

# MEDICAL WASTE REGULATION: RECOMMENDATIONS FOR CLEANING UP THE MESS

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## INTRODUCTION

The treatment and disposal of medical waste was of little public concern until the 1987 and 1988 beach washups of medical debris made national headlines.<sup>1</sup> In response to public outcry and fueled by the public's fear of AIDS and other public health perils, Congress passed the Medical Waste Tracking Act of 1988<sup>2</sup> (MWTa), a two year demonstration program, to monitor and formulate a solution to the perceived medical waste disposal "crisis." However, four years after the enactment of the MWTa, medical waste management remains without any uniform federal regulation.

Many state and local governments responded to the "crisis" by passing their own medical waste regulations or by making existing regulations more stringent. In the absence of comprehensive federal regulation, state and municipal laws have addressed medical waste management inconsistently,<sup>3</sup> creating uncertainty among medical waste generators, transporters and disposers.

The absence of uniform definitions of medical waste and infectious waste compounds the problems arising from the fragmentation of medical waste regulation.<sup>4</sup> The general term "medical waste" incorporates several categories of waste, including hospital waste, infectious waste, and regulated medical waste. Unfortunately, much of the literature addressing medical waste management uses the term "medical waste" without clearly identifying the particular subset of waste to which it is referring.<sup>5</sup> Inconsistent regulation also creates confusion and conflict over proper medical waste packaging, transporta-

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1. See, e.g., Robert Hanley, *Many Beaches in New Jersey Reopen; Source of Medical Waste Is Sought*, N.Y. TIMES, Aug. 16, 1987, § 1 at 42; James Barron, *Two Beaches Shut After Discovery of More Waste*, N.Y. TIMES, July 11, 1988, at A1; Marianne Yen, *N.Y. Beaches Reopen, but Few Take the Plunge; Reports of Medical Debris Keep Thousands From Shore*, WASH. POST, July 10, 1988, at A3.

2. 42 U.S.C. §§ 6992-6992K (1988).

3. Compare Comprehensive Regulated Medical Waste Act, N.J. STAT. ANN. §§ 13:1E-48.1 to 13:1E-48.28 (West 1991) (regulating many medical waste generators) with MO. CODE REGS. tit. 19, §§ 30-20.021(5), 30-22.030, 30-24.0040 (1988) (regulating on-site management by hospitals only).

4. See Michael R. Shumaker, Note, *Infectious Waste: A Guide To State Regulation and a Cry for Federal Intervention*, 66 NOTRE DAME L. REV. 555, 564 n.41 (1990) (discussing the lack of a standard definition of infectious waste and the lack of standard terminology among state infectious waste regulations).

5. Within this Note, the author will specify the subcategory of "medical waste" to which he refers when possible.

tion and disposal. The Clean Air Act and other new environmental regulations, which promise to alter the landscape of acceptable medical waste disposal techniques, will add to the uncertainty faced by generators.

This Note seeks to elucidate the general areas of confusion concerning medical waste management and provide the reader with a better understanding of the past, present and future status of the perceived "crisis" in medical waste management. Part II of this Note examines various legislative and industry responses to the medical waste disposal "crisis." Part III analyzes the definitions of various types of medical waste, indicating the amounts of specific types generated and the associated disposal costs. Part IV discusses the handling, packaging and transportation of medical waste and the associated health risks. Part V explores both the prevalent medical waste disposal technologies and some recent advances in disposal techniques. The Note concludes by refuting the federal government's justification for its failure to formulate a comprehensive medical waste management policy. The government claimed, in part, that more information about effective waste management methods and the corresponding health and safety risks is needed before a policy is formulated.<sup>6</sup> This author suggests that these issues have now been adequately studied and understood and recommends a harmonization of the inconsistent local, state and federal regulations.

### I. THE MEDICAL WASTE "CRISIS"

Over the years, hospitals, clinics, laboratories, physicians' offices, and other health care facilities have managed their medical waste discreetly. However, during the 1980s, landfill operators became more reluctant to accept medical waste because of its hazardous properties and increased liability risks.<sup>7</sup> In fact, some states and municipalities enacted laws prohibiting the dumping of medical waste into landfills without pretreatment.<sup>8</sup> As medical waste disposal became more difficult and costly, incentives for illegal dumping increased.<sup>9</sup>

During the summers of 1987 and 1988, the public became keenly aware of the medical waste management dilemma posed by illegal dumping. Beaches on both seaboard and the Great Lakes region were temporarily closed when sewage and floating debris washed ashore. Among the floating debris were blood vials and bags, needles, gauze dressings, syringes, and other medical

6. OFFICE OF TECHNOLOGY ASSESSMENT, FINDING THE RX FOR MANAGING MEDICAL WASTES, at 1, 3 (Sept. 1990) [hereinafter OTA REPORT].

7. Larry Tye, *Thousands of Tons of Infectious Debris Go Unregulated*, BOSTON GLOBE, Sept. 5, 1988, at 1.

8. THE COUNCIL OF STATE GOV'TS, STATE INFECTIOUS WASTE REGULATORY PROGRAMS, reprinted in *Health Hazards Posed in the Generation, Handling, and Disposal of Infectious Wastes: Hearing Before the Subcomm. on Regulation and Business Opportunities of the House Comm. on Small Business*, 100th Cong., 2d Sess. 307 (1988) [hereinafter *Hearing*].

9. Cheryl L. Coon & Howard L. Gilberg, *The New Regulatory Horizon: Regulation of Medical Waste*, 45 Sw. L.J. 1099, 1102 (1991).

waste.<sup>10</sup> There were also reports of illegal inland disposal of medical waste in places such as dumpsters and street curbs.<sup>11</sup> Confirming many people's worst fears, some of the medical waste was contaminated with the HIV and hepatitis B viruses.<sup>12</sup> The public's enjoyment of the beaches was replaced by trepidation over possible exposure to infectious diseases. Beach closings due to the public health threat cost the tourism industry billions of dollars.<sup>13</sup>

Most of the medical waste washups and dumpings could not be traced back to the original wrongdoer.<sup>14</sup> While some of the waste came from hospitals, laboratories, and other common medical waste generators, the vast majority of the medical debris that washed ashore came from sewage overflows containing wastes from home health care and from illegal drug users who dumped syringes into city sewers.<sup>15</sup> Many reports estimated that only a small percentage<sup>16</sup> of the total waste that washed up on shore was medical waste. Nevertheless, the

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10. 134 CONG. REC. S10737 (daily ed. Aug. 3, 1988); *see also* OFFICE OF TECHNOLOGY ASSESSMENT, ISSUES IN MEDICAL WASTE MANAGEMENT: BACKGROUND PAPER, at 1 (Oct. 1988) [hereinafter BACKGROUND REPORT]; *Medical Waste*, 19 ENV'T REP. (BNA) No. 28, at 1450 (Nov. 11, 1988); Sandra Friedland, *Rules on Handling Medical Waste Come Under Scrutiny*, N.Y. TIMES, July 31, 1988, § 12 (New Jersey), at 1.

11. OFFICE OF SOLID WASTE, U.S. EPA, MEDICAL WASTE MANAGEMENT IN THE UNITED STATES: SECOND REPORT TO CONGRESS, 3 (Dec. 1990) [hereinafter EPA SECOND INTERIM REPORT]. *See also* Lawrence D. Granite, *The Medical Waste Tracking Act of 1988: An Analysis of its Provisions and Its Effect on New York State*, 7 Touro L. REV. 259, 260 n.12 (1990) (recounting press accounts of shocking illegal medical waste dumpings); John Penner, *Orange County Focus: Huntington Beach; Toxic Medical Waste Dumped; 2 Sought*, L.A. TIMES, June 21, 1990, at B2 (medical waste left in dumpster); Nora Zamichow, *Medical Waste Found in Trash Brings No Action*, L.A. TIMES, Sep. 15, 1990, at B1 (medical waste dumped behind video store).

12. Among several instances where illegally disposed medical waste was found to be infected with the HIV virus, perhaps the most alarming occurred in June 1987, when twelve children were found playing "doctor" with syringes and vials of blood — two infected with the HIV virus — found in a trash bin in Indianapolis. BACKGROUND REPORT, *supra* note 10, at 1; Jane Gross, *2 Beach Vials Are Tainted by Hepatitis*, N.Y. TIMES, July 14, 1988, § B3.

