



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
SOLID WASTE AND EMERGENCY RESPONSE

**MEDICAL WASTE MANAGEMENT STRATEGY**

August 31, 1988

The EPA's Office of Solid Waste (OSW) plans to carry out the following tasks over the next several months:

- o Collect and evaluate information on medical waste generation and management, the environmental hazards of existing management practices, and State programs now in place to control infectious waste;
- o Determine what national regulations or guidance are necessary, e.g., tracking systems, packaging, etc.; and
- o Provide educational materials for the public to explain applicable national requirements or guidance, and to generally promote good management practices.

In the course of conducting these analyses, OSW will closely coordinate its program with those activities and studies being conducted in other EPA offices, such as the hospital waste combustion study being conducted by EPA's Office of Air Quality Planning and Standards, and the ocean disposal studies being conducted by EPA's Office of Marine and Estuary Protection. Also, OSW will consult with experts in health care and waste management, with environmental groups, and with State and local authorities, to obtain a broad spectrum of views on proper management of medical waste.

The objectives, short- and long-term goals, and end products of each task are detailed in the attached workplan.



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**OSW MEDICAL WASTE PROGRAM PLAN**

**AUGUST 31, 1988**

The following 8-point strategy includes the basic elements of OSW's infectious waste program:

1. Define Medical Waste.
2. Evaluate State and Municipal Programs.
3. Collect and Evaluate Information.
4. Evaluate Management Methods and Enforcement Activities.
5. Assess Need for A National Tracking/Reporting System.
6. Conduct An Environmental/Economic Assessment.
7. Conduct A Regulatory and Non-Regulatory Options Analysis.
8. Provide Education, Information Exchange, and Public Outreach.

The objectives, short- and long-term goals, and end products of each activity are detailed in the attached outline.

## 1. DEFINITION OF MEDICAL WASTE

Objective: To identify those medical wastes including those which are potentially infectious that require special handling, storage, treatment, and disposal. Variations in the definition of infectious waste result in inconsistent treatment, storage and disposal practices which, in turn, can affect waste management costs, worker safety practices, and environmental releases.

### Short-term

#### Activities:

- o Review the existing and accepted definitions of infectious waste used by EPA, CDC, JCAH, and state and municipal authorities.
- o Analyze the public comments received in response to the Federal Register notice (June 2, 1988) to identify alternative definitions of medical waste to those used by EPA and CDC. Compare these alternative definitions to existing ones.
- \* o Evaluate the implications of establishing medical waste definitions based on characteristic, type and/or source. Draw up pros and cons for each, including the impact of these definitions on the quantities of waste subject to existing and proposed treatment, storage and disposal practices.
- o Draft a "new" definition of medical waste. Send it to a selected audience of trade and medical association representatives, the scientific community, environmentalists, and public officials (e.g., Federal, state, city and county public health and/or environmental departments) for review.
- o Consolidate solicited comments and incorporate them into final draft definition. Evaluate this definition against criteria such as ease of comprehension, feasibility, enforceability, etc.
- \* o Re-convene EPA staff and Panel of Experts to review the final definition.

### End Products

- o Options paper on alternative definitions.
- o Convene Panel of Experts (11/15/88).
- o Federal Register notice, conveying new EPA definition of infectious waste (12/15/88).

## 2. EVALUATE STATE AND MUNICIPAL PROGRAMS

**Objective:** To evaluate the effectiveness of existing state programs in controlling the infectious waste problem, and, in particular, to identify those components of state programs that are successful versus those that are not so successful.

**Short term**

**Activities:**

- o Review existing state infectious waste programs, including:

- Definition of infectious waste/universe of generators.
- State regulatory authority.
- Treatment and disposal requirements.
- Tracking/Recordkeeping requirements.
- Permitting.
- Exclusions/Exemptions.
- Enforcement.
- Training requirements.

(A draft of this report has been prepared that identifies those states that have infectious waste programs, gaps in existing data, and a means of obtaining data to evaluate these programs.)

