U.S.EPA'S FINAL MEDICAL WASTE INCINERATOR REGULATIONS: REQUIREMENTS, IMPACTS, & COMPLIANCE

Presented by

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Regulatory Basis

Clean Air Act Amendments (Act) of 1990

Regulatory Basis

- 40 CFR Part 60
  - Original Title -

    "Standards of Performance for New Stationary Sources and Emissions Guidelines for Existing Sources: Medical Waste Incinerators"
  - New Title -

    "Standards of Performance for New Stationary Sources and Emissions Guidelines for Existing Sources: Hospital/Medical/Infectious Waste Incinerators"

Regulatory Basis

- **Final Rule Action -**

  Promulgates New Source Performance Standards (NSPS) and Emissions Guidelines (EG) by Adding Subpart Ec, Standards of Performance for New HMIWI and Subpart Ce, Emissions Guidelines for Existing HMIWI to 40 CFR 60 (Sections 111 & 129)

Regulatory Basis

- **Ec (NSPS)**
  - Federal Requirements
  - Apply to all New HMIWI built on or after February 27, 1995

- **Ce**
  - Emission Guidelines for States
  - Requires State Implementation Plans
  - For Existing Facilities (before February 27, 1995)

Historical Overview of HMIWI Regulations

- Initial *Deadline* of November 15, 1992
- EPA's *Background Documents* Published September 1991
- Litigation by NRDC & Sierra Club
- Court-Ordered Consent Agreement
  - Propose by February 1995
  - Final by April 15, 1996

Historical Overview of HMIWI Regulations

• *Draft Regulations* issued	June 1994
• Proposed in *Federal Register*	February 27, 1995
• *Supplemental Notice* Published	June 14,1996
• Final Promulgation	July 25, 1997

Regulated Entities

EPA Categories	Examples
• Industry	- Hospitals - Research Laboratories - Other Health Care Facilities - Commercial Disposal Companies
• Federal Government	- Armed Services - Public Health Services - Federal Hospitals - Other Federal Care Facilities
• State/Local Government	- State/County/City - Hospitals & Other Health Care Facilities

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Hospital/Medical/Infectious Waste Incinerator (HMIWI) -

"Any Device that Combusts any Amount of Hospital Waste or Medical/Infectious Waste"

"Medical/Infectious Waste" Definition

"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..."

Inclusive of:

- Cultures and stocks of infectious agents
- Human pathological waste
- Human blood and blood products
- Sharps (used & unused)
- Infected animal waste
- Isolation waste

From MWTA for RMW

"Hospital Waste" Definition

"Discards Generated at a Hospital, Except Unused Items Returned to Manufacturer"

Facilities Exempt From HMIWI Regulations

- Combustors Used Exclusively for
  - Pathological waste, and/or
  - Chemotherapeutic waste and/or
  - Low-level radioactive waste
  - Off-spec of "out-of-date" drugs
  - Human remains
  - Hazardous waste
- Co-Fired Combustors Burning Up to 10% HMIWI
  - Municipal waste combustors (MWC)
  - Cement kilns
  - Boilers
  - Industrial/commercial incinerators
  - Others
- Pyrolysis Units

Exempted Facilities

- All Solid & Pathological Waste Incinerators to be Regulated by 2000
- RCRA & NRC Already Regulates Hazardous, Chemotherapeutic, & LLRW Incinerators
- Pyrolysis Units to be Regulated by 2000 - Likely More Stringent Emission Limits

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Requirements for Exempted Facilities

- Notify EPA Administrator of Claim
- Provide Estimates of Waste Types, Quantities & Percentages to be Combusted
- Keep Records on Quarterly Basis of Types & Quantities of Waste (& Fuel) Combusted

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HMIWI Regulations Applicability

- **"New" MWIs**
  - Those permitted, constructed, modified, or reconstructed on or after February 27, 1995
- **"Existing" MWIs**
  - Those permitted, under construction, and/or operational before February 27, 1995

HMIWI Regulatory Categories

- Emission Limits
- Facility Siting
- Operator Training & Qualifications
- Monitoring
- Compliance & Performance Testing
- Inspections
- Reporting & Recordkeeping

Emission Limits
Requirements of the Act (Section 129)

EPA Must -

- Impose Numerical Standards for New & Guidelines for Existing HMIWIs
- Set Limits for 9 Specific Pollutants
- Use MACT for Setting the Limits