13. Allen Hershkowitz, *Without a Trace: Handling Medical Waste Safely*, TECH. REV., Aug.-Sept., 1990, 35, 35. Economic losses from beach closings are further discussed *infra* Part III.D.

14. Philip S. Gutis, *Trash, Some of It Medical Waste, Closes Beaches on Long Island for Second Day*, N.Y. TIMES, July 8, 1988, at A1 (comments of William Muszynski, deputy regional director of EPA addressing the difficulty in identifying illegally dumped medical waste). In some instances, however, perpetrators of illegal medical waste dumpings were traced and prosecuted. In one example, the Vice-President of Plaza Health Laboratories of Brooklyn, N.Y., was found guilty of dumping vials, some contaminated with the hepatitis B virus, in the waters off Staten Island and New Jersey in 1988. *Lab Official Guilty in Medical Waste Case*, N.Y. TIMES, Feb. 3, 1991, § L (Metropolitan) at 31.

15. *Hearing, supra* note 8, at 78 (statement of Jeffrey D. Denit, Deputy Director, Office of Solid Waste, EPA); Shell J. Bleiweiss & Janice M. Edwards, *A Cure for What Ails Us? Environmental Regulation of the Medical Industry*, 6 ENVTL. F. 7, 7 (Mar.-Apr. 1989).

16. *See, e.g.*, Shannon Brownlee, *Stopping Coastline Pollution at the Sewer and the Farm*, U.S. NEWS & WORLD REP., Aug. 21, 1989, at 52 (reports estimating one percent); Alan Burdick, *Hype Tide: Come on in, the Water's Fine*, NEW REPUBLIC, June 12, 1989, at 16 (reports estimating between one and ten percent).

public's *perception* of a "crisis" in medical waste management gave rise to a sort of hysteria exacerbated by the public's fear of AIDS.<sup>17</sup> As one report noted, "cigar holders were reported as blood vials, animal fat and parts became human organs, household rubber gloves became surgical gloves . . . ."<sup>18</sup> In response to the overwhelming public concern, it soon became obvious that new regulations, or at least stricter enforcement of existing medical waste management rules, was necessary to stem the apparent "tide" of illegal medical waste dumpings. Both state and federal legislatures reacted to the great public outcry and media attention over the medical waste "crisis."

## II. THE LEGISLATIVE RESPONSE TO THE MEDICAL WASTE "CRISIS"

After the initial beach washups in 1987, a number of senators from coastal states called on the EPA to take decisive action to regulate medical waste.<sup>19</sup> No action was taken, however, until subsequent washups in the summer of 1988 made new legislative action the only politically expedient choice. Congress, in an effort to study the problem closely, passed the Medical Waste Tracking Act of 1988,<sup>20</sup> a two year "cradle-to-grave" demonstration program designed to monitor the medical waste treatment and disposal chain. Under the MWTa, "regulated medical waste" from five states<sup>21</sup> was tracked from the point of generation through treatment and to ultimate disposal.<sup>22</sup> By tracking the

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17. David R. Mercer, Note, *A Prospectus on the Legislative Response to Medical Waste*, 55 MO. L. REV. 509, 515 n.40 (1990).

18. Janice Somerville, *MDs, Hospitals Facing More Cost, Regulation Over Red Bag Disposal*, AM. MED. NEWS, Aug. 25, 1989, at 1, 34.

19. Letter from Sen. Frank R. Lautenberg to Lee M. Thomas, Administrator of the EPA (Oct. 20, 1987) (discussing hospital waste management), *reprinted in* 134 CONG. REC. S10738 (daily ed., Aug. 3, 1988) (statement of Sen. Lautenberg). As of 1987, the EPA had declined to implement any type of effective regulatory program under the authority to regulate infectious medical waste management given to it by Congress pursuant to the Resource Conservation and Recovery Act (RCRA). 42 U.S.C. §§ 6901-6992 (1988). Instead, the EPA had issued suggestive guidelines and had relied on state and local governments to regulate medical waste management. See UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, EPA GUIDE FOR INFECTIOUS WASTE MANAGEMENT, at 3-1 to 3-3 (May 1986) [hereinafter EPA GUIDE].

20. 42 U.S.C. § 6992.

21. Under the MWTa, a number of states were designated to participate. However, several designated states were allowed to "opt out" of the program, while several others were allowed to "petition in." In the end, Connecticut, New Jersey, New York, Puerto Rico and Rhode Island participated in the demonstration program, which expired on June 22, 1991. OFFICE OF SOLID WASTE, U.S. EPA, MEDICAL WASTE MANAGEMENT IN THE UNITED STATES: EPA FIRST INTERIM REPORT TO CONGRESS, at V (May 1990) [hereinafter EPA FIRST INTERIM REPORT]. However, Connecticut participated in the MWTa in name only, due to a shortage of staff resulting from state budget cuts. *Connecticut's MW Program Sputters, Takes Off After End of MWTa*, MED. WASTE NEWS, Nov. 5, 1992, available in LEXIS, Nexis Library, NWLTRS File.

22. Detailed record keeping and labelling were required by the Act. For more thorough discussions of the MWTa, see Granite, *supra* note 11, at 264-77; Mercer, *supra* note 17, at 519-46. For a theoretical and critical public policy analysis of the passage and implementation of the MWTa, see Robert T. Nakamura et al., *A Blip on the Radar Screen: Formulation and*

medical waste, Congress hoped the EPA would gather enough information to recommend a prudent course of regulatory action.<sup>23</sup> Because the public had lost interest in the medical waste disposal issue by 1991, the MWTA's tracking program expired without much public attention. Now, nearly two years after the MWTA's expiration, and with continued public disinterest, the EPA has further delayed the issuance of its final report to Congress.<sup>24</sup>

Most of the states that declined to participate in the MWTA—along with several states that did participate—had either enacted medical waste legislation of their own prior to the passage of the MWTA, or did so shortly after the MWTA was enacted.<sup>25</sup> By 1989, only eight states had no regulations or recommendations on the proper disposal of medical waste,<sup>26</sup> and as of 1993, only four states lacked some sort of medical waste regulation.<sup>27</sup>

Unfortunately, states continue to define medical waste differently.<sup>28</sup> The reuse of old definitions from existing regulations,<sup>29</sup> varied state lobbying pressures from medical waste generators, and the absence of a widely accepted definition of medical waste have led to differing definitions of medical waste. The definitional conflicts create significant problems including "forum shopping," whereby medical waste is generated in one state and transported to another state with less stringent regulations allowing for cheaper treatment or disposal.<sup>30</sup> Furthermore, as a result of inconsistent state definitions, it is likely

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*Implementation of the Medical Waste Tracking Act*, 17 J. OF HEALTH POL., POL'Y & LAW 299 (Summer 1992).

23. See EPA FIRST INTERIM REPORT, *supra* note 21; EPA SECOND INTERIM REPORT, *supra* note 11. The EPA's Final Report to Congress has not been issued as of this writing.

24. According to a staff member at the EPA office of Solid Waste Management, the Final Report has been delayed so that members of the Clinton Administration have time to review the recommendations. The Final Report will be reported to the House Committee on Energy and Commerce and to the Senate Environment and Public Works Committee.

25. For a general discussion of state medical waste legislation, see Shumaker, *supra* note 4.

26. *Id.* at 556 n.4.

27. The four states that have enacted new medical waste laws since 1989 are: Montana, MONT. CODE ANN. § 75-10-1006 (1992); South Dakota, S.D. CODIFIED LAWS ANN. §§ 34A-6-93 to 34A-6-103 (1992); Utah, UTAH CODE ANN. § 19-6-105(h) (Supp. 1992); and West Virginia, W. VA. CODE § 20-5J-1 to 20-5J-10 (Michie Supp. 1992) (note that the certification requirement of West Virginia's Medical Waste Act of 1991, § 20-5J-10(b), was found unconstitutional under the Commerce Clause in *Medigen of Kentucky v. Pub. Serv. Comm. of West Virginia*, No. 92-1245, 1993 U.S. App. LEXIS 1909, at \*1 (4th Cir. Feb. 5, 1993)).