- o Obtain and review all state and major municipal regulations. (This effort is underway).
- o Identify criteria for evaluating the effectiveness of state infectious waste programs (e.g., containment achieved, extent of public exposure, extent of environmental release, extent of economic loss).
- \* o Evaluate effectiveness and successful elements of state programs.
- o Perform site-visits to states with active programs (e.g., we are aware of six states that currently have tracking and enforcement components) to evaluate administrative, tracking and enforcement activities. (Two site visits, to Massachusetts and Pennsylvania, have already been made.)
- o Meet with relevant trade associations (NGA, CSG, ASTSWMO) to discuss results of preliminary research and site visits and obtain additional information.
- o Develop guidance for a model state program.
- o Evaluate effectiveness of existing state programs against the model state program guidance, and refine the guidance.

### 3. PROVIDE EDUCATION, INFORMATION EXCHANGE, PUBLIC OUTREACH

Objective: To ensure that the general public and interest groups are provided with the information necessary to understand the nature of this problem and kept fully informed of all program developments, including program implementation requirements. To provide educational information for the affected industry and regulators.

#### Short Term

##### Activities:

- o Develop public outreach materials (e.g., brochures, fact sheets, press releases) to address public concerns and information needs and to demonstrate EPA's commitment to the program. Target audiences are expected to include the general public, health care institutions and providers, trade associations, waste management firms, and environmental interest groups. (Several brochures are presently being developed)
- o Work with trade associations (e.g., hospitals, physicians, waste handlers) to promote sound practices and to identify appropriate recipients for outreach materials.
- o Revise and publish guidance materials on infectious waste management.
- o Prepare and publish a special issue EPA Journal devoted to infectious waste management issues.
- o Develop public outreach plan to define: information needs, audiences, product format, and distribution channels. Consider appropriateness of materials such as videos, newsletters, and electronic bulletin boards.

##### End Products:

- o Target audiences and publish series of public outreach, guidance, and educational materials (Continuing through FY 89).
- o Consider an EPA Journal issue devoted to infectious waste (FY 89).
- o Public outreach program plan (Spring 1989).

#### Long Term

##### Activities:

- o Continue public outreach activities through the duration of project.



- o Identify regulatory options based on: effectiveness; legal authority; consistency with existing regulations, programs, or policies; ease of implementation; enforceability; cost; time constraints; and data availability. Options could include:
  - Regulation under various statutes;
  - Regulation at the state level (e.g., treatment standards, financial responsibility);
  - Seek new statutory authority for infectious waste;
  - Use of guidance.
- o Analyze regulatory impacts by quantifying, where practical, the reduction in public health and environmental risks and economic impacts. Analyze regulatory option feasibility in terms of implementation, compliance monitoring, enforcement, and significance to other regulatory efforts.
- o Select regulatory options and conduct regulatory impact analysis (including economic impact analysis and regulatory flexibility analysis).
- o Prepare regulatory dockets (e.g., background documents), draft proposed rules, and guidance manuals.

#### End Products:

- o Complete set of regulatory support materials. (Uncertain; dependent upon data gathering efforts of OAR, CAA, and OSW, and other Federal and State agencies.)

## 7. CONDUCT REGULATORY OPTIONS AND NON-REGULATORY OPTIONS ANALYSIS

**Objective:** To identify options for managing and tracking infectious wastes. Once options are identified, conduct a step-wise, but iterative, progression of analyses to narrow the set of options to a single, best regulatory or non-regulatory (or combinations of regulatory and non-regulatory) alternative.

### Short Term

#### Activities:

- \* o Establish initial set of regulatory and non-regulatory options to aid focus of short- and long-term data collection efforts.  
Options could include:
  - Regulation under Subtitle C, D, D+, CAA, CWA, MPRSA, MARPOL or TSCA;
  - Regulation at the state level (e.g., treatment standards, financial responsibility);
  - Establishment of new statutory authority for infectious waste;
  - Licensing, liability insurance requirements, accreditation;
  - No regulation (e.g., guidance).
- o Coordinate activities with the regions and with OSHA, FDA, DOT, CDC, and other appropriate federal agencies.
  - Evaluate existing and proposed regulations.
  - Coordinate development of regulations and guidance with other federal programs.
  - Identify conflicts or issues in implementation of regulations or guidance.
- o Prepare preliminary options paper citing pros and cons of each option.
- o Develop strategy for analyzing regulatory options. Determine critical factors that must be considered during options evaluation.

#### End Products:

- o Paper on regulatory and non-regulatory options for infectious waste management (Spring 1989).

### Long Term

#### Activities:

- o Evaluate the effect of alternative infectious waste definitions on regulatory options.
- o Identify and collect information (e.g., waste characterization data, cost data) required to support regulatory development (conducted under Task Area 3).



