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Report to the Chairman, Subcommittee on Regulation, Business Opportunities and Energy, Committee on Small Business, House of Representatives

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MEDICAL WASTE REGULATION

Health and Environmental Risks Need to Be Fully Assessed

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Resources, Community, and
Economic Development Division

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The Honorable Ron Wyden
Chairman, Subcommittee on
Regulation, Business
Opportunities and Energy
Committee on Small Business
House of Representatives

Dear Mr. Chairman:

As you requested, this report discusses the infectious medical waste regulatory programs of selected states and the status of the Environmental Protection Agency's implementation of the Medical Waste Tracking Act.

As arranged with your office, unless you publicly release its contents earlier, we plan no further distribution of this report until 30 days after the date of this letter. At that time, copies of the report will be sent to other appropriate congressional committees; the Administrator, Environmental Protection Agency; and the Director, Office of Management and Budget. We will also make the report available to other interested parties.

This work was performed under the general direction of Richard L. Hembra, Director for Environmental Protection Issues, (202) 275-6111. Other major contributors to this report are listed in appendix IV.

Sincerely yours,

J. Dexter Peach
Assistant Comptroller General

program's success, the present and potential threat to public health and the environment, and the various other medical waste management topics. The Agency for Toxic Substances and Disease Registry (the Registry) is to report to the Congress by November 1990 on the health impacts, including the number of people injured or infected by medical waste. This information is to help the Congress decide what type of national program, if any, is needed to address medical waste problems.

Results in Brief

All of the six states GAO examined regulate infectious medical waste in some way. However, the states vary in regulatory authorities; the types of waste defined as infectious; categories of waste generators regulated; and handling, treatment, and disposal requirements. As evidenced by limited monitoring and enforcement, the programs are generally low in priority compared to others such as those for hazardous waste. Program differences reflect individual state priorities and views on the amount of infectious waste mismanagement that is occurring and the resulting risk to public health and the environment.

EPA and the Registry have made progress in implementing the requirements of the Tracking Act. EPA has issued regulations for the demonstration program, and the participating states have started to carry them out. The agency also has under review a draft of its first interim report to the Congress, due in August 1989. The draft summarizes currently available data and describes EPA's planned approach to reporting on the topics required by the act. In addition, EPA has started to examine the public health and environmental threat. The agency plans an extensive data-gathering effort but also raises the possibility of data gaps and the need for more research to fully assess the health and environmental risks. The Registry has under review a draft of its report to the Congress on health impacts. The Registry's draft draws some conclusions about the impacts but recommends additional research.

The major concern over medical waste is that it may transmit disease. Currently, limited documented evidence of this likelihood, one way or the other, is available. Thus, the assessment of health and environmental risks is a logical first and critical step to deciding the future course of action—whether federal or state—to address medical waste problems. The assessment should also help address the related issue of the specific types of medical waste to be considered infectious for management and regulatory purposes. Any major data gaps, however, could limit the usefulness of the assessment for these purposes or delay deliberations on the need for additional regulation until the gaps are filled.

Only New York, New Jersey, Connecticut, Rhode Island, and Puerto Rico are participating in the program. Uncertain federal funding and preference for their own programs were cited as reasons for limited state interest.

The first EPA interim report required by the act, which was due August 1, 1989, is under review within the agency and is expected to be issued soon. The report, in describing EPA's general approach to reporting on the required medical waste topics, outlines what appears will be an extensive data gathering effort for the health hazard assessment. EPA plans to rely primarily on existing data but recognizes that sufficient data may not be available and more research may be needed to assess the risks. The final report to the Congress in September 1991 is to present the findings, options, and recommendations for future research.

The Registry's draft report on the health impacts of medical waste is available for public comment from January 31 to April 2, 1990. The Registry anticipates issuing the report by the mandated November 1990 date. A Registry official said the report will make some conclusions based on the available data but will also recommend additional research to obtain the data needed to fully report on the health effects.

Recommendations

To help ensure that the health and environmental risks posed by medical waste are fully assessed and the results are available to the Congress during the deliberations anticipated after the end of the demonstration program in June 1991, GAO recommends that EPA develop a plan to identify and fill the gaps in the data needed to make the assessment as soon as practicable. GAO also makes recommendations that concern obtaining consensus on the definition of infectious waste and EPA's examination of treatment and disposal methods. (See ch. 4.)

Agency Comments

GAO discussed the factual information presented in this report with EPA officials, who generally agreed with the facts. Their comments have been incorporated into the report as appropriate. As requested, GAO did not obtain official agency comments on the report.

Abbreviations

AIDS	acquired immune deficiency syndrome
ATSDR	Agency for Toxic Substances and Disease Registry
CDC	Centers for Disease Control
CSO	combined sewer overflow
EPA	Environmental Protection Agency
GAO	General Accounting Office
NRDC	Natural Resources Defense Council
OSHA	Occupational Safety and Health Administration
OTA	Office of Technology Assessment
RCRA	Resource Conservation and Recovery Act of 1976

body tissues and organs; (5) used "sharps," such as needles and scalpels; and (6) contaminated animal carcasses, body parts, and bedding. The actual ability of these wastes to produce infectious disease depends on the quantity or strength of the pathogen present, whether it has a portal of entry to a person's body, and that person's relative resistance or susceptibility to the disease.

The nationwide universe of medical waste generators is unknown but could well exceed one million, including household users of insulin syringes and illegal intravenous drug users. Reliable data on the total quantity of medical waste generated annually are also not available. However, EPA estimates that hospitals alone generate 3.2 million tons of medical waste each year and that between 10 and 15 percent of hospital medical waste may be infectious. According to EPA, hospitals produce about 77 percent of all medical waste, excluding that produced by households. The amount of infectious medical waste generated by hospitals may increase as the number of AIDS patients increases.

To minimize exposure to infectious wastes, common medical practice is to specifically identify and segregate these wastes at generation for special packaging and labeling before treatment and disposal. Color-coded polyethylene bags—most often red or red-orange—are used for these purposes. For sharps, puncture-proof containers are the preferred package.

Hospitals dispose of about 85 percent of their wastes on-site. EPA estimates that approximately 70 percent of infectious hospital waste is incinerated on-site and about 15 percent is steam-sterilized on-site in an autoclave. The other 15 percent is generally shipped off-site for autoclaving or incineration. Some semiliquid and liquid infectious waste is discharged to public sewer systems. Incinerator ash and autoclaved wastes are ultimately landfilled. Complete data on how other generators treat and dispose of infectious medical waste are not available. Much of it is placed in the general refuse or garbage and ends up in a municipal incinerator or landfill.

During 1987 and 1988, incidents of medical waste beach washups were reported in several areas across the nation, including Maryland, New Jersey, New York, New England, the Great Lakes region, California, and Texas. While the public health risks due to those washups are

as hazardous on this basis, thereby making them subject to federal regulation. It was the agency's thinking at that time that if the infectious wastes were improperly managed, they could pose a substantial hazard to human health and the environment.

EPA received about 60 public comments on the infectious waste provisions of the proposed regulations, most of which stated that considerable evidence did not exist that these wastes caused harm to human health and the environment. Based on these comments, infectious waste was not identified or listed as a hazardous waste when RCRA subtitle C regulations were issued in May 1980. Thus, infectious waste regulation was left to the states.

In lieu of national regulation, EPA initiated several activities to collect information and assess the problems posed by infectious waste management. It used this information to develop a draft guidance manual on infectious medical waste management that was issued in 1982. After obtaining additional information, the agency published a final guidance manual in May 1986.[1] The manual, which was issued in response to numerous requests for technical information and guidance on this subject, in the opinion of EPA, represented environmentally sound practices for handling, treating, and disposing of infectious waste. EPA also provided training to health care professionals in responsible management of infectious waste.

EPA'S Response to Recent Medical Waste Problems

As instances of improper disposal surfaced, EPA began to reconsider its position regarding regulation of infectious waste. In November 1987, EPA convened an expert panel of representatives from the medical and waste management industries, academia, and government to discuss the definition of, proper management of, and risks posed by infectious waste. The panel's consensus, stated in a report to EPA, was that the risks are greatest to those occupationally exposed to the waste, not to the general public. The consensus of the panel was that EPA should focus on the education of and guidance for those who generate, transport, store, treat, or dispose of the waste. According to the panel, this guidance would address the infectiousness of different types of medical waste and proper segregation, packaging, and treatment methods. The panel recommended that federal regulations be promulgated as a last resort.

[1] EPA Guide for Infectious Waste Management (EPA-530/SW-86-014, May 1986).

With regard to the health and environmental risks, the act requires ATSDR to report to the Congress on the health impacts of medical waste by November 1, 1990, and EPA to report on the present and potential public health and environmental threat. The act further requires EPA to report on the overall success of the demonstration program, the number and types of generators, amount and types of medical waste generated, handling methods used, cost of improper management, advantages and disadvantages of alternative treatment and disposal methods, and other medical waste topics. EPA's final report to the Congress on these matters, including the health and environmental threat, is due September 22, 1991, 3 months after the end of the demonstration program.

The Tracking Act authorized appropriations to EPA as necessary for fiscals year 1989-91 to carry out the required activities. In June 1989, the Congress passed Public Law 101-45, providing $9.0 million for abatement, control, and compliance activities, including implementation of the Tracking Act. EPA plans to use $4.7 million of these funds for Tracking Act implementation. About $1.05 million is to be used by EPA headquarters to conduct studies needed to complete the required reports to the Congress, and the EPA regional offices are to receive $650,000 to implement the demonstration program. The remaining $3 million is to go to the regional offices for distribution to the states, mostly the demonstration program participants.

ATSDR has not been appropriated funds specifically for the Tracking Act. However, the agency obligated from other funds about $108,000 in fiscal year 1989 for its work on the health impacts study.

Objectives, Scope, and Methodology

The Chairman of the Subcommittee on Regulation, Business Opportunities and Energy, House Committee on Small Business,[1] requested that we review state infectious waste regulatory programs. Witnesses at a prior Subcommittee hearing had testified that the lack of a federal policy was contributing to the careless or illegal dumping that had fouled the nation's beaches. Of specific concern to the Chairman was that EPA had decided to leave regulation of infectious waste to the states and the hearing had revealed inconsistencies in state regulation. We subsequently agreed with the Subcommittee's staff that we would determine (1) how infectious waste is managed in six states and (2) the status of EPA's implementation of the Medical Waste Tracking Act.

[1]At the time of the request, the Subcommittee's name was Subcommittee on Regulation and Business Opportunities.

various congressional hearings on infectious waste management held during 1987 and 1988.

Our work was conducted primarily from September 1988 through June 1989, with periodic updates through October 1989. The work was performed in accordance with generally accepted government auditing standards. Information contained in this report was presented in testimony to the Subcommittee on Regulation, Business Opportunities and Energy during a July 25, 1989, hearing on medical waste issues. We also discussed the factual information in this report with responsible EPA and state officials, who generally agreed with the facts. Their comments have been incorporated as appropriate. As requested by the Subcommittee staff, we did not obtain official comments on a draft of this report from EPA or the other agencies included in our review.

The states included in our review reflect a similar growth in regulation of infectious waste. Currently, California, Illinois, New York, South Carolina, and Wisconsin operate under specific infectious waste legislative authorities and/or regulations, while Arizona uses general authorities provided in its health and environmental statutes. Some state officials told us that they believe that their states have specific laws and/or regulations not because of a known public health or environmental threat but rather because it was decided to take a prudent or safe course of action in dealing with infectious waste. Arizona officials told us that the general provisions in state health and environmental statutes are adequate to respond to infectious waste problems that arise.

