

Regulatory Authority and Current Practices

Federal Authority

The two Federal laws that most directly provide the government with the authority to regulate or control the management of infectious wastes in some way are the Resource Conservation and Recovery Act (RCRA) and the Occupational Safety and Health Act (OSHA).¹ In addition, New Source Performance Standards (NSPS) of the Clean Air Act may apply to hospital incinerators.² Any special State and local regulations for general and infectious wastes also apply. Certain chemical wastes generated in healthcare facilities are considered hazardous waste and may be subject to provisions of RCRA, and radioactive waste disposal must conform with Nuclear Regulatory Commission standards.³

The agency with the most comprehensive authority to provide Federal leadership on the management of medical wastes is EPA. EPA has authority under RCRA to regulate the handling, storage, treatment, transportation, and disposal of medical wastes. Its regulations would apply to public and private facilities of all types.

Currently, as noted above, the Agency has only issued a guidance document for the management of infectious wastes. Other medical wastes are considered to be like any other solid waste and are subject to relevant RCRA Subtitle D regulations.

In contrast, the CDC does not have authority to issue regulations. OSHA may issue regulations or guidelines to protect the health and safety of workers, but they apply only to private facilities (unless a State extends the coverage to employees of public facilities as well).⁴ At present, OSHA does regulate employee exposure to toxic substances under the General Industry Health standards.⁵

¹42 U.S.C. 6901 et seq.; 29 U.S.C. 651 et seq., respectively.

²42 U.S.C. 7411. It is important to note that NSPS apply only if the source is over 50 tons per day, which few medical facilities are. In any case, these standards only apply to conventional criteria pollutants. Potential air toxics are not regulated at the national level at this time.

³40 CFR 260-265; 122-124; 10 CFR 20, respectively. These types of wastes, because of their need to be handled specially and the existence of regulations governing their disposal, will not be discussed extensively here.

⁴29 U.S.C. 652(5); 655(b); 657(c); 657(g)(2).

⁵29 U.S.C. 655.

Under Section 6 of OSHA, the Labor Secretary is given general authority to promulgate such standards in order to assure the "attainment of the highest degree of health and safety protection of the employee." Yet, the feasibility of the standards must be considered, and they must be set on the basis of the best available evidence. There is apparently nothing in the definitions of terms in OSHA that would preclude the application of the law's authority to the regulation of infectious wastes.⁶ At this time, however, OSHA has limited its specific activity on occupational exposure to infectious wastes to its rulemaking activity to control occupational exposures to Hepatitis B and AIDS.

State Regulatory Activities

Given the general lack of regulation on the national level, States have developed their own infectious or medical waste programs. As the Council of State Governments (CSG) report, *State Infectious Waste Regulatory Programs*, notes, without a Federal baseline and without Federal funds "to support the creation of a new environmental regulatory program [to manage infectious wastes], states, regardless of size *or location*, are in the process of meeting the public's demand for protection. It is [a] clear state-generated initiative . . ." (emphasis added) (4). Local governments (e. g., towns, cities, and counties) may also develop special medical requirements of one sort or another. This has led to tremendous variation in the regulation of these wastes.

The variation in State activities is worthy of Federal attention for at least two reasons. First, stricter regulations in one State may encourage the shipment of wastes to other States with less stringent regulations. Second, many States, in the absence of Federal guidance, apparently are "leap-frogging" one another to adopt the most stringent regulations. One of the most striking features of recent State action on medical/infectious waste issues is its rapidity. As the CSG notes, many

⁶The definition of the term employer appears sufficiently broad to include hospitals and possibly other generators; the definition of toxic materials or harmful physical agents' also appears broad enough to include infectious wastes (21 CFR 19 10.20(c)(11)). See ref. 16.

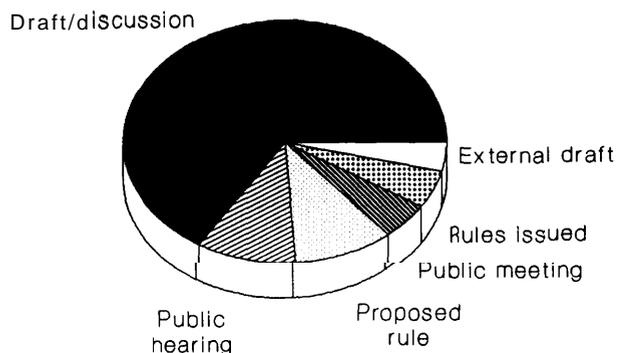
State legislative sessions are only a few months long and only meet every other year. Yet, States have been responding quickly to public concern over medical wastes: 88 percent of the States in 1988, compared with 57 percent in 1986 are or will be regulating infectious wastes (4). (See figure 3.)