28. See Shumaker, *supra* note 4, at 564.

29. Some of the definitions now used were originally formulated years ago when medical waste management was not as highly regulated. Some of these definitions may be incomplete, some may be overbroad, and yet others may be adequate even under today's standards.

30. From an economic perspective, "forum shopping" may reflect an efficient method of medical waste disposal if one assumes that the lax regulations of the "forum" state were enacted by a legislature that consciously accepted the social and health risks of medical waste disposal in return for the economic benefits gained from such disposal in terms of business generated and fees earned. On the other hand, lax medical waste regulations may not be the product of a cost benefit analysis, but rather they may be the product of a powerful industry lobby pressuring the

that many medical waste transporters, treatment facilities, and cleanup crews do not know the exact content of the out-of-state waste they handle. This lack of information could result in improper handling or increased safety risks for workers.

With the expiration of the MWTA tracking program in 1991 and the failure of the federal government to promulgate any follow-up legislative initiatives, state medical waste regulations remain the primary means of medical waste governance. Nevertheless, a discussion of the MWTA's framework and definitions is valuable given the likelihood that future federal regulation will be based on, to some degree, the successes and failures of the cradle-to-grave tracking program.<sup>31</sup>

### III. CONFLICTING DEFINITIONS AND INCONSISTENT DATA

#### A. Confusion Surrounding the Definition of Medical Waste

Effective regulation of medical waste depends largely on a common understanding of terms and standard definitions of different types of waste.<sup>32</sup> Medical waste, hospital waste, and "infectious waste," three separate definitional standards, are often used synonymously.<sup>33</sup> Definitions of medical waste and infectious waste vary from state to state and even among the federal agencies that have regulated medical waste.<sup>34</sup> Under one broad definition, medical waste includes *all* the wastes produced by hospitals, clinics, doctors' offices, and other medical and research facilities.<sup>35</sup> Even this broad definition fails to include potentially hazardous medical waste from home health care, such as used syringes. Yet, use of an overly broad definition of medical waste that includes household medical waste would surely hamper any workable regulatory efforts due to significant enforcement hurdles and high costs.<sup>36</sup>

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regulators into enacting lax regulations. It is also possible that the "forum" status of the state simply may have been the product of poor legislative or regulatory drafting or inadequate information.

31. See Coon & Gilberg, *supra* note 9, at 1100-11; Shumaker, *supra* note 4, at 596-601; Scott B. Goldie, Note, *Blood on the North American Soil: A Comparison of United States and Canadian Infectious Waste Disposal Regulations*, 16 SYRACUSE J. INT'L L. & COM. 129, 160-67 (1989).

32. As one American Hospital Association official has confirmed, "[t]here is a great deal of confusion as to what is really hospital waste." *Daily Report for Executives*, BNA, Apr. 17, 1991, available in LEXIS, Nexis Library, DREXEC File.

33. See William A. Rutala et al., *Management of Infectious Waste by U.S. Hospitals*, 262 JAMA 1635, 1636 (1989).

34. See generally, Shumaker, *supra* note 4, at 564-66 (discussing various state infectious waste definitions); BACKGROUND REPORT, *supra* note 10, at 4-6; see also, Suzan Onel, Note, *The Medical Waste Tracking Act of 1988: Will It Protect Our Beaches?*, 9 VA. ENVTL. L.J. 225, 227 n.12 (1989).

35. OTA REPORT, *supra* note 6, at 2.

36. Almost all current definitions of *regulated* medical waste do not include household waste, which is generally considered part of the municipal solid waste stream. *Id.* at 2 n.4. But see David P. Ruetz & Mary R. Giannini, *New Rules Affect All Medical Waste Generators*, J. OF BUS.-

The Resource Conservation and Recovery Act<sup>37</sup> fails to specifically define *regulated* medical waste.<sup>38</sup> For the purpose of the MWTAs, Congress defined regulated medical waste as “any solid waste which is generated in the diagnosis, treatment, or immunization of human beings or animals, in research pertaining thereto, or in the production or testing of biologics.”<sup>39</sup> Congress, through the MWTAs, also provided an illustrative list of medical waste potentially covered by the tracking program.<sup>40</sup>

Before implementing the MWTAs, the EPA narrowed the list of medical waste actually regulated under the MWTAs to only seven of the proposed eleven categories.<sup>41</sup> It is clear from this list that the MWTAs’s definition of regulated medical waste subsumes “infectious waste,” which is also subject to regulation by the Center for Disease Control (CDC) in Atlanta. However, household medical waste was specifically excluded from federal regulation.<sup>42</sup> Despite the exclusion of several categories of medical waste from EPA’s definition of “regulated medical waste,” the health care industry complained of the MWTAs’s overinclusiveness.<sup>43</sup> Conversely, many environmental groups and legislators complained that the list “improperly exclude[d] several types of infectious wastes.”<sup>44</sup> Such conflict over an appropriate standard definition of regulated medical waste persists today.

### *B. Infectious Waste Distinguished from Medical Waste*

Like medical waste, infectious waste is also susceptible to conflicting definitions.<sup>45</sup> In 1986, the Environmental Protection Agency issued the “EPA Guide for Infectious Waste Management,”<sup>46</sup> intended to provide guidance to state and local agencies regulating infectious waste.<sup>47</sup> The EPA defined

SPOKANE, Oct. 8, 1992, at B11 (discussing a local medical waste regulation promulgated by the Washington Utilities and Transportation Commission that includes home health wastes in its definition of regulated medical waste). Note that the debate over the proper definition of medical waste parallels a similar argument over the proper definition of hazardous waste. The battle over the reauthorization of RCRA provides a good example of this ongoing debate.

37. 42 U.S.C. §§ 6901–6987 (1988).

38. 42 U.S.C. § 6992.

39. 42 U.S.C. § 6903(40).

40. The list includes eleven categories of medical waste. See 42 U.S.C. § 6992a(a)(1)-(11).

41. See 40 C.F.R. § 259.30 (1992). The seven categories of regulated wastes were: (1) *contaminated sharps*, (2) *cultures and stocks of infectious agents and associated biologicals*, (3) *human blood and blood products*, (4) *pathological waste*, (5) *animal waste*, (6) *isolation waste*, and (7) *unused sharps* (emphasis added).

42. 40 C.F.R. § 259.30(b)(1)(ii).

43. Granite, *supra* note 11, at 267.

44. *Id.* (citing Tokarski, *EPA Sets Waste Tracking Plan*, MOD. HEALTHCARE, Mar. 17, 1989, at 4). Granite provides a detailed analysis of the MWTAs’s legislative history with regard to the treatment of the definitional problem of medical waste.

45. See Shumaker, *supra* note 4, at 564–73 (further addressing the confusion concerning the definition of “infectious waste”).

46. EPA GUIDE, *supra* note 19.

47. Note that the treatment and disposal methods outlined in the EPA’s guidance manual are

infectious waste in general as wastes that “contain pathogens with sufficient virulence and quantity so that exposure to the waste by a susceptible host could result in an infectious disease.”<sup>48</sup> The Center for Disease Control also promulgated guidelines.<sup>49</sup> However, the CDC used a less stringent definition of infectious waste, providing infectious waste generators more flexibility.<sup>50</sup> Despite this inconsistency in definitions, generators may adhere to the EPA or CDC guidelines if such use does not violate the governing state medical waste regulation.

Based on the EPA definition, ten to fifteen percent of all medical waste is potentially infectious.<sup>51</sup> However, according to one hospital waste consultant, only “about 3 to 5 percent of a hospital’s total waste stream would be classified as infectious waste according to . . . CDC guidelines for infectious wastes.”<sup>52</sup> Thus a generator following the CDC guidelines may dispose of a greater percentage of its waste as general medical waste, a less costly alternative.<sup>53</sup>

In the wake of the 1988 beach washups and the absence of federal regulation, most states have passed their own regulations concerning “infectious waste,”<sup>54</sup> thereby limiting the import of the CDC and EPA guidelines. Some

not binding but are merely suggestive. Therefore, absent a specific state or federal regulation passed under “notice and comment” requirements, a court could not rely on these guidelines as law when prosecuting a facility that has improperly disposed infectious waste. *See* Coon & Gilberg, *supra* note 9, at 1102 n.14.