The states we reviewed split the primary jurisdiction over infectious waste between their environmental and public health personnel, with the lead responsibility assigned to environmental divisions or agencies. State public health personnel usually are responsible for regulating the on-site segregation, packaging and labeling, storage, treatment, and disposal of infectious waste generated by health care facilities. When the infectious waste is to be treated and disposed of off-site, state environmental personnel are generally responsible for regulating the transportation, treatment, and disposal of such waste.

State Infectious Waste Definitions Are Not Uniform

Five of the states we reviewed—California, Illinois, New York, South Carolina, and Wisconsin—have defined infectious waste for regulatory purposes. South Carolina was the latest state to do so with its June 1989 legislation. Although not specifically defining infectious medical waste, Arizona's solid waste regulations consider infected materials to be dangerous refuse and not acceptable for collection with other solid wastes. Table 2.1 compares the categories of medical waste defined as infectious by these five states with EPA's 1986 guidance and current Centers for Disease Control (CDC) guidelines.[2]

[2]CDC's guidelines relate to infection control—generally referred to as universal precautions. The guidelines, which use four general categories of waste to be classified as infectious, are primarily intended to protect health care workers against the spread of disease.

requirements for certain types of waste, such as sharps and infectious cultures. However, some generators, such as physician and dentist offices, veterinarians, and nursing homes are not regulated in some states because of the types or quantities of infectious waste that they produce. Officials in these states believe that these generators' contribution to the total amount of infectious waste produced is relatively small. In addition, effective regulation is difficult because of the large number of these generators.

As shown in appendix I, New York, South Carolina, and Wisconsin regulate all the categories of generators except households for all infectious waste types; California regulates at least some types of infectious waste for all generator categories, including households. On the other hand, Arizona regulates only hospitals and laboratories for all infectious wastes types, and Illinois regulates only hospitals, laboratories, and blood banks for all infectious waste types. Neither Arizona nor Illinois, for example, regulates physician, dentist, and veterinarian offices (California only partially regulates them). These offices individually may not generate large amounts of infectious wastes but taken together the amount they generate may be significant if disposed of improperly. Illinois, for instance, has 25,195 physicians and surgeons, 7,572 dentists, and 1,902 veterinarians.

Requirements for Handling, Treatment, and Disposal Vary

Comprehensive infectious waste regulation involves requirements covering its packaging and labeling, storage, transportation, incineration, autoclaving, and/or landfill disposal. Only California and New York have requirements for all these major aspects of infectious waste handling, treatment, and disposal. Wisconsin has either requirements or guidelines for all of them, and South Carolina has requirements in place or, as a result of its June 1989 state law, plans to issue regulations during 1990 to cover all the major aspects. The other states—Arizona and Illinois—have requirements or guidelines for most of them. In cases where requirements have not been established or only guidelines have been issued, state officials do not believe that regulation is needed. (The status of infectious waste management requirements for the six states we reviewed is shown in appendix II.)

The specific state requirements can differ substantially, depending on state officials' views on how much and what type of regulation is needed. For example, of the five states with regulations for infectious waste incineration, California and Illinois do not specify requirements

Licensure inspections are conducted primarily by state health officials to ensure that hospitals and other health care providers are operating their facilities according to a broad range of requirements. Infectious waste management is but one of the numerous facility operations covered during these inspections. The infectious waste component varies by state, ranging from a file review of policies and procedures for controlling the transmission of infections to activities such as observing how infectious waste is handled.

Although New York, South Carolina, and Wisconsin have infectious waste requirements for physician and dentist offices, veterinary hospitals, funeral homes and other similar infectious waste generators, state officials do not routinely inspect their practices. Several state officials told us that these generators are usually inspected only on receipt of complaints alleging improper and illegal disposal practices, such as mixing infectious waste with regular garbage. These generators are thought to produce small quantities of infectious waste, but some state officials have expressed concerns about the appropriateness of their waste handling practices.

Incineration and autoclaving further illustrate the varying and generally limited state monitoring of infectious waste management. For some of the states included in our review, information on the number, types, and results of infectious waste incinerator inspections was not centrally maintained and readily available.

However, as described by state officials, the inspection programs differ in terms of the frequency and types of inspections. For example, in New York, the state is to inspect the performance of hospital incinerators annually and the commercial infectious waste incinerator facility is to be inspected quarterly. Effective January 1989, incinerators must conduct annual stack tests to ensure that the levels of certain pollutants emitted into the air do not have an adverse impact on public health. In addition, New York environmental officials recently updated performance standards for all incinerators and now require the testing of ash from infectious waste incinerators.

In comparison, Arizona and Illinois officials told us that they are not routinely monitoring small-capacity incinerators such as those in many hospitals. Arizona environmental officials told us that they do not view infectious waste incinerators as major sources of air pollution and do

revoke or suspend licenses of regulated health care facilities for improper infectious waste management practices and assess civil penalties of up to $5,000 plus up to $2,500 per day the violation continues. Under its Environmental Conservation Law, the state may revoke or suspend operating permits and assess penalties for the improper containment, storage, transportation, treatment, and disposal of infectious waste. Depending on the nature of the violation, civil penalties range from a maximum of $25,000 per day to a maximum of $50,000 per day. Criminal penalties range from $10,000 per day to $25,000 per violation ($1 million for organizations) and imprisonment ranges from 15 days to 15 years. (A brief description of the enforcement authorities for the states we reviewed is contained in appendix III.)

Readily available information on state enforcement actions was limited. The states do not organize their enforcement files so that infectious waste cases are easily identified, and the states did not have summary information for these cases. However, on the basis of our discussions with state officials, it appears that the number of enforcement actions taken against infectious waste management violators has generally been small. For example, according to Arizona Department of Environmental Quality officials, the state's only infectious waste enforcement actions have been the issuance of two cease and desist orders for inappropriate infectious waste storage conditions, one in September 1980 and another in May 1989, against a pet crematorium. In the earlier case, inspections were conducted in response to citizen complaints, and in the later case a routine inspection disclosed violations. California's Department of Health Services has taken three infectious waste enforcement actions since 1985. These cases resulted in a civil action against a hospital and corrective actions against a transporter and an off-site treatment, storage, and disposal facility. Several officials of the states we visited told us that enforcement is made more difficult by the need to prove the presence of an infectious agent in the waste. Such proof is difficult to provide because the threat of disease transmission depends on factors such as the quantity of pathogens present in or on each item. The quantity of live pathogens can vary, depending on when tests are conducted. In addition, testing for all possible types of pathogens can be expensive.

On the other hand, New York has taken numerous enforcement actions. For example, since January 1, 1989, New York's Department of Environmental Conservation has settled about 110 medical waste cases that resulted in fines and penalties totalling about $100,000. Many of these enforcement actions were against hospitals and physicians for the improper packaging, storage, transfer, and disposal of regulated medical

Definition of Infectious Medical Waste

A key component of any infectious waste management or regulatory program is the infectious waste definition that is used. That definition, in specifying what categories of waste will be segregated and receive special handling, treatment, and disposal, is important from both a health and cost standpoint. The inclusion of too few categories may mean that some potentially infectious wastes are not controlled and, as a result, health care and sanitation workers and the general public may not be adequately protected against the threat of disease transmission. On the other hand, including too many categories results in more waste receiving special and more costly attention, increasing overall health care delivery costs. Some experts have estimated that special precautions and treatment practices, depending on what they are, can increase infectious waste disposal costs by up to 20 times the cost of disposing of a hospital's general waste.

A number of federal, state, and private agencies have infectious waste definitions, and these definitions vary. At the federal level, for example, EPA and CDC have issued different definitions. Using an interpretation of CDC's definition, an estimated 3 to 5 percent of a typical hospital's wastestream would be designated infectious. Using EPA's more conservative definition, that estimate increases to between 10 and 15 percent. According to OTA, from 3 to 90 percent of a hospital's waste can be defined as infectious, depending on the definition and waste segregating and other procedures followed. The cost impact of what definition is followed can be large. OTA cited the example of one 600-bed hospital that reduced its costs by $250,000 annually by changing its infectious waste definition from 13 categories to the 4 designated by CDC.

Various studies (e.g., those by OTA and the Council of State Governments), state officials, medical and waste management industry representatives, and others have discussed the lack of a uniform infectious waste definition. Specific concerns include confusion and inefficiencies for generators and those involved in treatment and disposal in more than one state when they have to meet varying requirements or receive different guidance as to correct practices to follow. Another concern is that certain categories of medical waste will be shipped from states that include them in their definition and regulate them to states that do not. Illinois public health officials, for example, stated that a national definition would make it easier to standardize infectious waste handling practices.

A possibly larger concern is that with the use of different definitions, assurances of adequate protection from the threat of disease and of cost

leachate collection systems, and do not check for groundwater contamination.

Some states have banned landfill disposal of infectious waste on the premise that it presents a public health problem to landfill workers and others. In addition, some landfills are refusing to accept any infectious waste, including that which has supposedly been autoclaved or similarly treated, for this reason.

Key questions are under what, if any, circumstances untreated infectious waste may be landfilled and are standard procedures or controls needed to (1) protect the health and safety of landfill workers at sites where it is allowed and (2) prevent pathogens from migrating to groundwater underlying those sites. Consideration of worker protection controls could include (1) separate handling of infectious waste at the landfill, (2) burying of infectious waste immediately on arrival at the landfill, (3) burying of infectious waste prior to compaction, and (4) requiring that on-site workers wear proper safety attire.

Discharging Infectious Waste to Sewers

In its 1986 infectious waste guidance manual, EPA stated that it is prudent to manage all blood and blood products as infectious waste because it is impractical to test all blood for the presence of every possible pathogen. The manual also stated that blood and blood products may be discharged to the sanitary sewer for treatment in the municipal sewerage treatment plant provided that secondary treatment is available.[6] In addition to blood and blood products, ground-up body parts and organs and other infectious liquid or semiliquid hospital wastes may be legally discharged to public sewer systems.

One potential problem with sewage disposal of infectious waste is that many urban areas have combined sanitary and storm sewers. As a result, when rainfall occurs, untreated sewage and other wastes may be discharged to area waterways before reaching the treatment plant because the plant cannot accommodate the increased wastewater flows. These discharges are referred to as combined sewer overflows (CSOs). And they are not uncommon. In the New York City Metropolitan Area alone, there are more than 500 CSO points.

[6]Secondary treatment is waste water treatment in which bacteria consume the organic parts of the wastes. Effective secondary treatment removes virtually all floating and settleable solids and approximately 90 percent of suspended solids.

type hospital incinerators. In addition, the National Solid Wastes Management Association has recommended that incinerators burning infectious waste have their ash sampled at least twice a year to determine if it is still infectious and whether it is a hazardous waste.

