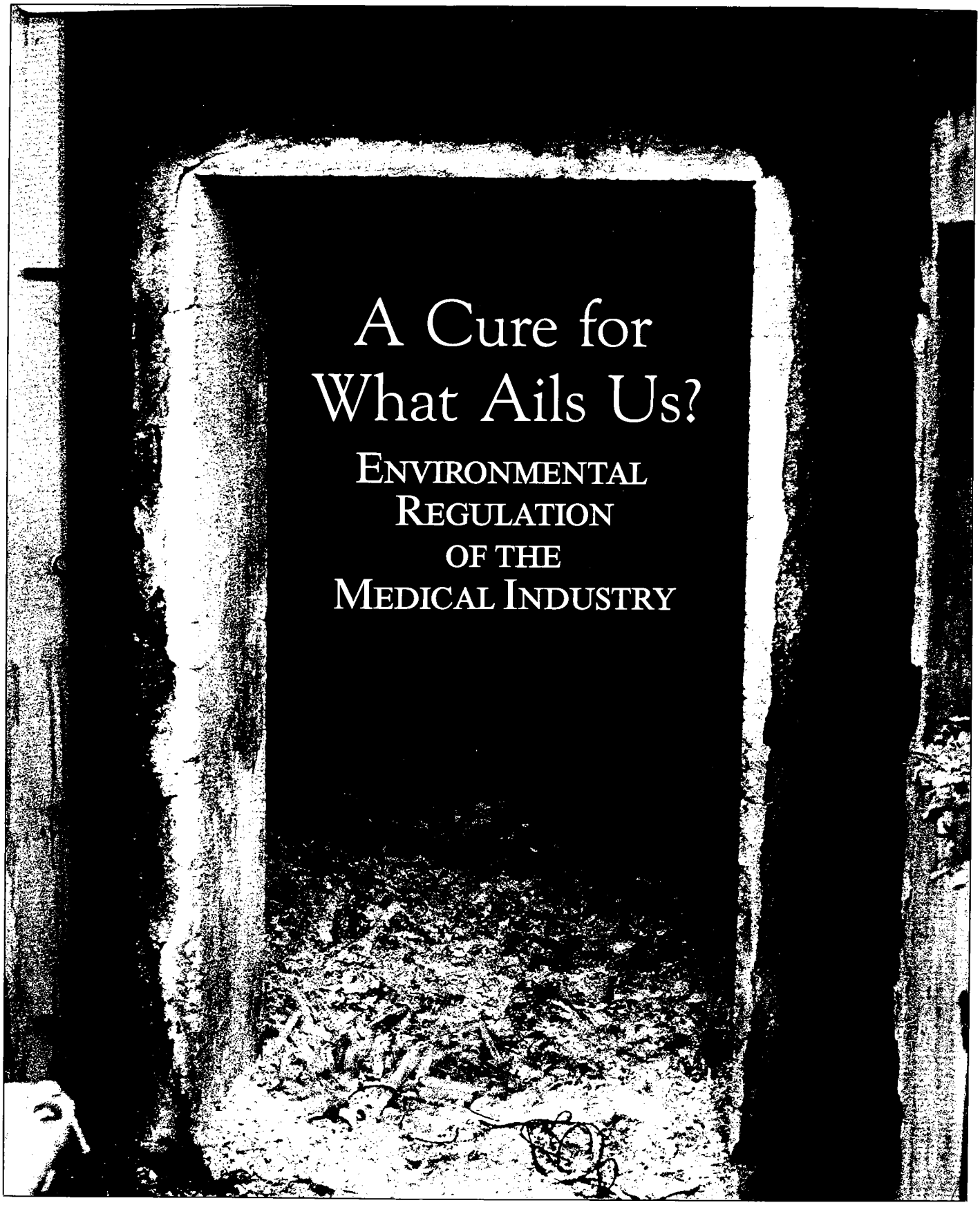

A Cure for What Ails Us?

Environmental Regulation of the Medical Industry

Inside view of a hospital incinerator.

Gershman, Brickner, Bratton, Inc.

