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Observations on Infectious Waste Management

Statement of
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Before the
Subcommittee on Regulation, Business
Opportunities and Energy
Committee on Small Business
House of Representatives

Mr. Chairman and Members of the Subcommittee:

Thank you for the opportunity to be here today to discuss our review of state infectious waste regulatory programs and infectious waste management issues. At this time, we have completed work in selected states and at the Environmental Protection Agency (EPA) and are in the process of analyzing the results and preparing the report. The states we selected--Arizona, California, Illinois, New York,[1] South Carolina, and Wisconsin--are representative in the sense that, as a group, they (1) are geographically dispersed, (2) have large and small populations, and (3) include states that have and do not have formal infectious waste regulatory programs.

In summary, we found that the extent to which infectious waste poses a public health risk is unknown. In this uncertain environment, we found that state programs vary in regulatory authorities; types of medical waste and categories of generators regulated; requirements established to handle, treat, and dispose of infectious waste; and extent of compliance activities. State officials, however, believe that their programs reflect the current public health and environmental risks associated with handling, treating, and disposing of infectious medical wastes and the extent

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[1]New York is participating in the medical waste tracking demonstration program required by the Medical Waste Tracking Act.

to which improper disposal and treatment is occurring within their states.

Nevertheless, a number of issues, if resolved, could help the states in carrying out their programs, as well as EPA and the Congress in deciding what additional federal action is needed. These include several treatment and disposal issues, such as whether hospital incinerators--many of which are antiquated--provide combustion adequate to prevent the emission of live pathogens or toxic substances that may be a health threat. Most important, however, is the issue of the extent to which infectious waste poses a public health risk. Efforts to address these issues are underway, and we believe the results, especially the assessments of the health risks of infectious waste called for by the Medical Waste Tracking Act, will be essential to the Congress, EPA, and the states in deciding on further action with regard to infectious waste management.

The rest of my testimony discusses our findings regarding state regulatory programs and infectious waste issues. First, let me spend a few minutes putting these issues into perspective.

BACKGROUND

The presence of medical waste in debris that washed up on our beaches aroused people's fears that these wastes could transmit

diseases like AIDS and hepatitis B. Generally, the sight of medical waste on beaches, infectious or not, causes severe public reaction. While the public health risks due to beach washups are uncertain, their economic impacts were apparent and significant. As a precaution, numerous beaches were closed last summer and many people were deprived of the opportunity to use them. Many others stayed away from beaches located in affected areas that remained open. A tourism organization estimated that billions of dollars in recreational revenues were lost.

Compounding the public's concern about the presence of medical waste in beach washups were other incidents of haphazard, aesthetically offensive, and illegal disposal of infectious medical waste on land. For example, vials of blood, syringes, and other types of discarded medical waste have been found in dumpsters, warehouses, and wooded areas. There are also concerns about the potential public health and occupational health risks from handling, incinerating, and landfilling infectious waste and discharging it to public sewer systems.

Medical wastes include waste produced by hospitals and health care facilities, clinics and laboratories, physicians' and dentists' offices, and even funeral homes and veterinary hospitals. EPA issued guidelines in 1986 to provide its perspective on acceptable infectious waste management practices. The guidelines define infectious waste as medical waste capable of producing an

infectious disease. It includes within this definition six categories of waste

-- microbiological wastes, such as cultures and stocks of infectious agents and associated biologicals;

-- human blood and blood products;

-- waste from patients in isolation with communicable diseases;

-- pathological wastes;

-- contaminated sharps, such as needles and scalpels; and

-- contaminated animal carcasses, body parts, and bedding.

Medical experts generally do not believe that infectious waste poses substantial public health risks. The extent of risk, however, is not clearly documented one way or the other. While beachgoers may risk being punctured by a tainted needle or a broken glass vial of blood, the risk of contracting an illness is not well established. Occupational exposure, however, is viewed by the experts as a greater risk. There may also be potential public and occupational health risks from incinerating and landfilling infectious waste and from discharging it to public sewer systems.

Subtitle C of the Resource Conservation and Recovery Act of 1976 (RCRA) lists infectiousness as one of the characteristics to be considered in determining whether or not a waste is hazardous and should be regulated. However, EPA opted not to regulate infectious waste as hazardous because of insufficient evidence that it poses a substantial public health risk. As a result, EPA treats these wastes as solid waste under RCRA Subtitle D, and regulation is left to state and local governments. EPA's role is limited to providing guidance and technical assistance to the states.