Do pathogens survive the incineration process? A paper prepared by representatives of the Bureau of Air Management of the Wisconsin Department of Natural Resources states that most stack tests on infectious waste incinerators confirm that under good operating conditions waste pathogens are not released from the smokestack. However, the paper states that such testing has been limited or unpublished. The paper goes on to say that viral agents such as hepatitis B and the AIDS virus are fragile organisms that are difficult to maintain even in the laboratory and that they are easily destroyed by high incinerator temperatures. However, the paper reports that pathogens in municipal waste have been shown to survive incineration if the incinerator is operated poorly. A study supported by the state of Illinois found that while one species of tested bacteria was destroyed by incineration, the ability of other organisms to survive incineration needs to be investigated. Other studies also suggest the need for more research into the likelihood of pathogens surviving incineration.

The release of toxic substances such as dioxins, furans, lead, and cadmium during medical waste incineration is of greater concern than the release of live pathogens. OTA has reported that the higher concentrations of dioxins and furans in medical waste incineration emissions may be attributed to the frequent startups and shutdowns of these incinerators, less stringent emission controls, poorer combustion controls, and differences in the waste composition, as compared with municipal solid wastes. We also found varying operating requirements and inspection intervals and concerns about the incinerators being old and operators being inadequately trained. For example, South Carolina has proposed regulations that would require operators to be certified before incinerators are issued operating permits.

Issues related to medical waste incineration include the following:

- What minimum temperature and residence time are needed to effectively incinerate infectious waste? Are national standards needed?
- For what substances should air emission limits be established for medical waste incinerators? Should limits on "infectiousness" be included?
- Should incinerator ash be tested before it is landfilled?

wastes if they have assurances that the wastes have been properly treated.

Issues relating to the autoclaving of infectious waste include:

- Is autoclaving effective for all types of infectious waste, or should other treatment methods be used for certain types?
- What minimum temperature, residence time, and pressure should be maintained throughout the autoclaving process? Should these conditions be established by national standards?
- What documentation of performance efficiency should autoclave operators be required to maintain? How frequently should state or local government personnel inspect autoclaves?
- How can assurances be provided to landfill operators that infectious waste, has, in fact, been effectively autoclaved?

Summary/ Observations

States have increasingly responded to public concerns by establishing programs to regulate infectious wastes. Because the programs were developed at different times and in response to different concerns or incidents, variances are to be expected. However, in several cases, practices different from EPA guidance or varying requirements and practices raise the issue of which of the practices are the most appropriate for efficient and effective regulation of infectious/medical waste and protection of public health and the environment. As discussed in chapter 4, EPA needs to address these issues in its examination of treatment and disposal methods for the required reports to the Congress.

program. Louisiana and the District of Columbia had petitioned for, been accepted into the program by EPA, and later opted out.

The Great Lakes states' notifications to EPA that they elected not to participate cited several reasons for their decisions. These reasons included a preference to use their own state regulations and the cost of implementing the demonstration program—estimated by one state to be $700,000 and by another to be $800,000.

In requesting to withdraw from the program, Louisiana cited recent state legislation placing restrictions on both the state's development of medical waste regulations and participation in the demonstration program. This legislation prohibited medical waste regulations until the state departments of public health and environmental quality certify that the regulations are necessary or after EPA issues its final report required by the Tracking Act. The District of Columbia asked to withdraw because it would be well into the second and final year of the demonstration program before the regulations and organization to implement the program could be put into place.

Uncertainty over the availability of adequate federal funding appears to have been a factor in limited state participation in the program. When EPA met in December of 1988 with representatives from states interested in the demonstration program, several of them expressed the view that lack of federal resources to implement the program would be a disincentive to participating. Although the Tracking Act authorized funding to be appropriated to EPA, agency officials decided to reprogram funds from other programs rather than request that the Congress appropriate additional funds. The reprogramming of $495,000 from other programs to be divided amongst the participants was done before the states had to notify EPA of their intention to participate, and may have been a disincentive to some states to participate in the program because they did not know how many states would share the limited funds. The funds provided by Public Law 101-45 for program participants came after the participants had been determined and replaced the reprogrammed funds.

EPA officials said that they considered giving states another opportunity to join the program but decided not to delay program completion. According to the officials, the number of participants is adequate to evaluate a tracking program because medical waste generators and the types of wastes produced are similar across the states. However, the participants provide a geograpically limited cross-section of states. For

After a review of available literature and input from the medical community, state regulators, and others, EPA's list of regulated medical waste consisted of the five mandatory categories, a narrowed definition of category 10 above—isolation wastes—and a new category—unused sharps. The mandated categories were qualified to the extent that cultures and stocks (category 1) were limited to those that cause disease in humans, pathological wastes (category 2) to those of human origin, and animal wastes (category 5) to those known to have been exposed to infectious agents.

EPA limited regulated isolation wastes to that associated with humans or animals known to be infected with highly communicable diseases. The agency determined, with the assistance of health care professionals, that including all isolation waste was unnecessary because much of it is either covered under other categories of regulated waste or is neither infectious nor aesthetically objectionable. Unused sharps were included because of the risk of injury that they pose and because of the aesthetic degradation that they cause, regardless of the presence of infectious agents. EPA's position is that certain items from categories 6-9 that are potentially infectious will be covered by the other regulated categories. In addition, they are to be covered if they are saturated or dripping with blood. According to EPA, representatives from the Centers for Disease Control, the National Institutes of Health, states, and the health care industry convened before issuance of the regulations generally asserted that the remaining wastes in categories 6-9 did not need to be regulated.

Some have criticized the listing of regulated medical waste as too broad while others have said that it is too narrow. In comments submitted to EPA following publication of the regulation, representatives from the medical industry charged that wastes that pose little or no threat to human health or the environment, such as tubing and unused sharps, have been included, resulting in additional waste management costs. On the other hand, others, including several Members of Congress, have urged EPA not to exclude from regulation items that are clearly medical waste and that have washed up on beaches or items that they believe pose a threat to public health or the environment. For example, NRDC has stated that EPA has not supported with sound technical information its decisions to exclude certain waste from the regulation. NRDC also disagrees with EPA's decision to limit regulated isolation waste to that from patients and animals with certain highly communicable diseases. Furthermore, the June 1989 Report of the Medical Waste Policy Committee, prepared by an ad hoc panel of representatives from health care providers, the medical supply and service industry, labor, waste disposers, and

reviewing the universe of manifests would be small, and that the benefits would be outweighed by the costs. For example, one official suggested that generators that would fail to report a discrepancy might also choose not to file a tracking form in the first place, in which case EPA would not be able to discover the discrepancy by reviewing tracking forms. In addition, EPA officials said that the regional office inspections of generators covered by the act include a review of tracking forms to ensure that reports are being properly submitted when discrepancies occur.

EPA's regulation provides several exemptions to the tracking requirements. As authorized by the act, EPA exempted from tracking any medical waste after it has been incinerated. In addition, EPA exempted waste that has been treated and rendered nonrecognizable, which can be accomplished a number of ways, including sterilizing the waste with steam, radiation, or chemicals and then shredding it. EPA believes that these procedures remove both the health and aesthetic concerns associated with certain types of medical waste, thereby removing the need to track it. Furthermore, EPA's regulations exempt small-quantity generators (those producing less than 50 pounds of the waste in any calendar month). These generators, however are required to segregate, package, label, and mark the waste in the same manner as large generators and maintain logs of their shipments. EPA believed that the paperwork burden resulting from individually tracking each shipment of the estimated 100,000 small-quantity generators would be overwhelming.

Enforcement

The Tracking Act gives EPA the authority to assess civil penalties of up to $25,000 per day per violation against violators of the act, to seek injunctive relief in U.S. district court, and to seek criminal penalties for knowingly violating the act. The act also gives the states the authority to conduct inspections and take enforcement actions. The act does not specify whether EPA or the states are to take the enforcement lead. And EPA's regulations do not explicitly describe the enforcement roles and responsibilities. EPA, however, has prepared an enforcement strategy.

According to the strategy, EPA's goal will be to encourage states to implement the program by providing them with the flexibility to develop a variety of implementation methods and innovative approaches to compliance and enforcement. The strategy also says that because of the size and diversity of the universe of medical waste handlers and the resources that would be needed to monitor them all, EPA and the states should seek to maximize voluntary compliance through outreach and

- Available and potentially available methods for handling, storing, transporting, and disposing of medical wastes and their advantages and disadvantages.
- Available and potentially available treatment methods, their advantages and disadvantages, and factors affecting their effectiveness.
- Existing state and local controls on handling, storage, transportation, treatment, and disposal of medical wastes, including enforcement and regulatory supervision.
- The appropriateness of using any existing state requirements or the requirements contained in subtitle C of RCRA as nationwide requirements to monitor and control medical wastes.
- The effect of excluding households and small-quantity generators from regulations and potential guidelines for the handling, storage, treatment, and disposal of medical waste by households and small-quantity generators.
- Available and potentially available methods for the reuse or reduction of the volume of medical waste generated.

In addition to the final report, the act required EPA to issue two interim reports containing the information available on these topics at the time of submission. The first interim report was due 9 months after passage of the act (August 1, 1989); the second is due 12 months after the effective date of the regulations (June 22, 1990). The final report is due September 22, 1991.

EPA has not issued the first interim report that was due August 1, 1989. The draft report is in the final stages of review and its issuance is anticipated shortly, possibly in March 1990. In addition to providing available information, this report is to describe EPA's general approach to gathering data to be included in subsequent reports.

The research and data collection needed for EPA to address the required medical waste topics will be extensive. Although EPA has not developed detailed plans to address each of the required topics, its approach, as set out in the draft interim report, calls for use of studies that the agency and others have already conducted; a search of available literature; input from the states, medical community, and others; and additional research if found necessary. Available data are limited, however, and EPA plans to rely to a large extent on extrapolation of the data submitted by the participants of the demonstration program. EPA officials believe that such extrapolation is valid. In a November 1988 meeting with health care and waste industry representatives, EPA discussed the question of how to gather national data on the amount and types of medical

Although their data collection efforts appear to be extensive and comprehensive, both ATSDR and EPA are relying primarily on available data. EPA has suggested, however, that sufficient data may not be available to perform a meaningful risk assessment and that more research may be needed. This concern was also expressed in a recent paper commissioned by the Rockefeller Institute of Government, State University of New York which states that the health assessment question that EPA is charged with is one that most interested parties admit is unanswerable at present.[1] The paper points out that EPA's past decisions on the risks associated with medical waste have been based on a lack of data showing incidents of disease transmission rather than laboratory studies of the survivability of various microorganisms and pathogens outside the body. EPA will have to decide whether meaningful conclusions can be drawn based on available data, or whether additional data must be generated. An ATSDR official told us that their report will contain conclusions based on available information but will also recommend areas for further research to obtain the data needed to fully report on the health effects.

Related EPA Medical Waste Activities

EPA has stated that it does not expect the tracking program to entirely eliminate the beach washup incidents that were a major motivating factor behind the Tracking Act. This view is based on the fact that some of the suspected sources of last summer's beach washups are not covered by the new tracking system. These sources include household medical care and intravenous drug use. These wastes are thought to have reached the beaches through improper handling of ordinary trash and combined sewer overflows.

A December 1988 State of New York Department of Environmental Conservation report supports the notion that a wide variety of sources, including some that are not being regulated under the demonstration program, contributed to the waste found on beaches last summer in the New York harbor area.[2] The report concluded that while most waste cannot be linked to a particular source, significant sources appear to be

[1]Thomas W. Church, Phillip J. Cooper, Robert Nakamura, The Political and Regulatory Environment of Medical Waste: Formulation and Implementation of the Medical Waste Tracking Act, University of New York at Albany.