48. *See* EPA GUIDE, *supra* note 19, at 2–1. This definition was incorporated into the federal MWTA. 42 U.S.C. § 6992a.

49. CENTER FOR DISEASE CONTROL, GUIDELINES FOR HANDWASHING AND HOSPITAL ENVIRONMENTAL CONTROL OF INFECTIOUS WASTE IN HOSPITALS (1985); CENTER FOR DISEASE CONTROL, ISOLATION PRECAUTIONS IN HOSPITALS (1983). Like the EPA’s 1986 guidance manual, the CDC’s guidelines do not have the force of law, but are instead merely suggestive.

50. *See* CENTER FOR DISEASE CONTROL, *Recommendations for Prevention of HIV Transmission in Health-Care Settings*, MORBIDITY AND MORTALITY WEEKLY REPORT, Aug. 21, 1987, at 12s (supp.):

[I]dentifying wastes for which special precautions are indicated is largely a matter of judgment about the relative risk of disease transmission. The most practical approach to the management of infective waste is to identify those wastes with the potential for causing infection during handling and disposal and for which some special precautions appear prudent.

*Id.*; *see also* Onel, *supra* note 34, at 227 (discussing the flexibility gained from using the CDC guidelines).

51. U.S. ENVIRONMENTAL PROTECTION AGENCY, ENVIRONMENTAL BACKGROUNDER: MEDICAL WASTE 1 (1989).

52. BACKGROUND REPORT, *supra* note 10, at 4.

53. *See infra* note 80 and accompanying text (discussing differences in the cost of general medical waste treatment as compared to infectious waste treatment).

54. Some states, such as Massachusetts, had existing medical waste regulations. After 1988, Massachusetts simply broadened the scope of their regulation beyond hospitals to include other medical waste generators. Wendy Hower, *Medical Waste Specialists Loom as Biotech Ally*, BOSTON BUS. J., Feb. 25, 1991, at 13. For a comprehensive treatment of state infectious waste regulation, *see generally* Shumaker, *supra* note 4.



states expanded the EPA's definition of "infectious waste" to include materials the EPA considered potentially infectious, but which have not yet been evaluated and classified by the EPA as such.<sup>55</sup>

The distinction between "infectious waste" and "medical waste" should be clearly drawn when possible because of the extra occupational and public health risks posed by infectious waste.<sup>56</sup> Its disposal is more highly regulated, labor intensive, and costly. Furthermore, the EPA's "regulated medical waste" definition, which includes infectious waste, has significance beyond the scope of the now defunct MWTA program because many of the state medical waste regulations enacted after the 1988 washups closely mimic the EPA's regulations.<sup>57</sup> However, these state regulations most often focus on problems posed by "infectious waste" as opposed to general "medical waste."<sup>58</sup>

### C. Generators of Medical Waste and Estimates of Annual Volume

Medical waste is generated by many different sources. The EPA has estimated that 500,000 tons of *regulated* medical waste are produced annually in the United States by about 375,000 generators.<sup>59</sup> Hospitals, clinical laboratories, physicians' offices, veterinarians, dental offices, clinics, blood banks, funeral homes, dialysis centers, long-term health care facilities, and other sources produce significant amounts of regulated medical waste. The 6,649 hospitals in the United States<sup>60</sup> are by far the largest generators of medical waste, accountable for between 77 to 90 percent of the total by volume.<sup>61</sup> However, small quantity generators, defined by the Medical Waste Tracking Act as those which produce less than 50 pounds of regulated medical waste per month,<sup>62</sup> are the most numerous sources of medical waste.<sup>63</sup> These small

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55. See, e.g., Minnesota's *Infectious Waste Control Act*, MINN. STAT. ANN. § 116.75 (West Supp. 1993).

56. See *infra* Part IV.D. (discussing occupational health risks from medical waste management).

57. Coon & Gilberg, *supra* note 9, at 1100. For an in-depth analysis of a New Jersey state statute which is largely similar to the MWTA, see generally Diane Sugrue, *Protecting Our Surf From Syringes: The Comprehensive Regulated Medical Waste Management Act*, 15 SETON HALL LEGIS. J. 568 (1991). For a critical assessment of the New Jersey statute, see Leo Carney, *Medical Waste Law Draws Criticism*, N.Y. TIMES, June 2, 1991, § 12 (New Jersey), at 1.

58. See Shumaker, *supra* note 4, at 556 n.1.

59. EPA FIRST INTERIM REPORT, *supra* note 21, at 1-3.

60. BUREAU OF THE CENSUS, U.S. DEP'T OF COMMERCE STATISTICAL ABSTRACT OF THE UNITED STATES 1992, at 113 (112th ed. 1992).

61. In its first report to Congress, the EPA estimated that about 77 percent of regulated medical waste was generated by hospitals, although they comprise less than 2 percent of the total number of generators. EPA FIRST INTERIM REPORT, *supra* note 21, at 1-3. In its second Interim Report to Congress, the EPA found that 90 percent of the regulated medical waste in the states participating in the MWTA was generated by hospitals. EPA SECOND INTERIM REPORT, *supra* note 11, at 32.

62. See 42 U.S.C. § 6992b(b).

63. EPA FIRST INTERIM REPORT, *supra* note 21, at 1-3.

quantity generators include many personal homes and smaller physicians' and dental offices.

Medical waste (including infectious waste) represents only a tiny fraction (.03 percent) of the solid waste generated in the United States.<sup>64</sup> Wide discrepancies, however, exist in estimates of the volume of medical waste generated annually, due to the inconsistent definitions of the term "medical waste,"<sup>65</sup> as well as differences in measurement variables.<sup>66</sup> As previously mentioned, the EPA estimates the amount of *regulated* medical waste at approximately 500,000 tons (1 billion pounds) per year.<sup>67</sup> However, estimates of annually generated *hospital* waste, which include medical waste as well as other general waste, range from approximately 3.2 million tons (6.4 billion pounds)<sup>68</sup> to 375,000 to 400,000 tons (750 to 800 million pounds).<sup>69</sup>

Estimates for "infectious waste," a subset of "medical waste," also vary greatly, from the American Hospital Association's estimate of 245,500 tons (491 million pounds) per year<sup>70</sup> to the American Medical Association's modest estimate of only 60,000 tons (120 million pounds) per year.<sup>71</sup> Some critics, however, have estimated the amount at as much as 500,000 tons (one billion pounds) per year.<sup>72</sup> One Office of Technology Assessment report states that the EPA estimated that 2 to 3 million tons of *infectious* hospital waste is generated annually.<sup>73</sup> The large variations in the estimates of medical and infectious waste volumes highlight, once again, the problems created by classifying waste as regulated, infectious, or general medical waste. In addition, an exact assessment of the volume of medical waste is impossible due to the indeterminate volume of waste produced by small quantity generators. Estimating the amount of medical waste from these generators is particularly

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64. Hower, *supra* note 54, at 13 (citing EPA estimate).

65. See Mercer, *supra* note 17, at 511.

66. Some estimates include liquid weight while others only account for the dry weight of the waste.

67. EPA FIRST INTERIM REPORT, *supra* note 21, at 1-3.

68. Mercer, *supra* note 17, at 511 (citing Tokarski, *supra* note 44, at 4).

69. Council on Scientific Affairs, Am. Med. Assoc., *Infectious Medical Wastes*, 262 JAMA 1669, 1669 (1989). On a per bed basis, hospitals in 1989 generated a median of 15.2 lbs. of medical waste per patient daily, a 15 percent increase from 9 years earlier. William Rutala et al., *supra* note 33, at 1635-38. A 1992 JAMA report estimates that hospitals produce from 20 to 30 pounds of waste per patient per day. Miles E. Tieszen & James C. Gruenberg, *A Quantitative, Qualitative, and Critical Assessment of Surgical Waste: Surgeons Venture Through the Trash Can*, 267 JAMA 2765, 2765 (1992). Tieszen and Gruenberg provide a detailed study of surgical waste and recommendations for its reduction.

