Chapter 5
Managing Medical Wastes—Institutional and Policy Issues

Whether the Federal Government should further regulate the management of medical/infectious wastes is an open issue. Within the policy debate over whether and how medical wastes should be regulated are classic divisions between those maintaining there is a need to ***document*** actual harm from medical wastes, and those primarily concerned with the ***potential*** harm posed by these wastes. Most environmental laws passed in the last 20 years have embodied a ' 'preventive' approach to human health and environmental risks as the basis for regulatory action. In practice, however, a more ' 'reactive' basis for policy development is often used. This latter approach reflects the incomplete shift of the "burden of proof' with which administrative agencies have had to cope in justifying the actual regulation of environmental practices. This pragmatic approach to regulation, in an effort to conserve regulatory resources, essentially finds regulation justified only when the relative degree of risks posed by the activities are known and appear high. It is in this context that the debate takes place over whether current management problems associated with medical waste disposal warrant Federal regulation.

At the moment, two regulatory trends are emerging in medical waste management, both primarily driven by the more "preventive" mode of regulation: one trend is toward regulating greater quantities of potentially infectious wastes; and the other trend is toward tightening controls over incineration and other disposal options. As one hospital consultant noted,

> **More and more waste quantities are required to be treated as "infectious," of which smaller percentages are truly infectious; but, simultaneously, viable treatment and disposal options are being eliminated or made cost-prohibitive (8).**

The concern of some generators of medical waste is that some, if not all, ' 'viable' management options will become less available (or more costly) due to the adoption of stricter air emission regulations by a number of States. This could affect, at least on a temporary basis, the availability of sufficient capacity in some areas for managing medical waste.

Several other general trends also appear to be emerging in the management of medical wastes. These include: 1) the likelihood of further regulation, at least at the local and State levels of government; 2) possible increases in off-site commercial and regional incineration facilities, depending on the levels of standards set in such regulations and on other cost factors; 3) an increase in the transportation of medical wastes if there is more off-site disposal (which will probably provide further impetus to establishing manifest or recordkeeping systems of some sort);[1] and 4) the likelihood of increased costs for disposing of medical wastes as more treatment becomes necessary and more stringent controls are adopted.

As noted above, most States are currently developing or revising regulatory programs that address medical wastes. The stringency of the emissions standards that medical incinerators must comply with will determine the type and cost of necessary air pollution controls. **The cost and engineering constraints (e. g., space) of retrofitting existing hospital incinerators with acid gas scrubbers and/or particulate matter controls may force many hospitals to cease on-site incineration in favor of off-site incineration at regional, centralized facilities. Regional facilities, however, are likely to face siting difficulties.**

Increased transportation of medical wastes to regional facilities, or to facilities that are located outside a State and in some cases outside of the country, will further increase disposal costs. It is also

[1]Ontario, Canada, has a manifest system in place and would 1 ike the United States to establish a manifest system of some sort to facilitate estimating better the amounts of medical wastes entering Canada from the United States, in order to better plan for the management of it. Some States (e. g., Massachusetts, New York, Missouri, and New Jersey) are establish ing or have established manifest systems of some sort for medical wastes.

likely to increase health risks to the public, given the greater potential for accidental exposure due to spills and possible illegal dumping or disposal. **These concerns provide support for proposals that require manifest or recordkeeping systems to track the movement of these wastes.** The Senate passed legislation (S. 2680) in August 1988 that will require EPA to establish a model tracking system in New York, New Jersey, and Connecticut for medical wastes. Similar legislation is pending in the House (H. R. 3515, H.R. 51 19).

Policy Issues for Federal Action

To best address issues associated with these trends, at least two types of policy activities are relevant: 1) further development and enforcement of standard operating procedures (SOPS) by hospitals and other medical waste generators for the handling, storage, treatment, and disposal of these wastes; and 2) further clarification and coordination of regulatory programs at the local, State, and Federal levels of government. In particular, the possibility of further Federal involvement warrants discussion, given the increased public concern over the management of medical wastes, the increased level of local and State regulatory activity (which has led to nationwide variation in the treatment of these wastes), the interstate transportation of medical wastes, and the current absence of a comprehensive medical waste policy at the national level.