[2]Investigation: Sources of Beach Washups in 1988, New York State Department of Environmental Conservation (Dec. 1988).

of the program were surveillance of the harbor for garbage slicks, regular cleanups, nonroutine cleanups when slicks are sighted, and a communications network. EPA functioned as the center of the network and coordinated cleanup activities. It also joined with others to conduct surveillance of the harbor by helicopter and boat.

Incineration

EPA is conducting several projects intended to address the growing concern over air pollution caused by medical waste incineration. EPA estimates that there are about 6,000 hospital waste incinerators in the United States and that hospitals incinerate about 70 percent of the medical waste they generate on-site. About 10 percent of the remaining 30 percent is estimated to be transported off-site to be incinerated. EPA officials and others suspect incineration will increase during the demonstration program because the waste does not need to be tracked after it has been incinerated. Similarly, according to EPA, state efforts to limit land disposal of untreated infectious waste could lead to an increased amount of incineration.

According to a December 1988 EPA report, hospital waste incinerators have the potential to emit such pollutants as acid gases (e.g., sulfur dioxide, nitrogen oxides, and hydrogen chloride), trace metals (e.g., arsenic, cadmium, lead, mercury, and nickel), pathogens, carbon monoxide, dioxins, and furans.[5] However, federal air emission standards generally do not apply to hospital incinerators because of their relatively small size. And according to EPA, most states do not regulate particulate matter emissions and opacity for these incinerators.

In March 1989, EPA initiated a regulatory program to address air emissions from medical waste incinerators. The regulatory program, according to EPA, will consist of three parts: performance standards for new incinerators, consideration of a training program for operators of existing incinerators, and the consideration of providing voluntary guidance to state and local agencies on the best available control technology to be used prior to issuance of the standards for new incinerators. According to an EPA official, the agency plans to issue the proposed standards in March of 1992.

[5]Hospital Waste Combustion Study: Data Gathering Phase (EPA-450/3-88-017, Dec. 1988).

Conclusions and Recommendations

The need for federal regulation of medical waste management has been an issue at least since 1976 when the Congress included infectiousness as one of the properties for EPA to consider in deciding what wastes to regulate as hazardous under Subtitle C of RCRA. However, in the absence of documented evidence of a substantial public health and environmental threat, EPA has left medical waste regulation to the states.

The recent beach washups and other incidents of medical waste mismanagement have heightened public concern and led to the revelation that many states did not have medical waste regulatory programs and that existing programs varied considerably. As evidenced by our work, several states responded to these concerns by establishing programs or strengthening existing ones. Nonetheless, the need for federal regulation is again an issue because of the concerns that national standards are needed to adequately protect public health and the environment or that varying state and local requirements are creating confusion and increasing handling costs for the medical and waste management industries.

At a minimum, medical waste is general refuse or garbage and its improper disposal in the environment is undesirable. The public's reaction to these wastes from an aesthetic and fear-of-disease standpoint and the possibility of injury from sharps add to the undesirability. However, whether stringent segregation, packaging and labeling, transport, treatment, and disposal controls are needed—at the federal or state level—primarily depends on the amount of threat to public health because of the wastes' potential infectiousness. Although it is generally agreed that some medical waste contains infectious agents, a clear consensus on the amount of threat to the general public and on whether medical waste is any more infectious than ordinary garbage (sick people spend part of their time at home before entering hospitals) has not been reached.

A major reason cited for this lack of consensus has been that sufficient research has not been performed to determine whether the threat is substantial or not. The Medical Waste Tracking Act requires EPA and ATSDR to assess the threat and report the results to the Congress. Although their planned efforts, as described in the draft interim report, appear to be extensive, drawing on published studies and representatives and data bases of several health organizations, ATSDR and EPA are primarily relying on existing data to conduct their respective parts of the assessment. An ATSDR official told us that the agency's health impacts report, which is under review in draft, will draw some conclusions but also recommend additional research. According to its draft interim report, EPA

waste may not be needed, raising handling, treatment, and disposal costs. Another concern is that regulation of certain items in one state but not another may encourage waste shipment from the regulated to the unregulated state.

The definition and classification of infectious waste has been controversial, as evidenced by the different definitions that currently exist. In addition, EPA's determination of regulated medical waste for the demonstration program has been criticized both for including too many and for including too few categories of medical waste. The assessment of the health and environmental threat should help, but we believe that obtaining a consensus on the part of the medical community; the waste management industry; regulators at the federal, state, and local levels; environmental advocacy groups; and the general public will prove difficult because of their different perspectives and likely differences in how they interpret the results of the health and environmental assessment. EPA needs to begin to develop the process (working groups, public hearings, etc.) that it will use to bring together these parties in an effort to reach consensus on a definition so that those deliberations can be a part of the deliberations on medical waste regulation that are anticipated after the agency's final report to the Congress.

A concern expressed by some generators and the waste management industry is the added cost of complying with varying state and local requirements. If federal regulations are deemed necessary to address the health and environmental threat posed by medical waste, the concerns about varying requirements should lessen. If federal regulations are not needed, a consensus on an infectious waste definition should help to standardize the scope of requirements. Updating EPA's 1986 guidance to include the results of the activities to implement the Tracking Act may also help standardize requirements.

The other issues discussed in chapter 3—landfilling untreated infectious waste, discharging these wastes to sewers, incineration, and autoclaving—are to be examined by EPA. The Tracking Act specifically requires EPA to report on the health and environmental effects and advantages and disadvantages of incineration. The act also specifically requires EPA to report on the discharge of medical waste to sewage systems. In addition, landfilling untreated infectious waste is a disposal practice and health issue, and autoclaving is a major treatment method. As required by the act, EPA plans to describe available and potentially available disposal methods and their advantages and disadvantages. EPA is also to describe the advantages, disadvantages, and effectiveness of treatment

- Is autoclaving effective for all types of infectious wastes, or should other treatment methods be used for certain waste types? What minimum temperature, residence time, and pressure should be maintained throughout the autoclaving process, and should these conditions be established by national standards? What documentation of performance efficiency should autoclave operators be required to maintain; how frequently should autoclaves be inspected? How can assurances be provided to landfill operators that infectious waste has been effectively autoclaved?

Status of On-Site and Off-Site Infectious Waste Management Requirements in Selected States

	On-site requirements			
State	Packaging and/or labeling	Storage	Incineration	Autoclaving
Arizona	G	G	R	G
California	R	R	R	R
Illinois[a]	R	N	R	R
New York	R	R	R	R
South Carolina	R	R	U	U
Wisconsin	G	G	R	G

	Off-site requirements				
	Transportation	Storage	Incineration	Autoclaving	Landfill disposal
Arizona	N	G	R	G	R
California	R	R	R	R	R[b]
Illinois[a]	R	N	R	R	R
New York	R	R	R	R	R
South Carolina	R	R	U	U	R
Wisconsin	R	G	R	G	R

Key
G = Guidelines only, not enforceable.
R = Requirements in place.
U = Statute requires regulations to be developed.
N = Not regulated by the state and no guidelines.

[a]Generally limited to infectious waste from hospitals.

[b]Except for body parts and infectious cultures, landfills may receive untreated infectious waste if they have permission from the local health department.

State agency	Enforcement authority	Who is regulated	Enforcement actions and penalties
South Carolina:			
Department of Health and Environmental Control	Infectious Waste Management Act, Section 44-93-150.	Persons who manage infectious waste in violation of law and regulations.	Injunction. Civil penalties up to $10,000 per day. Criminal penalties up to $10,000 per day and 1 year imprisonment. For second and subsequent violations, up to $25,000 per day and 2 year's imprisonment.
Wisconsin:			
Department of Health and Social Services	Uniform Licensure Code, Section 50.04.	Nursing homes.	Revoke licenses. Penalties ranging from $100 to $5000 per day.
	Uniform Licensure Code, Section 50.03.	Community based residential facilities.	Revoke license. Injunction. Civil penalties from minimum of $10 up to $1,000 per day.
Department of Natural Resources	Public Health Code, Sections 144.73, 144.735, 144.74.	Persons who violate solid and hazardous waste law and regulations.	Compliance and corrective action orders. Civil penalties up to $25,000 per day. Criminal penalties for first violation up to $100,000 plus 1 to 5 year's imprisonment. For second and subsequent violations, up to $150,000 and 10 year's imprisonment.

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Infectious Waste Regulatory Authorities for Selected States

State agency	Enforcement authority	Who is regulated	Enforcement actions and penalties
Arizona:			
Department of Health Services	Public Health and Safety Code, Section 36-601	Persons who create public nuisance dangerous to the public health	Cease and desist order. Injunction.
	Public Health and Safety Code, Section 36-431.01.	Licensed health care institutions.	Civil penalties up to $300 per day.
Department of Environmental Quality	Public Health and Safety Code, Sections 36-3131, 36-3151.	Persons who violate solid waste law and regulations.	Cease and desist order. Civil penalties up to $1,000 per violation. Criminal penalties up to 4 month's imprisonment.
California:			
Department of Health Services	Public Health and Safety Code, Sections 25187 et seq.	Persons who manage hazardous and infectious waste in violation of law and regulations	Compliance and corrective action orders: civil penalties for noncompliance with order up to $25,000 per day. Civil penalties for violations up to $25,000 per day. Criminal penalties up to $250,000 per day and 6 year's imprisonment.
Illinois:			
Environmental Protection Agency	Illinois Environmental Protection Act. Illinois Code, Title 111 1/2, para. 1042, 1044.	Persons who manage solid waste in violation of law and regulations.	Injunction. Civil penalties ranging from $10,000 plus $1,000 per day violation continues to $25,000 per day of violation. Criminal penalties up to $500,000 per day.
Department of Public Health	Hospital Ill. Licensing Act. Ill. Code, Title Ill 1/2, para. 148	Hospitals that fail to comply with law and regulations.	Suspend or revoke license.
	Clinical Laboratories Act. Ill. Code, Title 111 1/2, para. 628-101, 629-103.	Clinical labs that fail to comply with law and regulations.	Revoke license. Penalties up to $1,000 per day.
	Blood Bank Act. Ill. Code, Title Ill 1/2, para. 608-101.	Blood banks that fail to comply with law and regulations.	Revoke license.
New York:			
Department of Public Health	Public Health Law, Section 1389-gg.	Regulated health care facilities: hospitals, residential health care facilities, clinical labs.	Revoke or suspend license. Injunction. For first violation, civil penalties up to $2,500 plus up to $1,000 per day violation continues. For second and subsequent violations, up to $5,000 plus $2,500 per day.
Department of Environmental Conservation	Environmental Conservation Law, Sections 71-2704, 71-2705	Persons who violate infectious waste law and regulations.	Revoke or suspend permit. Injunction. For first violation, civil penalties up to $25,000 per violation, plus $25,000 per day violation continues. For second and subsequent violations, $50,000 per violation, plus $50,000 per day. Criminal penalties range from $10,000 per day of violation to $250,000 per violation ($1 million for organizations) plus imprisonment for 15 days to 15 years.