70. Tieszen & Gruenberg, *supra* note 69, at 2765.

71. Mercer, *supra* note 17, at 512 (citing Wormser, *Proprietary to the United Press International* (Dec. 7, 1988)).

72. Mercer, *supra* note 17, at 512 (citing *The Crisis of Infectious Waste*, HIGH TECH. BUS., Oct. 1988, at 30).

73. OTA REPORT, *supra* note 6, at 2 n.7.

difficult because of their large numbers, their diversity, and a lack of any data or studies.<sup>74</sup>

#### *D. Costs for Medical Waste Disposal*

The medical community's increasing use of disposable products, such as disposable syringes, has increased the volume of medical waste generated and the cost of disposal.<sup>75</sup> New medical waste regulations have also increased the costs of medical waste management and disposal since the mid-1980s. For example, the EPA's 1986 Medical Waste guidelines suggested segregating medical waste from other waste produced by the generator. Segregation alone increased the cost of waste incineration from two cents per pound to \$1.50 per pound in one New England hospital.<sup>76</sup> Similarly, compliance with new state and federal regulations on emissions from medical waste incinerators may cost each hospital with existing incinerators approximately \$500,000 to comply.<sup>77</sup> Other regulations, such as the MWTAs' cradle-to-grave reporting requirement, increase paperwork and administrative costs.<sup>78</sup> In addition, health care facilities must now pay for increased liability insurance to cover medical waste liability.<sup>79</sup>

Disposal of infectious waste costs significantly more than disposal of normal medical waste due to increased labor costs, stringent packaging and transportation measures, and greater over-all regulation. According to one American Hospital Association official, regular medical waste disposal costs 3 cents per pound, while infectious waste disposal costs 50 cents per pound.<sup>80</sup> If forced to comply with an overinclusive definition of "infectious waste," generators will face increased disposal costs, significantly adding to present health care costs.<sup>81</sup>

When medical waste—especially infectious waste—is improperly disposed of, the public incurs substantial economic costs in addition to the normal medical waste disposal costs. For example, the Northeast beach closings in 1988

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74. See Mercer, *supra* note 17, at 511-12.

75. See Hershkowitz, *supra* note 13, at 36. For example, one hospital in Boston has increased its waste by 57 percent since 1986. *Hospital Waste "Crisis" Called Political; More Federal Leadership Needed, Group Agrees*, 19 Env't Rep. (BNA) No. 13, at 422, 423 (July 29, 1988).

76. *Hospital Waste "Crisis" Called Political*, *supra* note 13, at 423.

77. Terese Hudson, *Hospitals Adjust to New State Pollution Regulations*, HOSPITALS, July 5, 1990, at 52.

78. The EPA estimated that compliance with the MWTAs would cost the average hospital only \$2,093 per year. EPA FIRST INTERIM REPORT, *supra* note 21, at 3-11. The American Hospital Association (AHA) estimated that a 200 to 300 bed hospital would face an increase of between \$150,000 and \$200,000 in order to comply with the Act. David Holthaus, *EPA Plans to Revise Medical Waste Regulation*, HOSPITALS, Feb. 20, 1989, at 42, 43.

79. See David Dybdahl & David Verona, *Covering Medical Waste Liability; Environmental Impairment Liability*, 91 BEST'S REV.—PROP.-CASUALTY INSUR. ED. 70 (June 1990).

80. *Tracking System Called Expensive Burden; Congress Overreacted, Medical Community Says*, 21 Env't Rep. (BNA) No. 51, at 2258, 2259 (Apr. 19, 1991).

81. See Onel, *supra* note 34, at 230.

resulted in a loss of an estimated \$2 billion to \$3 billion for local businesses,<sup>82</sup> in addition to the cleanup costs. According to New York's Department of Environmental Conservation, Long Island alone lost an estimated \$2 billion in tourism revenues as a result of the 1988 beach washups.<sup>83</sup> Inland communities also faced cleanup costs, as improperly disposed medical waste was found on street curbs, in city parks, in front of schools, and in rivers.<sup>84</sup> Effective medical waste regulation and enforcement would help reduce these huge economic losses. Moreover, increased education and public awareness of the actual sources and risks of medical debris can further reduce economic losses. Armed with the facts, the public and the press may not overreact to the occasional syringe, from sewer overflows or careless home health users, appearing on a beach, in a park, or in a dumpster.

Responding to the demand for safe and effective medical waste disposal methods, the medical waste disposal industry has grown significantly. The market for services and equipment in medical waste disposal was estimated at \$628 million in 1981 and may reach \$2.6 billion by 1998.<sup>85</sup> While a boon for the waste disposal industry, the health care sector cannot afford any increased waste treatment costs. Medical waste generators unable to pay the ever-increasing disposal costs face an incentive to cut corners through improper disposal. In addition to cutting costs, the incentive to improperly and illegally dispose of medical waste is compounded by recent attempts by some municipalities to limit the use of local incinerators to treatment of only locally generated medical waste.<sup>86</sup> As a result of the increasing difficulty and cost of the present medical waste disposal regime, generators eagerly await the development of less costly disposal technologies.

#### IV. MEDICAL WASTE HANDLING, PACKAGING AND TRANSPORTATION

With an increasing shift from on-site medical waste disposal to off-site treatment<sup>87</sup> and disposal, the effective storage, separation, packaging and

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82. Hershkowitz, *supra* note 13, at 36. Beach closings did not stop after 1988, however. In 1989, dozens of Northeast beaches had to close more than 570 times after contaminated waste was released into coastal waters by the area's sewage treatment plants. *Id.*

83. *Daily Report for Executives*, BNA, Nov. 6, 1991, available in LEXIS, Nexis Library, BNA File.

84. See Shumaker, *supra* note 4, at 561-62; see also Goldie, *supra* note 31, at 129 n.5.

85. Debra K. Rubin, et al., *Medical Market Gets Infectious*, ENGINEERING NEWS REC., Jan. 7, 1991, at 26 (citing a 1992 study issued by Market Intelligence Research Corp., an international high-technology research firm specializing in healthcare markets). See also John W. Dancer, *Conquering the Growing Problem of Medical Waste*, MICH. HOSPITALS, Feb. 1991, at 4, 7 (predicting that the medical waste disposal market may reach \$5 billion by 1994).

86. Baltimore enacted a municipal zoning ordinance banning medical waste generated in other counties from its newly constructed \$25 million medical waste incinerator. The operator of the incinerator has challenged this ordinance's geographic limitations under the Commerce Clause. See *Medical Waste Assoc. L.P. v. Mayor and City Council of Baltimore*, 966 F.2d 148 (4th Cir. 1992).

87. See *infra* Part V.B. (discussing the future shift away from on-site incineration).

transportation of medical waste is becoming even more important. State agencies have addressed the concern over the storage, packaging and transportation of medical waste in new regulations.<sup>88</sup> These regulations target generators, handlers and transporters and create criminal and civil liability for violations.<sup>89</sup> Liability for improper handling, storage, transportation or disposal has also become a grave concern for those not targeted by the regulations, such as owners and managers of buildings leased to medical waste generators.<sup>90</sup>

#### *A. Segregation of Regulated Medical Waste from the General Waste Stream*

Some states require only the segregation of "infectious waste" from the general waste stream while others require the segregation of "regulated medical waste," a larger category.<sup>91</sup> Both segregation schemes serve three functions: (1) to avoid contamination of the larger general waste stream; (2) to ensure special treatment for infectious waste or regulated medical waste, which is hazardous to human health and the environment; and (3) to avoid handling and treating general waste by the costly methods required for infectious or regulated medical waste.<sup>92</sup>

For states that did not participate in the MWTA tracking program, waste management practices "depend largely upon the make-up of the waste, the disposal method and location of the disposal facility, and the existence or lack of state and local regulations."<sup>93</sup> In order to reduce their overall waste disposal costs, many medical waste generators implemented waste segregation and recycling programs.<sup>94</sup> Non-infectious general waste, once segregated, may be disposed of or recycled without special attention to potential health and safety risks. However, in some circumstances, especially for small volume generators, it may be safer and more cost-efficient for a generator to treat all of its waste as hazardous "infectious waste."<sup>95</sup> Waste segregation can save larger generators a great deal of money in their disposal and management costs.<sup>96</sup> However, the task of segregating waste places health care and disposal

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88. See Shumaker, *supra* note 4, at 574-84; see also *infra* Part IV.C. (discussing new Department of Transportation rules regulating medical waste).