Eleven States split the jurisdiction over infectious wastes between solid waste management offices and health department offices, while other States designate one or the other of these types of offices as the lead authority. Enforcement authority is usually in the solid waste office for off-site disposal, with the air pollution control board responsible for regulating incinerator emissions, and with the hospital licensure office responsible for monitoring on-site generation, treatment, and disposal of infectious wastes. Seven States delegate this authority to county health departments, and in five it is delegated to the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) (4).⁷

A majority of States target hospitals in their regulation of infectious wastes. Of these, three-quarters also regulate clinics, but only half also include doctor and dental offices, veterinary hospitals, and other small generators (4). (See figure 4.) Five States currently exempt or are proposing to explicitly exempt small quantity generators from infectious

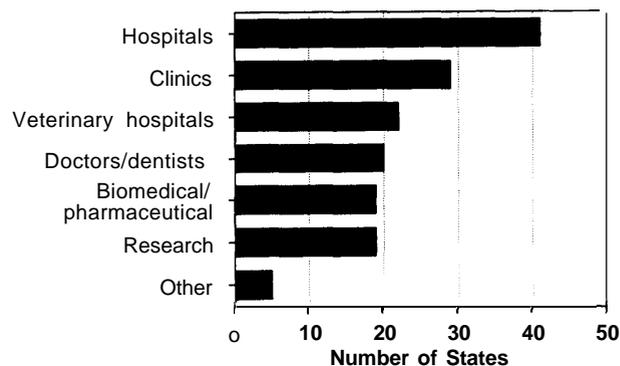
⁷The JCAHO inspects hospitals periodically and determines their accreditation. Despite their recognized authority, and potential to effect the waste management practices of hospitals, there has been criticism of the thoroughness of their inspections. See, e.g., ref. 53.

Figure 3.-Stages of State Changes in Medical Waste Management Programs-As of March 1988



SOURCE: The Council of State Governments, *State Infectious Waste Regulatory Programs* (Lexington, KY: 1988).

Figure 4.-Types of Medical Waste Generators Regulated by States-As of March 1988



SOURCE: The Council of State Governments, *State Infectious Waste Regulatory Programs* (Lexington, KY: 1988).

waste regulations or policies (4).⁸ Regulating infectious wastes on the basis of listed generators versus types of wastes can lead to some important incongruities. In Rhode Island, for example, wastes from animal research in a laboratory associated with a hospital are subject to infectious waste regulations, however, wastes from animal research at a laboratory unaffiliated with a hospital are not subject to the regulations (4). As will be discussed further below, whether small quantity generators should be exempt from infectious waste regulations is a significant, unresolved issue.

Unless a State specifically regulates infectious wastes as hazardous wastes (4),⁹ permits are not likely to be required by States. Instead, infectious waste guidances and rules appear to be the norm and are designed to be "self-enforcing. The Council of State Governments identifies the logic as:

Best management practices (emphasizing biosafety), liability issues, and haulers' refusals to handle red-bagged wastes are recognized and depended upon as strong voluntary compliance inducements (4).

A concern expressed by some hospital administrators, however, is that the regulations proposed or adopted by some States are inappropriate, unrealistic, and costly. For example, the New York State Department of Environmental Conservation's

⁸These are: California, Indiana, Minnesota, Missouri, and Ohio. ⁹This is true for: the District of Columbia, Hawaii, Iowa, Kentucky, Maine, and Washington.

(DEC) draft regulations, referred to as the “most far-reaching and comprehensive waste management laws in the nation” for solid and infectious waste management, contain the following incinerator emission standards:

- 0.010 grains per dry standard cubic foot of flue gas, corrected to 7 percent oxygen (for new facilities processing over 50 tons/day);
- 90 percent reduction of hydrogen chloride (HCl) emissions;¹⁰
- At least 1 second residence time at least 1,800 °F for combustion gas.¹¹

These new regulations are expected by many, including the DEC, to increase the cost of on-site incineration of infectious wastes (31). This may lead to more off-site treatment of hospital wastes.

One hospital consultant’s opinion of the New York State regulations, and other State regulations, based on best available control technology for incineration of infectious wastes is that:

... [they] appear to have no technical basis, and many are also reflective of unproven, unrealistic, and sometimes unattainable technology What appears most disturbing, however, is that there appears to be no evidence or documentation which show that there will be any significant environmental benefits or reduced health risks if such proposed legislation is enacted (8).

He maintains that more analysis is needed before such standards are adopted. The need for standards set on the basis of sound analysis is rarely disputed. Currently, lacking such an analysis, it is unclear which level of standards are most appropriate. Variation between the levels adopted by States is readily evident, however, and is one justification frequently noted for the development of national standards. (See table 8.)