## 6. CONDUCT ENVIRONMENTAL/ECONOMIC ASSESSMENT

**Objective:** To determine the environmental, economic, and health risks of improper disposal of infectious wastes.

### Short Term

#### Activities:

- o Identify major potential impacts of infectious wastes and categorize them by environmental, economic, and health effects.
- o Determine which of the potential impacts are supported by data through a review of current literature and convening work groups with trade associations.

#### End Products:

- o Preliminary report on the identification of the potential impacts of the universe of infectious wastes (Summer 1989).
- o Identify future study needs for a general analysis of economic and environmental impacts (Summer 1989).

### Long Term

#### Activities:

- o Obtain data to support or refute reported risks through new studies (e.g., infectiousness of infectious waste after release to the environment, economic impact of environmental release).
- o Perform a comprehensive study of the sources, probabilities of releases, environmental transport, and significant impacts nationwide.
- o Identify health effects data gaps through research and development and scientific studies.

#### End Products:

- o Final report on economic and environmental impacts (early 1991).

**End products**

- o Technical report on management effectiveness (9/30/89).
- o Develop enforcement strategy (Fall 1989).

## 5. EVALUATE MANAGEMENT METHODS AND ENFORCEMENT ACTIVITIES

**Objective:** To determine which transportation, treatment, storage and disposal methods are most effective in minimizing environmental release by each waste type, and what resource requirements (e.g., for enforcement) are required for each method.

### Short term

#### Activities:

- o Develop flow chart of treatment, storage, and disposal scenarios by waste type.
- o Assess potential for release and ultimate fate of wastes by waste type and by management method.
- o Evaluate magnitude of release and relative ease of remediation by waste type.
- o Coordinate with other programs (e.g., OAQPS, OW, OMEP) to identify the regulatory limitations and multi-media impacts of specific management methods.
- o Identify enforcement activities required by each management method.
- o Evaluate resource requirements for enforcement of existing laws prohibiting release.

#### End products:

- o Flow charts of treatment, storage, and disposal scenarios (early 1989).
- o Matrices of mismanagement events and consequences (early 1989).
- o Report on enforcement activities (Spring 1989).

### Long term

#### Activities:

- o Determine effectiveness of current management methods and compare effectiveness of alternative methods.
- o Develop criteria to assess effectiveness of methods (e.g., magnitude of potential release, potential for containment and remediation).
- o Develop minimum standards for collection, treatment (e.g., autoclaving, incineration, chlorination), storage, and disposal under Subtitle D or other statute.
- o Recommend enforcement strategy for compliance monitoring and enforcement to ensure proper management of infectious waste.

- o Develop national data base, similar to Biennial Reports, if necessary, to establish on-going capability to evaluate compliance, waste generation amounts, transportation and management practices, and compliance costs.

End Products:

- o Evaluate effectiveness of pilot tracking system and suitability for a national system one year following implementation of the pilot tracking system (about 1 year following implementation of the pilot system).
- o Determination of what wastes need to be tracked and when wastes no longer need to be tracked.
- o In conjunction with above analyses, evaluation of alternative approaches to tracking and reporting infectious waste and plan for implementation of a national system.
- o Implementation of national tracking system or detailed guidance to the states including the associated OMB, regulatory, and Federal Register notice documents, as necessary based on above analysis.
- o Development of a national data base including the preparation of OSWER's system life cycle support documents.

#### 4. NATIONAL TRACKING AND REPORTING SYSTEM

**Objective:** To develop the most effective means of tracking and reporting the handling of infectious waste and to ensure the proper containment and destruction of the waste.

##### **Short Term**

##### **Activities:**

- o Evaluate tracking systems currently being used by the states and those documented in other readily available information sources (e.g., public comments) to determine the most effective means of tracking infectious waste. (Based on information obtained during State Evaluation Activity.)
- o Work with Congress on the development of a pilot tracking system. If legislation is passed, develop the regulations required to implement the provisions of the legislation.

##### **End Products:**

- o Evaluation of current tracking and reporting systems (Winter 1988).
- o Completion of regulations for pilot tracking system within time frame specified in the legislation.

