APPENDIX 129B

HOSPITAL/MEDICAL/INFECTIOUS WASTE INCINERATORS

EXISTING SOURCE EMISSION GUIDELINES 40 CFR 60, Subpart Ce and NEW SOURCE PERFORMANCE STANDARDS 40 CFR 60, Subpart Ec

CAA SECTION 129 SOLID WASTE COMBUSTION STANDARDS

REGULATION STATUS

The final Hospital/Medical/Infectious Waste Incinerator (HMIWI) rules were published 15 Sep 97 (62 FR 48348). The final rules establish Emission Guidelines (EG) for existing HMIWIs and New Source Performance Standards (NSPS) for new HMIWIs. New HMIWIs are defined as incinerators for which construction or modification was commenced after 20 Jun 96. Subsequent corrections and amendments are reflected in the latest version of the <u>Code of Federal Regulations</u>, Volume 40, Part 60, Subpart Ce (EG) and Subpart Ec (NSPS).

Ongoing Litigation....

A lawsuit filed by the Sierra Club and National Resources Defense Council claims that the procedures EPA used to develop the MACT floors was improper and illegal. Oral arguments were heard on 9 Nov 98. On 2 Mar 99, the court issued an opinion stating that *"EPA's method looks hopelessly irrational"* and remanded the case to EPA for further explanation on how the MACT floors were determined. The HMIWI rules remain in place as the litigation continues.

The 2 Mar 99 opinion for this case (No. 97-1686) can be found under the Litigation Update heading on the HMIWI page of EPA's Unified Air Toxics Website at <u>http://ww.epa.gov/ttn/uatw/129/hmiwi/rihmiwi.html</u>.

Possible outcomes from this litigation include:

- 1. The EPA wins by convincing the Court that the MACT development method was not irrational and the regulations stand.
- 2. The Sierra Club wins. The existing regulations stand. The EPA revises the MACT floor and issues a more stringent regulation and facilities have to comply with both the existing and revised standards.
- 3. Sierra Club wins and the rules are thrown out and EPA begins the whole regulation process again from scratch. This is what happened with the municipal waste combustor (MWC) regulations (Subparts Cb and Eb). On 8 Apr 97, the court ordered EPA to remove all requirements for MWC units less than 250 tons per day capacity. EPA is in the process of redeveloping the MWC standards.

RULE SUMMARY

Applicability

These regulations affect all medical waste incinerators except for the exempt units identified below. Although requirements vary by unit size, even the smallest units are affected. Facilities must operate pursuant to a permit issued under an EPA approved Title V Operating Permit Program by 15 Sep 00, or on the effective date of an EPA approved operating permit program, whichever date is later.

The following units or combustion situations <u>are exempt</u> from both the EG and NSPS:

- Any combustor is not subject during periods when only pathological waste, low-level radioactive waste, and/or chemotherapeutic waste is burned, provided the owner or operator of the combustor:
 - 1. Notifies the Administrator of an exemption claim; and
 - 2. Keeps records on a calendar quarter basis of the periods of time when only pathological waste, low-level radioactive waste, and/or chemotherapeutic waste is burned.
- Any co-fired combustor if the owner or operator of the co-fired combustor:
 - 1. Notifies the Administrator of an exemption claim;
 - 2. Provides an estimate of the relative weight of hospital waste, medical/infectious waste, and other fuels and/or wastes to be combusted; and
 - 3. Keeps records on a calendar quarter basis of the weight of hospital waste and medical/infectious waste combusted, and the weight of all other fuels and wastes combusted at the co-fired combustor.
- Any combustor required to have a permit under Section 3005 of the Solid Waste Disposal Act.
- Any combustor which meets the applicability requirements under subpart Cb, Ea, or Eb (standards or guidelines for certain municipal waste combustors).
- Any pyrolysis unit.
- Cement kilns firing hospital waste and/or medical/infectious.
- Physical or operational changes made to an existing HMIWI unit solely for the purpose of complying with emission guidelines under this subpart are not considered a modification and do not result in an existing HMIWI unit becoming subject to the provisions of subpart Ec.

Key Definitions

The following definitions apply to both the EG and NSPS.

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

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

Continuous HMIWI. An HMIWI that is designed to allow waste charging and ash removal during combustion.

