

DEC 18 1990

MEMORANDUM FOR: Robert M. Bernero, Director
Office of Nuclear Material Safety
and Safeguards, NMSS

FROM: Richard L. Bangart, Director
Division of Low-Level Waste Management
and Decommissioning, NMSS

SUBJECT: SUMMARY OF THE U.S. ENVIRONMENTAL PROTECTION AGENCY (EPA)
MEDICAL WASTE WORKSHOP

Enclosed for your information, is a summary describing the EPA Medical Waste Workshop, held on November 6 and 7, 1990, in Washington D.C.

The goal of the workshop was to exchange information and experiences on the regulation of medical waste. The workshop was organized to focus on individual State experiences and EPA's research and analysis relative to the Medical Waste Tracking Act. The workshop was attended by 57 participants, including representatives from EPA, Department of Transportation, Department of Interior, Nuclear Regulatory Commission (NRC), Department of Labor-Occupational Safety and Health Administration, Department of Health and Human Services-Agency for Toxic Substances and Disease Registry, seventeen states and two foreign countries (Canada and Spain). The topics discussed included: an overview of EPA medical waste activities; status of air emission regulation development; medical waste field testing studies; medical waste characterization; alternative waste treatment technology assessment; landfill requirements/regulations; public health implications of medical waste; status of federal workplace regulations relative to medical waste management; and an overview from each state representative of medical waste activities in their state.

Questions and issues regarding the management of radioactive medical waste included: incineration of radioactive materials; treatment of radioactive medical waste; decay-in-storage; beta regulatory concern (BRC) waste; and medical waste containing radioactive materials being sent to medical waste incinerators and landfills. Radioactive medical waste management was suggested for inclusion in the next workshop, which is tentatively scheduled for May 1991. Other topics for inclusion in the next workshop are: educational material; waste minimization and segregation; cytotoxic compound management strategies and air regulations for treatment technologies. EPA requested that NRC provide a speaker at the next workshop to discuss radioactive medical waste management.

If you have any comments or questions please contact Samuel Z. Jones, of my staff, at X-20554 or me at X-23340.

Richard L. Bangart, Director
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and Decommissioning, NMSS

Enclosure: As stated

Distribution: Central File#
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PDR YES NO Category: Proprietary or CF Only
ACNW YES NO

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SUMMARY

U. S. EPA Medical Waste Workshop

Held at
Omni Shoreham
Washington DC

November 6 and 7, 1990

Sponsored by
EPA Office of Solid Waste
EPA Risk Reduction Engineering Research Laboratory
California Air Resources Board

Summary Prepared by
Energy and Environmental Research Corporation
18 Mason
Irvine, CA 92718

U.S. EPA Medical Waste Workshops
Omni Shoreham, 2500 Caivert St., NW
Washington, D.C. 20008
November 6 and 7, 1990

November 6, 1990

- 8:30-8:40 Opening Remarks-Elizabeth Lapointe-Deputy Division Director-EPA-OSW
8:40-8:45 Explanation of Workshop Format-C.C. Lee-EPA-ORD/RREL

I. Lecture Session-Moderator - Michaelle Wilson-EPA-OSW

Individual presentations by the following groups:

- 8:45-9:15 Overview of EPA Medical Waste Activities-Mary Greene-EPA-OSW
9:15-9:45 Status of air emission regulation development-Ken Durkee-OAQPS
9:45-10:30 Medical waste field testing studies
 1.US EPA/State of Michigan field test- Glen England-EER
 2.Other OSW/OAQPS field testing-Ken Durkee-OAQPS
10:30-11:00 Break
11:00-11:30 Medical waste characterization-Randy Seeker-EER
11:30-12:00 Alternative waste treatment technology assessment-Eugene Cole-RTI
12:00-1:30 Lunch
1:30-2:00 The Public Health Implications of Medical Waste-Sven E. Rodenbeck, P.E.-
 ATSDR
2:00-2:30 Status of federal workplace regulations relative to medical waste management-
 Kevin Landkrohn-OSHA
2:30-3:00 Break