(continued)

Regulated and Nonregulated Infectious Waste Generators in Selected States

Category	AZ	CA	IL	NY[a]	SC[b]	WI[c]
Hospitals	R	R	R	R	R	R
Nursing homes	P	R	N	R	R	R
Laboratories	R	P[c]	R[d]	R	R	R
Ambulatory surgical treatment centers	P	R	P	R	R	R
Medical research facilities	N	P[c]	N	R	R	R
Blood banks	N	P[c]	R[d]	R	R	R
Dialysis centers	N	R	N	R	R	R
Physicians' offices	N	P[c]	N	R	R	R
Dentists' offices	N	P[c]	N	R	R	R
Veterinarians' offices	N	P[c]	N	R	R	R
Funeral homes	N	P[c]	N	R	R	R
Home health agencies	N	P[c]	N	R[e]	R[e]	R[e]
Households	N	P[c]	N	N	N	N

Key
R = Subject to state health and/or environmental regulations.

P = Only certain types of infectious waste, such as used sharps, are subject to state packaging, treatment, and/or disposal regulations.

N = Not subject to state regulations.

[a]Generators of less than 50 pounds a month are exempt from the permitting requirements of the state's waste transporter regulation.

[b]With the exception of sharps, cultures, and blood and blood products, generators of less than 50 pounds of infectious waste per month are exempt from state requirements.

[c]With the exception of sharps, cultures, and body parts, generators of less than 220 pounds a month are exempt from state regulations.

[d]Subject to health care facility licensing regulations only.

[e]Infectious waste generated and disposed of by home health care workers in households is not regulated.

methods. However, EPA's plans to examine these issues have not progressed to the point where it can be determined whether the specific issues or questions we set out in the chapter will be addressed.

Recommendations to the Administrator, EPA

To help ensure that concerns about mismanaged medical waste and the need for federal regulation are adequately addressed in a timely manner, we recommend that the Administrator, EPA, take the following actions:

- Develop a plan to identify and fill the gaps in the data needed to determine the level of threat to public health and the environment posed by medical waste as soon as practicable.
- Begin to develop a process for bringing together CDC and other federal agencies, the medical and waste management industries, the states, environmental groups, and other parties, as appropriate, to obtain consensus on a definition of infectious waste and the other medical waste that needs to be regulated or receive other special attention.

We also recommend that the Administrator ensure that the agency's examination of treatment and disposal methods include the following specific issues:

- Under what, if any, circumstances may untreated infectious waste be landfilled, and are standard procedures or controls needed to (1) protect the health and safety of landfill workers at sites where it is allowed and (2) prevent pathogens from migrating to groundwater underlying the sites?
- What are the impacts on receiving waters and public health from hospitals and other medical facilities discharging infectious waste to combined sanitary and storm sewers? What are the occupational health risks to hospital and sewer system workers from exposure to these wastes? Does household disposal of medical waste to sewers present similar environmental, public health, or occupational risks?
- What minimum temperature and residence time are needed to effectively incinerate infectious waste, and are national standards needed? For what substances should air emission limits be established for medical waste incinerators, and should the ash be tested before it is landfilled? Should operators of medical waste incinerators be certified; should the incinerators be inspected at set intervals to determine if performance standards are being complied with? Should those siting medical waste incinerators consider prevailing winds and nearby buildings?

plans to evaluate whether sufficient information exists to adequately address the questions posed by the Congress on the health and environmental threat and, if minimum data needs cannot be fulfilled, the agency will propose research to obtain such data. EPA's final report to the Congress, due in September 1991, is to present findings, options, and recommendations for further research needs.

The level of threat to health and the environment is critical to selecting a course of action for medical waste regulation, and an assessment of the risks is a logical first step in the decision-making process. If the EPA and ATSDR assessment is to fully serve the process, it has to be scientifically sound, complete, and timely. To help better ensure that the assessment meets these requirements, EPA's identification of critical gaps in existing data needs to take place as soon as practicable. EPA then needs to develop a plan to fill the gaps in time for a complete and sound assessment to be available for the deliberations on medical waste regulation anticipated at the end of the demonstration program and after EPA submits its final report to the Congress. We believe that an initial emphasis on early identification of gaps and development of the plan to fill them would help reduce the likelihood that (1) the assessment due in 1991 will not be complete because of insufficient data and (2) EPA's final report will recommend significant research, reducing support for the findings and delaying deliberations on medical waste regulation.

If the assessment finds that medical waste is a substantial public health or environmental threat, available options would be to establish federal regulations, strengthen state programs, and/or improve medical and waste management industry practices. If these wastes are found not to be a substantial threat warranting greater regulation, some special procedures or controls are still likely for at least some medical waste categories because they contain infectious agents, for aesthetic reasons, or because of their potential for causing physical injury. These controls could continue to be exercised through existing state and local infectious waste, public health, and solid waste programs. However, a public education program may be needed to deal with public concerns and fears about these wastes.

Under either of the above circumstances, a consensus on the definition of infectious waste and what categories of medical waste are to receive special attention would be beneficial to ensure adequate protection without undue costs to implement controls. CDC's, EPA's, and the individual states' definitions vary. As a result, some people may not be receiving adequate protection or controls over some categories of medical

EPA has also taken steps to improve operator training and incinerator inspection. In March 1989, EPA published training materials on incinerator operations and maintenance.[6] In February 1989, EPA published the Hospital Waste Incinerator Field Inspection and Source Evaluation Manual. This manual, which is intended to be used by state and local air pollution program inspectors, discusses, among other things, the inspectors' legal authority, responsibilities, and liabilities; observation methods for visible emissions of pollutants; types of incinerator systems, including air pollution control equipment; inspection procedures and special considerations such as the training and experience of the incinerator operator; and startup and shutdown procedures for a variety of incinerators and pollution control devices.

Summary/ Observations

EPA, the demonstration program participants, and ATSDR have begun to carry out the requirements placed upon them by the Medical Waste Tracking Act. EPA promulgated regulations more quickly than called for by the act but missed the first reporting date set for it by the Congress. Few states are participating in the demonstration program, but it is unclear whether the limited number and geographic distribution of participants will adversely affect the evaluation of the tracking program's effectiveness. ATSDR has a draft of its report to the Congress on the health effects under review and anticipates meeting the mandated November 1990 reporting date.

EPA and others believe that the demonstration program as designed will not entirely solve medical waste problems because of unregulated sources. As a result, the agency has begun to take additional actions, such as the education program for syringe users, that might supplement the tracking system.

As discussed further in chapter 4, the activity under the Tracking Act that is key to deciding on the future course of action with regard to regulating medical waste is the assessment of the risks to human health and the environment. The controversy surrounding EPA's listing of regulated medical waste for the demonstration program illustrates the lack of conclusive information and consensus on these risks. It is important that EPA's and ATSDR's efforts provide a complete and convincing assessment of the risks in time for the deliberations on medical waste regulation anticipated at the end of the demonstration program.

[6]Hospital Incinerator Operator Training Course, Vols. I-III. (EPA-450/3-89-002,003, and 004, Mar. 1989).

the Fresh Kills landfill operations on Staten Island, New York,[3] combined sewer overflows, raw sewage discharges, and storm water outlets. Less significant sources appear to be beach use, recreational boating, and commercial shipping. The report adds that a "final possible source" is illegal disposal, particularly of blood vials, into or near the water. In addition, a March 1989 report prepared for EPA catalogs over 3,800 items of medical waste found on beaches in the Northeast, 73 percent of which are syringe-related.[4] While most of the syringe-related waste cannot be traced to a particular source, some syringes are the type used in hospitals and others are those generally used by households or drug abusers.

According to the New York Department of Environmental Conservation report, estimates indicate that in New York City alone there are between 60,000 and 112,000 diabetics who must inject themselves at least daily with insulin. The insulin syringe is used once and then discarded in either the trash or the toilet. Therefore, the report states, approximately 60,000 to 112,000 syringes per day are placed in the solid waste stream or are discharged through the sewers. This practice occurs in cities across the country.

EPA has begun to work with the American Medical Association, the U.S. Food and Drug Administration, the state of Maryland, and medical supply manufacturers to develop a nationwide educational program for home users of medical items such as needles and syringes. The point of the program would be to encourage users to properly dispose of their medical wastes. Draft guidelines have been prepared for home users, which EPA plans to disseminate to the public through health care professionals. EPA also plans to have the guidelines published in medical trade journals so that practitioners will be made aware of the need for home users to properly manage their medical waste.

On March 7, 1989, EPA also announced a $1 million joint federal, state, and local effort to monitor and collect floating debris in the New York/New Jersey Harbor in the summer of 1989. The objective of the program was to minimize beach washups of plastic, paper, cans, bottles, and other floatable debris from May 15 to September 15. The key elements

[3]In New York City, garbage is transported via barge to the Fresh Kills landfill on Staten Island. In the course of that operation, garbage can fall off of the barges into the harbor. Not all of the garbage is contained or retrieved when this occurs.

[4]Inventory of Medical Waste Beach Wash-Ups, June-October 1988, ICF Incorporated (Fairfax, Va.: Mar. 13, 1989).

waste generated, the treatment and disposal practices used, and the cost of complying with management regulations. The participants' general opinion was that projections could be made from sample data.

Status of the Health and Environmental Hazard Assessment

The Tracking Act requires ATSDR to report to the Congress by November 1, 1990, on the health effects of medical waste, including a description and potential for infection or injury from the segregation, handling, storage, treatment, or disposal of medical waste and an estimate of the number of people annually infected or injured by sharps and other medical waste. It must also contain a description of the nature and seriousness of those incidents and, for diseases that could be spread by medical waste—particularly AIDS and hepatitis B—an estimate of the percentage of the total number of cases traceable to medical waste. EPA is responsible for reporting to the Congress on the present or potential threat to human health or the environment posed by medical waste or its incineration. This information is required to be included in EPA's two interim and final reports on medical waste.

ATSDR anticipates completing its report sometime before the date required by the act. According to ATSDR, the agency has completed data collection and analysis and the draft report is being made available for public comment for a period of 60 days. The public comment period is scheduled from January 31 to April 2, 1990.

EPA's current plan for reporting on the human health and environmental threats is to describe the approach and methodology for the risk assessment in the first interim report and to address data gathered and progress made in conducting the assessment in its second interim report, due in June 1990. According to the draft interim report, the final report to the Congress in September 1991 is to present findings, options, and recommendations for future research needs. Whereas ATSDR is focusing on the number of actual cases of infection or injury resulting from medical waste, EPA plans to identify the types and numbers of pathogens expected to be present in medical waste and associated morbidity and mortality from exposure to these pathogens. The ATSDR data will be incorporated into EPA's work to help evaluate the likelihood of disease transmission. EPA anticipates that the health hazard assessment, when coupled with data on current medical management practices, will provide a basis for determining the types of medical waste requiring controls and whether controls could reduce or eliminate the hazard.

education efforts. (Toward this end, EPA has produced brochures directed to the generators, transporters, and treatment, destruction, and disposal facilities that describe the tracking program requirements.) The strategy explains that states will have the lead for conducting medical waste inspections and taking enforcement actions. The strategy does not recommend a specific approach for states to take, nor does the act authorize EPA to approve or disapprove state enforcement programs. EPA's role, according to the strategy, is to ensure compliance by providing information, guidance, and assistance to the states and to enforce the act when appropriate, for example, when problems develop with waste shipped to or from nonparticipating states or when enforcement by the covered states is unsuccessful or inadequate.

The states and EPA regions have begun to conduct inspections of regulated facilities. An EPA official told us that, in addition, the agency is counting on the vigilance of the waste management industry to point out improper disposal by generators, particularly small-quantity generators such as private medical and dental practices and small clinics. He said that the industry is very concerned about employee exposure to needles and other medical waste, knows that in participating states these items must be handled separately from the normal waste stream and, as a result, will exert pressure on the generators to comply with the program.