##### **Long Term**

##### **Activities:**

- o Evaluate effectiveness of pilot tracking system and suitability for a national system.
- o Evaluate alternative approaches to tracking and reporting on infectious waste transport and management based on the pilot and additional data obtained during the data collection and management evaluation activities. Alternative approaches include: generator or transporter manifest; generator reporting; state or federal tracking systems.
- o Determine what wastes need to be tracked and when wastes drop out of the system.
- o Evaluate existing manifest tracking and reporting systems to determine strengths and weaknesses, and identify methods to overcome identified problems.
- o Develop national tracking and reporting system and/or provide detailed guidance to states on tracking and reporting system requirements.

## Long Term

### Activities

- o Determine whether a comprehensive nationwide survey of infectious waste generators, storage, treatment, and disposal facilities is needed to quantify the amount generated, the current storage, treatment, disposal methods, and compliance costs or if a smaller independent random sample of medical facilities is sufficient to validate the models developed above.
- o If needed, design a comprehensive nationwide survey or a smaller survey to validate the models. Identify the universe that will be required to complete the survey. A representative statistical survey may be necessary given the number of small quantity generators.
- o Obtain OMB approval for the survey including preparation of all required recordkeeping clearance packages.
- o Conduct survey pretest and modify survey as required if comprehensive nationwide, or smaller, survey is necessary.
- o Implement and administer survey and develop analytical tools including data management systems.
- o Analyze survey results: volumes of waste generated by type of wastes and type of generator; collection and storage methods; treatment, storage, and disposal practices; compliance costs; and environmental impacts.
- o Modify national estimates of waste generation.

### End Products:

- o Option paper and management decision on necessity of conducting detailed survey (early 1989).
- o Nationwide survey of infectious waste generators, transporters, and TSDFs, including required OMB support documents (FY 1989).
- o Preparation of draft and final results of survey (FY 1990).
- o Data base and quantitative information of the generation, transportation, treatment, storage and disposal practices, and compliance costs (late FY 1990).

### 3. COLLECT AND EVALUATE INFORMATION

**Objective:** To quantify the extent of the problem by determining the amount and types of infectious waste that are generated, the treatment and disposal practices, relative contribution of each source (doctors offices, clinics, hospitals), and compliance costs.

#### Short Term

#### Activities:

- o Collect readily available information on the amount and type of infectious waste generated by type of generator (e.g., doctors offices, veterinarians, clinics, medical laboratories, small hospitals, and large hospitals using DHHS Medicare/Medicaid definitions) and conduct site visits under RCRA 3007. Information sources include public comments, trade associations, states, generators, commercial haulers and TSDFs, and Centers for Disease Control.
- o Develop generic generator models (e.g., doctors offices, veterinarians, clinics, medical laboratories, small hospitals, and large hospitals) that can be used to estimate the volume of waste generated on a national basis. Models may be developed for rural, suburban, and urban areas depending on the variability in the type and amount of waste generated. Models will be based on such factors as number of beds, patient visits or employees.
- o Review generic generator models with trade associations and Panel of Experts and seek specific information on volumes of waste generated.
- o Collect information to fill data gaps and characterize waste (e.g., send RCRA 3007 letters and conduct site visits).
- o Develop national estimates (and to the extent possible, state estimates) of amount of infectious waste generated; transportation patterns including collection and storage; treatment and disposal practices; and compliance costs.
- o Identify trends in the medical industry that may impact the model assumptions such as growth of group practices or health maintenance organizations.

#### End Products

- o Generic generator models (to be reviewed by a subgroup of the Panel of Experts) (Winter 1988).
- o Preliminary national estimates of amount of infectious waste generated (early 1989).

## End Products

- o Preliminary state report, "Analysis of Existing Conditions" including relevant case studies and detailed matrices of elements of state programs (Winter 1988).
- o Preliminary guidance for a model state program (Winter 1988).
- o Draft Final Report, "Effectiveness of State Programs", to evaluate how well each state manages infectious wastes, how much they follow the guidelines of the model state program, and how much they adhere to EPA's definition of infectious wastes.
- o Final Report, "Effectiveness of State Programs" (Spring 1989).
- o Final guidance for a model state program (late Spring 1989).

## Long term

### Activities:

- o Develop a network that will provide for continued monitoring of activities at the state level.
- o As regulation of infectious wastes is in a state of flux, continue to monitor activities of the various states.
- o Modify model state program guidance as necessary.