II. State and Provincial Activities in Medical Waste-Moderator-Mary Greene-EPA-OSW

- 3:00-3:15 Opening Remarks
3:15-5:00 Representatives from each state will be provided a 10-15 minute time slot and an
 opportunity to discuss regulations and other activities pertaining to medical waste.
5:00 Adjourn

November 7

State and Provincial Activities in Medical Waste (continued)

Moderator-Mary Greene-EPA-OSW

- 8:30-8:45 Opening Remarks
- 8:45-10:30 Same format as previous afternoon
- 10:30-11:00 Break
- 11:00-12:00 Format continued

November 7

III. Open Session / Discussion on Medical Waste Issues-Moderator -C.C. Lee-ORD/RREL

- 1:00-1:15 Opening Remarks
- 1:15-1:35 Sterilization and Alternate Treatment Technologies-Terry Pierson-RTI
Issues: How effective are they and should they be encouraged, discouraged, or should the regulations remain neutral?
- 1:35-1:55 Incineration-Steve Lanier- EER
Issues: How does the state regulatory position impact an on-site vs. regional siting? How does incineration influence source separation and onsite management of medical waste? Should certification of incinerator operators be a regulatory requirement? How tightly should CO, PM, HCl, NO_x, CDD/CDF, ... be regulated?
- 1:55-2:25 Presentations by visiting international environmental agencies-
Alvero Feliu- Institut Cerdà-Spain
Marcel Gaucher- Environmental Ministry of Quebec-Canada
- 2:25-2:55 Landfill Requirement/ Regulations- C.C. Lee-EPA- ORD/RREL
Issues: When should medical waste be landfilled? What ash characteristics should be required? What are the technical requirements for landfill construction?
- 2:55-3:15 Break
- 3:15-3:45 National Medical Waste Tracking- Michaelle Wilson- EPA-OSW
Issues: Should the tracking act go national? What lessons have we learned? Does this new knowledge really matter?
- 3:45-4:15 Enforcement Issues-Lisa Warner-OWPE

IV. Conclusion/Summary--Moderator-Randy Seeker-EER

- 4:15-5:00 A summary of the issues raised during the workshop will be presented. Group participation is encouraged.
- 5:00 Adjourn

1. Introduction

On November 6 and 7, 1990 a workshop was held at the Omni Shoreham in Washington DC. This workshop was a fourth in a series of workshops on medical waste sponsored by the EPA and the California Air Resources Board. The goal of these workshop was to exchange information and experience on regulating medical waste. This workshop was organized to focus on individual State experience and EPA's ongoing research and analysis relative to the Medical Waste Tracking Act. It was attended by 57 participants involved in either research or development and implementation of medical waste management regulations. The invitation list focussed on representatives from state government agencies who are responsible for medical waste regulations in each state. Seventeen different states were represented along with two foreign countries (Canada and Spain) and representatives from EPA regional offices, Office of Research, Office of Solid Waste, and Office of Air Quality and Planning Standards, the DOT, the Department of Interior, NRC, OSHA, and ATSDR. A complete list of attendees is included in Appendix 1.

In Figure 1 is shown the final agenda for the workshop. It consisted of four major sessions: Federal Activities, State Activities, Discussion Sessions, and Conclusions/summary. Several of the presenters provided handouts relevant to their presentations and these are included in Appendix 2 in the order they were presented. The goal of this document is to provide a complete set of this information to the workshop participants as well as provide a summary of the major conclusions of the workshop.

2. Summary of Workshop

2.1 State Activities

Representatives from each State, provided a verbal overview of the activities within the state on development and implementation of Medical Waste Management regulations. These presentations provided a broad overview of the range of regulatory activities in the participating States. The major components of most of the State regulations are a definition of regulated medical waste, regulated medical waste manifesting and/or tracking, some form of small quantity generator exclusion, transporter/hauler registration, treatment technologies approval, and fee collection. A summary of the different approaches used by different States represented at the workshop are provided in Table 1. This table also includes some information concerning the number of regulated generators and treatment facilities within the State and the responsible department. For further information, the workshop participant can be contacted at the provided number.