The Federal Government could usefully specify its policy(ies) regarding medical wastes in a number of areas: 1) designation of a lead authority (presumably EPA) to clarify the definition, classification, and regulation of these wastes; 2) the establishment of emission standards and ash regulations for medical waste incinerators, autoclaving/landfilling performance standards, and possibly operator training guidelines/regulations; 3) handling, storage and transportation guidelines/regulations to ensure worker safety and possible establishment of some sort of a manifest system; and 4) research and data needs on medical waste practices. Some of these issues could be addressed under RCRA's current authority or could be clarified as part of the RCRA re-authorization process.[2] Other relevant laws are OSHA, the Clean Air Act, and possibly the Toxic Substances Control Act.

A number of important, related issues noted throughout this paper re-surface as the implications of these areas for possible further policy development are discussed. The implications of three of these areas, the definition/classification of medical wastes, the issue of small quantity generators of medical wastes, and research and data needs associated with medical waste management are discussed briefly to indicate the range of regulatory issues the Federal Government will need to address if it revises or expands its role in medical waste management.

The definition of medical wastes under RCRA is of critical importance to determining the type of regulatory effort EPA is likely to undertake. Its clarification is also likely to facilitate State actions and commercial development of medical waste incineration. Another important dimension of the medical waste management issue is which types of sources should be regulated, i.e., the question of whether small generators of medical wastes should be exempted. Further research into the nature of the risks (both occupational and environmental) associated with medical wastes, research on new treatment technologies, and performance data for existing facilities is desirable in order to develop more informed and effective policies.

Defining/Classifying Medical Wastes

If infectious wastes are classified and regulated as hazardous under RCRA, a comprehensive management program is likely for infectious wastes. For example, regulating infectious wastes as hazardous wastes under RCRA could address transportation issues associated with infectious waste management. This would involve: 1) recordkeeping concerning the waste transported, its source and delivery points; 2) transportation of the waste only if properly labeled; 3) compliance with the manifest system (Section 3002); and 4) transportation only to

[2]Some issues, e.g., concerning occupational risks, could be addressed under other statutory authority, such as OSHA. The focus here is on RCRA given the primary focus of this paper on waste disposal issues.

the waste facility that the manifest form designates as holding a proper permit.[3] In addition, waste treatment, storage, and disposal facilities would be subject to hazardous waste standards and permitting procedures.[4]

As the Council for State Governments (CSG) has noted, existing State infectious waste programs do not tend to include three requirements usually associated with hazardous waste laws. These are requirements for contingency plans and spill management, closures, and financial assurances (4).

As noted above, in RCRA, the statutory definition of hazardous waste includes ' 'infectious' as a defining characteristics EPA interprets RCRA as providing it with discretionary authority to classify infectious wastes as either hazardous wastes or solid wastes. [b] EPA, in 1978, did include infectious waste as part of its first set of proposed hazardous waste regulations. The final rule published in 1980, however, stated that infectious waste regulations would be published separately. As the CSG notes,

> . . . [e]ight years and two reauthorizations of RCRA later, still no Federal regulations have been promulgated (4).

Instead, in 1986, the EPA issued its ***Guide for Infectious Waste Management*** stating that

> . . . [w]hile the Agency has evaluated management techniques for infectious waste, considerable evidence that these wastes *cause* harm to human health and the environment is needed to support Federal rulemaking (emphasis added; **81).**

RCRA (Section 1004), however, states that the term "hazardous waste' refers to a waste with infectious characteristics which may

> . . . ***pose*** a substantial present or potential hazard to human health or the environment . . . (emphasis added).

[3] 42 U.S.C. 6924.
[4] 42 U.S.C. 6924; 6925.
[5] 42 U.S. C. 6903(5).
[6] 42 U.S. C. 6903(5); 6921. The hazardous characteristics, of which infectious is one, listed in 6903 are to be considered when the Administrator of EPA identifies or lists hazardous wastes as per 6921. EPA, however, in their regulatory interpretation, left the infectious characteristic **out of the definition of "hazardous waste'** *(40 C* FR *240.* 101(m)).