Shell J. Bleiweiss and Janice M. Edwards

A recent EPA report estimates that hospitals in the United States generate about 10,500 tons of waste per day, or more than 3 million tons of medical waste per year. In response to the handling and disposal problems posed by this substantial quantity of waste, a flurry of legislative and regulatory proposals are making their way through federal and state agencies and legislatures. Past deliberations over medical waste disposal issues have often generated more wind than substantive regulation. However, the climate has now changed, owing primarily to an increased public awareness and widespread fear of health hazards—most notably AIDS—generated by the improper disposal of medical wastes.

It is ironic that medical facilities working to save lives are now coming under fire for infecting others in the process. EPA studies indicate that the most likely sources of last summer's beach washups were not medical facilities, but ordinary trash that was improperly handled, and sewage overflows containing wastes from home health care and illegal drug use. Yet, these suspected sources will not even be affected by the new tracking system. Nonetheless, thousands of hospitals and clinics around the country, largely unregulated until now, will soon face a labyrinth of federal and state laws and regulations. It is therefore worth exploring these initiatives and their potential effects on the medical community.

Federal Activity

The Medical Waste Tracking Act of 1988. The Medical Waste Tracking Act, enacted last October, established a two-year demonstration program that employs detailed recordkeeping to track medical waste from its generation to its ultimate place of disposal, or "from cradle to grave." The demonstration program will be implemented in New York, New Jersey, Connecticut, and all states contiguous to the Great Lakes (Illinois, Indiana, Michigan, Minnesota, Ohio, Pennsylvania, and Wisconsin). In addition, any other state that petitions to be included may participate.

The Act permits any of the Great Lakes states to opt out of the program. However, New York, New Jersey, and Connecticut may opt out only if they have in place another medical waste tracking program no less stringent than the federal demonstration program. New York and New Jersey are likely to participate in the program, even though both states already have tracking systems in place. American Samoa plans to petition to be in the program. Montana, South Carolina, and California have expressed substantial interest, and several other states have made written inquiries. Thus far, only Minnesota has opted out of the program, citing cost and lack of need. North Dakota, Utah, Nebraska, Hawaii, Arizona, and Missouri have stated that they will not participate.

The Act specifies both the regulated community and the types of medical waste that must be tracked. All generators of 50 pounds or more a month of regulated medical waste (excluding on-site incinerator ash) are subject to the tracking requirements. The Act identifies regulated medical waste by listing several nonexclusive categories. The first five categories *must* be regulated: (1) infectious agents, (2) pathological wastes, (3) human blood and blood products, (4) sharps used in patient care or in laboratories (e.g., hypodermic needles, syringes, pasteur pipettes, broken glass, and scalpel blades), and (5) contaminated animal carcasses, parts, or bedding. The next five categories are discretionary: (6) surgery or autopsy wastes, (7) laboratory wastes, (8) dialysis wastes, (9) certain discarded medical equipment, and (10) isolation wastes. These may be excluded from regulation if the EPA Administrator finds that they do not pose a substantial present or potential hazard to human health or the environment, even if improperly handled.

Special containers and labeling are required to protect both waste handlers and the public from exposure. Detailed records must be kept not only along the tracking route for wastes disposed off site, but also for wastes incinerated on site. Generators, transporters, and waste disposal facilities, among others, must consent to reasonable requests from EPA for access to records and information, as well as access to the facilities for inspection and sampling.

The Act provides for civil and criminal penalties, including fines of up to $25,000 per day for civil violations, and up to $250,000 and 15 years imprisonment for criminal violations. Corporations as well as individuals can be held liable for violations, and an organization knowingly placing another person in imminent danger of death or serious bodily injury is subject to a fine of up to $1 million.

EPA Regulations Implementing the Act

In mid-March, EPA adopted regulations mandated by the Medical Waste Tracking Act. These Interim Final Regulations will be subject to a 60-day public-comment period and then will go into effect 30 days after that. According to the Interim Final Regulations, EPA will regulate isolation wastes and certain unused, discarded sharps, but does not intend to regulate the remaining discretionary categories.

