Introduction, Major Findings, and Policy Issues

Two years after the beach washups of medical wastes in a hot summer,[1] preliminary results from investigations by Federal agencies into medical waste management issues are being reported.[2] At the same time, many State and local governments (107, 139,110) and several private groups (77) have undertaken efforts to better address the management of medical wastes. Certainly, more is known about current medical waste management practices than prior to the passage of the Medical Waste Tracking Act (MWTA) in October 1988[3] (see app. A). Yet, much of the confusion and inconsistency associated with medical waste policy persist. Basic information as well as consensus on some fundamental management issues remain absent from the efforts to formulate a adequate national medical waste policy.

As current governmental studies and efforts are completed, it is clear that critical aspects of medical waste issues need to be addressed further:

- Consensus on the definition of regulated medical wastes must develop, based on the potential health risks posed by these wastes (e.g., the ability of a particular type of medical waste to pose a risk of infectious disease transmission beyond that associated with municipal solid waste).
- Basic, more precise information on the generation (amounts and disposal methods) of medical wastes, particularly by non hospital sources, is needed.
- Potential waste reduction and recycling opportunities to improve medical waste management need to be investigated, including consideration of product redesign to produce reusable and recyclable medical products where appropriate, or to avoid use of problematic (e.g., cadmium and lead) components in products.
- Appropriate workplace practices for occupational groups in frequent contact with medical wastes (e.g., health-care workers, refuse workers) need to be developed by relevant governmental agencies and adopted by employers to minimize the occupational hazards posed by these wastes.
- Information on treatment technologies, inparticular nonincineration alternatives, needs to be more readily available to State and local regulators, to generators, and to the general public.
- Air emission standards for medical waste incinerators, expected to be completed in a couple of years by the Environmental Protection Agency (EPA), are needed to create a more certain regulatory climate. Procedures to establish the safety and efficacy of new treatment technologies are needed.
- Management options for small generators of medical waste (including households) must be developed and information on their availability should be more readily available.

Before a comprehensive approach to medical waste management can be pursued, gaps in information and research that limit resolution of these issues must be better addressed. Some of the necessary studies, particularly those that better characterize the nature of health risks posed by medical wastes, will require significant commitments of time and funding, e.g., for epidemiologic and longitudinal studies.

The Office of Technology Assessment (OTA), in a background paper released in October 1988, Issues in Medical Waste Management, briefly examined the adequacy of current medical waste disposal practices, the potential risks from such practices, and the need for further Federal requirements for the handling, treatment, storage, and disposal of medical wastes. The focus of this OTA report is: 1) to place medical waste problems in a broader waste reduction and materials management perspective, as is evolving for municipal solid waste (MSW) and hazardous waste; and 2) to address a number of outstanding issues on incineration and other medical waste treatment technologies.

[1] The causes and impacts of the beach washups of medical waste are discussed in a separate effort (11s).

[2] Namely, the studies of medical waste issues mandated by the Medical Waste Tracking Act to be completed by the Environmental Protection Agency and the Agency for Toxic Substances and Disease Registry, as discussed below.

[3] The Medical Waste Tracking Act is amended as new Subtitle J to the Solid Waste Disposal Act and the Resource Conservation and Recovery Act (Public Law 89-272; 42 U.S.C. 6901 et seq.).

Medical wastes are defined to include all the types of wastes produced by hospitals, clinics, doctors' offices, and other medical and research facilities.[4] These wastes include infectious, hazardous[5] radioactive, and other general wastes from these health-care and medical facilities. Infectious wastes are a relatively small portion of medical wastes, although a high level of concern regarding their management exists.[6] For purposes of this report, regulated medical wastes are those infectious, potentially infectious, and special wastes designated by EPA as such under MWTA (see app. A). Throughout this report, the regulated medical waste stream is the primary focus and is usually referred to as such unless another type of medical waste (e.g., low-level radioactive, hazardous, etc.) is being discussed.