MAXIMUM ACHIEVABLE CONTROL TECHNOLOGY (MACT)

MACT Requirements for New HMIWIs

Limits based on "maximum degree of reduction achievable through the best system of emission reductions" and "which are achievable in practice by the best controlled similar unit"

MACT Requirements For Existing HMIWIs

Limits to be no less stringent than "the average emission limitation achieved by the best performing 12 percent of existing units in the category"

HMIWI Categorization

Categories	Capacities
• Small Rural (Existing	- To 200 lb/hr - Burns less than 2000 lb/wk - More than 50 miles from Standard Metro Area
• Small Capacity	- To 200 lb/hr
• Medium Capacity	- Over 200 lb/hr to 500 lb/hr
• Large Capacity	- Over 500 lb/hr

Maximum Charge Rate For Intermittent & Continuous HMIWIs

- "110% of Lowest 3-Hour Average Charge Rate Measured During Most Recent Performance/Compliance Test"
- Formula Established for Rating Incinerator Capacity:

$$C = Pv \times 15{,}000/8{,}500$$

C = Capacity (lb/hr)
Pv = Primary Chamber Volume (cu-ft)

Emission Limits For Existing Small Rural HMIWIs

Pollutants	Limits
PM	0.086 gr/dscf
CO	40 ppmv
HCl	3100 ppmv
S02	55 ppmv
NOx	250 ppmv
Dioxins	800 ng/dscm Total (35 TEQ)
Pb	10 mg/dscm
Cd	4 mg/dscm
Hg	7.5 mg/dscm

Combust less than 2,000 lb/wk & more than 50 miles from border of nearest Standard Metro Statistical Area

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Emission Limits for *Existing* HMIWIs

Size Categories	Emission Limits PM gr/dscf	CO ppmv	HCl ppmv	NOx ppmv	SO2 ppmv
• Small	0.05	40	100 (93%)	250	55
• Medium	0.03	40	100 (93%)	250	55
• Large	0.015	40	100 (93%)	250	55

Corrected to 7% oxygen

Emission Limits For *Existing* HMIWIs (Continued)

Size Categories	Emission Limits: Dioxins ng/dscm	Pd mg/dscm	Cd mg/dscm	Hg mg/dscm
• Small	125 Total (2.3 TEQ)	1.2	0.16	0.55
• Medium	125 Total (2.3 TEQ)	1.2	0.16	0.55
• Large	125 Total (2.3 TEQ)	1.2	0.16	0.55

Connected to 7% oxygen

Emission Limits for *New* HMIWIs

Size Categories	Emissions Limits: PM gr/dscf	CO ppmv	HCl ppmv	NOx ppmv	SO2 ppmv
• Small	0.03	40	15 (99%)	250	55
• Medium	0.015	40	15 (99%)	250	55
• Large	0.015	40	15 (99%)	250	55

Corrected to 7% oxygen

Emission Limits For *New* HMIWIs (Continued)

Size Categories	Emission Limits: Dioxins ng/dscm	Pd mg/dscm	Cd mg/dscm	Hg mg/dscm
• Small	125 Total (2.3 TEQ)	1.2	0.16	0.55
• Medium	25 Total (0.6 TEQ)	0.07	0.04	0.55
• Large	125 Total (0.6 TEQ)	0.07	0.04	0.55

Corrected to 7% oxygen

Optional Emission Limits for All HMIWIs Built Between February 27, 1995, & Final

Pollutants	Limits
PM	0.013 gr/dscf
CO	50 ppmv
HCl	42 ppmv (97%)
SO2	45 ppmv
NOx	210 ppmv
Dioxins	80 ng/dscm Total (1.9 TEQ)
Pb	0.10 mg/dscm
Cd	0.05 ng/dscm
Hg	0.47 ng/dscm

Other Emission Limits

- Fugitive Emissions (Ash Handling)
  - Large HMIWIs
  - Maximum 5% visible (opacity)
- Stack Opacity
  - All HMIWIs
  - Maximum 10%
- Excludes
  - Emissions inside buildings/enclosures
  - Periods of M&R to ash conveyors (10 days/yr maximum)

Emission Limits

Apply at all times except during periods of startup, shutdown, or malfunction provided no HMI waste is charged during such conditions