In exercising its limited discretion over which medical wastes are regulated by the Act, EPA appears to be following Congress' lead in defining regulated wastes by type, rather than by degree of infectiousness. Although EPA defines "infectious" and "infectious agents," only *some* of the regulated medical wastes are in fact infectious. Thus, generators of certain medical wastes not proven to be infectious are nonetheless subject to the tracking requirements. The Agency has interpreted the regulated universe of medical waste broadly to include any mixture of regulated waste and solid waste. Therefore, it is imperative that facilities separate their wastes so that each category will be subject only to the regulations pertaining to it, and so that tracking requirements for nonregulated waste are avoided.

In addition, the Act allows EPA to vary the regulations

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Gershman, Brickner, Bratton, Inc.

It is ironic that medical facilities working to save lives are now coming under fire for infecting others.

Incinerated waste is hauled from this hospital in closed metal containers.

for different types of waste generators. According to the draft rules, a "generator" is any person, by site, whose act or process produces regulated medical waste. Where more than one person is located in the same medical facility, each person is considered to be a separate generator. This means that doctors practicing independently of each other, but located in the same building, are each considered a separate generator. Therefore, independent doctors are exempt from the tracking requirement if they generate fewer than 50 pounds of medical waste per month, regardless of the total amount of medical wastes generated by the entire group. Where physicians constitute a clinic or practice group, the entire facility is subject to the 50-pound monthly threshold.

In its preamble to the regulations, EPA interprets the universe of medical waste generators to include, among others, hospitals, physicians' offices, dental offices, veterinary practices, funeral homes, research laboratories that perform health-related analyses or services, nursing homes, and hospices. Medical waste generated in private homes is excluded from regulation under the tracking program.

EPA has decided to adopt a tracking form unique to the medical waste program, rather than adopting the Uniform Hazardous Waste Manifest tracking form used under RCRA Subtitle C. The new EPA form is based on and consistent with forms used in New York and New Jersey medical waste tracking programs. In fact, EPA modeled the federal program after these state programs.

The tracking form serves as a shipping document and record to verify the movement and ultimate disposal of regulated medical waste following its generation. The generator must complete, sign, and date the tracking form certification, and obtain the transporter's signature and date of acceptance before releasing custody of the waste to the transporter.

Before transporting regulated medical wastes off site, a generator must segregate certain categories of waste, and meet detailed packaging requirements so that sharps do not puncture their containers and liquids do not leak during storage or shipment. Generators must also comply with decontamination standards for reusable containers and labeling requirements. Storage of regulated medical waste prior to disposal on or off site requires that it be kept in a secure and inaccessible place, and in a nonputrescent (nonrotting) state. This may require refrigeration.

Generators of waste *over* the 50-pound threshold may ship medical waste off site only via authorized transporters. Generators are also responsible for preparing the proper tracking form that will accompany the waste to its ultimate disposal. The tracking form must be signed by the designated treatment or disposal facility operator and returned to the generator, who is responsible for determining the whereabouts and status of the waste. If the generator has not received the signed tracking form within 45 days after initially sending the waste, it must report the missing form to both EPA and the state.

Generators of waste *under* 50 pounds need not use a tracking form for waste transported off site, but still must comply with segregation, packaging, labeling, and storage requirements. However, any generator of less than 50 pounds of waste monthly who transports more than 50 pounds in any one shipment will be subject to standard tracking and transporter requirements.

Generators who dispose of medical waste on site by incineration, sewer disposal, or burial are not subject to segregation, packaging, labeling, and tracking requirements. Nonetheless, those who incinerate their medical waste on site must keep careful records and submit reports to EPA and the state waste management agency. Moreover, because incineration concentrates metal constituents as it reduces waste volume, ash from incinerated medical wastes may become hazardous waste. If so, this ash must be managed as a hazardous waste under Subtitle C of RCRA.

EPA estimates that the average annual compliance costs per facility will range from about $3,750 for hospitals to

about $70 for dental offices. The average cost increase per pound to dispose of medical waste is approximately eight cents, according to the Agency. These numbers contrast sharply with those of the American Hospital Association, which estimates annual disposal costs for a medium-sized, 300-bed hospital will increase by $200,000, if all ten categories of medical waste listed in the Act are taken into account.