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

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

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

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

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

Large HMIWI means:

- 1) Except as provided in (2),
 - i) An HMIWI whose maximum design waste burning capacity is more than 500 pounds per hour; or
 - ii) A continuous or intermittent HMIWI whose maximum charge rate is more than 500 pounds per hour; or
 - iii) A batch HMIWI whose maximum charge rate is more than 4,000 pounds per day.
- 2) The following are not large HMIWI:
 - i) A continuous or intermittent HMIWI whose maximum charge rate is less than or equal to 500 pounds per hour; or
 - ii) A batch HMIWI whose maximum charge rate is less than or equal to 4,000 pounds per day.

Medical/infectious waste means any waste generated in the diagnosis, treatment, or immunization of human beings or animals, in research pertaining thereto, or in the production or testing of biologicals that is listed below:

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

- 2) Human pathological waste, including tissues, organs, and body parts and body fluids that are removed during surgery or autopsy, or other medical procedures, and specimens of body fluids and their containers.
- 3) Human blood and blood products including:
 - i) Liquid waste human blood;
 - ii) Products of blood;
 - iii) Items saturated and/or dripping with human blood; or
 - iv) Items that were saturated and/or dripping with human blood that are now caked with dried human blood; including serum, plasma, and other blood components, and their containers, which were used or intended for use in either patient care, testing and laboratory analysis or the development of pharmaceuticals. Intravenous bags are also included in this category.
- 4) Sharps that have been used in animal or human patient care or treatment or in medical, research, or industrial laboratories, including hypodermic needles, syringes (with or without the attached needle), Pasteur pipettes, scalpel blades, blood vials, needles with attached tubing, and culture dishes (regardless of presence of infectious agents). Also included are other types of broken or unbroken glassware that were in contact with infectious agents, such as used slides and cover slips.
- 5) Animal waste including contaminated animal carcasses, body parts, and bedding of animals that were known to have been exposed to infectious agents during research (including research in veterinary hospitals), production of biologicals or testing of pharmaceuticals.
- 6) Isolation wastes including biological waste and discarded materials contaminated with blood, excretions, exudates, or secretions from humans who are isolated to protect others from certain highly communicable diseases, or isolated animals known to be infected with highly communicable diseases.
- 7) Unused sharps including the following unused, discarded sharps: hypodermic needles, suture needles, syringes, and scalpel blades.

The definition of medical/infectious waste does not include hazardous waste identified or listed under the regulations in part 261 of this chapter; household waste, as defined in \$261.4(b)(1); ash from incineration of medical/infectious waste, once the incineration process has been completed; human corpses, remains, and anatomical parts that are intended for interment or cremation; and domestic sewage materials identified in \$261.4(a)(1).

Medium HMIWI means:

- 1) Except as provided in (2),
 - i) An HMIWI whose maximum design waste burning capacity is more than 200 pounds per hour but less than or equal to 500 pounds per hour; or

- ii) A continuous or intermittent HMIWI whose maximum charge rate is more than 200 pounds per hour but less than or equal to 500 pounds per hour; or
- iii) A batch HMIWI whose maximum charge rate is more than 1,600 pounds per day but less than or equal to 4,000 pounds per day.
- 2) The following are not medium HMIWI:
 - i) A continuous or intermittent HMIWI whose maximum charge rate is less than or equal to 200 pounds per hour or more than 500 pounds per hour; or
 - ii) A batch HMIWI whose maximum charge rate is more than 4,000 pounds per day or less than or equal to 1,600 pounds per day.

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

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

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

TABLE 1. EMISSION LIMITS FOR SMALL, MEDIUM, & LARGE HMIWI (EXISTING)

Summary of Subpart Ce Existing Source Emission Guidelines For HMIWIs

§60.33e Emission Guidelines for Existing HMIWIs

State plans must include emission requirements at least as protective as those outlined in Tables 1 and 2. The emission limits in Table 2 were written specifically for rural healthcare facilities. In order to be regulated under the rural emission guidelines, a HMIWI must be located more than 50 miles from the boundary of the nearest Standard Metropolitan Statistical Area and burn less than 2,000 pounds per week of hospital and medical/infectious waste. The 2,000 lb/week limit does not apply during performance testing.

§60.34e Operator Training Guidelines

State plans must include requirements for operator training and qualification. The Federal requirements are the same for both new and existing HMIWIs. They include a formal training course, which includes specific topics; and qualification by having either 6 months of experience operating an HMIWI or 6 months as the direct supervisor of an HMIWI operator, or completion of two burn cycles under the observation of two qualified HMIWI operators. In addition, annual refresher training is required to maintain qualification.