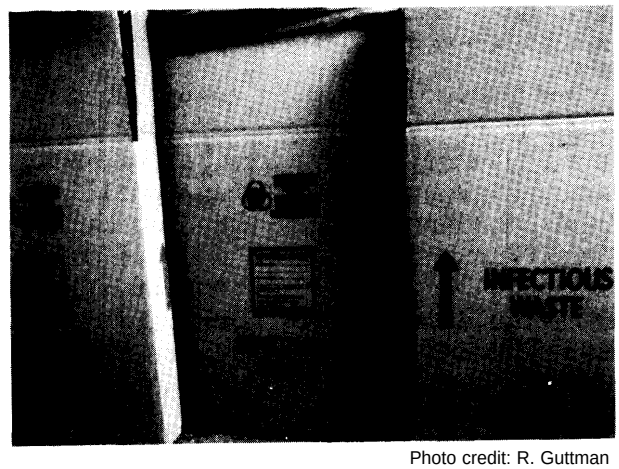

Photo credit: R. Guttman

Infectious wastes, although a relatively small portion of all types of medical wastes, are the principal focus of regulatory concern.

All medical wastes represent a small portion of MSW. Estimates for medical waste, exclusive of that generated from home health-care (for which reliable national estimates do not exist), range from 0.3 to 2 percent of the total municipal solid waste stream (130, 114).[7] The amount of infectious waste generated by medical facilities as a percentage of their total waste stream varies widely depending on the type of health-care facility, the definition of infectious waste used, and the standard operating procedures specified by it for designating and separating waste types. Most hospitals, however, designate about 15 percent of their waste as infectious (95).

EPA reports that autoclaving (i.e., steam sterilization) is utilized nationally to treat most infectious medical waste (141, 49, 139). However, medical waste incinerators continue to be a source of public concern, particularly because there are no national emission control standards for them (because their small size exempts them from current standards). EPA is in the process of developing new source performance standards (NSPS) for medical waste incinerators, which are expected to be proposed in 1992 (41; see ch. 4). Meanwhile, many States have developed new regulations to control these sources (107). To date, even less regulatory development has occurred for autoclaves or other nonincineration treatment alternatives (see ch. 3).

Nearly 70 percent of the Nation's hospitals use on-site incinerators. There is, however, great variation in the type, nature, and use of these incinerators. Some are used only for pathological waste disposal; others are used for disposal of infectious and noninfectious medical wastes.

Only a few States have reliable information on the number, types, and conditions of treatment units operating in their States. The State of Washington, for example, in its recent survey of medical waste practices, found that somewhere between 48 and 87 percent of the incinerators operating in the State were doing so without emission control equipment (139). The State of California reports that most of its 146 operating medical waste incinerators are small, uncontrolled units; 94 percent are on-site units (107). Recently, data has been reported that indicates that the rates of toxic emissions from medical waste incinerators (without emission controls) exceed those from modern MSW incinerators (106). Interestingly, the State of California also reports that a maximum of 60 percent of the waste burned in these

[4]Medical wastes from households are generally considered to be part of the municipal solid waste stream. As noted throughout this report, however, certain items such as syringes, which can be generated in significant quantities by households, may warrant separate and special management practices. Further, wastes similar to those identified as medical wastes may be generated by such facilities as police crime investigation units, mortuaries, veterinary clinics, etc.

[5]It should be noted that in this context "hazardous" is a legal designation, not necessarily a measure of the actual hazard of a particular waste.

[6]It is important to emphasize that not all medical waste is infectious. As EPA noted in its guidance document, defining infectious waste as waste capable of producing an infectious disease requires consideration of factors necessary for induction of disease. These factors include: presence of a pathogen of sufficient virulence, dose, portal of entry, and resistance of the host (122).

[7]EPA estimates that 2 to 3 million tons of infectious *hospital* waste is generated annually.

incinerators is regulated medical waste, the remaining 40 percent being municipal waste (107).

EPA, the Centers for Disease Control (CDC), the Occupational Safety and Health Administration (OSHA), and other Federal agencies have issued different, general guidelines for infectious and medical waste management (see table 1). Differences of opinion exist over the importance and impact of variations between the definitions and recommendations of these government agencies. Any remaining confusion over government positions on these matters could be eliminated if Congress designated a lead agency to coordinate and clarify the Federal Government positions on medical waste issues. As noted in OTA's previous background paper on medical waste, EPA is the agency with the most comprehensive authority to provide Federal leadership on the management of medical wastes (114).

