFR 60.37e(f)] However, after a retrofit or operational changes, previous stack tests may no longer be representative of the current operation of the HMIWI.

3. During initial testing, would there be a wider emissions standard that allows for experimentation?

Answer: Sources are given 180 days to complete the initial performance test. [40 CFR 60.8(a)] Prior to conducting the initial performance test, experimentation could be done to optimize the system, but the initial performance test should demonstrate compliance with the emissions limits. Following the initial performance test, the HMIWI should be operated in compliance with the emissions limits and established operating parameters at all times. [40 CFR 60.37e(a)(2), (b)(2), and (c)(2); 60.56c(a), (d)(2), and (h)(2)]

4. Would testing be required for nitrogen oxides (NO_X) and sulfur dioxide (SO_2)?

Answer: Yes. The amended EG and NSPS would require both NO_X and SO_2 testing. [40 CFR 60.37e(a)(2) and (b)(2); 60.56c(b), referencing paragraphs (b)(7) and (b)(8)] However, affected/designated facilities could use the results of previous NO_X and SO_2 emissions tests to demonstrate compliance with the amended NO_X and SO_2 emissions limits, provided the source

demonstrates to the state or Administrator (or delegated authority) that the previous NO_X and SO_2 test results are representative of current operations. [40 CFR 60.37e(f)] It should be noted that NO_X and SO_2 testing were not required under the 1997 EG and NSPS, as reflected in §60.37e(a)(1) and (b)(1) of the EG and the first sentence in §60.56c(b) of the NSPS. The new requirements for NO_X and SO_2 testing under the amended EG and NSPS are reflected in §60.37e(a)(2) and (b)(2) of the EG and the second sentence in §60.56c(b) of the NSPS.

5. What would it cost a facility to perform the initial stack/performance test to demonstrate compliance with the amended emissions limits? What would the difference in cost be between that test for small rural facilities and other HMIWI?

Answer: Designated facilities could use the results of previous emissions tests to demonstrate compliance with the amended emissions limits, provided the source demonstrates to the state or Administrator (or delegated authority) that the previous test results are representative of current operations. [40 CFR 60.37e(f)] Consequently, the cost would vary from facility to facility. We estimate initial performance testing costs for these facilities would range from $0 to $36,000, with a nationwide average of $22,100. The memorandum which documents the testing costs for these existing units is available in the docket at http://www.regulations.gov [Item No. EPA-HQ-OAR-2006-0534-0384]. The title of the memorandum is "Revised Compliance Costs and Economic Inputs for Existing HMIWI." Under a worst-case assumption (i.e., facility needs to conduct initial performance tests for all nine pollutants), initial performance testing would cost approximately $55,800. The amended EG would also require small rural HMIWI to conduct initial tests for all nine pollutants, so there would be no difference in the worst case cost. In the aforementioned memorandum, we estimated initial performance testing costs of $18,700 and $14,000 for the two small rural facilities currently operating.

For new sources subject to the amended NSPS, initial performance testing would cost an additional $9,300 above the testing that new sources are already required to conduct under the original 1997 NSPS—i.e., PM, CO, HCl, Pb, Cd, Hg, and dioxin/furan testing. The additional testing cost includes the cost to conduct the NO_X and SO_2 stack tests that are required for the first time under the amended NSPS. The memorandum which documents the testing costs for these new units is available in the docket at http://www.regulations.gov [Item No. EPA-HQ-OAR-2006-0534-0385]. The title of the memorandum is "Revised Compliance Costs and Economic Inputs for New HMIWI."

6. Could the initial performance test that our facility conducted to demonstrate compliance with the commercial/industrial solid waste incinerator (CISWI) rule—which included testing of the same pollutants as the HMIWI rule using the same test methods and procedures required by the HMIWI rule—be used to satisfy the testing requirement under the HMIWI Federal Plan that is used to implement the HMIWI EG in our state? Our facility is currently not subject to the HMIWI emissions standards because it is operating under the co-fired exemption, with a limit on the amount of hospital/medical/infectious waste that can be burned in the incinerator.

Answer: No, for the reasons stated below.

1. The August 15, 2000 Federal Plan does not provide for using previous emissions test results to demonstrate compliance. Although the amended EG includes this option [see §60.37e(f)], it has not yet been incorporated into a revised Federal Plan or a revised/new State Plan that would implement the amended EG.