In light of the medical waste beach washups and other examples of medical waste mismanagement in recent years, EPA announced, in August 1988, an 8-point plan to bring the agency to the point where it could determine whether the federal government should have a greater role in regulating medical waste. The plan called for EPA to gather data on state and local programs, the amount of medical waste generated, treatment and disposal methods, and the health risks associated with medical wastes. Subsequently, on November 1, 1988, the President signed into law the Medical Waste Tracking Act, which requires EPA to establish a 2-year demonstration program to track medical wastes in selected states from the point of generation to disposal, and to issue a final report to the Congress on the results of the demonstration

program and other medical waste-related matters in 1991.[2] The act also requires the Agency for Toxic Substances and Disease Registry (ATSDR), within the Department of Health and Human Services, to submit a report to the Congress by November 1, 1990, on the health risks associated with medical waste. These requirements and studies largely supplant EPA's 8-point plan.

STATE INFECTIOUS WASTE REGULATORY PROGRAMS

We estimate that 90 percent of states regulate or plan to regulate medical waste (see attachment I). This compares to 57 percent of the states in 1986. These programs vary considerably. Each of the six states we reviewed has taken a somewhat different approach to regulating infectious waste. We found that states do not necessarily have separate infectious waste laws or programs, and some program responsibilities are delegated to county and local governments for implementation. In addition, some county and local governments have passed their own laws and ordinances that further control infectious waste handling, treatment, and disposal practices.

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[2]EPA is also required to issue two interim reports--the first one is due August 1, 1989, and the second on June 22, 1990.

Legislative Authorities and Regulations

California, Illinois, New York, South Carolina, and Wisconsin operate under legislative authorities and/or regulations specific to infectious waste, while Arizona uses general authority provided in its health, air, and solid waste legislation. Some state officials told us that they believe that their states have specific infectious waste laws and regulations because it was decided to take a prudent or conservative course of action. In addition, some officials told us that laws or regulations setting out specific infectious waste requirements and authorities tend to simplify enforcement efforts. On the other hand, Arizona officials believe that the general provisions in their health and environmental statutes are sufficient to respond to any infectious waste problems that arise.

Definition of Infectious Waste

Five states we reviewed--California, Illinois, New York, South Carolina, and Wisconsin--have defined infectious waste for regulatory purposes. As shown in attachment II, their definitions include most categories listed in EPA's or the Centers for Disease Control's (CDC) guidance.[3] Arizona's solid waste regulations

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[3]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 intended to protect health care workers.

consider infected materials as dangerous refuse and not acceptable for collection with other solid wastes.

Generators Regulated

Turning now to the states' regulation of infectious waste generators, we found that not all generators are regulated in the six states we reviewed. As shown in attachment III, all six states regulate hospitals and many regulate other health care facilities, like nursing homes and dialysis centers. Other generators are also regulated for certain types of waste, such as sharps and infectious cultures. However, there are generators, such as physicians' and dentists' offices, veterinarians, and even some hospitals and nursing homes, that are not regulated because of the types and quantities of infectious waste produced.

Requirements for Handling, Treatment, and Disposal

As attachment IV indicates, five states have generally established written requirements or guidelines for generators and other medical waste handlers subject to regulation. California, Illinois, and New York have specific requirements to cover most major aspects of handling, treatment, and disposal. By comparison Arizona and Wisconsin have guidelines that cover many of the major

aspects of their infectious waste management process. South Carolina, as a result of a June 1989 state law, is required to issue regulations covering major aspects of its infectious waste management process.

Inspections

New York routinely inspects generators, transporters, treaters, and disposers of infectious waste for compliance with appropriate regulations. The remaining five states we reviewed do not routinely inspect one or more of these infectious waste handlers. Aside from inspections required under health care facility licensing regulations and permitting requirements for solid waste treatment and disposal facilities, many infectious waste management inspections result from complaints.

In the three states with treatment and disposal requirements for physicians' and dentists' offices, veterinary hospitals, funeral homes and other small-quantity infectious waste generators, there are no routine inspections of their practices. These generators are usually inspected in response to complaints alleging improper and illegal disposal practices, such as mixing infectious waste with regular garbage, and inappropriate storage practices.

Enforcement

Officials in the six states told us that few enforcement actions have been taken for inadequate infectious waste management. One factor contributing to taking few enforcement actions may have been the absence of routine inspections to detect violations by infectious waste generators and handlers. Another factor cited by a state official was that enforcement against RCRA hazardous waste violations is a higher priority than enforcing infectious waste regulations.