89. See, e.g., 42 U.S.C. § 6992d (civil and criminal penalties for violation of the MWTA); 33 U.S.C. § 1415 (1988) (civil and criminal penalties for ocean dumping of medical waste); see also Coon & Gilberg, *supra* note 9, at 1119-23 (discussing federal and state criminal prosecutions for violations involving medical waste dumpings).

90. Ruetz & Giannini, *supra* note 36, at B11.

91. Shumaker, *supra* note 4, at 574.

92. *Id.*; see *supra* text accompanying notes 75-86.

93. EPA FIRST INTERIM REPORT, *supra* note 21, at 5-1 to 5-2.

94. For some recycling efforts among hospitals, see OTA REPORT, *supra* note 6, at 24-26.

95. For example, a dentist may generate such a small volume of medical waste that segregating the waste would be inefficient.

96. See *Minor Waste Segregation Changes Save Some Major Dollars for NY Hospital*, MED. WASTE NEWS, Dec. 31, 1992, available in LEXIS, Nexis Library, NWLTRS File.

workers at greater risk of infection or other injury. Nonetheless, segregation protects the population at large from potential health risks associated with careless medical waste disposal and reduces medical waste management costs for some generators.

Because medical waste often is not treated the same day it is generated, storage is required.<sup>97</sup> As a result, most states have regulations governing the duration, temperature and location of medical waste storage.<sup>98</sup> Once again, these state regulations vary in their stringency and specificity;<sup>99</sup> however, all medical waste storage regulations share the principal of preventing public exposure to the stored waste.

### *B. The Packaging of Medical Waste for Transport, Storage and Disposal*

Medical wastes, excluding sharps<sup>100</sup> and fluids, are generally packaged in disposable, leak-proof containers or plastic bags at the point of generation. These containers or bags are either red or labeled with the international biohazard symbol.<sup>101</sup> Many states also require additional labeling, such as the words “infectious waste,” “biohazardous waste,” or “medical waste” on the bag or exterior of the container.<sup>102</sup>

The occupational hazard that sharps pose to health care workers, particularly the risk of transmission of the HIV virus, has led to the increased use of rigid, leak-proof, puncture-resistant, and break-resistant containers that can be tightly sealed.<sup>103</sup> Prior to liquid-medical waste regulation, liquids were commonly poured into the sink for disposal in the municipal sewer system.<sup>104</sup> Now, states that regulate liquid wastes require that they be put in leak-proof containers that can be transported off-site without spilling.<sup>105</sup> As hospitals increasingly turn to off-site commercial medical disposal companies,<sup>106</sup> the leak-proof and puncture-proof rigid containers will likely be re-used to cut

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97. Whether treated on-site or off-site, medical waste may be stored in indoor or outdoor storage areas. The location of a storage facility will depend on various factors, such as the quantity of medical waste generated, the frequency of pick-ups, and urban versus rural location. EPA FIRST INTERIM REPORT, *supra* note 21, at 5-5.

98. Shumaker, *supra* note 4, at 574-75.

99. *See id.* at 575-76.

100. Sharps include various needles, hypodermic syringes, scalpels, scalpel blades, etc. *See* 42 U.S.C. § 6992a(a)(4).

101. EPA FIRST INTERIM REPORT, *supra* note 21, at 5-2.

102. State regulations determine if the “red bag waste” is single or double bagged and also govern “bag strength” standards. *See* Shumaker, *supra* note 4, at 579-80 (discussing various state regulations concerning bag strength, durability, and minimum thickness requirements).

103. *Id.* at 579; *see also id.* at 582 (discussing various state regulations governing packaging of sharps).

104. EPA FIRST INTERIM REPORT, *supra* note 21, at 5-5.

105. *See id.* at 5-3 & 5-5.

106. *See infra* Part V.C. (discussing the future increase in the use of off-site medical waste disposal methods).

down on the total volume of waste and costs. However, such recycling practices will result in greater worker exposure to such liquid wastes and the corresponding health risks. Thus, while stricter packaging regulations may further protect the public, they create a difficult dilemma by increasing the exposure of health care workers to the potentially infectious waste.

### C. The Transportation of Medical Waste

Once packaged, medical waste is transported, usually by truck, but sometimes by barge, from the generator to a waste treatment site, such as an incinerator or landfill.<sup>107</sup> In response to the paucity of state and federal legislation addressing proper transportation methods, the United States Department of Transportation has issued new rules regulating the packaging and transportation of "regulated medical waste."<sup>108</sup> However, implementation of these rules is being delayed until April of 1993 due to challenges from such groups as the American Hospital Association, which asserts that the new rules employ an overly broad definition of "regulated medical waste."<sup>109</sup>

Medical waste is also transported by unconventional means. The shipment of sharps and other regulated medical waste via the United States Postal Service and specialized sharp transporters has gained in popularity for small quantity and rural generators.<sup>110</sup> The generators, such as physicians' offices and long term care facilities, are supplied with specialized containers for packaging and transporting sharps to a final disposal location.<sup>111</sup> Mailing medical waste is a relatively cheap disposal method for small generators, although the practice has created concern in the United States Postal Service, especially among workers. As a result, in 1992 the United States Postal Service began regulating the manner in which medical waste could be packaged and mailed.<sup>112</sup>

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107. EPA FIRST INTERIM REPORT, *supra* note 21, at 5-6.

108. 49 C.F.R. § 173.197 (1991).

109. Karen Pallarito, *Medical Waste Rules Delayed*, MOD. HEALTHCARE, Oct. 5, 1992, at 18; *see also* Terese Hudson, *Hospitals Work Through Superfund Citations*, HOSPITALS, Jan. 5, 1993, at 14, 15. In fact, at the time of this writing, the Department of Transportation is considering changes in the rules. *Major Rule Changes Not Expected Under Clinton, DOT Official Says*, BNA WASH. INSIDER, Nov. 13, 1992, available in LEXIS, Nexis Library, BNAWI File (interview with Alan Roberts, DOT's associate administrator for hazardous materials safety).

110. OTA REPORT, *supra* note 6, at 60.

111. EPA FIRST INTERIM REPORT, *supra* note 21, at 5-7.

112. *See* 57 Fed. Reg. 29,028 (June 30, 1992) (this section will not be codified, but instead appears in the Postal Service's Domestic Mail Manual, *see* 39 C.F.R. § 111 (1992)). The regulation requires all sharps and unsterilized containers to be shipped as registered first class mail or registered priority mail, in addition to certain packaging requirements. The final rule was subsequently amended to require that packages containing medical waste bear the "International Biohazard Symbol" instead of the written biohazard phrase. 57 Fed. Reg. 55,112-13 (Nov. 24, 1992).

### *D. The Occupational Health Risks Posed by the Handling of Medical Waste*

The health risks posed to health care and other workers from handling medical waste justifies the additional costs of extra-precautionary packaging and disposal measures. The National Solid Waste Management Association estimates that U.S. health care workers accidentally stick themselves with needles or sharps some 2,200 times a day.<sup>113</sup> The Center for Disease Control reports that as many as 15,000 health care workers contract the hepatitis B virus each year,<sup>114</sup> resulting in as many as 200 to 300 deaths annually.<sup>115</sup> Consequently, in 1991 the Occupational Safety and Health Administration (OSHA) developed standards to protect all workers whose jobs can be "reasonably anticipated" to expose them to blood or other infectious materials.<sup>116</sup> Under OSHA's "blood-borne pathogen rule," all blood and body fluids are presumed infected and must be treated accordingly. Additionally, all clothing or rags soiled with blood or bodily fluids and all sharps are treated as potentially infectious materials.<sup>117</sup>

Lack of enforcement of federal, state and local regulations governing the proper disposal of medical wastes, as well as inadequate worker training, increases the risk of exposure to hazardous medical waste for workers and the public. Since 1989, however, federal and state enforcement agencies have increasingly penalized and prosecuted violators of federal and state medical waste handling and disposal regulations.<sup>118</sup> Rigorous prosecution and punishment of violators will help deter the improper handling of medical waste.