The commercial waste disposal industry is responding to this new burden on the medical community by providing new services and assistance. Several of the large waste disposal companies are establishing procedures for disposing of medical wastes. These companies appear to be targeting hospitals and other large generators for their services. New companies are also forming to cater to the smaller generators. In Illinois, for example, at least one new company has been formed by a group of medical and other professionals to offer, in conjunction with an existing trash hauler, a training, consulting, management, and disposal service to individual doctors' offices and other small generators of medical waste. This company will also provide assistance and representation in the event of compliance inquiries.

Ocean Dumping Ban Act of 1988

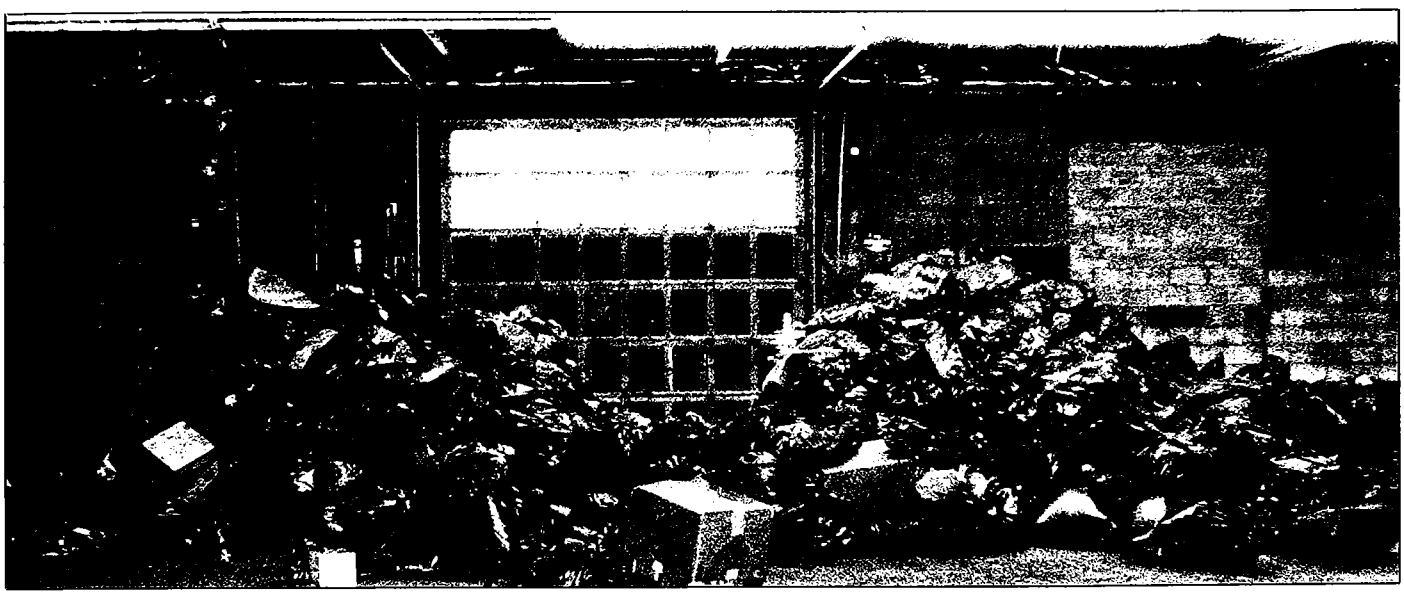
In November of 1988, Congress enacted P.L. 100-688 amending various environmental statutes to prohibit dumping of medical waste into the ocean or any navigable waters of the United States. Title III of the Act, "Dumping of Medical Waste," provides fines of up to $250,000 and/or five-years imprisonment for any person who is knowingly involved in dumping medical waste into ocean waters. For the purposes of this law, medical waste is defined as: "isolation wastes; infectious agents; human blood and blood products; pathological wastes; sharps; body parts; contaminated bedding; surgical wastes and potentially contaminated laboratory wastes; dialysis wastes; and such additional medical items as the [EPA] Administrator shall prescribe by regulation."

The Act is designed to regulate not only the actual dumper, but also any generator or shipper of medical waste. A violator is not only subject to fines and imprisonment, but must forfeit any profits or property derived from the violation, as well as any property used to commit the violation (e.g., the vessel). It is unclear as a practical matter, however, how this forfeiture provision may be applied to generators of wastes if they are not the actual dumpers.