Status of EPA Reports to the Congress

The Tracking Act requires EPA to report to the Congress no later than 3 months after the end of the demonstration program on the program's success and changes in incineration and storage practices attributed to the program. In addition, the act required EPA to report on various other medical waste topics, including the following:

- The type, number, and size of generators in the United States, the types and amounts of medical waste generated, and the on-site and off-site methods currently used to handle, store, transport, treat, and dispose of it, including the extent to which it is disposed of in sewers.
- The present and potential costs to local economies, persons, and the environment from improper handling, storage, transportation, treatment, or disposal of medical waste and to generators, transporters, and treatment, storage, and disposal facilities from regulations establishing requirements for tracking, handling, storing, transporting, treating, and disposing of the wastes.

environmental groups, stated that its members were not able to arrive at a consensus view of the appropriate definitions of medical waste to be tracked under the act.

Establishing Tracking Requirements

The Tracking Act required EPA to establish a tracking system that provides the generator of regulated medical waste with assurance that the waste is received by the disposal facility and uses a uniform tracking form among the participating states. As part of the system, EPA was also required to establish requirements for the segregation, packaging, and labeling of the waste. EPA specified the tracking system and segregation, packaging, labeling, and storage requirements in its March 24, 1989, regulation. These requirements became effective for New York, New Jersey, and Connecticut—the first program participants—in June 1989, and for Rhode Island and Puerto Rico in July 1989.

EPA's tracking system specifies that each party (i.e., generator, transporter, or treatment and disposal facility operator) in the chain-of-custody of regulated medical waste must take responsibility for ensuring that the waste is properly accounted for. Copies of the tracking form, or manifest, are signed and retained by each handler of the medical waste shipment. If less than the specified amount of medical waste reaches its final destination, if the waste is unaccompanied by a complete and signed tracking form, or if the waste containers are broken, torn, or leaking, the recipient is required to attempt to resolve the discrepancy with the generator, transporter, and/or intermediate handler. If it is not resolved, the recipient must report the discrepancy within 15 days to the EPA regional administrator(s) for both the state of generation and the state in which the recipient is located (if it is different), as well as to the appropriate state agency for the state in which the waste was generated. Both EPA and the states have authority under the Tracking Act to initiate enforcement actions against those responsible for the discrepancy.

NRDC believes that EPA's decision not to require that copies of the tracking forms be routinely sent to EPA or the state regulatory agencies limits the states' and EPA's enforcement capabilities and reduces EPA's access to data. However, an EPA official told us that the agency does not have the resources to collect and review potentially hundreds of thousands of manifests that will be generated during the demonstration program. He also said that he thought the number of discrepancies discovered by

example, all except Puerto Rico are in the Northeast. Moreover, sufficient nationwide data on generators; types of medical waste generated; handling, treatment, and disposal practices; and disposal problems are not available to determine whether the participants are representative. Therefore, it is unclear whether the lack of broader geographic distribution will adversely affect the evaluation of the effectiveness of the tracking program for nationwide use. EPA officials said that they would not expect other states to be very different from the participating states.

Listing of Medical Waste to Be Tracked Has Been Controversial

In requiring EPA to list the types of waste to be tracked under the demonstration program, the act mandated that the agency include five categories of medical waste: (1) cultures and stocks of infectious agents and associated biologicals; (2) pathological wastes, including tissues, organs, and body parts that are removed during surgery or autopsy; (3) waste human blood and products of blood, including serum, plasma, and other blood components; (4) sharps (e.g., hypodermic needles, scalpel blades, broken glass) that have been used in patient care, medical research, or industrial laboratories; and (5) contaminated animal carcasses, body parts, and bedding of animals that were exposed to infectious agents during research, production of biologicals, or testing of pharmaceuticals.

The act also gave EPA the discretion to exclude from the tracking system any or all items from five additional waste types if the agency determined that they do not pose a substantial present or potential hazard to human health or the environment even when improperly stored, treated, or managed. These waste types were (6) wastes from surgery or autopsy that were in contact with infectious agents, including soiled dressings, sponges, drapes, lavage tubes, drainage sets, underpads, and surgical gloves; (7) laboratory wastes from medical, pathological, pharmaceutical, or other research, commercial, or industrial laboratories that were in contact with infectious agents, including slides and cover slips, disposable gloves, laboratory coats, and aprons; (8) dialysis wastes that were in contact with the blood of patients undergoing hemodialysis; (9) discarded medical equipment and parts that were in contact with infectious agents; and (10) biological waste and discarded materials contaminated with blood, excretion, exudates, or secretion from human beings or animals who are isolated to protect others from communicable diseases. EPA also had the discretion to add to the list any other medical wastes found to pose a threat to human health or the environment.

EPA's Implementation of the Medical Waste Tracking Act

The three major requirements of the Medical Waste Tracking Act are

- implementation of the 2-year tracking demonstration program by EPA and participating states;
- EPA reports to the Congress on the success of the demonstration program and various medical waste topics, such as treatment and disposal methods in use; and
- assessment by EPA and the Agency for Toxic Substances and Disease Registry (ATSDR) of the health and environmental risks posed by medical waste.

Some progress has been made in meeting each of these requirements. EPA has promulgated implementing regulations for the demonstration program, the participating states have been determined, and these states have started to carry out the program. EPA's first interim report to the Congress has been drafted and is expected to be issued soon, possibly in March 1990. This interim report is to outline EPA's approach to (1) determining the present and potential human health and environmental threat and (2) collecting the information to report on the demonstration program and other required topics. ATSDR has completed the data collection and analysis and drafted its health impacts report.

Status of the Demonstration Program

EPA issued regulations to implement the demonstration program on March 24, 1989, earlier than the May 1, 1989, date required by the Tracking Act. The regulations identify the types of medical waste to be tracked and the tracking procedures to be followed in the participating states. After issuance of the regulations, the states had 30 days to decide whether to participate.

Few States Are Participating

As set out by the Tracking Act, the demonstration program could have potentially included all the states. The act specifically targeted New York, New Jersey, Connecticut, and the Great Lakes states (Indiana, Illinois, Michigan, Minnesota, Ohio, Pennsylvania, and Wisconsin) but allowed other states to also participate. New York, New Jersey, and Connecticut were required to participate unless they could demonstrate to EPA that they have implemented a program at least as stringent as the demonstration program. The Great Lakes states could be removed from the program simply by notifying EPA that they elected not to participate. Other states could be included at EPA's discretion by petitioning EPA for inclusion. However, outside of New York, New Jersey, and Connecticut, only Rhode Island and Puerto Rico have elected to be covered by the

- Should medical waste incinerators be inspected at set intervals to determine if performance standards are being complied with?
- Should old and poorly-performing hospital incinerators be replaced or upgraded?
- Should operators of medical waste incinerators be certified?
- Should siting of medical waste incinerators consider prevailing winds and nearby buildings?

Autoclaving Infectious Waste

As with incinerators, proper operation of autoclaves is critical to effective elimination of pathogens in medical waste. In that regard, EPA's 1986 guidance manual recommends establishing standard operating procedures and monitoring all treatment processes, such as autoclaving, to ensure efficient and effective treatment.

Inconsistencies exist, however, in how autoclaves are operated. NRDC has found, for example, that although killing certain bacteria requires 90 minutes of exposure, some facilities apply only a 20-to 30-minute time period. NRDC also found that only four states regulate time, temperature, and pressure conditions for autoclaves--all key to proper sterilization of infectious materials. Other states suggest use of the manufacturers' specifications, but some studies have questioned whether these specifications ensure adequate decontamination. For example, some experiments have shown that even when recommended procedures are followed, sterilization may not occur. If autoclave contents are large, bulky, unusually compacted, or contain a large amount of moisture, the time to achieve sterilization may be long.

According to officials of the states covered by our review, health care facilities are required to periodically test autoclaving effectiveness and maintain logs of infectious waste autoclaved for review during inspections of facility operations. However, none of the states has a system to identify infectious waste that has been effectively autoclaved. Such a system may be beneficial.[8] For example, state officials told us that sanitation workers and private citizens have expressed concerns about whether autoclaved waste had, in fact, been rendered noninfectious. New York state officials told us that most of the state's landfill operators are refusing to accept autoclaved waste because of employee health and safety concerns. Landfill operators may be willing to accept these

[8]A possible system, if shown to be effective, would involve the bags containing the infectious waste to change color when autoclaved. Currently, most of these bags, which are usually red or orange-red, do not change color when autoclaved and thus do not appear any different from non-autoclaved bags.

Some hospital-based engineers and plumbers and sewer system workers are also concerned about the potential health risks of their exposure to untreated infectious waste discharged to public sewer systems. In a report released in 1989, NRDC recommended stopping all dumping of medical waste, directly or through municipal treatment plants, to make sure that it does not wash up on beaches or threaten public health.[7] According to NRDC, discharging infectious blood into the sewer system is already prohibited in Switzerland, Sweden, and West Germany.

Key issues include (1) the impacts on receiving waters and public health of infectious wastes, such as blood products, being discharged untreated by hospitals and other medical facilities through sewers; (2) the occupational health risks to hospital and sewer system workers from exposure to these wastes; and (3) whether household disposal of medical waste to sewers, including areas of combined sanitary and storm sewage systems, presents similar environmental, public health, or occupational risks.

Incineration of Medical Waste

Incineration is the most prevalent method for rendering infectious waste noninfectious. In fact, the Council of State Governments reported in 1988 that 72 percent of the states have existing or proposed regulations recommending that infectious waste be incinerated. Carried out properly, incineration destroys disease-causing pathogens and reduces the volume of waste that ultimately has to be disposed. Concerns exist, however, that the incineration of infectious waste is not carried out consistently or effectively nationwide; and, as a result, live pathogens and toxic substances, such as metals and dioxins, may be emitted into the air during the burning process. Another concern is that the ash may contain pathogens or toxic residues.

Hospital incinerators, which burn most of the medical waste generated by those institutions, have generally not been closely regulated by states and, in many parts of the country, their emissions are monitored only for opacity (density or intransparency) and odors. Further, the waste stream handled by hospital waste incinerators has changed—primarily an increase in its plastic content—and the incinerators, many of which are old, may not be able to effectively burn the materials, resulting in incomplete combustion. With incomplete combustion, live microorganisms and toxic substances could be released into the atmosphere. An official of the Commonwealth of Massachusetts, for example, has stated that substantial health risks are associated with the prevalent older-

[7] Ebb Tide for Pollution: Actions for Cleaning Up Coastal Waters.

containment in medical care may not be provided. A California official, for example, said that, without a clear state definition, many hospitals are disposing of almost all of their medical waste as infectious, thus raising the possibility of unnecessary increases in health care costs.

The medical waste beach washups have further complicated the issue of a definition by adding aesthetics and risk of injury to the general public to infectiousness as considerations in defining what medical wastes are to receive special attention. Some parties have called for these factors to be included in establishing a definition; others have objected to their inclusion. As discussed in chapter 3, EPA's definition of regulated medical waste for the tracking demonstration program includes unused sharps, which would not be infectious, to ensure that they do not end up on beaches where they may cause injury or public concern that they may be infectious.