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113. Bleiweiss & Edwards, *supra* note 15, at 11.

114. *Id.*

115. 134 CONG. REC. H9541 (daily ed. Oct. 4, 1988) (statement of Rep. Wyden).

116. 29 C.F.R. § 1910.1030 (1992). The American Hospital Association expects few problems with OSHA's new rules because such precautions are routinely taken at hospitals. Kevin Lumsdon, *Purchasing: Hospitals Weigh Environment Factor*, HOSPITALS, Jan. 20, 1992, at 62.

117. 29 C.F.R. § 1910.1030. Note also that these new OSHA regulations put responsibility for compliance on health care providers, opening them up to non-compliance penalties, as well as liability risks from worker lawsuits. On the other hand, these regulations seek to help avoid future costs to both employers and taxpayers by reducing the incidence of illness among workers who rely on employer-provided health plans or government health and disability programs.

118. *See, e.g.,* Coon & Gilberg, *supra* note 9, at 1119-23 (discussing several federal and state criminal prosecutions of medical waste violators). In November of 1989, the EPA assessed \$239,500 in penalties against five firms for violations of the MWTA. Three of the firms were waste transporters, who improperly packaged and loaded the waste on their trucks. *EPA Cites Five Firms for Medical Waste Tracking Violations; Proposes \$239,500 in Penalties*, PR NEWSWIRE, Nov. 6, 1989, available in LEXIS, Nexis Library, PRNEWS File. The EPA fined Centrastate Hospital in New Jersey \$21,600 in 1991 for improperly handling and storing its medical waste pursuant to the MWTA. *For the Record*, MOD. HEALTHCARE, Feb. 25, 1991, at 12. The EPA assessed a \$37,000 penalty on a New Jersey Hospital for failing to (1) determine if its waste was regulated under the MWTA, (2) to prepare tracking forms, and (3) to use an authorized medical waste transporter. *EPA Fines Fair Oaks Hospital*, ENVTL. COMPLIANCE REP., Aug. 1991, available in LEXIS, Nexis Library, PROMT File.



Such prosecution and punishment will also increase compliance with existing regulations and enhance worker and public safety.

## V. MEDICAL WASTE TREATMENT AND DISPOSAL METHODS

Until recently, the management of medical waste meant waste *disposal*. However, as landfill space becomes increasingly scarce, medical waste generators are attempting to minimize the quantity of waste requiring disposal.<sup>119</sup> Both waste reduction and recycling reduce the volume of medical waste.<sup>120</sup> Nevertheless, an increased reliance on disposable products often frustrates the goal of waste reduction, as does the high cost of waste segregation and recycling. As a result, most medical waste is currently processed through methods including incineration, steam-sterilization, and compacting.<sup>121</sup> Afterwards, the treated and packaged medical waste or ash is placed in landfills.<sup>122</sup> New medical waste technologies may replace these traditional methods as the market for safe and cost-efficient medical waste disposal continues to grow.<sup>123</sup> Cost, type of medical waste, availability of landfill space, local air quality conditions, and other demographic and geographic factors will help determine which disposal technology is most appropriate for a given generator.<sup>124</sup>

### A. Incineration

Incineration, a process by which medical waste is transformed by fire into non-combustible ash,<sup>125</sup> remains a prevalent disposal method for medical waste from hospitals, laboratories, and other health care institutions.<sup>126</sup> Incineration may take place on-site or off-site at regional, municipal or commercial waste incinerators. About two-thirds of all U.S. hospitals have on-

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119. Plastic products are a common ingredient in medical waste. Recently there has been an effort to "get the plastics out" of medical products. Manufacturers of plastic medical products are now using new molding techniques and "thin-walling" to reduce the volume of plastics in their products. Carl Kirkland, *Precision Molding Remedies Medical Waste Problems*, PLASTICS WORLD, Dec. 1990, at 32.

120. For an overview of methods of pre-treatment waste reduction and recycling for health care facilities, see OTA REPORT, *supra* note 6, at 19-26. See also Tieszen & Gruenberg, *supra* note 69 (discussing recommendations for the reduction of surgical waste).

121. Alarming, as recently as 1988, medical waste was, at times, legally dumped in the ocean under the sanction of the law. In November of 1988, Congress prohibited dumping medical waste into the oceans or any navigable waters of the United States, with fines of up to \$250,000 and/or five years imprisonment for knowing violators. See 33 U.S.C. § 1415(b)(2)(A) (1988).

122. EPA FIRST INTERIM REPORT, *supra* note 21, at 5-8.

123. See *infra* notes 163-72 (discussing recent technological innovations in medical waste treatment).

124. OTA REPORT, *supra* note 6, at 27.

125. EPA FIRST INTERIM REPORT, *supra* note 21, at 6-2.

126. See EPA SECOND INTERIM REPORT, *supra* note 11, at A-14; see also OTA REPORT, *supra* note 6, at 41.

site incinerators.<sup>127</sup> However, continued operation of these on-site incinerators has become increasingly difficult as they are now subject to regulation under the Clean Air Act Amendments of 1990.<sup>128</sup> On-site incinerators must also comply with federal hazardous waste material regulations pursuant to RCRA and standards established by the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO).<sup>129</sup>

Incineration of medical waste reduces the volume of waste sent to landfills from medical facilities by approximately 90 percent.<sup>130</sup> Other benefits of incineration include sterilization of infectious bacteria, conversion of medical waste into a more aesthetically pleasing form, suitability for most types of waste, reduced costs due to elimination of off-site transportation and disposal fees, and secondary benefits such as generation of electrical power from steam generated by larger incineration units.<sup>131</sup>

Despite numerous benefits, incineration of medical waste also poses potential risks. First, the post-combustion ash may be hazardous and must be disposed of pursuant to state and federal hazardous waste regulations.<sup>132</sup> Second, incinerators pose a moderate occupational risk to operators because of high operating temperatures and the corresponding risk of fire. Third, incinerators create monitoring problems because it is difficult to consistently measure the ability of an incinerator to destroy pathogens.<sup>133</sup> Fourth, combustion of plastics, which by some estimates account for 60 percent of the volume of waste handled by on-site incinerators,<sup>134</sup> results in the emission of air pollutants such as dioxins and furans.<sup>135</sup> Finally, and most importantly after the passage of the Clean Air Act Amendments of 1990, medical waste combustion generates other potentially hazardous emissions, such as pathogens, organic chemicals, carbon monoxide, particulate matter, trace metals, and acid gases.<sup>136</sup> As a result of these health concerns, new incinerators and existing medical waste incinerators, even after upgrading, face increasing public

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127. EPA FIRST INTERIM REPORT, *supra* note 21, at 2-17; *see also* Roger Etter, et al., *Medical Waste Combustion: Current and Future Prospects*, WASTE AGE, July 1990, at 77. For an overview of the different types of incinerators, *see* EPA FIRST INTERIM REPORT, *supra* note 21, at 6-2 to 6-4.

128. 42 U.S.C. § 7429(g)(1) (1990).