OTA's statement in that background paper still applies: "Currently, no Federal regulations exist that comprehensively address the handling, transportation, treatment, and disposal of medical waste" (emphasis added; 114). This means that variation exists among the requirements that States and localities have devised for medical waste management. In recent years, such variations have led observers to suggest that the Federal Government needs to establish some baseline, uniform standards and guidelines for medical waste management. To date, the Federal Government has been reluctant to act without greater information on a number of issues related to medical waste management (114).

Some of this information may come from studies that both the EPA and the Agency for Toxic Substances and Disease Registry (ATSDR) are required to conduct under MWTA (sees. 11008 and 11009). MWTA (sec. l1008(a)) requires EPA to evaluate and include in reports to Congress: generator information (types, number, and size); on-site and off-site management practices, including sewer use; types and amounts of medical wastes; costs associated with the improper management of medical waste and those from compliance with the regulatory requirements of MWTA demonstration program; available and potential reduction, reuse, and management methods; implications of regulatory exemptions of household and small quantity generators; guidelines for the management of medical waste from households and small-quantity generators; existing State and local controls; and the appropriateness of applying Subtitle C requirements

Table l—Major Federal Agencies Addressing Medical Waste Issues

Agency	Authority	Activity
U.S. Environmental Protection Agency (EPA)	Guidance and Regulatory [a]	Issued Guide for Infectious Waste Management; issued regulations to establish the Medical Waste Tracking Program; establishing new source performance standards for medical waste incinerators; completing studies requested by the Medical Waste Tracking Act; authority under the Resource Conservation and Recovery Act to regulate the handling, storage, and transportation of medical wastes.
Occupational Safety and Health Administration, U.S. Department of Labor (OSHA)	Guidance and Regulatory [b]	Issues advisory notices and workplace standards focusing on occupational exposure to infectious materials and wastes.
Centers for Disease Control, U.S. Department of Health and Human Services (CDC)	Guidance and Recommendations [c]	Issues notices and advisories, sometimes jointly with OSHA, focusing on infection and control issues.
Agency for Toxic Substances and Disease Registry, Public Health Service, U.S. Department of Health and Human Services (ATSDR)	Study and Reviev [c]	Completing study required by the Medical Waste Tracking Act, focusing on evaluating health effects associated with medical wastes.

[a] EPA's comprehensive authority to regulate medical waste management is granted under the Resource Conservation and Recovery Act. The Agency also has special regulatory authority to administer a demonstration medical waste tracking program and is required to complete a number of studies related to medical waste management under the Medical Waste Tracking Act (42 U.S.C. 6901 et seq.).
[b] OSHA's primary authority is granted under the Occupational Safety and Health Act (29 U.S.C. 651 et seq.). Guidelines or regulations only apply to private facilities, unless a State extends coverage to employees of public facilities as well.
[c] Does not have the authority to issue regulations.

SOURCE: Office of Technology Assessment, 1990.

(i.e., the hazardous waste provisions) of the Resource Conservation and Recovery Act (RCRA) to medical wastes.

EPA has concentrated its implementation efforts thus far on promulgating and implementing the requirements for the MWTA demonstration program. The regulations were promulgated ahead of schedule in March 1989 and became effective in June 1989 (Federal Register, Mar. 22, 1989). The Agency and its contractor convened a meeting in November 1988 with health-care and waste industry, environmental, and various State and Federal Government representatives to discuss ways to collect information on medical waste generation and management practices as part of this effort (123). EPA's first of three required reports to Congress under the law, highlighting the efforts to address the issues under study, was delayed by more than a year. This delay was due, at least in part, to inaction by the Office of Management and Budget (OMB) in its review of the report. The first report is expected to review what EPA plans to study and focus on the proposed approach for a health hazard assessment (89).

ATSDR is required to report on such health effects of medical waste as: estimates of the number of people annually infected or injured by medical wastes (including sharps), including descriptions of the nature and seriousness of those incidents; and estimates of the number of cases traceable to medical waste of diseases that could be spread by improper management of such wastes (in particular, hepatitis B virus (HBV), and immunodeficiency virus (HIV), or AIDS). Its report to Congress on the public health implications of medical waste is expected to be released on schedule on November 1, 1990.[8]

The EPA and ATSDR studies are limited because existing information and data are inadequate (134). Still needed are research, surveys and studies that generate new information and address existing data gaps.