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Siting Requirements

- Owner or Operator of Proposed Facility Must Prepare Analyses of Potential Facility Impacts
- Analyses to Consider
  - Air pollution control alternatives
  - Potential risks to public health & environment

"Waste Reduction Plan"

- Required for New and Existing Facilities
- "Plan" Must -
  - Consider feasibilities & approach of increased segregation to reduce waste incinerated
  - Consider feasibilities of product substitutions
  - Consider feasibilities of separating various items & components for recycling
  - Consider different target goals in context of waste program

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Compliance & Performance Testing

- Initial Compliance Tests Required for all Regulated Pollutants
- Annual Performance Tests for PM, CO, HCl, and Opacity
  - "Small rural facilities" require annual opacity testing only
- Test PM, CO, HCl Every Third Year if First Three (3) Show Compliance
- Annual Fugitive Emissions (Fly Ash/Bottom Ash) Testing for Large HMIWIs Only
- Testing Per EPA-Approved Reference Methods

Monitoring Requirements

- Install & Maintain Equipment & Devices to Continuously Monitor & Record All Key Operating Parameters at All Times During Operation Per Minimum Frequency Schedule
- Valid Data Required for 75% of Operating Hours & 90% of Operating Days Per Quarter

Minimum Monitoring Requirements

- Charge Rate
- Secondary Chamber Temperature
- Flue Gas Temperature (After APC Device)
- Sorbent Flow Rates
  - Caustic
  - Lime
  - Activated carbon
- Scrubber System
  - pH
  - Liquor flow rate
  - Pressure drops
- Time & Duration of APC Bypass

Operator Training & Qualifications

- Trained & Qualified Operator Must Be Accessible At All Times During Operation
  - Either at facility or
  - Available within 1 hour

Operator Training & Qualifications

- Must be Trained & Qualified By Completing State-Approved HMIWI Course
- Minimum Course/Programming Requirements
  - 24-hour classroom training
  - Reference material/manuals of course topics
  - Examination designed/administered by instructor

Operator Training & Qualifications

- Training Course Curricula

  - Environmental concerns & impacts
  - Combustion principles
  - Operations of incinerator type to be used
  - Combustion controls & monitoring
  - Operations of APC equipment
  - CEMS
  - Inspections & maintenance
  - Malfunction responses
  - Ash handling
  - Work safety practices
  - Applicable regulations
  - Recordkeeping requirements

Operator Training & Qualifications

- Qualification Requirements

  - Complete training course
  - Pass examination
  - 6 month experience as operator or as supervisor or complete 2 burn cycles under observation of 2 qualified operators

- Qualification Valid From date of Passing Examination or Completion of Experience - Whichever Later

Operator Training & Qualifications

- Maintaining Qualification Status
  - Completion & passing of annual 4-hour refresher course:
    - -- Regulatory updates
    - -- O&M procedures
    - -- Inspection & maintenance requirements
    - -- Malfunction responses
- Facility Owner To Document successful completion of all qualification requirements
  - Establish program to review qualification essentials

Facility Inspections

- Initial & Annual Inspections Required
- Condition of All Components, Devices, Appurtenances, & Accessories
- Operations & Performance of System & Equipment
- Make All Necessary Repairs & Adjustments Within 10 Days Unless Approved State Compliance Schedule

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Reporting & Recordkeeping

- Submit Site Analyses Reports, Waste Reduction Plan, Initial & Annual Test Reports, & Records of Malfunctions to Agency
- Submit Operator Training & Qualification Data & Documents to Agency
- Submit Construction Schedule & Engineering/Design Data (for New Facilities)
- Submit Reports of Emissions or Parameters that Exceed Limits
- Maintain All Operating Data & Records, Test Reports, Inspection Reports, Etc. for 5 Years

Compliance Timing
State Implementation Plans (SIPS)

- To be Submitted to EPA within 1 Year of *Guidelines* Adoption (*Federal Register*)
- Must be at Least as Protective as *Guidelines*
- EPA Must Approve/Disapprove Within 6 Months
- If No Approval Within 2 Years - Federal Plans Automatically Adopted
- SIP Approvals/Disapprovals Published in *Federal Register*
- Public Hearings Involved

Compliance Timing

- Existing Facilities
  - Full compliance within one year of EPA's approval of State Plan
  - Up to 3 years if negotiated/approved compliance schedule
- New Facilities
  - Effective 6 months after promulgation
  - Full compliance at initial start-up