2. Even if the Federal/State Plan allowed §60.37e(f), the initial performance test would have to meet the test methods and procedures of §60.56c(b) and be representative of conditions at the facility, per §60.8. If the facility were previously tested when burning commercial and/or industrial solid waste, those conditions would not likely be representative of burning hospital, medical, and/or infectious waste.

7. If an annual stack test shows that an HMIWI is out of compliance with the emissions limit for one pollutant, should the facility continue annual stack testing for all pollutants for the next 3 years or for only the pollutant that was above the emissions limit?

Answer: As noted previously, annual stack tests would only be required for PM, CO, or HCl. [40 CFR 60.37e(a)(2) and (b)(2) and 60.56c(c)(2)] If all three performance tests over a 3-year period indicate compliance with the emissions limit for one pollutant (PM, CO, or HCl), the owner or operator could forego a performance test for that pollutant for the subsequent 2 years. [40 CFR 60.37e(a)(2) and (b)(2) and 60.56c(c)(2)] If any performance test indicates noncompliance with the respective emissions limit, a performance test *for that pollutant* should be conducted annually until all annual performance tests over a 3-year period indicate compliance with the emissions limit. [40 CFR 60.37e(a)(2) and (b)(2) and 60.56c(c)(2)]

8.3 Monitoring

1. What types of CEMS monitoring (e.g., PM, HCl, multi-metals and Hg) would be required? Would these requirements apply to MWCs that process treated regulated medical waste (TRMW) and/or treated and destroyed medical waste (TDRMW)?

Answer: CEMS for CO emissions monitoring would be required for sources subject to the amended subpart Ec. [40 CFR 60.56c(c)(4)] CEMS for HCl, PM, multi-metals, and Hg would be options for sources subject to the amended subparts Ce and Ec, and CEMS for CO would be an option for sources subject to the amended subpart Ce. [40 CFR 60.37e(a)(2) and (b)(2) and 60.56c(c)(5)(ii)] There is no distinction between subparts Ce and Ec concerning the burning of treated and untreated waste. Therefore, the CEMS monitoring would apply to MWCs to the extent that they meet the applicability of either subpart Ce or Ec by burning sufficient hospital and/or medical/infectious waste that they would be considered HMIWI.

2. If a facility has CEMS, could the emissions be averaged over a period of 24 hours?

Answer: Yes, for sources subject to subpart Ec, as amended. [40 CFR 60.56c(4)(i) and (5)(ii)] Sources subject to subpart Ce could not use a 24-hour average until after the revised or new State Plan has been approved. Under currently existing State Plans (implementing the 1997 EG), designated facilities employing CEMS should use a 12-hour rolling average, calculated each hour as the average of the previous 12 operating hours, as indicated in §60.56c(c)(5)(i), which is referenced in §60.37e(a)(1) of the amended EG. Revised or new State Plans implementing the amended EG should require designated facilities employing CEMS to use a 24-hour block average (calculated as specified in Part 60, Appendix A-7, EPA Reference Method 19, Section 12.4.1), as indicated in §60.56c(c)(5)(ii), which is referenced in §60.37e(a)(2) of the amended EG.

3. Are PS-12A and Procedure 5, both referencing direct Hg monitoring requirements and quality assurance (QA) protocols, included in the HMIWI rule? If not, does the rule require Hg or any other metal HAP monitoring, and, if so, what method is acceptable?

Answer: As an alternative to metals testing, the HMIWI final rule allows sources to use multi-metals CEMS, Hg CEMS, or integrated sorbent trap Hg monitoring (continuous sampling with periodic sample analysis). [40 CFR 60.37e(a)(2) and (b)(2) and 60.56c(b)(13)] Regarding performance specifications for these monitoring systems, the rule says the following:

"Facilities using CEMS to demonstrate compliance with any of the emissions limits under §60.52c shall...[o]perate all CEMS in accordance with the applicable procedures under appendices B and F of this part. For those CEMS for which performance specifications have not yet been promulgated (HCl, multi-metals), this option for an affected facility as defined in §60.50c(a)(3) and (4) takes effect on the date a final performance specification is published in the Federal Register or the date of approval of a site-specific monitoring plan." [40 CFR 60.56c(c)(5)(iii)]