To address these research needs is beyond the scope of this report, which is intended to provide a framework for considering medical waste management issues and to assess in a preliminary way the potential of various reduction and treatment methods for medical waste.[9] The report is divided into six chapters: 1) applying a comprehensive waste management strategy to medical waste and a brief review of Federal efforts undertaken to date; 2) exploring pretreatment approaches (e.g., waste reductions and recycling options); 3) exploring nonincineration medical waste treatment technologies and emerging treatment technologies; 4) examining current issues regarding incineration of medical wastes; 5) discussing special treatment issues, such as sharps (e.g., needles, glass, etc.) management and small generator issues; and 6) comparing various management treatment alternatives.

SUMMARY OF FINDINGS

Two of the critical findings of this study are consistent with a comprehensive waste reduction and materials management approach to waste management. First, treatment technologies will continue to be needed for waste management, but they can be preceded and complemented by prevention and pretreatment efforts (i.e., reduction and recycling). Second, while there is no one preferred treatment method, source separation practices (i.e., separating wastes based on the physical, chemical, and infectious characteristics) are key to targeting particular materials/wastes for the most appropriate treatment method.

Other findings of this report include:

. The commercial viability of nonincineration treatment alternatives has increased in recent years due to the increased cost of incineration, the difficulty associated with permitting incinerators, and the perceived desirability of reducing dependence on incinerators given concern over their emissions. Alternative treatment technologies such as autoclaving (steam sterilization) with compaction, microwaving, and mechanical/chemical disinfection are likely to be less capital intensive and have fewer emission concerns than incineration processes. Yet, further investigation of treatment alternatives (e.g., health

[8]These findings, however, will be limited by the nature of the existing &M base and literature from which the findings are drawn. The number Of unreported occupational injury cases, the baseline health status of workers, and the significance of potential exposure routes not yet studied (e.g., aerosolization of substances during treatment, etc.) are crucial unknowns which could strongly impact risk determinations of various treatment technologies.

[9]Treatment methods throughout this report refer broadly to any management technique and processes intended to render the wastes suitable for disposal. Treatment of medical wastes is intended both to render wastes noninfectious and to lead to environmentally sound disposal.

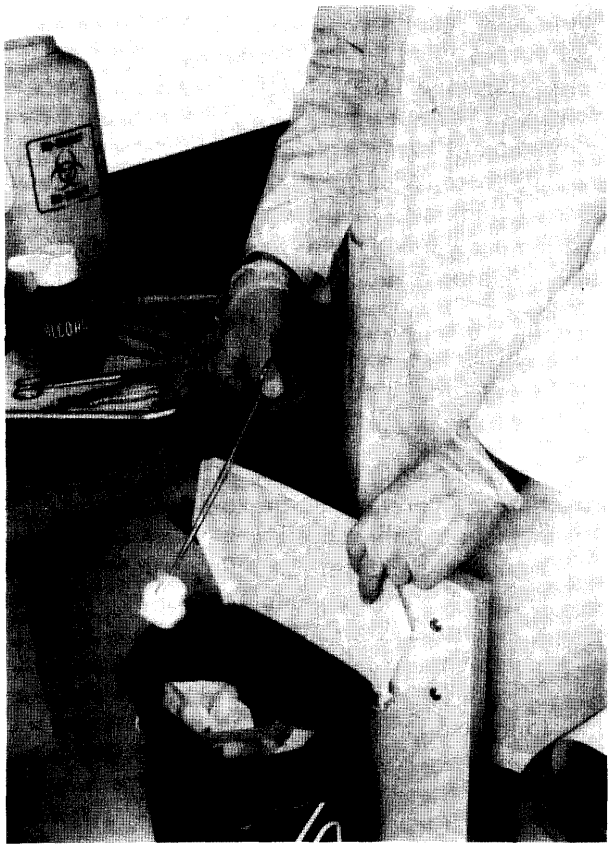

Photo credit: Extrufix, Orlando, Florida

The diversity of the medical waste stream indicates that source separation practices can help target particular materials/wastes to the most appropriate management method, based on the physical, chemical, and infectious characteristics of that waste.

risks) and determination of appropriate performance standards is warranted, as well as consideration of research and development funding to encourage innovative technologies.