Title III further amends the Clean Water Act to prohibit the discharge of any medical waste into navigable waters of the United States. This amendment ranks medical wastes along with radiological, chemical, or biological warfare agents and high-level radioactive wastes as extremely dangerous substances that must not be discharged into navigable waters. Moreover, other provisions of the Clean Water Act governing permits for direct discharges of wastewater are now apparently foreclosed insofar as they might allow discharges of medical wastes. The amendment effectively prohibits the issuance of any discharge permit for medical wastes—possibly even sewer permits—under the National Pollutant Discharge Elimination System (NPDES) or otherwise.

EPA estimates the average cost increase per pound to dispose of medical waste is approximately eight cents.

EPA has not yet determined whether this provision prevents pretreated discharges to sewers. Arguably, pretreated medical waste is no longer prohibited waste and can thus be discharged into publicly owned treatment works (POTWs). However, EPA is concerned that pretreatment of medical wastes may not meet the proper standard. Although EPA is reportedly planning new rules on this issue,



Thomas Moran, NYSDEC

Rebagged medical waste was illegally stored here by a contracted hauler and then put out for general collection.

Thomas Moran, NYSDEC

In the absence of federal regulation, the states have taken the initiative in responding to public demand.

Bags of infectious waste left outside without covers, failing to meet storage requirements.

this effort has been impeded by a lack of data concerning the effectiveness of POTW medical waste treatment.

The agency also considered—and apparently rejected—adding "hospitals" as a new industrial-source category, requiring hospital waste discharges to be regulated under the Clean Water Act's New Source Performance Standards. However, EPA believes that existing regulations governing hospitals' wastewater discharges are adequate, and plans to issue a notice later this year that discusses this issue.

Resource Conservation and Recovery Act

The statutory definition of hazardous waste in the Resource Conservation and Recovery Act (RCRA) specifically cites *infectiousness* as one of the characteristics that may cause wastes to be hazardous. Despite this language, EPA declined to regulate any infectious wastes as hazardous in its 1980 RCRA regulations, instead offering nonenforceable guidelines in 1986 for managing such wastes.

In response to the public outcry and media attention inspired by last summer's washed-up medical wastes on the nation's beaches, EPA has agreed to reevaluate the problems posed by infectious wastes. Last June, the agency sought public comment on several aspects of the problem, including its definition of infectious waste; whether different waste types require different controls; the degree of risk posed by exposure; the extent to which mismanagement contributes to the problem; whether the federal role should be regulatory or educational; the most appropriate type of tracking system; and whether any group of generators should be exempt from management controls. EPA has used the responses to these questions to determine the proper scope for regulating medical waste under the Medical Waste Tracking Act.

Congressional Activity—RCRA and Medical Waste

Congress is currently considering legislation to reauthorize and revise RCRA. Among its considerations may be an amendment that would *require* EPA to regulate infectious medical wastes as hazardous wastes. Further, Representative Robert Roe (D-NJ) introduced a bill in January requiring EPA to conduct research on the management of infectious medical wastes. The bill specifies the focus of the research and authorizes financing for the years 1990 through 1995. If the bill is enacted, Congress would likely delay legislation requiring EPA to regulate infectious waste as a RCRA hazardous waste until the agency completes its research.

In addition, several bills were proposed last year requiring EPA to promulgate regulations governing the generation, transportation, treatment, storage, and disposal of medical waste and medical equipment. Three of these measures have been reintroduced this year, and congressional staffers indicate that several others are likely. This abundance of legislation demonstrates congressional impatience with EPA's failure to regulate medical waste more forcefully.

Determined as Congress may be to mandate regulation of medical waste disposal under RCRA, the passage of such legislation may be postponed by the Clean Air Act and other important environmental issues on its agenda. Moreover, President Bush has affirmed his commitment to zealous prosecution of medical waste dumpers and to seek new penalties, but he has also made strong commitments to solving other environmental problems such as acid rain and smog. Similarly, the Senate Majority Leader, George Mitchell (D-ME), has stated that clean air legislation will be his top priority.