Recently, EPA has increased its attention to infectious and medical waste issues. In early 1988, EPA assigned for the first time a full-time staff person to handle infectious waste issues. In June, the Agency issued a request for comment on infectious waste issues in the ***Federal Register.*** Most recently the Agency has formed a task force to address infectious waste issues. Publicly, the Agency has not ruled out the possibility that ultimately it may issue regulations, although at present its efforts seem to be on developing an education program.

As noted above, infectious wastes are unlike other types of hazardous wastes that can be consistently identified by a test. Detection of infectious microbes in landfill leachate is not highly likely given that they are generally less persistent in the environment than toxic substances such as heavy metals, oils, solvents, etc. Exposure to sunlight or dry air can render infectious wastes non-infectious. It is also true, however, that infectious microbes in medical wastes could multiply and are potentially contagious under certain conditions. In this context, developing a separate statutory category for infectious and medical wastes is seen by some observers as desirable. Applicable hazardous waste provisions from RCRA Subtitle C could be adopted and appropriate adjustments made given the particular nature of the medical wastestream.

It is not entirely clear how EPA may ultimately define, classify, and regulate infectious wastes (or if it will). As noted above, EPA's June 2, 1988, ***Federal Register*** request for comment on infectious wastes issues indicates the initiation of some information gathering action on this issue. EPA's position in the summer of 1988 was that an education program, but not regulation, was justified. Later in 1988, after several congressional hearings, EPA announced that it would consider the need for Federal regulation and established a task force on medical waste issues.

Meanwhile, Congress, as part of the RCRA reauthorization process, will address the issue of infectious and medical waste management (H. R. 3515; S. 2773).[7] H.R. 3515 is the more detailed

[7] The House Energy and Commerce Subcommittee on Transportation, Tourism. and Hazardous Materials held one hearing October

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of the two bills with respect to medical waste management. For example, it would require EPA to issue regulations for all aspects of infectious waste management including generation, transportation, treatment, storage, and disposal.

H.R. 3515 distinguishes between medical and infectious wastes. Infectious wastes would only be classified as hazardous wastes under this bill if they were mixed with hazardous wastes already regulated under Subtitle C. In September 1988, a substitute for H.R. 3515 added a provision to establish a demonstration tracking system for medical waste in New York, New Jersey, Connecticut, and the Great Lakes States. * As of September 21, 1988, the House Energy and Commerce Committee was scheduled to "mark up" H.R. 3515.

A number of other bills regarding medical waste management issues have been introduced. As indicated in table 9, the proposed pieces of legislation address a number of aspects of medical waste management, beyond the definition and classification issues. Some significant action on several of the bills appears likely before the current session of Congress **ends.** [g]

Regulating Small v. Large Generators of Medical Wastes

Whether incineration emission standards should be set at the Federal level and on what basis (tech-

(continued from previous page)

21, 1987, on the regulation of infectious wastes. The House Small Business Subcommittee on Regulation and Business Opportunities held a hearing **on** August *9, 1988,* on medical waste issues.

[f]The Senate passed legislation (S. 2680) which would establish a model tracking system for New York State, New Jersey, and Connecticut. Similar legislation (H. R. 51 19), in addition to H.R. 5215, is pending in the House.

[g]For example. a bill (H. R. 5231) to amend the Marine Protection, Research and Sanctuaries Act (Public Law 92-532; MPRSA, commonly referred to as the Ocean Dumping Act) of 1972 is expected to reach the floor of the House before the end of the current session. The bill would increase criminal penalties for illegal ocean dumping of medical waste and provide recovery of damages associated with illegal dumping. The Senate included similar provisions in the amendments of MPRSA (S. 2030) that it passed in August 1988.

Table 9.–Legislation Pending in Congress on Medical Wastes (as of Sept. 20, 1988)[a]