We found variations in the enforcement actions states can take. Such actions range from issuing cease and desist orders to criminal penalties and imprisonment. Some state officials told us that existing authorities are adequate for taking enforcement actions; however, some states indicated that more authority is needed in certain areas. For example, Illinois and Wisconsin environmental officials stated that they do not have the legal authority to assess fines for infectious waste-related violations without taking the matter to court. If they had this authority, officials believe their enforcement programs would be more effective.

INFECTIOUS WASTE MANAGEMENT ISSUES

I would now like to discuss what we believe are several issues that warrant further attention. These issues relate to the pilot manifest system being implemented under the Medical Waste Tracking Act and to major treatment and disposal practices.

Medical Waste Tracking Act's Manifest Program

The manifest system mandated by the act provides a paper trail for infectious waste as it moves from generator to transporter to a designated treatment and disposal facility. A number of factors, however, serve to detract from the manifest system's potential for improving infectious waste management.

First, significant quantities of waste are not subject to the manifest system, including autoclaved waste rendered nonrecognizable and medical waste incinerator ash. In addition, the manifest system won't control syringes used in home health care or by intravenous drug users who discard them in household trash or flush them down toilets. Second, EPA's regulations implementing the manifest system do not require the participating states either to conduct routine inspections of infectious waste handlers to determine if the regulations are being complied with or to take specific enforcement actions when violations are disclosed.

EPA has recognized that there are limitations to the Tracking Act and is taking some steps to supplement it in order to reduce the number of mismanagement incidents. For example, EPA is working with representatives of the health care industry to develop an outreach program to educate home users on the proper disposal of syringes and other medical waste. And EPA has joined with the Army Corps of Engineers and state and local governments in an effort to remove medical and other wastes from the New York Harbor and adjacent waters.

EPA has prepared an enforcement strategy for the demonstration program that gives the states lead responsibility for devising and carrying out an enforcement program. EPA intends to provide guidance to the states and legal assistance when necessary. The strategy does not specify how or how often the states should inspect medical waste generators, transporters, or disposers; rather, it suggests that the states rely on voluntary compliance and their own innovative methods. In EPA's view, both legal and financial obstacles make it difficult for the agency to require participating states to take specific inspection and enforcement actions.

Treatment and Disposal Issues

Incineration

Incineration is the most prevalent method for rendering infectious waste noninfectious. 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 of.

Although incineration is widely used, performance standards for infectious waste incinerators are either nonexistent or not as stringent as those for other solid waste incinerators. Concerns exist that the incineration of infectious waste is not carried out consistently or effectively nationwide and that these incinerators, many of which are old, may not completely burn infectious waste. As a result, they may emit live pathogens as well as other toxic substances. Finally, the ash produced by infectious waste incinerators may be toxic and require disposal as a hazardous waste.

EPA has begun a regulatory process to develop performance standards for new hospital incinerators by 1992. In addition, EPA

has developed training materials for incinerator operators that it hopes will be used to improve the combustion efficiency of existing facilities, thereby reducing hazardous emissions. The materials have been disseminated to state pollution control offices.

Autoclaving

Autoclaving, or steam sterilization, is a process by which medical wastes are decontaminated prior to disposal in a landfill. As with incineration, proper operation of the autoclave is critical to its effective functioning. In that regard, EPA's 1986 guidance manual recommended establishing standard operating procedures for treatment processes like autoclaving and monitoring those processes to ensure efficient and effective treatment.

Inconsistencies exist, however, in how autoclaves are operated. According to the Natural Resources Defense Council, an environmental advocacy group, although killing certain bacteria requires 90 minutes of exposure, some facilities operate their autoclaves for only 20 to 30 minutes. The Council has also reported that only four states regulate time, temperature, and pressure conditions for autoclaves--all key to proper sterilization of infectious materials. Of the six states we reviewed, only California has regulations for both on-site and off-site operation of autoclaves.

During our review, state officials told us that sanitation employees and private citizens expressed concerns about whether autoclaved waste had, in fact, been rendered noninfectious. In the absence of national or state performance standards for autoclaving systems, several state officials told us that they believe health care institutions and other generators usually follow manufacturer-prescribed operating standards. None of the states we reviewed has a system for identifying autoclaved waste that may be safely handled by sanitation workers and landfill personnel.

Landfilling

EPA's 1986 guidance manual recommends that only treated infectious waste should be landfilled. State and local policies differ on this issue, however, and 12 states currently allow untreated medical waste to be landfilled.

Based on discussions with officials in the six states reviewed, we found that requirements for the landfilling of infectious waste varied considerably. With the exception of household waste, New York prohibits the landfilling of untreated infectious waste, while Arizona officials told us that the state allows untreated infectious waste from any source to be landfilled. According to Wisconsin officials, the state prohibits the landfilling of untreated infectious waste from sources other than households. Illinois' officials told us that the landfilling

of untreated hospital waste is prohibited, but untreated infectious waste from other sources can be landfilled. In California, state officials told us that landfills may accept untreated infectious waste if the local enforcement agency grants permission.