The rule also says: "An affected facility as defined in §60.50c(a)(3) and (4) using a continuous automated sampling system to demonstrate compliance with the Hg emissions limits under §60.52c shall record the output of the system and analyze the sample at set intervals using any suitable determinative technique that can meet appropriate performance criteria. This option to use a continuous automated sampling system takes effect on the date a final performance specification applicable to Hg from monitors is published in the Federal Register or the date of approval of a site-specific monitoring plan. The owner or operator of an affected facility as defined in §60.50c(a)(3) and (4) who elects to continuously sample Hg emissions instead of sampling and testing using EPA Reference Method 29 of appendix A-8 of this part, or an approved alternative method for measuring Hg emissions, shall install, calibrate, maintain, and operate a continuous automated sampling system and shall comply with the requirements specified in §60.58b(p) and (q) of subpart Eb of this part." [40 CFR 60.56c(c)(7)]

Metals testing provisions in the final rule include Method 29 for all metals (including Pb, Cd, and Hg) and an alternative method (ASTM D6784-02) for Hg only. [40 CFR 60.37e(a)(2) and (b)(2) and 60.56c(b)(13)]

4. How many incinerators would be required to directly monitor emissions of toxic metals in the U.S.? If there are no performance specifications, how would the metals monitoring systems be certified?

Answer: We are not requiring any HMIWI to directly monitor emissions of metal HAP under the 2009 final rule, and there was no such requirement in the 1997 rule either. Multi-metals CEMS and Hg CEMS are options under the 2009 final rule. [40 CFR 60.37e(a)(2) and (b)(2) and 60.56c(b)(13), (c)(5), and (c)(7)] It would be up to the states whether to include or not include such a requirement in their state plans.

As noted previously, if a performance specification already exists for a particular emissions monitoring system, the monitoring system would be certified under the applicable performance specification in Part 60, Appendix B, as we specify in §60.56c(c)(5)(iii) of the 2009 final rule. (Performance specifications for these systems are located in Appendix B, while QA procedures are located in Appendix F.) If a performance specification is not currently available for the monitoring system, then the monitoring system would be certified for use once a performance specification for it has been published in the FR or a site-specific monitoring plan has been approved.

8.4 Inspections

1. Who should conduct the HMIWI equipment and control device inspections for HMIWI facilities?

Answer: The owner or operator of the HMIWI would be responsible for ensuring the HMIWI equipment and control device inspections are conducted. [40 CFR 60.36e(a)-(d) and 60.57c(f) and (g)] The inspection could be conducted by an outside party or by the facility. Minimum requirements for inspecting the HMIWI equipment and control device are included in the amended EG and NSPS. [40 CFR 60.36e(a)(1), (b), (c)(1), and (d); 60.57c(f)(1) and (g)] The owner or operator would need to ensure that any repairs are completed within 10 operating days following the inspection, unless written approval is obtained from the state establishing a date whereby the repairs should be completed. [40 CFR 60.36e(a)(2), (b), (c)(2), and (d); 60.57c(f)(2) and (g)] Facilities would need to keep records and submit annual reports of the inspections. [40 CFR 60.38e(b) and 60.58c(b)(2)(xvii)]

9.0 Waste Management Plans

1. What should be included in a facility's revised Waste Management Plan (WMP)? By what date should facilities complete the revised WMP? How would facilities demonstrate that the revised WMP has been implemented?

Answer: The September 15, 1997 NSPS and the State Plans implementing the September 15, 1997 EG required facilities to submit WMPs that identified opportunities for recycling or reducing wastes such as paper, plastics, cardboard, glass, batteries, etc. and may also have evaluated the approach, costs, feasibility, and impacts of additional waste management measures. [40 CFR 60.35e and 60.55c] The purpose of the WMP was to prompt facilities to seek opportunities for waste reduction and identify wastes that could be recycled, rather than burned. As part of the October 6, 2009 amendments to the HMIWI regulations, §60.55c was revised to include some new provisions that may necessitate that facilities revise their current WMPs. The revised provisions provide greater detail regarding the segregation and recycling of wastes such as paper, cardboard, plastics, glass, batteries, food waste, and metals (e.g., aluminum cans, metals-containing devices) and the segregation of non-recyclable wastes (e.g., polychlorinated biphenyl-containing waste, pharmaceutical waste, and mercury-containing waste, such as dental waste). [74 FR 51409, October 6, 2009]

Facilities would need to submit their revised WMPs no later than 60 days following the initial performance test conducted to demonstrate compliance with the amended HMIWI regulations. [40 CFR 60.38e(a) and 60.58c(c)(3)] Revised and new State Plans developed to implement the amended subpart Ce may include requirements by which facilities can demonstrate implementation of their revised WMPs.