Recommendations

- Assess Current Waste Management Programs
- Evaluate Alternatives
  - Upgrade & retrofit
  - Replace
  - Alternative technology
  - Off-site disposal
- Plan & Budget *Now* for Compliance

ENVIRONMENTAL CONSIDERATIONS

FACTOID -

MWIs ARE THE LARGEST SOURCE OF DIOXINS IN THE ENVIRONMENT

FACT -

MWIs ARE AN INSIGNIFICANT SOURCE OF DIOXINS IN THE ENVIRONMENT

Sources of Dioxins In The Environment

• Natural Sources (forest & brush fires, etc.)	62.4%
• Motor Vehicles	20.5%
• Manufacturing & Industrial	10.9%
• Electricity Generation	2.0%
• Residential Wood Burning	1.3%
• Municipal Incinerators	2.6%
• Medical Waste Incinerators	<1%

1994 Report Ohio Health Dept.

FACTOID -

ELIMINATING PVC PLASTICS FROM MWIs WOULD GREATLY REDUCE (ELIMINATE) DIOXIN EMISSIONS

FACT -

1900 INCINERATOR EMISSIONS TESTS SHOW NO RELATIONSHIP BETWEEN PVC IN WASTE STREAMS TO DIOXIN EMISSIONS

FACTOID -

DIOXINS ARE THE DEADLIEST SUBSTANCE KNOWN TO MAN

FACT -

DIOXINS ARE THE DEADLIEST SUBSTANCE KNOWN TO GUINEA PIGS

FACTOID -

DIOXINS FROM MWIs HAVE BEEN FOUND TO BE ENDANGERING OR SEVERELY THREATENING THE PUBLIC HEALTH

FACT -

EPA DOCUMENTS, THE SAB, THE AHA, MOST SCIENTISTS, & EPIDEMIOLOGISTS, AND LARGE-SCALE EXPOSURE STUDIES HAVE CONCLUDED THAT DIOXINS HAVE NOT BEEN SHOWN TO BE A SIGNIFICANT PUBLIC HEALTH RISK

Findings of EPA's *MWI* Background "Documents for Proposed Standards & Guidelines:

> "Maximum environmental impact for all pollutants of concern are ..less than 15% of established health or welfare effect levels .. even without add-on controls"

Comparative Risks

Lifetime Exposures (70 Yrs)	Risks/Million
• Normal Risk (lower)	250,000
• Eating One Peanut Butter Sandwich/Month @ 15 Yrs	250
• One Diagnostic X-Ray	20
• Drinking & Showering In Chlorinated Water	2.4
• Smoking One Cigarette	1.4
• Worst-Case Incinerator Emissions	0.01 to 1

FACTOID -

SHUTTING DOWN MWIs WOULD ELIMINATE DIOXIN EMISSIONS & OTHER POLLUTANTS WHICH IMPACT THE ENVIRONMENT & PUBLIC HEALTH

FACT -

ALTERNATIVES TO MWIs, INCLUDING OFF-SITE TRANSPORT & LANDFILLING, HAVE BEEN FOUND TO HAVE EQUAL OR GREATER DIOXIN & POLLUTANT EMISSION RATES WITH POTENTIALLY GREATER RISKS TO THE ENVIRONMENT & PUBLIC HEALTH

FACTOID -

SHUTTING DOWN ALL MWIs WOULD ONLY COST HOSPITALS "PENNIES PER DAY" EXTRA

FACT -

SHUTTING DOWN ALL MWIs WOULD COST THE NATION'S HOSPITALS WELL OVER $2 BILLION PER YEAR - EQUIVALENT TO ABOUT 1/2 BILLION PATIENT-CARE DAYS PER YEAR

"[It has been reported] that pickles cause cancer, communism, airline tragedies, auto accidents and crime waves. About 99.9% of cancer victims had eaten pickles some time in their lives... So have 100% of all soldiers, 96.8% of Communist sympathizers and 99.7% of those involved in car and air accidents. Moreover, those born in 1839 who ate pickles have suffered 100% mortality rate and rats force-fed 20 pounds of pickles a day for a month ended up with bulging abdomens and loss of appetite."

- Barry Siegel, "World May End with a Splash," Los Angeles Times, 9 October 1982.