MWTA establishes a demonstration tracking system (Sections 11001-11003) and, as noted in the introduction, directs EPA and ATSDR to undertake studies of certain medical waste management issues (see box D).[1] Unlike any other environmental law, MWTA was designed to structure a process for gathering sufficient information to evaluate the nature and risks posed by a waste, so that Congress could then reevaluate and identify whether any further policy action is warranted. The intent of the law is to develop a basis for determining, after the completion of the demonstration program and the government-mandated studies, whether and in what ways the Federal Government should regulate medical wastes.

MWTA specifically applies to the Great Lakes States and Connecticut, New Jersey, and New York (Section 11001). All of the Great Lakes States were given the option to decline to participate in the demonstration program (and any other State was given the opportunity to participate); and Connecticut, New Jersey, and New York could petition out if their State had a program at least as stringent as that of the Federal Government.[2] None of the Great Lake States chose to participate, while none of the other three States petitioned out. Thus, MWTA applies only to New York, New Jersey, Connecticut, and also to Rhode Island and Puerto Rico, which voluntarily entered the program. Louisiana and the District of Columbia voluntarily joined the program, but later petitioned out of it.

MWTA defines medical waste as "... any solid waste which is generated in the diagnosis, treatment, or immunization of human beings or animals, in research pertaining thereto, or in the production or testing of biologicals."[3] Section 1004(40) of RCRA, as amended by MWTA, notes further that medical waste "does not include any hazardous waste identified or listed under Subtitle C or any household waste as defined in regulations under Subtitle C." Any solid waste mixed with a regulated (i.e., listed) medical waste (see below) is also a regulated waste under MWTA. As noted earlier, special regulations exist for the management of LLW (see box A).[4] MWTA regulations do require tracking of LLW medical waste, unless it is mixed with hazardous wastes that would be regulated under RCRA Subtitle C (40 CFR 259).[5] It should also be noted that domestic sewage is not included in the RCRA definition of solid waste (Section 1004(27)).

It is possible that the EPA definition of regulated medical wastes, codified as part of MWTA, might become more widely used and help forge consensus on the categories of wastes designated as infectious. These categories are now frequently referred to as "regulated medical wastes." Box D outlines the major features of the tracking program established by MWTA.

EPA cost estimates, although provided to EPA by the regulated community, are considered low by some waste industry officials and regulated sources (141). These estimates are that the cost to comply with MWTA will increase disposal of regulated medical wastes by approximately $0.08/pound on average; with average annual compliance costs per facility range, according to EPA, from about $3,750 for hospitals to about $70 for dentists (*Fed. Reg.*, vol. 54, No. 56, Mar. 24, 1989). According to the preliminary results of the New York City medical waste study, while the per pound cost of medical waste disposal has remained relatively stable since MWTA passed, overall waste management has become highly costly. For example, "a typical 500-bed acute-care hospital in New York City has experienced a 400 percent cost increase in waste disposal as a result of MWTA" with an actual cost "in excess of $400,000 per year for such a hospital" (63). This could result from poor segregation practices at certain facilities and/or to shortages of personnel for such tasks.

Upon completion of the demonstration program, EPA and the participating States will review the generator reports and evaluate the program, including the impacts of the program on management practices and the costs of complying with the tracking regulations. As noted above, EPA's report to Congress on the program is due in September 1991.

The importance of MWTA demonstration tracking program to abating medical waste problems is not clear; if a more comprehensive regulatory program is adopted in the future, the contribution of a tracking system to the

[1]This discussion is based in part on that contained in (137); see also (36), (86), and (22).

[2]Independently, a number of actions have been undertaken by States to address medical waste problems (e.g., New York State and New Jersey cooperatively adopted a tracking system in August 1988 (before passage of the MWTA)). Also, the New York Bight Floatables Action Plan, a multi-agency effort led by EPA Region II, is part of the New York Bight Restoration Plan and addresses some medical waste handling procedures in the New York Bight area.

[3]There is a difference between this definition of "medical waste" in the MWTA and wastes identified as "regulated medical wastes" (see ch. 1).

[4]The Low-Level Radioactive Waste Policy Act of 1980 and the Low-Level Radioactive Waste Policy Amendments Act of 1985 (117).

[5]LLW medical waste, upon radioactive decay, would still have to be tracked as regulated medical waste, disposed of through the sewer system, or treated and destroyed onsite, or tracked as a hazardous waste.