Pollutant	Unite	
Foliulant	Units Z porcept exugen dry basis	
Particulate matter	milligrams per dry standard cubic meter (grains per dry standard cubic foot)	197 (0.086)
Carbon monoxide	parts per million by volume	40
Dioxins/furans	nanograms per dry standard cubic meter total dioxins/furans (grains per billion dry standard cubic feet) or nanograms per dry standard cubic meter TEQ (grains per billion dry standard cubic feet TEQ)	800 (350) or 15 (6.6)
Hydrogen chloride	parts per million by volume	3100
Sulfur dioxide	parts per million by volume	55
Nitrogen oxides	parts per million by volume	250
Lead	milligrams per dry standard cubic meter (grains per thousand dry standard cubic feet)	10 (4.4)
Cadmium	milligrams per dry standard cubic meter (grains per thousand dry standard cubic feet)	4 (1.7)
Mercury	milligrams per dry standard cubic meter (grains per thousand dry standard cubic feet)	7.5 (3.3)

TABLE 2. EMISSION LIMITS FOR SMALL RURAL HMIWI (EXISTING)

§60.35e Waste Management Guidelines

Hospitals are required to prepare a waste management plan to identify the feasibility and approach to separating certain components of the solid waste stream.

§60.36e Inspection Guidelines

State plans must require existing incinerators qualifying for the rural definition to undergo initial and annual equipment inspections. Specific items to be inspected are included in the rule. All repairs must be made within 10 days of the inspection unless written approval is obtained from the State.

§60.37e Compliance, Performance Testing, and Monitoring Guidelines

Initial stack tests will be required for a minimum of stack gas composition, particulate, stack opacity, carbon monoxide, dioxin/furan, hydrogen chloride, lead, cadmium, and mercury, and fugitive ash.

Annual testing is required for particulate, carbon monoxide, and hydrogen chloride. If 3 consecutive years of annual tests indicate compliance, testing is not required for the next 2 years. In addition, specific operating parameters must be monitored and recorded on a continuous basis.

Rural HMIWI testing is the same except hydrogen chloride, lead, and cadmium are not included. Rural HMIWI must install, calibrate, maintain, and operate devices to continuously measure and record the temperature in the secondary chamber and a device to automatically measure and record the date, time, and weight of each charge.

§60.38e Reporting and Record keeping Guidelines

You must maintain records for 5 years on various data to include performance testing, continuous monitoring, operating parameters, operating training, calibration data for equipment, charge rate to include dates and times. In addition, specific data must be submitted to the State agency within specified periods of time. Rural HMIWI operators must maintain records of annual equipment inspections and any required maintenance and repairs. Annual reports must be submitted within 60 days following the year in which data were collected.

§60.39e Compliance Times

States must submit plans to EPA by 15 September 1998. Facilities must then comply within 1 year of EPA approval of the State plans. Facilities planning to install control equipment necessary for compliance with the rule may be allowed up to 3 years beyond the date of EPA approval of the State plan. However, all facilities must be in compliance within 5 years of the promulgation date of the rule (15 Sep 02). Facilities must have an enforceable plan in place to illustrate their intent to comply with the rule in order to be granted an extension. Figure 1 is a timeline depicting EPA deadlines.



FIGURE 1 - HMIWI IMPLEMENTATION TIMELINE FOR EXISTING SOURCES

- 1. 62 FR 48348
- 2. §129(b)(2) requires State plans be submitted no later than one year after promulgation of the rule.
- 3. §129(b)(2) requires EPA to approve or disapprove a State plan within 180 days of submission.
- 4. §129(b)(3) requires EPA to develop a Federal plan within 2 years of the rule promulgation (if necessary).
- 5. Due 12 months after EPA approval of State plan under §60.39e of Subpart Ce unless the State has granted an extension to a source (up to 3 years after approval of State plan but not more than 5 years after promulgation).
- 6. §60.24 (e)(1) of Subpart B (General requirements for all §111(d) State plans. Amended 19 Dec 95 to allow subsequent subparts (Ce and Ec) to supercede subpart B) requires legally enforceable increments of progress for any compliance schedule extending beyond 12 months from State Plan approval. §60.39e(c)(1)-(9) of Subpart Ce contains nine suggested increments of progress and §60.21 of Subpart B contains five required increments of progress.
- 7. Both new and existing sources have 36 months from promulgation to get a complete permit application in to their permitting agency.