Clean Air Act

According to EPA, about 70 percent of all community hospitals incinerate all or part of their waste on site. Burning medical wastes in hospital and municipal incinerators has come under increasing scrutiny because of concern over possible toxic air emissions, particularly dioxins and furans. EPA's *Hospital Waste Combustion Study; Data Gathering Phase, Final Draft Report*, updated in 1988, indicates that hospital incinerators may also emit acid gases, toxic trace metals,

low molecular weight organic compounds, particulate matter, carbon monoxide, pathogens, and viruses.

In addition, the ash resulting from medical waste incineration often contains hazardous substances, including cadmium, lead, and other metals. This ash is frequently stored in open containers and hauled to landfills in open trucks.

Thus, the issue of toxic ash residue and potentially dangerous air emissions from incinerators of medical waste is ripe for discussion this year in congressional consideration of Clean Air Act legislation. Indeed, various bills have already been introduced.

In January, Senator Quentin Burdick (D-ND) introduced a bill to control emissions of air pollutants from waste incinerators and to provide for the safe disposal of ash. Although the bill is aimed principally at municipal waste incinerators, its provisions would also apply to hospital and other infectious waste incinerators if EPA fails to promulgate equally strict standards for them. The bill requires EPA to promulgate emission standards for new or modified waste incinerators to attain the greatest degree of emissions limitation achievable with the best available control technologies. Further, two years after enactment, the bill requires all incinerators to submit an ash management plan in order to receive an operating permit.

In March, EPA announced its initiation of a regulatory program addressing air emissions from medical waste incinerators. According to the agency, its planned regulatory program will include: 1) development of a new source performance standard (NSPS) under the Clean Air Act; 2) development of an operator training program for existing medical waste incinerators; and 3) consideration of best available control technology (BACT) guidance for voluntary use by state and local agencies prior to proposal of the NSPS. The BACT guidance is likely to be similar to the EPA operation guidance issued in June 1987 for new municipal waste combustion facilities.

Another bill introduced in January by House Energy and Commerce Chair John Dingell (D-MI) establishes a "Pollutant List" requiring both new and existing sources to meet emission standards. Most of the acid gases, low molecular weight organics, and trace metals that EPA's study identified as being emitted from large hospital waste incinerators are included on the Pollutant List. This bill may thus cover medical waste incinerators by virtue of the emissions they produce.

This bill would require compliance by existing sources within three years after EPA sets an emission standard. EPA standards must require the "maximum degree of reduction" achievable, while taking into account the cost, any nonair quality health and environmental impacts, and energy requirements. The law would allow a grace period of five years from any previous installation of control technology by existing sources, and variances and extensions may also be granted.

Another bill introduced in January by Representative Al Swift (D-WA) focuses on ozone and carbon monoxide nonattainment areas, and requires annual emission monitoring reports from stationary sources that emit, or have the potential to emit, 25 tons or more of volatile organic compounds, nitrogen oxides, or carbon monoxide per year. Importantly, these substances are among those found by the EPA to be emitted from hospital incinerators.

OSHA Regulations

There is a general consensus among experts that the occupational hazards associated with medical wastes are much more serious than any environmental hazards, particularly for health-care workers and waste handlers. The National Solid Waste Management Association claims that U.S. health-care workers accidentally stick themselves with needles some 2,200 times a day. The Center for Disease Control in Atlanta reports that as many as 15,000 health-care workers *contract* the hepatitis B virus every year.

In mid-1987, the Service Employees International Union petitioned the Occupational Safety and Health Administra-

The occupational hazards associated with medical wastes are much more serious than any environmental hazards.

Gershman, Brickner, Bratton, Inc.

A protective locked fence surrounds this hospital incinerator to keep both animals and humans away from infectious materials.

tion (OSHA) to develop a standard to protect health-care workers. Consequently, in November of 1987 OSHA began a rulemaking process for the development of a standard aimed at reducing health-care workers' exposure to the hepatitis B virus, (HBV) and the human immunodeficiency virus (HIV or AIDS virus). OSHA has acknowledged that regulating occupational exposure to HBV and AIDS viruses may have an impact on the environment by generating increased quantities of hazardous infectious wastes.