Landfilling of untreated infectious waste may also pose public health and occupational health risks as well as the potential for groundwater contamination. In that regard, the Natural Resources Defense Council reported in 1988 that the vast majority of landfills that accept untreated infectious waste are unlined, lack leachate collection systems, and do not check for groundwater contamination. There is concern, therefore, that pathogens that survive the conditions in a landfill could travel through the soil and reach the underlying groundwater.

Discharges to Sewers

EPA's 1986 infectious waste guidance manual states 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 guidance also states that blood and blood products may be discharged to the sanitary sewer for treatment at the municipal treatment plant, provided that secondary

treatment is available.[4] In addition to blood and blood products, ground-up body parts and organs, as well as other infectious liquid or semi-liquid hospital wastes, may be legally discharged to public sewer systems.

Such discharges pose a number of problems, one being the potential for surface water contamination. While the acceptability of sewer discharges is predicated on those discharges receiving secondary treatment, significant quantities of sewage never reach the treatment plant. In many urban areas, the sanitary and storm sewers are combined, which presents a problem. That is, when even rainfall occurs, untreated sewage may be discharged to area waterways before reaching the treatment plant because the plant can't 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 sewer system alone, for example, there are more than 500 CSO points. Besides the CSO problem, hospital-based engineers and plumbers and sewer system workers are faced with potential health risks from exposure to untreated infectious waste discharged to public sewer systems.

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[4]Effective secondary treatment, in which bacteria consume the organic parts of the wastes, removes virtually all floating and settleable solids and approximately 90 percent of suspended solids.

Although EPA has not begun a regulatory process regarding autoclaving procedures or the disposal of untreated medical wastes in landfills or sewers, it recognizes that these issues warrant investigation. A draft of EPA's first interim report to the Congress indicates that the agency will gather data on the potential health risks of current disposal techniques and will report on them in later reports.

FRAMEWORK FOR FUTURE DECISIONS

The issues I have just discussed will be especially critical if mismanaged medical waste is found to be a threat to human health and the environment. Unfortunately, there is no clear consensus about the risks of medical waste. The Congress recognized this when it passed the 1988 legislation requiring EPA and ATSDR to report on the present or potential health risks associated with medical waste. EPA and ATSDR are working to gather the data for these reports, and their efforts appear to be on schedule.[5]

Determining whether and what infectious wastes pose health risks appears, to us, a sensible first step. If such wastes are found to pose a hazard, a logical second step is to identify those

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[5]An ATSDR schedule indicates that the report may be finished in March 1990, and EPA's second interim report, due in June 1990, may contain some preliminary results.