2.2 Developing a Base Knowledge of Medical Waste

Significant progress has been made in the last two years since this workshop series was initiated in developing an adequate knowledge base for making regulatory decisions. This progress has been made in three general areas: clarifying the definition of the characteristics of medical waste, clarifying the definition of the level of protection provided by traditional management practices, and evaluating the performance of conventional medical waste treatment technologies.

In the last year, significant new information has become available on the characteristics of medical waste. The EPA Office of Solid Waste (OSW) has recently sponsored a project to characterize medical waste at seven different medical institutions including hospitals, laboratories, and clinics. These three categories have been found to be responsible for over 95 % of the waste generated in States participating in the Medical Waste Tracking pilot program. A comprehensive data base has been developed in this study that provides the waste component type, the type of

TABLE I. SUMMARY OF STATE ACTIVITIES IN MEDICAL WASTE REGULATIONS

State	Contact Person	Department	Definition of Medical Waste	Small Quantities General Exclusion	Manifesting	Transport Registration	Approved Treatment
New Jersey	Robert Confer	New Jersey Department of Environmental Protection	Same as MWTA	None	Yes	Yes	Landfill of treated wastes
Michigan	Larry Chalzynski	Michigan Department of Public Health State Health Dept.	Five Categories	None	No - however, cradle to grave responsibility	No - however, proper containers must be used	Steam autoclave, incineration, and grinding
Ohio	Phil Farnlacher	U.S. EPA - Ohio	EPA Regulations	No registration for < 50 lbs/mo.	Yes	Yes - 110 are currently registered	Steam autoclave and incineration
California	John Winn	California Department of Health Services	EPA Regulations	No registration for < 200 lbs/mo.	Yes	Yes - however, there is small quant. generator exclusion	Steam autoclave, incineration, microwave
Texas	Patricia Garland	Texas Department of Health	Special Waste from health care facilities limited to 5 categories > 100 ml fluid	None	Record keeping	Storage must be permitted. Transporter bill	Landfilled separately if untreated. Pathogens incinerated. Sharps encapsulated. W/P = 40 psi. Treated waste land-filled with MSW Incineration Air Regulations.
Alabama	Lindsay Mothershed	Alabama Department of Environmental Management	EPA Definition	None - with the exception of home health care	Plan required, record keeping, no tracking	Yes - transp. permit - can transport small quantities - notification of spills - storage also included	Incineration, autoclaving and landfilling of treated waste
Louisiana	James Brent	Louisiana Department of Environmental Quality/Department of Environmental Health	Potentially infectious biomedical waste. Similar to MWTA definition.	None	None	Some transp. and packaging registration	Landfilling treated waste: - moratorium on incinerators - incinerator regulations under development
Florida	Tom Moore	Florida Department of Environmental Regulations	Biohazardous Waste	None	None	None	Landfilling treated waste. Due to new air regulations, 338 on-site incinerators will shut down

TABLE 1 (CONTD). SUMMARY OF STATE ACTIVITIES IN MEDICAL WASTE REGULATIONS.

State	Contact Person	Department	Definition of Medical Waste	Small Quantities General Exclusion	Manifesting	Transport Registration	Approved Treatment
New York	David Mafri Richard Torrey	NY State Dept. of Environ. Conservation/ State Health Dept.	MWTA	None - however, < 50 lbs/mo. can transport	MWTA	Permitted annual report	Landfilling of treated waste, incineration, other approved treatments
Virginia	Bob Wickline	Virginia Department of Waste Management	Infectious waste defined in state law	None	None	Registration but not licensing, standards for transp. and storage	Incineration/steam sterilization (w/ permit stds.). Approved sewer systems.
Rhode Island	Roger Greene	Rhode Island Dept. of Environmental Management	MWTA	Yes	MWTA	Must be permitted (\$100 fee), emergency response required, storage and backhandling required.	Autoclaving
West Virginia	Joe Schock	Dept. of Health & Human Serv./Air Poll. Control Comm./Highway Dept./Dept. of Nat. Resources	No reg. at this time	Possibly	None	None	None
Iowa	Pete Hamlin	Iowa Department of Natural Resources	-----	-----	-----	-----	Autoclaving Permitted incineration
Illinois	Larry Eastep	U.S. EPA Region V	Hospital Haz Waste (non-RCRA Haz Waste)	Hospital only?	Yes, as special waste	License	Landfilling treatment waste, incinerator, autoclave?
Oklahoma	Harriet Muzljakovich	Oklahoma State Department of Health	-----	NA	No	Will be addressed	Incineration
Maine	Scott Austin	Maine Department of Environmental Protection	-----	Yes, < 50 lbs/mo. exempt from mgmt. plan but must register, household exempt for packaging	Yes, incinerators must register (4-part manifest, 3-5 day turnaround)	Transfer license (5 yr - \$100 fee)	On-site incineration. License by rule.
Minnesota	Sheila Brunelle Anne Jackson Lauri Mezner	Minnesota Dept. of Health/Minnesota Poll. Control Agency	EPA definition with exception of isolation wastes		Management plan required	Required mgmt. plan - generators exempt. Off-site transp. regulated	Incineration Autoclaving