2. Would facilities without changes to the WMP need to resubmit the plan after the initial performance test demonstrating compliance with the amended HMIWI regulations?

Answer: Facilities could simply reference the previously submitted WMPs in their notification and inform the state know that they are still operating under those plans. Only if the facilities have changed their WMPs would they need to submit the revised plans within 60 days after the initial performance test.

3. If a facility demonstrates compliance with the amended subpart Ce emissions limits using previous emissions test results (rather than conducting an initial performance test) and demonstrates that those test results are representative of current operations, when would the revised WMP be due to the state or Administrator (or delegated authority)?

Answer: In general, the revised plan would be due 60 days following their demonstration of initial compliance. In this case, the facility should submit the revised WMP when it submits the previous emissions test results demonstrating compliance with the amended subpart Ce

emissions limits, along with documentation demonstrating that the test results are representative of current operations.

4. Would hospitals that are operating as de facto commercial treatment facilities be required to account for receipt and handling of medical waste accepted from offsite generators in their WMPs?

Answer: Facilities operating commercial HMIWI have limited control over the wastes that are accepted from offsite locations. To address this situation, the revised WMP provisions in the October 6, 2009 amendments include requirements that commercial HMIWI conduct training and education programs in waste segregation for each of the their waste generator clients and ensure that each client prepares its own WMP that includes, but is not limited to, the provisions listed for such plans in the amended EG and NSPS. [40 CFR 60.35e and 60.55c] The amendments define "commercial HMIWI" as HMIWI offering incineration services for hospital/medical/infectious waste generated offsite by unrelated firms. [60.31e and 60.51c] As defined, commercial HMIWI would include all commercial treatment facilities, including the facilities noted here.

5. What is the title of the American Hospital Association (AHA) publication on waste reduction, and where could copies be obtained?

Answer: The title of the AHA publication that health care facilities are encouraged to consider when developing WMPs 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 catalog number is WS-057007. This document could be obtained (1) online at http://www.aha.org (click on AHA Online Store); (2) by phone at (800) 242-2626; (3) by fax at (866) 516-5817; or (4) by mail at AHA Services Inc., P.O. Box 933283, Atlanta GA 31193-3283. The cost of the document is $29.95 for members and $75.00 for non-members, plus shipping and handling.

10.0 Title V Permits

1. When would HMIWI need to revise their title V permits?

Answer: Owners and operators of all currently operating HMIWI should have already submitted permit applications, either as a result of being subject to (1) a State Plan or the Federal Plan following the promulgation of the original EG in 1997; (2) the NSPS issued in 1997; or (3) being subject to title V permitting for another reason, e.g., being located at a major source. All of these sources should have by now been issued a title V permit. With the 2009 revision of the EG, states will need to develop and seek EPA approval for revised or new State Plans, and EPA will need to promulgate a revised Federal Plan for states that do not have an approved revised or new State Plan.

If there are 3 or more years remaining on the title V permit term for a particular HMIWI when an applicable revised/new State Plan is approved and becomes effective or the revised Federal Plan is promulgated and becomes effective, then the HMIWI owner and/or operator will receive from its permitting authority a notice of intent to reopen the title V permit to include the new requirements of the applicable revised or new State Plan or revised Federal Plan. [40 CFR 70.7(f)(1)(i) and 65 FR 49868, 49878, August 15, 2000]

If there are less than 3 years remaining on the permit term at the time that the applicable State Plan or Federal Plan becomes effective, then the owner and/or operator would not need to modify its title V permit to include the new applicable requirements until permit renewal--bearing in mind that the sources would be subject to the applicable requirements of the revised or new State Plan or revised Federal Plan, even though the requirements are not yet contained in the permit. [40 CFR 70.7(f)(1)(i) and 65 FR 49868, 49878, August 15, 2000] Owners and operators would need to wait until the revised or new State Plan has been approved and becomes effective or the revised Federal Plan has been promulgated and becomes effective before they can determine how much time remains on their permit term. [65 FR 49868, 49878, August 15, 2000]