Landfilling Untreated Infectious Waste

To prevent the spread of pathogens during handling or into the environment, EPA's 1986 guidance manual recommends that only treated infectious waste be disposed of in landfills. In addition, the Great Lakes Commission[1] in 1988 recommended that only properly processed or incinerated infectious waste be sent to landfills. However, during our review we found that some untreated infectious waste is disposed of in this way. Illinois infectious waste regulations apply only to hospitals, which means that untreated infectious waste from sources such as doctors' offices and funeral homes can be landfilled. In California, landfills may accept certain categories of untreated infectious waste if the local enforcement agency grants permission. New York and Wisconsin prohibit the landfilling of untreated infectious waste from any regulated source, which does not include households.[2] In October 1988, OTA had reported that, under certain conditions, at least 12 states allowed untreated infectious waste to be landfilled.

One concern about the landfilling of untreated infectious waste is that it may contaminate groundwater. The Natural Resources Defense Council reported in 1988 that the vast majority of landfills are unlined, lack

[1]The Great Lakes Commission is an interstate compact commission of eight states in the region. It serves as a research, coordinating, and advisory agency on the development and use of the water and related land resources of the Great Lakes Basin.

[2]Infectious waste may be generated by households when diabetics use and dispose of insulin syringes or when waste generated by home health care agencies are left for disposal.

waste. The state has also taken enforcement actions against transporters, who have paid penalties averaging about $2,400 for transporting infectious waste without a permit and, in some cases, dumping the waste illegally.

Infectious Waste Regulation Can Also Take Place at the Local Level

Some local governments have developed their own infectious waste regulatory programs, either because the state did not have a specific program or more stringent requirements were believed necessary. We identified local programs in Arizona, California, and New York. For example, in response to medical waste being found along its beaches, California's San Diego County, on November 22, 1988, passed an emergency medical waste ordinance. This ordinance is more stringent than the state's law in that it applies more broadly to generators of small quantities of infectious waste.

Another example is New York City, which began regulating infectious waste in 1985, before the existence of a state program. Responding to increased sightings of medical waste—especially needles at municipal incinerators and landfills—and the perceived occupational risks to sanitation employees, the city passed a law prohibiting both decontaminated and contaminated medical waste from the New York City sanitation system. According to officials from the city's Department of Sanitation, their monitoring efforts have detected numerous violations of the city's infectious waste laws. Most of these violations involve mixing hypodermic needles, blood vials, and body parts with municipal waste.

Resolution Needed for Treatment and Disposal Issues

Our examination of selected state programs and relevant studies and reports identified several medical waste treatment and disposal issues. These issues relate to how infectious waste is defined for control purposes, the landfilling and discharging to sewage systems of untreated infectious waste, incineration, and autoclaving. The issues are important because the general public, along with health care and sanitation workers, needs to be assured that treatment and disposal practices are sound and adequately protect human health and the environment but do not unreasonably raise health care and waste management costs. These assurances must address not only infectiousness but other factors, such as toxic air emissions from medical waste incinerators. As discussed in chapter 3, the Medical Waste Tracking Act requires that EPA examine and report to the Congress on treatment and disposal methods.

not routinely inspect them, instead leaving the inspections to local officials. Illinois environmental officials said that they do not inspect hospital incinerators except to respond to complaints and to conduct the permitting process. The officials cited limited resources as the reason for less attention to these incinerators.

Autoclaving systems are used to decontaminate infectious waste in some hospitals, clinics, physician and dentist offices, and other types of health care facilities. Only California and Illinois regulate autoclaving under regulations specifically for infectious waste, and none of the states we reviewed observed the actual operation of these autoclaves. State officials told us that, during licensure inspections of hospitals and other major facilities, they rely on reviews of the generators' logs noting the time and temperature of operation. Several state officials also told us that they believe health care institutions and other generators usually follow operating procedures prescribed by autoclaving system manufacturers.

State Enforcement Efforts

Officials of the states we reviewed told us that they have adequate legal authority, but generally the number of enforcement actions against cases of inadequate infectious waste management has been limited. A factor cited by officials of three states was that enforcement of RCRA hazardous waste violations is a higher priority than enforcing infectious waste regulations. Another factor for few enforcement actions may have been that three states had recently developed or revised their infectious waste programs. A contributing factor may also have been the limited number of inspections to detect violations by infectious waste generators and handlers. Once violations are detected, states have different authorities and enforcement tools available to them.

Arizona and New York illustrate the differences in enforcement authorities for infectious waste mismanagement. Arizona does not have enforcement authorities specifically for infectious waste. Instead, under the nuisance provisions of the Public Health and Safety Code, state officials may issue cease and desist orders and obtain injunctions against persons who create a public nuisance. Under licensure provisions of the code, the state may impose a maximum civil penalty of $300 per day on licensed health care institutions. In addition, under the solid waste management provision of the code, the state may issue cease and desist orders and assess a maximum civil penalty of $1,000 for improper disposal. A criminal conviction may result in up to 4 months of imprisonment. In contrast, under New York's Public Health Law, the state may

for combustion time and temperature, and only New York and Wisconsin require the testing of incinerator ash prior to its disposal in landfills. Another example is landfilling of untreated infectious waste. Although all the states have some requirements prohibiting the landfilling of untreated wastes, disposal of some quantities is allowed. For instance, in California, small quantity generator exemptions result in landfilling certain types and quantities of infectious waste. In Illinois, only the landfilling of untreated hospital waste is prohibited. Further, infectious waste generated by households can be landfilled, without treatment, in Arizona, Illinois, New York, South Carolina, and Wisconsin.

Monitoring of Compliance With Requirements

State monitoring of compliance with infectious waste requirements varies but is generally limited. New York routinely inspects infectious waste transporters, treatment and disposal facilities, and major generators for compliance with its infectious waste regulations. Officials of the remaining five states told us that inspections specifically to check compliance with state infectious waste requirements are usually not routine but rather in response to complaints about the handling of these wastes. Inspections for the purposes of health care facility licensing and permitting of solid waste treatment and disposal facilities are generally routine, but infectious waste management is only one aspect of operations that may be examined in deciding whether to issue and renew a facility's license to operate. Monitoring is limited because state officials generally do not believe that infectious waste poses a substantial threat, and programs such as those for hazardous waste receive higher priority for state resources.

In the states we reviewed, major infectious waste generators, such as hospitals, nursing homes, and laboratories, are often inspected on a routine basis as part of the state's process to award and renew licenses to operate. The frequency of these inspections varies from state to state, however. For example, hospitals are inspected annually under Arizona's[3] and South Carolina's licensure programs, every 3 years in New York and California, and every 5 years in Illinois. Hospitals in Wisconsin are not subject to annual licensure inspections after receiving initial approval to operate.

[3]According to an Arizona state official, hospitals can have state licensing officials review their reports to the Joint Commission on the Accreditation of Healthcare Organizations in lieu of an inspection. The Joint Commission, whose membership includes the American Medical Association and the American Hospital Association, nationally establishes standards and conducts voluntary accreditation programs for hospitals and other health care facilities or organizations. As part of this program, it requires hospitals to demonstrate an effective waste management program.

Table 2.1: Wastes That Are Defined as Infectious by EPA, CDC, and Selected States

Waste category	EPA	CDC	CA	IL	NY	SC	WI
Microbiological[a]	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Human blood and blood products	Yes	Yes	No[b]	Yes	Yes	Yes	Yes
Isolation wastes	Yes	Optional[c]	Yes	Yes	Yes[d]	Yes	No
Pathological wastes[e]	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Contaminated sharps[f]	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Contaminated animal carcasses, body parts, and bedding	Yes	No	Yes	Yes	Yes	Yes	Yes
Other contaminated wastes							
Miscellaneous laboratory wastes	Optional[g]	No	Yes	Yes	Yes[d]	No	Yes
Surgery and autopsy wastes	Optional[g]	No	Yes	Yes	Yes[d]	No	Yes
Dialysis unit wastes	Optional[g]	No	Yes	No	Yes[d]	No	Yes
Equipment	Optional[g]	No	Yes	Yes	Yes[d]	No	Yes
Any other infectious waste	No	No	Yes	Yes	Yes	Yes	Yes

[a]Such as cultures and stocks of infectious agents.

[b]Human blood and blood products that are proven to contain pathogens are subject to California's infectious waste law and regulations.

[c]CDC recommends that this waste be treated according to hospital policy.

[d]The New York State Commissioner of Environmental Conservation may exclude this category.

[e]Such as human body parts, tissues, fluids, and organs.

[f]Such as syringes, needles, scalpel blades, and glass.

[g]EPA's 1986 guidance states that the decision to handle these wastes as infectious should be made by a responsible, authorized person or committee at the individual facility.

As shown in table 2.1, these state definitions generally include the categories that are recommended by both EPA and CDC. In addition, many of the states appear to be taking a cautious approach by also regulating wastes that EPA's guidance considered optional (for the individual facility to decide whether to handle as infectious) and CDC considers noninfectious. However, the states are not consistent in that certain categories are regulated in most but not all states. These differences exist because state officials have different views on what waste types need to be regulated to protect public health and the environment.

States Are Not Regulating All Infectious Waste Generators

All of the states we examined regulate hospitals, which generate the most infectious waste, and many of them regulate other health care facilities such as nursing homes, dialysis centers, ambulatory surgical treatment centers, laboratories, and medical research facilities. Other generators may also be required to comply with minimum handling

State Regulation of Infectious Medical Waste

State regulation of infectious waste has increased to the point that most states now have regulatory programs. In the six states we reviewed, these programs differ in the specific wastes that are regulated, the requirements that have been established, and who has to meet them. In some cases, practices that are different from EPA's 1986 guidance or varying state requirements and practices raise the issue of which practice is the most appropriate to efficiently and effectively manage the treatment and disposal of infectious waste to protect public health and the environment.

State Approaches to Infectious Waste Regulation Vary

States are increasingly regulating the handling, treatment, and disposal of infectious waste. However, each of the six states we reviewed has taken a somewhat different regulatory approach. As a result, the programs vary in regulatory authorities; types of medical or infectious waste and categories of generators regulated; handling, treatment, and disposal requirements; compliance activities; violations detected; and enforcement actions taken. Nevertheless, state officials believe that the programs reflect the current public health and environmental risks associated with infectious waste and the extent to which improper treatment and disposal is occurring within their respective states. Some local governments have their own laws or ordinances that further regulate these wastes.

Most States Regulate Infectious Waste

The number of states with regulatory requirements specifically for infectious waste has increased. According to the Office of Technology Assessment (OTA), 57 percent of the states nationwide had an infectious waste regulatory program in 1986. An October 1987 survey by the National Solid Wastes Management Association[1] showed that 80 percent of the states were already regulating or were planning to regulate these wastes within the next year. According to the association, 88 percent of the states had laws and/or regulations in place as of July 1, 1989. In addition, three of the six remaining states said that they were drafting regulations. The association also reported that between July 1, 1988 and July 1, 1989, 8 states had passed medical waste legislation, 10 states had promulgated new or revised regulations, and 4 states had done both.

[1]The National Solid Wastes Management Association is a trade group representing 2,200 private waste service companies in the United States and Canada. Its members include refuse haulers, landfill and resource recovery operators, recyclers, hazardous and biomedical waste treatment and disposal firms, equipment manufacturers, and others.