Box D—The Medical Waste Tracking Program

EPA established the 2-year pilot Federal tracking program authorized by MWTA by publishing its "Standards for the Tracking and Management of Medical Waste; Interim Final Rule and Request for Comments" in the *Federal Register* in March 1989, which took effect in June 1989.[1] The tracking system for medical wastes designates recordkeeping requirements for facilities that generate over 50 pounds a month of medical waste and requires the use of a four-part form for any off-site shipment of medical wastes. EPA and the State must be notified if a generator does not receive a copy of the manifest form from the final destination facility. Generators of medical waste that produce less than 50 pounds are subject to the same handling requirements, except instead of using the tracking form they must maintain a log (i.e., as a reporting requirement).

EPA has authority to assess civil penalties of up to $25,000 per day for each violation, criminal penalties of up to $50,000 per day per violation, and jail terms of up to 5 years may be imposed in States implementing the tracking system (sec. 11005). States have the authority to conduct inspections and take enforcement actions as well. The MWTA does not specify whether the EPA or the States has lead enforcement authority and the EPA regulations do not specify enforcement roles, but the Agency prepared an enforcement strategy which encourages State implementation. Flexibility is given to the States to develop a variety of approaches to compliance and enforcement (134). EPA restricts its role to encouraging voluntary compliance through its various education efforts and by providing States with guidance and assistance when needed (e.g., when a violation involves wastes from or transported to a nonparticipating State).

EPA, also as part of the MWTA demonstration program, issued requirements that generators of waste must follow *before* medical wastes leave the site to be shipped to authorized treatment or disposal facilities. Under the demonstration program, generators include institutional and commercial sources of wastes in the participating States and territories. Of course, any treatment facilities accepting regulated medical wastes may be subject to other Federal, State, and local laws and regulations. The MWTA does not consider residential sources of medical waste to be regulated generator sources, nor does it address problems with the disposal of wastes associated with illegal drug use. EPA issued guidance information on proper home medical waste disposal and states in its pamphlet describing the MWTA that drug enforcement, Clean Water Act programs, and citizen litter control projects will help eliminate "flagrant dumping of wastes." (130)

According to the MWTA requirements, generators must separate regulated medical wastes from general refuse, meet storage requirements (if such wastes are stored before treatment), and package regulated wastes in labelled, rigid, leak-resistant containers. In addition, special separation and packaging requirements are specified for both sharps and fluids. To help ensure that packages retain their integrity during handling and transportation, secondary packaging (i.e., a rigid outer container) is generally required for shipping. This secondary packaging can be reused if thoroughly cleaned. The package labels must identify the content, generator, and transporter of the wastes.

Medical wastes incinerated on-site, or treated by other methods (e.g., some type of disinfection unit) that meet both regulatory criteria of treatment and destruction (i.e., waste is "processed by a means to reduce levels of infectious agents" and waste is "no longer generally recognizable as medical waste"), do not need to be tracked under the demonstration program, but instead generators must submit a report to EPA. The position of the EPA is that if the biological and physical hazard of the waste, as well as their "visually offensive nature," is altered they can be managed according to regulations applicable to solid waste. The required report must be a summary of the volumes and types of medical waste treated on-site during the first 6-month period of the program; a second report covers the 13 to 18 months of the program.

[1]Since this time, the Agency has issued a number of guides for the public, generators and transporters about the Federal MWTA program (128).

improved management of medical waste will need to be evaluated independently. GAO (134) has evaluated the efforts to date of the EPA and States to implement MWTA. For this reason, their implementation activity is not evaluated here. Apparently, despite early controversy over the listing of wastes by the Agency to be tracked and concerns over compliance costs, as well as the initial type of confusion usually associated with new regulatory programs, the implementation of MWTA demonstration program has been rather smooth. EPA reports that most of the early violations were minor in nature (e.g., errors in completing manifest forms, etc.), although fines have been levied against responsible parties for such violations as incomplete record keeping and failing to lock storage areas (88).

A number of issues that EPA and ATSDR are required by MWTA to address (e.g., health effects of medical waste, generation information, cost implications, small-quantity generator issues) also is not discussed extensively in this study. The focus of this effort is on available and emerging management methods, including waste reduction and recycling possibilities. This emphasis on the evaluation of treatment technologies is intended to alleviate immediate concerns over the nature, availability, and tradeoffs of various treatment methods and to stimulate a broader consideration of management alternatives for medical waste than is currently typical.

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