Summary of Subpart Ec New Source Performance Standards For HMIWIs

§60.50c Applicability and Delegation of Authority

Subpart Ec applies to all HMIWIs for which construction commenced after 20 June 96 or for which modification is commenced after 15 Mar 98. Combusters burning only pathological, low-level radioactive, and/or chemotherapeutic waste are not subject to this rule provided proper notification is given to the EPA administrator and required records are kept. In addition, cofired combustors, permitted hazardous waste, certain municipal waste combustors, pyrolysis units, and cement kilns are exempt from this regulation. Changes made solely for the purpose of complying with the emission guidelines under subpart Ce are not considered modifications. The requirements of this subpart become effective on 15 Mar 98.

§60.52c Emission Limits

The emission limits in Table 3 apply to new HMIWIs. In addition, stacks may not emit greater than 10 percent opacity in a 6 minute block average. Visible emission of ash may not exceed 5 percent for 9 minutes per 3 hour time period.

§60.53c Operator Training and Qualification

A fully trained and qualified HMIWI operator must be accessible either at the facility or available within 1 hour of the site. The Federal requirements are the same for both new and existing HMIWIs and include a formal training course, which includes specific topics; and qualification by having either 6 months of experience operating an HMIWI or 6 months as the direct supervisor of an HMIWI operator; or completion of two burn cycles under the observation of two qualified HMIWI operators; annual refresher training is required to maintain qualification.

Pollutant	Units	Emission limits		5	
	7 percent oxygen, dry basis	HMIWI size			
		Small	Medium	Large	
Particulate matter	milligrams per dry standard cubic meter (grains per dry standard cubic foot)	69 (0.03)	34 (0.015)	34 (0.015)	
Carbon monoxide	parts per million by volume	40	40	40	
Dioxins/furans	nanograms per dry standard cubic meter total dioxins/furans (grains per billion dry standard cubic feet) or nanograms per dry standard cubic meter total dioxins/furans TEQ (grains per billion dry standard cubic feet TEQ)	125 (55) or 2.3 (1.0)	25 (11) or 0.6 (0.26)	25 (11) or 0.6 (0.26)	
Hydrogen chloride	parts per million by volume or % reduction	15 or 99%	15 or 99%	15 or 99%	
Sulfur dioxide	parts per million by volume	55	55	55	
Nitrogen oxides	parts per million by volume	250	250	250	
Lead	milligrams per dry standard cubic meter (grains per thousand dry standard cubic feet) or % reduction	1.2 (0.52) or 70%	0.07 (0.03) or 98%	0.07 (0.03) or 98%	
Cadmium	milligrams per dry standard cubic meter (grains per thousand dry standard cubic feet) or % reduction	0.16 (0.07) or 65%	0.04 (0.02) or 90%	0.04 (0.02) or 90%	
Mercury	milligrams per dry standard cubic meter (grains per thousand dry standard cubic feet) or % reduction	0.55 (0.24) or 85%	0.55 (0.24) or 85%	0.55 (0.24) or 85%	

TABLE 3. EMISSION LIMITS FOR SMALL, MEDIUM, AND LARGE HMIWI (NEW)

§60.54c Siting Requirements

Facilities must conduct an analysis of the impacts of installing a HMIWI and submit the analysis data to the EPA. This analysis must include air pollution control alternatives that minimize potential risks to public health or the environment.

§60.55c Waste Management Plan

Facilities must prepare a waste management plan. The waste management plan will identify the feasibility and approach to separating certain components of the solid waste stream.

§60.56c Compliance and Performance Testing

Facilities must conduct an initial performance test to determine compliance with the emission limits. The testing must include gas composition, particulate matter, opacity, carbon monoxide, dioxin/furan, hydrogen chloride, lead, cadmium, mercury, and fugitive ash. Annual testing must be conducted for opacity, particulate matter, carbon monoxide, and hydrogen chloride. Large HMIWIs must do annual visible emission monitoring of their flyash/bottom ash storage and handling. There are special requirements for HMIWIs that are using continuous emission monitors to demonstrate compliance. Table 4 presents operating parameters to be monitored. Specific parameters to be monitored vary based on the type of equipment being operated (i.e. air pollution control devices).