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

Answer: Plasma (pyrolysis) units at major sources would not be subject to any part of the HMIWI rule , but would still be required to be included in a permit application and permit for a major title V source. [40 CFR 60.32e(f) and 60.50c(f)] A large facility with multiple emissions units and a major source under title V should develop a permit application listing all of the emissions units, describing the emissions from those units, and including all applicable requirements relative to those units. [See 40 CFR 70.5(c) for all application requirements.] For multiple units of the same type, many states allow the facility to list and describe the units as a group. For instance in this case, if a facility has six of the same unit, then the facility would only need to describe the unit once. Of course, application requirements will vary from state to

state, and sources should check with their permitting authorities regarding the forms that need to be used in their state.

3. Suppose the state permit for an HMIWI facility was renewed in 2010, and the permit term is five years, expiring in 2015. If the HMIWI EG is implemented for all states before 2015, would the state have to void the facility's permit and change their permitted limits to comply with the October 6, 2009 rule? Or would the facility be allowed to continue emitting the pollutants at the old, higher levels until the facility's permit expires in 2015?

Answer: If there are 3 or more years remaining on the permit term of the HMIWI facility in question, the permitting authority is required to reopen the HMIWI facility's permit and include the applicable requirements from the relevant State Plan or Federal Plan. This reopening needs to be completed no later than 18 months after the State Plan becomes effective following EPA approval or the Federal Plan is promulgated and becomes effective. Again, the 18-month clock is triggered by the effective date of the Plan that is relevant to the source.

If there are 3 or more years remaining on the title V permit term for an HMIWI when the applicable State Plan is approved and becomes effective or the Federal Plan is promulgated and becomes effective, then the HMIWI owner and/or operator will receive from his permitting authority a notice of intent to reopen the title V permit to include the new requirements of the applicable State/Federal Plan. [40 CFR 70.7(f)(1)(i) and 65 FR 49868, 49878, August 15, 2000]

If there are less than 3 years remaining on the permit term at the time that the applicable State Plan or Federal Plan becomes effective, then the owner and/or operator need not modify his title V permit to include the new applicable requirements until permit renewal--bearing in mind that the sources are subject to the applicable State/Federal Plan requirements, even though the requirements are not yet contained in the permit. [40 CFR 70.7(f)(1)(i) and 65 FR 49868, 49878, August 15, 2000]

Owners and operators are reminded that they need to wait until the revised/new State Plan has been approved and become effective or the revised Federal Plan has been promulgated and become effective before they can determine how much time remains on their permit term. [65 FR 49868, 49878, August 15, 2000] If a reopening is required, the permitting authority needs to complete the reopening no later than 18 months after the revised/new State Plan becomes effective following EPA approval or the revised Federal Plan is promulgated and becomes effective. [40 CFR 70.7(f)(1)(i)]

Regardless of whether a title V permit is revised through a reopening or at the time of permit renewal, an HMIWI facility must comply with the new requirements in the revised/new State Plan or the revised Federal Plan according to the compliance time frames established in the revised/new State Plan or the revised Federal Plan.

4. Subpart Ce (as amended on October 6, 2009) specifies that the State Plan and, thus, the enforceable mechanism (e.g., state regulation) include the requirements for §60.32e(a)(2), relating to NSPS facilities under the 1997 HMIWI rule. If a state certifies that it has no affected sources under §60.32e(a)(2), would this mean there is no need for such requirements in the enforceable mechanism (e.g., state regulation)?

Answer: Section 129(b)(2) states, "The State plan shall be at least as protective as the guidelines promulgated by the Administrator ..." [Emphasis added.] If a state has one or more designated facilities under a specific EG category, the state should not conveniently delete EG provisions that they believe should not be included in the state's enforceable mechanism under the plan. In other words, a state enforceable mechanism should not circumvent or delete any applicable or potentially applicable requirement of subpart Ce, as revised. The exception is the use of alternative compliance methods and/or monitoring provisions, as provided in the EG revision.