¹⁰Unless it is demonstrated that either the stack concentration is less than 50 parts per million by volume, dry basis corrected to 7 percent oxygen; or, the uncontrolled emission rate is less than 4 pounds per hour and the total charging rate is less than 500 pounds per hour.

¹¹For multichamber incinerators, these parameters must be met after the primary combustion chamber, which must be maintained at no less than 1,400 °F.

More than half of the States require or plan to require treatment (e. g., autoclaving) of infectious wastes before land disposal. Yet, under certain conditions, at least 12 States allow infectious wastes to be landfilled without treatment. Seventy-two percent of the States name incineration in their existing or proposed regulations as a recommended treatment for medical wastes. Five States *require* incineration (4).¹² Twenty-three States are considering establishing performance standards, which could be in addition to any other applicable standards set by State air control agencies for incinerators. Twenty-seven States recommend steam sterilization as a treatment process for infectious wastes. Fourteen of these States specify or are considering specifying time/temperature/pressure standards. Eighteen States include chemical treatment as an alternative, and other treatment alternatives are considered on a case-by-case basis by other States (4).

Handling of infectious wastes on-site is usually governed by State health departments. They issue guidelines usually based on the periodically issued recommendations on biosafety from JCAHO, CDC, NIH, EPA, and OSHA (4). Packaging and labeling requirements are included in the infectious waste regulations of 31 States. These include such requirements as rigid containers, double bagging, and labeling requirements. Storage requirements (currently in place in 7 States and being considered by 14 others) include such elements as the length of time wastes can be maintained on-site and refrigeration requirements. Transportation requirements (including the designation of only non-compacting trucks for transporting infectious wastes, requiring truck labeling and shipping procedures, and specifying cleaning procedures) and record-keeping requirements (usually recordkeeping by the generator rather than a manifest system of submitting records to the State) are being considered by three-fifths of the States (4).

¹²These are: Alaska, Arkansas, Colorado, New Hampshire, and Tennessee.

Table 8.—Status of Selected State Infectious Waste incinerator Regulations^a

Parameter	New York	Pennsylvania	Minnesota	Mississippi	California	Wisconsin
Air emissions:						
Particulate	0.01 gr/dscf (for new and old facilities over 50 tons/day); 0.015 (for new facilities if less than 50 tons/day); 0.03 (for existing facilities if less than 50 tons/day)	0.1 gr/dscf (for existing facilities); 0.08 gr/dscf (for new facilities less than 500 lbs/hr); 0.03 (for facilities of 500-2000 lbs/hr); and 0.015 (for facilities over 2000 lbs/hr)	0.01 gr/dscf (for facilities less than 1000 lbs/hr)	0.2 gr/dscf (at 12 % CO ₂)	0.1 gr/dscf at 12% CO ₂ (for existing facilities); 0.08 (for new facilities)	0.03 gr/dscf at 12% CO ₂ for greater than 200 lbs/hr
Visible emissions (opacity)	Hourly average 100% maximum content, 6 minutes average less than 20%	300/0 (anytime 10% for any 3 minute hourly average)	—	40%	20%	50/0 (as measured by U.S. EPA Method 9)
HCL (acid gas)	90% HCl reduction, or 50 ppm HCl	30 ppm (or 90% reduction)	Testing required	—	—	50 ppm at 120/0
S O₂	50 ppm	30 ppm (or 75% reduction)	—	—	—	CO ₂ over any continuous 1 hour period
Carbon monoxide	Hourly average no more than 100 ppm at 70/02	Hourly average no more than 100 ppm at 70/02	—	—	99 %	75 ppm at 70/0 reduction
Combustion: Efficiency	—	99.9 %	—	—	—	—
Operator training:						
Training	Yes	Yes	—	—	—	Yes
Certification	Yes	—	—	—	—	—
Solid waste: Residual burn out	—	—	—	—	—	Maximum ash content 5%, no visible unburned combustibles

Abbreviations: gr/dscf = grains per dry standard cubic foot; ppm = parts per million ^aMany States are currently revising their regulations for infectious waste incineration. These figures should not be cited without confirming their current status.

SOURCE: Adapted from F. Cross, "Comments on Background Paper," prepared for OTA Workshop on Biomedical Waste Management (Washington, DC: July 19, 1988); R. Kerr, New York State Department of Environmental Conservation, personal communication, Sept. 20, 1988; J. Salvaggio, Pennsylvania Department of Environmental Resources, personal communication, Sept. 20, 1988; and Gary Yee, California Air Resources Board, personal communication, Sept. 21, 1985.