In January, OSHA released a draft of its proposed standard for blood-borne pathogens. Under this proposal, all blood and body fluids are presumed infected; therefore, health-care workers are protected not only from exposure to infectious wastes, but also from exposure to "other potentially infectious material."

The proposal requires each employer to establish an infection control plan to comply with the standard. Whenever feasible, engineering and work practice controls are to be used rather than personal protective equipment. However,

EPA estimates that annual compliance costs will be about $3,750 for hospitals and $70 for dental offices.

when required, the employer must provide specified protective work clothing and equipment to employees at no cost, and must ensure their use. In addition, the employer must follow listed housekeeping practices to assure a clean and sanitary worksite.

The proposed standard directly addresses infectious waste disposal. All infectious wastes destined for disposal must be placed in closable, leakproof containers or bags that are color coded or labeled. If outside contamination is likely, a second leakproof container or bag must enclose the first. Immediately after use, sharps must be disposed of in closable, leakproof, puncture resistant, disposable containers that are labeled or color coded as required. Laundry that may be soiled with blood or other potentially infectious materials or which may contain contaminated sharps must be treated as if contaminated. Contaminated laundry must be bagged at the location where it was used, labeled or color coded, and, if wet, transported in leakproof bags. The standard also establishes additional requirements for AIDS and HBV research laboratories and production facilities.

Superfund

Even though medical waste has not yet been characterized as hazardous under RCRA, it may nonetheless be a "pollutant or contaminant" governed by the 1980 Superfund law. Superfund provides for emergency and long-term cleanup of hazardous substances, pollutants, or contaminants, including disease-causing agents. Thus, certain releases of medical waste may be subject to this authority, which could impose cleanup costs on waste generators, among others.

Department of Transportation Regulations

The Department of Transportation (DOT) recently embarked on a comprehensive review of rules for the transportation of etiologic agents under the Hazardous Materials Transportation Act. As a first step, DOT proposes to amend its rules defining an etiologic agent as a "viable microorganism, or its toxic, which causes or may cause human disease." The new definition will include agents specifically listed by the Center for Disease Control and "any agent that poses a degree of hazard similar to those agents." Based on the shipper's knowledge that pathogens not currently listed in the CDC regulations present a substantial risk to health and safety, such pathogens (including the AIDS virus) would have to be shipped as etiologic agents. DOT has special regulations for packaging and shipment of such agents.

State Activity

In the absence of federal regulation, the states have taken the initiative in responding to the public demand for the regulation of medical waste. Currently, nearly 90 percent of the states have regulations in place or in the legislative pipeline (compared to 57 percent of the states in 1986). Many states have regulated medical wastes for years, and these programs vary immensely.

State legislative activity continues to be intense, both in states with existing regulations and in those that have none. For example, until mid-1988 Michigan had no legislation proposed or planned to govern infectious waste. Michigan now has 24 bills pending, ranging broadly from general coverage of the handling and disposal of infectious medical wastes to very narrow coverage of specific issues, such as licenses for physicians' clinical laboratories.

Many states are not only amending their substantive regulations but are increasing penalties for violations of existing statutes. Florida, for example, has a bill pending that would increase the fines for unsafe packaging, storage, treatment, or disposal of "bio-hazardous" wastes to $10,000 per day, and would provide a second-degree felony penalty for a violation resulting in infectious disease in any person. Maryland has legislation pending that would increase penalties for unauthorized dumping of certain medical waste from a misdemeanor to a felony subject to a maximum fine of $1 million and ten years imprisonment. Similar bills elsewhere indicate that the states are serious about enacting strong laws to govern strictly the handling and disposal of medical wastes.

Conclusion

The media and the medical community have paid much attention to the new federal pilot program for medical waste tracking. However, comparatively little attention has been directed to the proliferation of other federal and state legislative and regulatory initiatives on this issue. It is quite probable that in the next one to three years the medical community will be subject to several new or expanded regulatory programs that match or exceed the burden of the Medical Waste Tracking Act of 1988. Some of the requirements under consideration, such as a sewer discharge ban, regulation of medical wastes as hazardous under RCRA, and more stringent controls on hospital incinerator emissions, have the potential for major impact on the medical community.□