Bill number	Sponsor (original)	Brief summary
H.R. 1156	Dwyer (D-NJ)	Permits citizens of one State to bring Federal civil action against any person in another State creating a public nuisance through improper management of medical wastes
H.R. 3467	Rinaldo (D-NJ)	Requires that within 12 months after completing a study of infectious and pathologic waste, EPA must determine whether to regulate these wastes as hazardous wastes under Subtitle C of RCRA
H.R. 3478	Saxton (D-NJ)	Amends MPRSA (Public Law 92-532). Bans the dumping of medical wastes in ocean and navigable waters
H.R. 3515	Luken (D-OH)	Amends RCRA (Public Law 94-580) to require EPA to regulate the management of infectious and medical wastes; provisions include definition of waste types by EPA, and establishment of a model manifest system in New York, New Jersey, Connecticut, and the Great Lake States
H.R. 3595	Hughes (D-NJ)	Requires vessels to manifest the transport of municipal or other nonhazardous wastes to ensure they are not illegally disposed of at sea
H.R. 5119	Florio (D-NJ)	Amends RCRA to regulate medical wastes by requiring EPA to establish a model tracking system for New Jersey and New York
H.R. 5130, 5225	Hughes (D-NJ)	Amends U. S. C., Title 18, to provide penalties for illegal ocean dumping of medical wastes
H.R. 5231	Studds (D-MA)	Amends MPRSA to increase criminal penalties for illegal ocean dumping of medical wastes and provide for recovery of damages associated with illegal dumping
H.R. 5249	Davis (R-MI)	Purpose is to protect the Great Lakes from the improper disposal of medical wastes
H.R. 5302	Hertel (D-MI)	Establishes a pilot program for the tracking of medical wastes in States bordering the Great Lakes
S. Res. 470	Riegle (D-MI)	A resolution relating to medical wastes improperly disposed of in the Great Lakes
s. 1751	Lautenberg (D-NJ)	Requires vessels to manifest the transport of municipal or other nonhazardous wastes to ensure they are not illegally disposed of at sea
S. 2628	Lautenberg (D-NJ)	Amends RCRA to establish a pilot program to track medical wastes in New York and New Jersey
S. 2726	Dodd (D-CT)	Amends RCRA to require EPA to regulate medical wastes
S. 2773	Baucus (D-MT)	Amends RCRA to define infectious waste and the basis for regulating infectious waste

Abbreviations: EPA = U.S. Environmental Protection Agency; MPRSA = Marine Protection, Research, and Sanctuaries Act (also referred to as the Ocean Dumping Act); RCRA = Resource Conservation and Recovery Act (also referred to as the Solid Waste Disposal Act); U.S.C. = United States Code

[a]The Senate passed legislation (S. 2680) in August 1988, which would establish a model tracking system for New York State, New Jersey, and Connecticut. The Senate also passed in August amendments to MPRSA (S. 2030) that include a provision prohibiting the dumping of medical waste in the oceans and navigable waters. Similar bills (H.R. 3515, H.R. 5119, H.R. 3478, H.R. 5231, respectively) are pending in the House.

nology - or health-based) is an open issue, as is whether small generators (e. g., doctor offices, home care) should be exempt from medical waste regulations. While hospitals and clinics may generate larger quantities of wastes, those generated by smaller facilities may be more susceptible to direct public exposure. The two incidents of children playing with untreated wastes in the summer of 1987, which focused national attention on medical waste management, occurred outside of doctor offices—not hospitals (32).

A problem is how these smaller generators can efficiently and economically dispose of their infectious wastes. Commercial off-site facilities may not be readily available or may be highly costly. Hospitals which could accept the waste (if there are not State or local regulations prohibiting it) may be reluctant to do so for potential liability reasons. Some hospitals allow affiliated doctors to dispose of infectious wastes, and potentially funeral homes (with crematories) could also accept wastes from doctor offices. Again, liability issues and other factors (e. g., the additional staff time for handling such waste) may make these types of facilities reluctant to accept such wastes.

The relative risk posed by wastes from home-care patients and other infectious materials generated in homes versus that produced by commercial generators is not known. Although the public's general concern about AIDS and infectious wastes has led to a focus on hospital wastes, most treatment of AIDS is apparently done on an out-patient basis. [10] As hospital stays have generally become shorter in recent years, home care of patients has increased. Infected wastes from these individuals, as well as such items as disposable diapers and feminine sanitary products, are potentially infective wastes, and they are directly landfilled in most cases. Information on appropriate packaging and special disposal procedures may be one way to encourage prudent disposal of home-care infectious wastes. [11]

It is not clear, however, whether these wastes, any more than it is clear whether hospital wastes (especially those which have been treated by autoclaving or some other sterilization process), pose a significant contamination problem when landfilled. [12] EPA has noted that no groundwater impacts associated with landfilling any medical wastes have been identified to date (84). Yet, with little information on the quantities of infectious waste from small generators, as well as on the risks of these wastes, it is an open question as to what types of controls are appropriate. Controls could focus on handling and direct exposure (through improper disposal) and/or on environmental risks from disposal of these wastes.