construction material of each component, and the generation rate of regulated medical waste at the department level of each of the medical institutions. These data have been analyzed to define opportunities for waste minimization, treatability characteristics of medical waste, and national generation rates of medical waste. In another OSW study, floatable materials found in harbors have been analyzed and the likely sources have been identified to be from diabetic insulin and illegal intravenous drug use. Finally, the State of Minnesota has conducted a detailed study in which medical waste was characterized at three small hospitals by opening and surveying their contents. These recently completed studies present a much clearer picture of the important characteristics of medical waste that have never before been available.

Studies have recently been completed that will provide comprehensive environmental characterizations of different types of incineration systems. These include studies conducted by OAQPS with the State of Michigan on large modern hospital incinerators, studies conducted by OSW and OAQPS on smaller older design units, and studies conducted by several states such as California, New York and Minnesota on a variety of incinerator types. Multimedia emissions data and control efficiency for a full range of pollutants such as metals, total particulate matter, chlorinated dioxin and related compounds, other trace organics, pathogens, and acid gases will soon be available for this full suite of incineration technologies. Further information is still required on the impact of combustion parameters on emissions. In other related studies, ORD and the State of California have conducted assessments on the current state of the art in medical waste incinerator technologies and developed guidelines on retrofitting existing incinerators to upgrade them to meet new stringent air standards.

For other treatment technologies specifically steam sterilization and chemical disinfection, OSW is sponsoring studies at both laboratory and full scales, on the level of sterilization achieved as a function of operation conditions. These studies will provide much needed information on the efficacy of these technologies but there was a general indication of interest at the workshop for more information on multimedia emissions from these technologies.

Studies have been conducted on assessing the adequacy of traditional medical waste management practice in protecting human health. In an exhaustive study conducted by the ATSDR, it was concluded there was little evidence of disease transmission from medical waste. The EPA is sponsoring continuing studies to assess the potential health impacts of various aspects of medical waste management.

2.3 The Medical Waste Disposal "Crunch"

A major concern raised by a large majority of the State representatives was the disappearance of many of the traditional disposal methods for medical waste. This lack of disposal options could result in a severe shortage in capacity for medical waste disposal in the future. This disposal "crunch" is being caused by a number of factors. Specifically, the use of landfills is becoming less of a disposal option due to pretreatment requirements dictated by most states, and the landfill operators refusal to accept recognizable medical waste. Several participants at the workshop indicated that there was no scientific evidence to suggest that landfilling untreated medical waste posed an unacceptable risk.

In addition to the loss of the landfill option, many existing on-site incinerators will likely shut down due to the high cost of retrofitting to meet new, more stringent air regulations being promulgated by several States. For example, the State of New York has indicated that none of 374 onsite incinerators in the State can currently meet the proposed air standards for medical waste incinerators. The State authorities expect many of the facilities won't upgrade and will likely shut down. A similar conclusion has been made by authorities in California after a stringent air toxic regulation was promulgated. Thus, existing on-site incineration systems will likely be phased out and there may be a significant gap in time before retrofits or new systems can be completed. Since

performance standards and approval protocol for alternative treatment technologies are not available, no significant new technology capacity can be developed rapidly.