- Current regulatory activity at all levels of government tends to encourage incineration either by focusing most of its activity on incineration and/or by identifying it as a preferred treatment method in regulations or guidelines with minimal attention to alternatives. Congress may alleviate concerns over the difficulties associated with introducing alternative treatment technologies by directing EPA to specify approval or certification processes for treatment alternatives capable of rendering infectious medical wastes noninfectious. A program taking these factors into account might help stimulate the development of innovative and improved treatment processes.
- Incineration remains and is likely to continue to remain a primary treatment method for medical wastes for the foreseeable future. Advanced pollution control equipment is becoming a standard part of many new incinerators. An important concern is the impact Federal regulation of air emissions from medical waste incinerators will have when they are finalized in 1991, since stringent regulations have been already enacted by some States.
- New incinerators for a variety of reasons (as noted above) are tending to be larger facilities that operate on a more continual basis than facilities in the past. A number of regional incinerators, either nonprofit/generator or commercial ones, are being planned. Yet some medical waste generators prefer to continue managing their own waste in an effort to maintain greater control over their costs and liability. A number of factors weigh in favor of or in opposition to on-site and off-site management, leaving the particular circumstances of the medical waste generator and the host community to be the main determinants for the type of treatment selected.
- A fundamental policy issue of importance that the Federal Government could address is the extent to which medical wastes are to be regulated on the basis of their potential threat to public health (i.e., infectious nature) and their aesthetic characteristics (i.e., recognizability as a medically related item). That is, Congress could clarify whether the nonrecognizability criteria of MWTA should remain a part of future regulations by addressing this issue either as part of the current Resource Conservation and Recovery Act (RCRA) reauthorization or as part of the evaluation of MWTA upon its expiration in 1991.
- A need exists for further education about the nature of the risks posed by medical wastes and methods for their proper handling and management for health-care workers, other workers at risk, and the general public. These efforts could be undertaken by either or both the health-care community and the government. Such efforts could include instruction for health-care workers and housekeeping staff exposed to medical wastes and incinerator

operating training for workers responsible for medical waste management.

This brief study discusses what is known regarding various medical waste treatment technologies and related management issues. Possible directions for Federal policy and areas where further information to facilitate policy development and improved management are suggested by the study's findings.

POLICY ISSUES FOR FEDERAL ACTION

The reauthorization process for RCRA provides an opportunity to revisit the medical waste issues first addressed by Congress in 1988. In 1991, the completion of the MWTA demonstration program will provide further opportunity to incorporate what is learned from the program and from the mandated studies by EPA and ATSDR into the decision making process for any further Federal action on medical wastes management.

One possible option regarding medical waste issues for Congress to choose is to do nothing in this area once the MWTA demonstration program and agency studies are completed. EPA will set air emission standards for medical waste incinerators and Congress could defer to the Agency, as it has in the past, for any further policy action as considered necessary. Given the general concern over EPA's past reluctance to act on medical waste issues and current efforts at improving waste management practices in the country coupled with concern over State variations in the regulation of medical wastes, this appears to bean unlikely course for Congress.

More likely, Congress will address at least some issues regarding medical waste management as part of the RCRA reauthorization, whatever action may or may not be taken once MWTA expires. 10 Congress could move beyond the current approach to medical waste management and define a more comprehensive approach. A comprehensive approach might incorporate medical waste into the type of waste reduction and materials management approach suggested by OTA (1 16) for MSW. Such an approach could, for example, include determinations on the definition of regulated medical wastes; address waste reduction and recycling goals/objectives; encourage the development and adoption of baseline, uniform standards for each type of treatment method; establish a protocol for approving or certifying new treatment alternatives; and include medical wastes in State waste management plans. In these plans, States could be required to consider waste reduction options, recycling opportunities, capacity needs for treatment, and similar planning issues for medical waste, as they would be required to do for MSW.