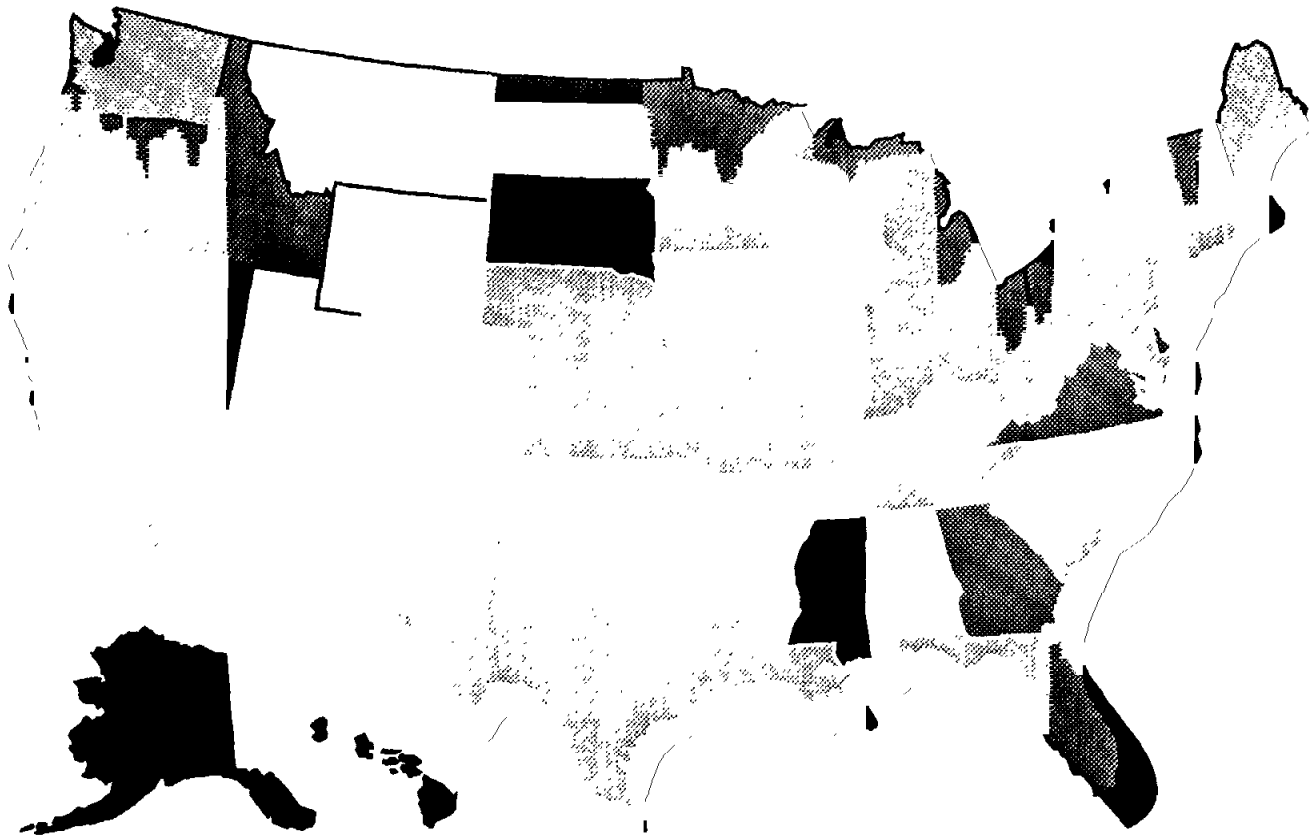
(the general public and certain occupational groups) at risk. Once such groups are identified, it will then be possible to design an effective strategy for controlling these risks, including whether to regulate infectious wastes as hazardous or to continue treating them as nonhazardous solid waste.

The Medical Waste Tracking Act has started a process that we believe is in line with this framework. If successfully implemented it should provide a sound basis for deciding how to address the nation's infectious waste management problems.

Mr. Chairman, this concludes my prepared statement. I will be glad to respond to any questions that you or members of the Subcommittee may have.

Attachment I

Status of State Infectious Waste Regulations



- No Rules in Place, and No Action Expected (5)
- No Rules in Place, but Action Expected (5)
- Rules in Place, and Modifications Expected (21)
- Rules in Place, and No Modifications Expected (19)

Source: GAO's June 1989 update of the National Solid Waste Management Association's October 1987 survey.

Attachment II

Comparison of Federal Infectious Waste Guidance and Waste Regulation in Five 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	Yes	Yes	Yes	Yes
Isolation wastes	Yes	Optional[b]	Yes	Yes	Yes[c]	Yes	No
Pathological wastes[d]	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Contaminated sharps[e]	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[f]	No	Yes	Yes	Yes[c]	No	Yes
Surgery and autopsy wastes	Optional[f]	No	Yes	Yes	Yes[c]	No	Yes
Dialysis unit wastes	Optional[f]	No	Yes	No	Yes[c]	No	Yes
Equipment	Optional[f]	No	Yes	Yes	Yes[c]	No	Yes
Any other infectious waste	No	No	Yes	Yes	Yes	No	Yes

[a]Such as cultures and stocks of infectious agents and associated biologicals

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

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

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

[e]Such as syringes, needles, scalpel blades, and glass

[f]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

Regulated and Nonregulated Infectious Waste Generators in Six States

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

Key

R = Subject to state health and/or environmental regulations
P = Only certain types of infectious waste are subject to state packaging, treatment, and/or disposal regulations
N = Not subject to state regulations

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

[b]Generators of less than 50 lbs /month are exempt from the permitting requirements of the state's waste transporter regulation

[c]This information reflects conditions prior to the state's passage of infectious waste legislation on June 8, 1989 Regulations are not yet in place

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

Attachment IV

Infectious Waste Management in Six States

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

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

Key

G = Guidelines only, not enforceable
R = Requirements in place
U = Under consideration as regulations are upgraded
N = Not regulated by the state and no guidelines.

[a]Limited to infectious waste from hospitals, and AIDS-contaminated waste from ambulatory surgical treatment centers and clinical laboratories

[b]The information above reflects conditions prior to the state's passage of infectious waste legislation on June 8, 1989. Regulations are not yet in place, but are anticipated to address most of these areas

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