11.0 Miscellaneous

1. What would be the alternatives to onsite incineration (i.e., autoclaves, microwave, etc.)?

Answer: The HMIWI regulations are not "medical waste disposal" regulations, and we do not discuss alternatives to the combustion of hospital and/or medical/infectious waste under subpart Ce or Ec. However, we did briefly discuss alternatives to onsite incineration in the preamble to the October 6, 2009 rule [74 FR 51396, October 6, 2009] and included a discussion of alternatives in an April 9, 1996 memorandum [Legacy Docket No. A-91-61, Item No. IV-B-43], entitled "Alternative Methods of Medical Waste Treatment: Availability, Efficacy, Cost, State Acceptance, Owner Satisfaction, Operator Safety, and Environmental Impacts."

2. What are the specific decommissioning provisions: (1) complete dismantlement, or (2) disconnect fuel supply for control power to unit?

Answer: There are no specific decommissioning provisions stated in either subpart Ce or subpart Ec. States should use their best judgment to determine which HMIWI that have ceased operation are capable of reopening. For those HMIWI which have ceased operation, but are capable of reopening, 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.

[see 65 FR 49876, August 15, 2000]

3. How would the startup/shutdown/malfunction (SSM) issue be applied to an MWC that burns hospital and/or medical/infectious waste and is subject to the HMIWI rule? In the HMIWI rule, waste is not processed during startup or shutdown, whereas, in MWCs, wastes are processed during these periods. How would this differ for periods of malfunction?

Answer: For a large MWC unit (i.e., unit capacity greater than 250 tpd), the HMIWI rule would not be applicable. [40 CFR 60.32e(e) and 60.50c(e)] If a small MWC unit (i.e., unit capacity less than or equal to 250 tpd) burns sufficient hospital/medical/infectious waste to be considered subject to the HMIWI rule, it would be subject to the HMIWI standards during all periods of HMIWI operation, including all periods of SSM.[40 CFR 60.32e(e) and 60.50c(e)]

4. When setting the new emissions standards, did EPA use a health- or risk-based standard for off-site concentrations of each of the subject pollutants? There is an HMIWI demonstrating compliance with a local, health-based air toxics standard, which is based on the modeled concentration of individual pollutants at or beyond the property line, and it would be helpful to compare these allowable concentrations with the ones used by EPA for this regulation.

Answer: There are no health- or risk-based standards in the HMIWI regulations. Under section 129(a)(1) of the CAA, the standards in the HMIWI regulations are required to address emissions from the incinerator, not off-site or fenceline emissions. However, under sections 129(h)(3) and 112(f), EPA would be required to look at the residual risk remaining 8 years after the standards have been promulgated. If EPA determines at that time that there is some residual risk, then EPA would be obligated to issue risk-based standards that address that risk.

5. Why are the HMIWI emissions data used in developing the amended HMIWI regulations not found in EPA's Toxics Release Inventory (TRI), and how could they be added to the TRI?

Answer: The aforementioned HMIWI emissions data are found only in the HMIWI test data database and baseline emissions estimates found in the HMIWI docket [Item Nos. EPA-HQ-OAR-2006-0534-0318 and 0386, respectively] and in the HMIWI inventory found on EPA's HMIWI website (http://www.epa.gov/ttn/atw/129/hmiwi/rihmiwi.html). Those emissions estimates are based on averages of emissions tests conducted at HMIWI over a span of several years (2000 to 2007).

The TRI, on the other hand, compiles data submitted each year by regulated facilities to EPA and states, under section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA). Consequently, the TRI includes emissions data for specific years submitted directly by HMIWI to EPA and states. The TRI system is set up to allow retrieval of emissions data for a particular facility, location, industry classification, or chemical. TRI queries could be conducted at the following website: http://www.epa.gov/enviro/html/tris/tris_query.html. Further information about the TRI may be found starting here: http://www.epa.gov/tri/.

6. Does the HMIWI rule require certification of the compliance data reported to the state under a State Plan or EPA (or delegated authority) under the Federal Plan? If not, could such a compliance certification requirement be included under the title V reporting requirements?

Answer: The HMIWI rule does not specifically include certification requirements, but title V sources are required to follow the certification requirements of Part 70. [See specifically, 40 CFR 70.5(d).] This language reads as follows:

> "Any application form, report, or compliance certification submitted pursuant to these regulations shall contain certification by a responsible official of truth, accuracy, and completeness. This certification and any other certification required under this part shall

state that, based on information and belief formed after reasonable inquiry, the statements and information in the document are true, accurate, and complete."