The feasibility of controlling small quantity generators presents another policy dilemma. [13] Currently, the confusion over how best to address this issue is evident in proposed legislation in some States. California, for example, has two bills pending, one of which (S. 1448) would prohibit ***any*** person from disposing of untreated infectious wastes; the other **(S. 2469)** requires the disposal of sharps in puncture-proof containers, except those from private homes, physicians' offices, or health-care facilities.

Research and Data Needs

As noted throughout this paper, little data exists on the management of medical waste. Indeed, the "vital signs' for medical waste management are thereby difficult to read or interpret. **Basic information on sources, amounts, composition, and treatment/disposal of medical waste is not known in any useful detail.** In addition, insufficient research data exist to determine to what degree medical wastes are a public health problem. Information on occupational exposure to hazards associated with managing these wastes is not available. Comprehensive data on the operation of incinerators (e. g., types, comparisons of air emissions levels for a range of pollutants (including patho-

[10] It is also worth noting that CDC studies found that HIV does not persist well in the environment, at least not after drying, which causes a 90 to 99 percent concentration reduction within several hours. See ref. 77.

[11] For example, puncture-proof containers could be provided with the sale of syringes (which in many areas can only be purchased with a prescription) (48a)

[12] Items such as disposable diapers and feminine sanitary products are not generally considered a serious source of infectious contamination to landfills. It is on this basis that some observers maintain that these wastes do not warrant special waste handling procedures, and that bans of these products are unjustified.

[13] The Association for Practitioners in Infection Control has recently proposed a guideline for infection control in home-care which covers waste treatment in this setting (69).

gens), ash content analysis, etc.) do not exist at this time.

As Ode Keil, Joint Commission on Accreditation of Healthcare Organizations, noted at the OTA Workshop on Medical Waste Management, held July 19, 1988, "We have a problem, but we do not have a scientific analysis of the problem to support development of a rational system. **It appears it would be highly prudent for Congress and Federal agencies to address the inadequacy of data and research, and therefore information, on medical wastes and their management. This *is* essential for determining the need for and nature of any regulatory program for medical wastes.**

A number of possible areas for further research and information gathering exist. Several key areas include:

1. developing the basis for a consistent, concrete definition of medical wastes, which all relevant Federal agencies issue jointly or at least adopt;
2. the nature and extent of occupational risk, including risks not only to healthcare workers, but housekeeping, maintenance and other relevant workers as well;
3. use and comparison of different incineration processes and other technologies, including emission rates and health risk assessments of these disposal options;
4. examination of the use of sewers for medical waste disposal (e. g., the survival of viruses in sewer discharges; problems associated with combined sewer overflows, such as beach washups of medical wastes; etc.);
5. identification of potential waste reduction options for medical facilities; and
6. comparisons of State regulatory programs, specifically to highlight experiences relevant to the development of possible Federal programs (e. g., model programs for managing medical wastes from small generators; manifest systems, etc.).

Concluding Remarks

This chapter highlights the types of regulatory issues that could be clarified by Congress and/or the EPA and other Federal agencies when examining the adequacy of current medical waste management policies. One critical need that is readily apparent and rarely disputed with respect to medical waste management is the need for more information on the risks posed by these wastes and on their actual management, and for more research of alternative treatment technologies and management techniques. **Nonetheless, the need for research should not be taken as a suggestion for postponing consideration of adopting a comprehensive regulatory program to address medical waste management. In fact, research efforts could be a part of a regulatory program, if it is promulgated in phases.**

The most coherent Federal policy for medical waste management is likely to result only if the variety of issues (e. g., the definition, classification, nature of risks, types of available disposal options, and the implications of regulatory action) discussed in this paper are ***comprehensively*** addressed. At a minimum, this preliminary assessment of the status of medical waste management practices in the United States today indicates that to adequately address the public's growing concern over the management of medical wastes, policy makers will need to address these issues as expediently as possible.