§60.57c Monitoring Requirements

You must install, calibrate, maintain, and operate devices for monitoring all required parameters and for measuring use of the bypass stack including date, time, and duration. At a minimum, valid monitoring data shall be obtained for 75 percent of the operating hours per day and 90 percent of the operating days per calendar year.

§60.58c Reporting and Record keeping Requirements

You must provide notification prior to commencement of construction and prior to initial start up. In addition, you are required to maintain records for a period of at least 5 years on testing data; monitoring data; waste charging data; operating parameter data; dates when required monitoring data was not obtained; dates, times, durations and descriptions of malfunctions and corrective actions; dates when emission limits were exceeded; siting documentation; operator training/qualification records; equipment calibration data. The facility manager must sign all reports pertaining to the initial performance test, site specific operating parameters, and the waste management plan and submit the reports within 60 days of the initial performance test.

An annual report must be submitted which contains a summary of the records listed above. This report must also be signed by the facility manager. Once the unit is subject to permitting under Title V, these reports must be submitted semi-annually.

TABLE 4. OPERATING PARAMETERS TO BE MONITORED AND MINIMUM MEASUREMENT AND RECORDING FREQUENCIES

	Minimum Frequency		Control System		em	
Operating Parameters To Be	Data	Data	DS+FF	WS	DS+FF+	
Monitored	Measurement	Recording			WS	
Maximum operating parameters						
Maximum charge rate	continuous	1 x hour	Ö	Ö	Ö	
Maximum fabric filter inlet temperature	continuous	1 x minute	Ö		Ö	
Maximum flue gas temperature	continuous	1 x minute		Ö	Ö	
Minimum operating parameters	Minimum operating parameters					
Minimum secondary chamber temperature	continuous	1 x minute	Ö	Ö	Ö	
Minimum dioxin/furan sorbent flow rate	hourly	1 x hour	Ö		Ö	
Minimum HCI sorbent flow rate	hourly	1 x hour	Ö		Ö	
Minimum mercury (Hg) sorbent flow rate	hourly	1 x hour	Ö		Ö	
Minimum pressure drop across the wet scrubber or minimum horsepower or amperage to wet scrubber	continuous	1 x minute		Ö	Ö	
Minimum scrubber liquor flow rate	continuous	1 x minute		Ö	Ö	
Minimum scrubber liquor pH	continuous	1 x minute		Ö	Ö	

DS = Dry Scrubber; FF = Fabric Filter; WS = Wet Scrubber

SUBSEQUENT REGULATORY ACTIVITY

None.

MILITARY SOURCES

Most existing, non-rural, military incinerators will be required to add on air pollution control devices to meet the emission guidelines. Other concerns include:

- The operator training and qualification requirements, inspection, and the performance testing requirements will add to the annual operating costs of incinerators.
- The EPA included a definition of hospital waste in the rule and the rule addresses the incineration of "hospital/medical/infectious waste". This could have an impact on the cost of general refuse (i.e. cafeteria and office waste, etc.) disposal from hospitals.

• Many existing incinerators will not be able to comply with the guidelines, forcing the hospital to find alternative methods of waste disposal.

COMPLIANCE COST

Good Combustion Practices and Emission Control Devices

The following table summarizes the expected capital costs for existing sources to comply with the EG. Given the high capital costs, sources should investigate alternative disposal means.

Incinerator Size	Incinerator Capacity	Control Method	Capital Cost
Small Rural	< 2,000 lb/week (usage)	Good Combustion Practices	\$25K
Small	< 200 lb/hr	Moderate Efficiency Wet Scrubber	\$250K
Medium	200 - 500 lb/hr	Moderate Efficiency Wet Or Dry Scrubber	\$325K
Large	> 500 lb/hr	High Efficiency Wet Or Dry Scrubber	\$475K

Table 5: Capital Cost for Existing Sources to Comply with the EG

Pollution Prevention (P2) Alternatives

For cost and information regarding the latest P2 alternatives refer to the contacts listed in the "P2 Links" section of the HAP Status Binder Web Page for this appendix. Costs for alternatives range from \$200 to \$600K.

Alternatives include:

- Subcontracting Disposal to a Better Controlled Incinerator
- Steam Disinfection (Autoclave)
- Microwave
- Chemical Disinfection
- Electro-thermal Deactivation
- Pyrolysis

CONTACTS

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