This disposal crunch is resulting in a number of changes in traditional medical waste disposal. These include the transport of significant quantities of medical waste out of the generating States to those States with larger commercial disposal capacity. For example, over 50% of the waste generated in States participating the medical waste tracking act is currently exported out of State. There is also a significant increase in the steam sterilization systems. A significant push is on to develop commercial disposal facilities. This push is being offset by the prohibitive siting problems. Finally, new unproven technologies are being championed by numerous entrepreneur organizations for approval as acceptable medical waste disposal systems.

2.4 National Medical Waste Tracking

The participants were unanimous in their support for a national program in medical waste tracking. The advantages of a national program were identified as providing an universal definition of regulated medical waste, providing standardized regulations and manifesting procedures, and allowing tracking across State lines. While the large number of enforcement activities carried out to date in the pilot demonstration might suggest some administrative difficulties of components of the regulations, the participants generally indicated agreement with the structure of the program. In fact, several States have copied the program structure. Nonetheless, there was some suggestions that the EPA should also consider alternative approaches such as a management plan structure similar to that developed by Minnesota.

2.5 Education

A major reoccurring theme of the workshop was the critical importance of education in the overall process of regulating medical waste. Education at every level was required including within the responsible regulatory departments, to regulated industry, to institutional administrators, to health care workers who ultimately must decide what is regulated medical waste and appropriately segregate it, to household users of medical components who must know how to properly dispose of the components, and finally to the public. The key educational topics suggested are as follows:

- Medical Waste Definitions
- Tracking and Manifest Procedures
- Packaging of Sharps
- Liabilities of Generators for Mismanagement of Medical Waste
- Operator Training on Treatment Technologies
- Inspection Procedures

The States and EPA are using an impressive array of educational procedures that they are attempting to tailor to the specific audience. Several of these were discussed in the workshop and included techniques such as videos, training sessions, information booklets, cartoons, inspection/warning activities, and a clearing house for information.

2.6 Future Needs

The participants proposed several areas that need further support and development. One of the areas that received considerable support was the need to develop procedures to approve new treatment technologies for medical waste. Because of the disposal crunch facing many areas of the country, there is a need to approve alternative treatment technologies. An approval protocol is necessary to ensure adequate consideration of the performance issues of the new technology. This approval protocol requires the development of a criteria for disinfection and sterilization. In order

to approve these technologies, multi-media performance data are required on a range of waste types to determine not only the efficacy but any other adverse health effects and the suitable waste stream components that can be treated. Only with this kind of information can the appropriate use of the treatment technology be defined. Both the States and EPA indicated such testing is likely beyond their current resources.

The participants totally supported the development of an operator certification and training program for incinerator systems. Such a certification system is under development by the American Society of Mechanical Engineers. The participants also suggested that similar certification programs are necessary for other treatment technologies. The level of training required will depend upon the complexity of the operation of the treatment process.

The participants discussed the need to develop capacity assurance. With the disposal crunch likely to become more severe as new regulations are phased in, individual States and regions must plan for disposal capacity needs. This plan will help to direct regulatory and management activity for the region in order to avoid illegal disposal activities.

There was a call for more activity on management and regulatory strategies for all types of mixed wastes. Specifically medical waste, radioactive wastes and hazardous waste can be mixed in literally any combination. More information is necessary to develop more appropriate strategies for these mixtures.

The final future activity that was of significant interest to the workshop participants was the need for significantly more information exchange. The participants recognized the rapid increase of the knowledge base due to EPA research activities but were concerned that they would not have access to data quickly enough for their regulatory development activities. They indicated that they need the information now and cannot wait for the results to appear in the Reports to Congress. The participants were unanimous in their support for future workshops as one vehicle for the information exchange. The consensus was that another workshop should be held within the next six months that could be either in Washington or at another major airport hub. There was a suggestion to hold the meeting near a weekend to allow the use of weekend rates. Several additional subjects were suggested for inclusion in the next workshop:

- Educational material
- Radioactive Waste
- Cytotoxic Compound management strategies
- Waste Minimization and Segregation
- Air Regulations for Treatment Technologies

A few logistical improvements were suggested including better presentation time management, presenting the State activities up front, and a reception on the first night to introduce the participants.