Within this more comprehensive approach to medical waste management, or independent of it, a number of other policy issues can be addressed. These include the following:

- Reduction and recycling issues-Greater attention to opportunities for toxicity and volume reduction and recycling of medical wastes would complement the efforts suggested and being adopted throughout the country for MSW. Dissemination of information through the EPA clearinghouse and possibly research and development (R&D) funding, could bring attention to these opportunities.
- Non-incineration treatment technologies—Further investigation of treatment alternatives is warranted, e.g., health risks; need for performance standards (e.g., waste loadings, temperatures); operator and maintenance procedures, etc.
- Incineration treatment issues—Monitoring and operating requirements for medical waste incinerators and operator training and certification requirements could be specified; standards for air emissions and ash management could be established.
- Small generator management-Information and assistance for households and other nonhospital sources of medical wastes could be made available through the clearinghouse for solid waste, which RCRA already directs EPA to establish and the Agency is currently developing.

A number of these issues will need to be addressed by nongovernmental entities, such as hospitals and other generators of medical wastes, the manufacturers of medical supplies, and the waste management industry. In particular, a hospital or medical facility itself can best identify standard operating procedures that affect waste

[10]Note that a number of bills on various aspects of medical waste management have been introduced in Congress, yet the focus Of activity is likely to center on how medical waste issues are addressed in the reauthorization of RCRA.

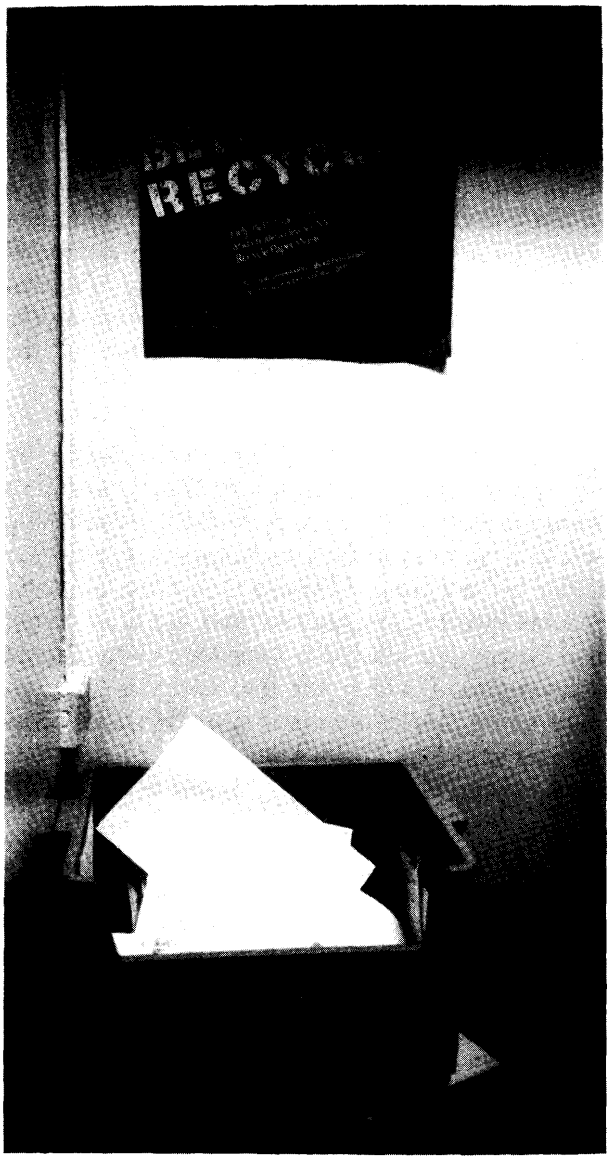

Photo credit: R. Guttman

Careful planning and a comprehensive approach to waste management, which may include recycling efforts, are likely to reap cost savings to a medical facility, as well as environmental benefits for its community.

segregation practices, safe handling of waste materials, and adoption of waste reduction, reuse, or recycling practices.

Medical waste management is a small part of a health-care facility's function, but careful planning and a comprehensive approach to waste management are likely to reap cost savings to the facility, as well as environmental benefits for its community. This type of planning would involve consideration of purchasing practices, use of different types of products, methods of waste segregation, and selection of treatment option(s) based on consideration of the full range of available alternatives. The benefits of such efforts may include cost savings to the facility as well as a reduction in the amount of waste requiring management.