To address the objective regarding state infectious waste regulatory programs, we selected Arizona, California, Illinois, New York, South Carolina, and Wisconsin. The selection was based on agreement with the Subcommittee staff to include states that, as a group, (1) are geographically dispersed, including both predominantly coastal and inland states; (2) have large and small populations; and (3) have had infectious waste regulatory programs for various numbers of years. Five of the states have regulatory programs specifically for infectious waste. New York is the only selected state that is participating in the tracking demonstration program.

In each selected state, we interviewed appropriate state officials and reviewed documents, studies, state laws and regulations, and other pertinent information to identify regulatory authorities and requirements and responsible state agencies. We also obtained information on (1) each state's definition of infectious waste, (2) the infectious waste generators that are regulated, (3) compliance monitoring/inspections to detect violations of requirements, and (4) enforcement authorities and actions against violators. In addition, we obtained similar information for selected local governments that had established infectious waste programs in lieu of or in addition to the state program.

To address the objective concerning the Tracking Act, we reviewed appropriate reports, studies, and other documents and discussed with EPA officials the agency's implementation of the act and related activities. The documents reviewed included the summary of responses to EPA's June 2, 1988, Federal Register request for comments, the results of the November 1987 experts panel, EPA's regulations implementing the Tracking Act, and the results of meetings EPA held with health care professionals, waste management firms and associations, and state regulatory agencies to discuss the act's implementation. In addition, we reviewed the fiscal year 1989 Federal Managers' Financial Integrity Act report of the EPA Administrator and found no previously reported internal control weaknesses related to the agency's medical waste activities.

To provide perspective for these objectives as they relate to the issue of medical waste management, we reviewed studies prepared by EPA, the Office of Technology Assessment (OTA), the Council of State Governments, the National Solid Wastes Management Association, the Natural Resources Defense Council (NRDC), the Marine Sciences Research Center's Waste Management Institute, the Illinois Department of Energy and Natural Resources, the Great Lakes Commission, the American Hospital Association, and others. We also reviewed testimony presented at

On June 2, 1988, EPA published a Federal Register notice requesting public comments on a wide range of infectious waste issues, including the definition of infectious waste, the risks posed by such waste, EPA's role in infectious waste management, the merits of a system to track infectious waste from generation to disposal, and possible exemptions for certain generators from an infectious waste management program. EPA's stated intent for gathering the information was to gain a better understanding of the issue, to identify additional sources of information, and to determine whether further guidance or rules should be developed.

EPA received 111 comments from various organizations, including associations representing the health care and waste management industries, state health and environmental agencies, federal health agencies, and environmental protection advocacy groups. Although there was a wide range of views, the prevailing message was that current medical waste management practices—particularly at large medical facilities such as hospitals—are sufficient, that medical waste poses little risk to the public, and that increased federal regulation of medical waste is unnecessary.

Continued public and congressional concern about improper medical waste disposal; the lack of documented evidence one way or the other about the public health and environmental risks; the absence of comprehensive information both on infectious waste generation, treatment, and disposal practices and on state and local programs; and disagreement on what medical waste should be considered infectious led EPA to announce on August 31, 1988, what it termed an 8-point plan to develop this information. According to EPA officials, the activities required by the Medical Waste Tracking Act essentially replace those that were planned under the 8-point plan

Requirements of the Medical Waste Tracking Act

The 2-year tracking demonstration program mandated by the Medical Waste Tracking Act specifically targeted New York, New Jersey, and Connecticut—the states most affected by washups of medical waste on beaches—and the states on the Great Lakes, where some washups and other incidents had occurred. However, as discussed in chapter 3, these states could opt out of the program under certain circumstances and any state or territory could petition EPA to participate in the program. A factor in selecting a tracking system to control medical waste in the states was familiarity with such a system already in place for controlling hazardous wastes

unknown,[2] their economic impacts were apparent and substantial. Numerous beaches were closed and millions of people were deprived of the opportunity to use them. Many others stayed away from beaches located in affected areas that remained open. As a result, billions of dollars in recreational revenues may have been lost. In New York, for example, the Long Island Tourism and Convention Commission reported that 1988 beach attendance was down by 4.6 million persons over 1987, an estimated loss of $1.4 billion in beach revenues. The Commission noted, however, that some tourists who did not visit the beaches probably participated in other activities on Long Island. Reports of beach washups of medical waste continued during the summer of 1989, but the beaches were not closed because of the washups. Maryland, New Jersey, and New York, for example, responded with quick cleanup of the waste rather than closing the beaches.

Other well-publicized incidents in recent years have also served to heighten the public's awareness and concern about medical waste mismanagement. For example:

- A New Jersey medical lab was charged with illegally dumping 2,000 vials of blood in a wooded area.
- Children were found playing with discarded tubes of blood from an Indiana clinic's trash dumpster.
- Youngsters were found jabbing each other in the arm with syringes from a trash dumpster in Ohio.
- Some 1,400 bags of medical waste were discovered abandoned in a New York City warehouse.

As discussed later, concerns also exist about the potential health and environmental effects of medical waste incineration and the landfilling and discharging of untreated infectious waste to public sewer systems.

Medical Waste Regulation Is Primarily a State and Local Responsibility

In December 1978, EPA proposed regulations under Subtitle C of the Resource Conservation and Recovery Act of 1976 (RCRA) to regulate hazardous wastes at the federal level. Under RCRA, the definition of hazardous waste specifically cited infectiousness as one of the properties that EPA should consider in evaluating and designating wastes as hazardous. The proposed regulations would have classified certain medical wastes

[2]These washups included a variety of medical waste, including vials of blood that tested positive for exposure to the AIDS and hepatitis B viruses. Although the medical community does not believe that these viruses can survive the conditions they are subjected to during their time in the water and on the beach, research has not been performed to document this opinion.

Introduction

The presence of medical waste in debris that washed up on beaches in the Northeast and elsewhere during the summers of 1987 and especially 1988 aroused public fear: Could these wastes transmit diseases like acquired immune deficiency syndrome (AIDS) and hepatitis B? As a precaution, many beaches were closed and millions of people stayed away from these and other beaches in affected areas, resulting in revised vacation plans and lost revenues for local businesses. Compounding the public's concern over medical waste on beaches were other well-publicized incidents of haphazard, aesthetically offensive, and illegal disposal of medical waste on land.

In October 1988, the Congress responded to the public's concern with passage of the Medical Waste Tracking Act.[1] The act required (1) the Environmental Protection Agency (EPA) and the Agency for Toxic Substances and Disease Registry (ATSDR) within the Department of Health and Human Services to examine the health and environmental risks posed by medical waste, (2) EPA and certain states to implement a demonstration program to track medical waste from its generation to its disposal, and (3) EPA to report on a broad range of medical waste topics, including how much of this waste is generated and alternative methods of treating and disposing of it. This information is to help the Congress determine whether national regulations are needed and what type of program should be implemented to manage medical waste.

The Medical Waste Problem

Medical waste is generated by hospitals and other health care facilities, medical laboratories, physician and dentist offices, and others such as nursing homes, funeral homes, and veterinary hospitals. Improper disposal of this waste, as with other types of refuse, is an environmental concern. In addition, certain types of medical waste, such as intravenous bags, can be aesthetically displeasing, and other items, such as hypodermic needles and scalpels, can result in physical injury. However, the major concern is that some medical waste is potentially infectious.

EPA has defined infectious medical waste as "waste capable of producing an infectious disease." Because it is impracticable to test the infectiousness of each piece of medical waste, EPA included within this definition certain waste categories that routinely should be considered infectious: (1) microbiological wastes, such as stocks and cultures of infectious agents; (2) liquid blood and blood products; (3) isolation wastes from patients with communicable diseases; (4) pathological wastes, such as

[1] The President signed the act into law on Nov. 1, 1988.

Contents

Principal Findings

State Regulatory Programs

The states GAO examined varied in regulatory authority, the definition of infectious waste, and the generators regulated. The states generally had legislation and/or regulations defining what types of medical waste should be considered infectious and setting out handling, treatment, and disposal requirements. However, the definitions varied. For example, some definitions include surgery and autopsy wastes, whereas EPA identifies them as optional and the Centers for Disease Control considers them noninfectious. Varying authorities and definition differences may mean that infectious wastes are not effectively controlled or that some wastes unnecessarily receive special and more costly attention.

The states also differed in the waste generators that they regulated. Three of the states regulated all categories of generators except households; one state regulated at least some types of infectious waste for all categories. Another state regulated hospitals and laboratories only, and the remaining one regulated hospitals, laboratories, and blood banks only. The latter two states did not regulate physicians, dentists, and veterinarians, for example. The specific handling, treatment, and disposal requirements differed by state. For example, some states specified incinerator combustion time and temperature, and others did not.

The states varied in the inspection process and how often generators, transporters, and others were inspected. Hospitals, for example, were inspected annually in two states, every 3 years in two, every 5 years in one, and only at initial approval to operate in another. The states generally conducted a limited number of inspections and had taken few enforcement actions against violations of their requirements. State officials cited higher priorities, such as enforcing hazardous waste programs, as the reason. Nevertheless, state officials believed that their programs reflected the public health and environmental risks and the extent to which improper disposal was occurring in their states.

Tracking Act Implementation

EPA issued regulations for the demonstration program in March 1989. The regulations listed the medical waste types to be regulated and specified the tracking procedures. The listing of regulated waste has been controversial. EPA has been criticized for both including waste that does not present a substantial health risk and not including some items thought to be infectious or aesthetically displeasing.

Executive Summary

Purpose

Medical waste that washed up on the nation's beaches during the summers of 1987 and 1988 raised concerns about whether these wastes could transmit diseases such as AIDS. Some beaches were closed, and many vacationers stayed away from those that remained open. Other instances of haphazard or illegal disposal added to the public's concern about state management of the wastes. In considering the need for federal regulation, the Congress found limited data on the dangers of medical waste and the most effective way to control it. To obtain such data, the Medical Waste Tracking Act was enacted in November 1988 to establish a 2-year demonstration program—four states and one U.S. territory chose to participate—to track medical waste from generation to proper disposal. The act also required an assessment of the health and environmental threat and the collection of information on the generation, treatment, and disposal of these wastes.

Concerned about the adequacy of medical waste management, the Chairman of the Subcommittee on Regulation, Business Opportunities and Energy, House Committee on Small Business, requested that GAO examine how states regulate infectious medical waste and the implementation of the Medical Waste Tracking Act. As agreed with the Subcommittee's staff, GAO selected Arizona, California, Illinois, New York, South Carolina, and Wisconsin for examination. These states are geographically dispersed and have large and small populations. Five of the states—including New York, a participant in the demonstration program—have regulatory programs specifically for infectious waste.

Background

Medical waste is generated during health care by hospitals, clinics, laboratories, physician and dentist offices, and others such as nursing homes and diabetics who use insulin syringes. Common medical procedure is to segregate medical waste that is potentially infectious from other wastes and package and label it for treatment (to render it noninfectious) and disposal. Because it is impractical to test each item, categories or types of medical waste are defined or designated as infectious for control purposes. Examples of medical waste generally considered infectious are human blood, used needles, and body tissues removed during surgery. Most infectious medical waste is incinerated, usually on-site. The next most prevalent disposal method is to autoclave (steam sterilize) the waste and send it to landfills.

The Environmental Protection Agency (EPA) has the primary responsibility for implementing the Tracking Act. By September 1991, EPA is to provide two interim and a final report to the Congress on the demonstration