Education efforts regarding the nature of the risks posed by medical wastes and methods for their proper handling and management can also be effectively undertaken by health-care providers-for health-care workers, other workers at risk, and the general public. These efforts can include incinerator operating training and personal protective equipment and instruction for housekeeping staff exposed to medical wastes. The government, waste generators and others involved in medical waste management also can undertake such efforts (see ch. 4).

For example, the American Diabetes Association helps educate diabetic patients on the safe disposal of their syringes (4). The government also could make information and assistance for households and other nonhospital generators of medical wastes more readily available. One possibility is to include such a focus in the clearinghouse for solid waste being established by EPA, as currently required by RCRA. The resources spent on various education efforts would improve understanding of how medical wastes can properly be managed, their associated risks, and would facilitate adoption of improved management practices.

Other more specific issues for which policy clarification by Congress will be useful are whether the nonrecognizability criteria of MWTA will remain a part of future regulations; whether shredding requirements should or will be adopted; and also some specific packaging, transportation, and mailing issues.[11] Of these issues, a fundamental one of critical importance that the Federal Government could address is the extent to which medical wastes are to be regulated on the basis of their

[11] For example, two bills (S. 2393 and H.R. 3386) currently before Congress address the transportation of medical wastes as it is part of the backhauling of waste. The legislation seeks to require the use of dedicated vehicles for some substances, such as medical wastes, to avoid the transportation of food in vehicles used to haul such wastes. The Department of Transportation, however, does not want the authority to regulate backhauling (as the proposed law would grant them) and instead believes the EPA, Department of Agriculture, and the Food and Drug Administration could better take the lead in determining the necessary standards.

potential threat to public health and their aesthetic characteristics.

Considerable expense can be associated with managing wastes (e.g., certain IV tubing) that pose little public health threat but are recognizable as medical items. A health-care organization official recently mused something to the effect that medical waste is probably as much in need of an image consultant as it is in need of regulation. The adoption of regulations that treat wastes purely for aesthetic reasons reinforces a "bad image" for medical wastes, or at least the notion that more of this waste poses hazards than may be true. It may be that the most appropriate treatment criterion with respect to medical waste is the ability of a treatment system to render wastes noninfectious.

Clarifying the definition of regulated medical wastes to include only the waste types considered infectious based on objective criteria may facilitate special management of those wastes that pose the greatest risk to human health without risking" over-regulation" (e.g., special management of wastes for primarily aesthetic reasons). Concerns over such ''needless and expensive' requirements are particularly heard from public officials and generators of medical wastes in rural areas or areas where medical wastes have not been as much of a public concern as they have in the Northeast and other coastal and more densely populated areas. The potential implications of national legislation on areas of the country primarily concerned with the infectious potential (and not appearance per se) of medical wastes need to be carefully considered and balanced against the needs of coastal areas and more densely populated areas. In these areas, the medical waste beach washups and other waste related problems in recent years create entirely different waste management circumstances.

Another important issue centers on addressing whether a "level playing field" exists for all the available treatment alternatives. Congress might facilitate the introduction of new treatment technologies through specification of certification or approval processes for treatment alternatives capable of rendering infectious medical wastes noninfectious. The same testing will not be appropriate for all treatment technologies and determining potential risks and identifying any necessary control measures will also vary depending on the nature of the treatment technology.

A protocol to evaluate new technologies by identifying appropriate tests, establishing standards to demonstrate effective microbial kill, establishing operating parameters and evaluating potential risks could be adopted. Veterans hospitals or other Federal medical laboratories and facilities might also be possible pilot/test sites for new treatment technologies. Funding for the research, development, and testing of alternatives would also encourage innovation and improvement in medical waste management.

It will be an important part of any program regarding the management of medical wastes to include a provision addressing how the adequacy of various treatment alternatives (which in fact might evolve in response to the regulatory program) will be considered. As noted, such a program could provide interim approval or certification status and/or funding for a pilot/test facility to facilitate gathering the information necessary to determine whether routine adoption of the technology would be acceptable. Such a program might help stimulate the development of improved treatment processes.