129. COUNCIL ON SCIENTIFIC AFFAIRS, *Infectious Medical Wastes*, 262 JAMA 1669, 1670 (Sept. 22, 1989).

130. *Id.*

131. OTA REPORT, *supra* note 6, at 41; *see also* EPA FIRST INTERIM REPORT, *supra* note 21, at 6-4 to 6-5.

132. EPA FIRST INTERIM REPORT, *supra* note 21, at 6-5.

133. *Id.*

134. Hershkowitz, *supra* note 13 at 35, 37.

135. Coon & Gilberg, *supra* note 9, at 1107.

136. EPA FIRST INTERIM REPORT, *supra* note 21, at 2-17. For a summary of available information on hospital waste incinerators, *see* RADIAN CORP., HOSPITAL WASTE COMBUSTION STUDY: DATA GATHERING PHASE FINAL DRAFT REPORT (EPA report No. EPA-450/3-88-017, Oct. 1987).

resistance.<sup>137</sup> In response, several states have imposed moratoriums on new medical waste incinerators,<sup>138</sup> while other states have proposed more stringent emissions standards for existing medical waste incinerators.<sup>139</sup> Operation of medical waste incinerators may become more difficult in the future because the EPA is developing new source performance standards and emissions guidelines in 1995, specifically for medical waste incinerators.<sup>140</sup>

The approximately 6,000 on-site incinerators at hospitals or medical centers which dispose of about 80 percent of all medical wastes<sup>141</sup> are of particular concern because many are located in urban areas.<sup>142</sup> In New York City alone, there are about 60 hospital incinerators.<sup>143</sup> On-site hospital incinerators are usually designed to operate at lower than optimum combustion temperatures and shorter than optimum residence times in the combustion chamber. In addition, the operators of many existing hospital incinerators lack proper training, adding to the problem of increased emissions.<sup>144</sup> Modification of outdated incineration technologies and proper training may significantly reduce the emission of air pollutants,<sup>145</sup> but such modernization would require great expenditures by medical facilities. In this era of spiralling health care costs and controlled spending, many medical facilities cannot afford such large capital

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137. In 1991, St. Petersburg, Florida residents voiced their concern to help defeat the approval of a new \$1.3 million waste incinerator at Bayfront Medical Center. Rubin et al., *supra* note 85, at 27. Likewise, operation of a virtually completed medical waste incinerator in New York which could handle 48 tons of medical waste every 24 hours was challenged by residents fearful of its toxic emissions. The residents filed a lawsuit claiming that the incinerator should not be licensed without an environmental impact study or an assessment of the health risks. *Modification of Incinerator Plan Does Not Justify New Review*, N.Y. L.J., June 26, 1992, at 21, 22.

138. At least five states have a current moratorium on medical waste incinerators. See LA. REV. STAT. ANN. § 30:2154 (West 1992); N.J. STAT. ANN. § 13:1E-48.14 (West 1991); W. VA. CODE § 20-5J-4 (1992). Kentucky and Tennessee also have moratoriums on new medical waste incinerators. Barbara Buck, *Mid-Atlantic Dumping Ground*, WASH. POST, Mar. 22, 1992, at C8. Other states have medical waste incinerator moratorium bills pending in their legislatures. See, e.g., 1992 Fla. Sess. Law Serv. 31 (West).

139. See Hudson, *supra* note 77, at 52; see also *Air Board Sets Controls for Dioxin Emissions, Other Releases from Medical Waste Incinerators*, 21 Env't Rep. (BNA) No. 12, at 517 (July 20, 1990) (discussing expected passage of a 1991 California regulation of medical waste incinerator emissions). New rules promulgated by the Louisiana Department of Environmental Quality also singled out medical waste incinerators for stricter emissions standards in 1992. *D.E.Q. Has Plan to Tighten Rules on Biomedical Incinerators*, NEW ORLEANS CITY BUS. Aug. 31, 1992, available in LEXIS, Nexis Library, NOCB File [hereinafter NEW ORLEANS CITY-BUS.].

140. 57 Fed. Reg. 52,086 (Nov. 3, 1992) (proposed rules due in September of 1993; final rules expected in February of 1995).

141. Rubin, et al., *supra* note 85, at 26.

142. See, e.g., Nancy Zeldis, *Hospital Incinerators Stir Concern*, N.Y. TIMES, May 31, 1987, § 11 (Long Island), at 1 (reporting on concerns of residents about foul smells and discharged ash from a nearby medical waste incinerator).

143. Hershkovitz, *supra* note 13, at 37.

144. EPA FIRST INTERIM REPORT, *supra* note 21, at 2-20.

145. Coon & Gilberg, *supra* note 9, at 1107.

expenditures. Reflecting this situation, smaller hospitals in particular, many with older incinerators, have had trouble complying with the new state and federal clean air standards, forcing some to discontinue incineration.<sup>146</sup>

Given the high rate of toxic emissions from hospital incinerators, their outdated technology, and their often urban location, it has been suggested that medical waste should instead be incinerated at the more highly regulated and safer municipal solid-waste incinerators and treatment facilities.<sup>147</sup> Switzerland and the former West Germany both require medical facilities to treat their waste at such municipal or regional facilities.<sup>148</sup> Given the large number of operational on-site incinerators and the high cost and risk associated with packaging and transporting medical waste to regional or municipal-waste incinerators, such a policy may face great opposition in the United States. However, as more stringent federal or state air pollution regulations are enacted and as hospitals encounter greater difficulty in obtaining licenses to operate new or existing incinerators, they may have no choice but to turn to off-site disposal methods.<sup>149</sup> Such concerns are prompting a growing market in off-site, regional medical waste incinerators and treatment facilities.<sup>150</sup>

Currently, there are no uniform state or federal regulations addressing the proper method of medical waste incineration. State and local regulations governing minimum temperatures and minimum residence time in the secondary chamber (important in the process of killing infectious pathogens) are as inconsistent as the definition of medical waste.<sup>151</sup> Similarly, as of 1990, there were no federal regulations to control the high levels of heavy metals, acid gases, and toxic organic compounds that hospital incinerators emit.<sup>152</sup> If incineration is to remain a major medical waste disposal method, the inconsistencies in regulation must be addressed.

### *B. Autoclaving or Steam Sterilization*

Steam sterilization, also known as autoclaving, is commonly used to decontaminate medical waste, especially infectious waste. Bags of contaminated

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146. See, e.g., *NEW ORLEANS CITY-BUS.*, *supra* note 139, at 16.

147. Hershkowitz, *supra* note 13, at 37.

148. *Id.* In these countries, municipal or private incinerators generally have the advantage of more sophisticated air-pollution control technology. *Id.*

149. The EPA is slated to propose new-source performance standards for medical waste incinerators. In addition, several states, such as Minnesota, New York and California, have enacted their own stringent air quality rules governing medical waste incinerators, which render many on-site incinerators out of compliance. In order to comply, hospitals will have to spend a significant amount of money to update their incinerators. Rubin, et al., *supra* note 85, at 26.

150. *Id.* at 27. The Baltimore regional medical waste incinerator discussed *supra* note 86, will close down about twelve on-site hospital incinerators. Rubin, et al., *supra* note 85, at 27; see also *supra* note 85 and accompanying text for a discussion of the new market in medical waste disposal.

151. Shumaker, *supra* note 4, at 588.

152. Hershkowitz, *supra* note 13, at 37.

material are placed in a sealed chamber and exposed to steam and pressure for a predetermined period of time, depending on the volume of waste being treated.<sup>153</sup> While steam sterilization decontaminates most of the medical waste, the resulting waste is not necessarily "sterilized."<sup>154</sup>

Health care facilities have used steam sterilization technology for many years and thus are familiar with the method. Unlike incineration, autoclaving and compaction of medical waste do not produce high levels of air emissions that may run afoul of clean air standards. Additionally, the process is well adapted for treating microbiological cultures and stocks, as well as clothing or other types of material easily penetrable by steam.<sup>155</sup> By one estimate, steam sterilization is suitable for treating approximately 90 percent of the regulated medical wastes generated.<sup>156</sup> As with incineration, there is no federal regulation of steam sterilization. Many states have regulated steam sterilization by setting minimum time, temperature and pressure level requirements.<sup>157</sup> However, these state regulations are by no means uniform.

Despite the health care industry's general familiarity with steam sterilization and its low capital and operating costs,<sup>158</sup> the process has its disadvantages. The main disadvantage is that the process does not reduce the mass of material that must be disposed of after treatment.<sup>159</sup> The autoclaved medical waste must still be packaged and transported to the ultimate disposal facility, commonly a landfill. Furthermore, pursuant to the MWTa and similar state regulations, autoclaving alone is an insufficient treatment method for infectious waste because it leaves waste recognizable and intact.<sup>160</sup> In addition, autoclaving can produce extremely foul odors, which are potentially volatile and toxic, presenting occupational health risks.<sup>161</sup>

### C. Alternative Medical Waste Treatment and Disposal Methods

Steam sterilization and incineration remain the most common methods of medical waste treatment. However, pursuant to stricter clean air standards, new

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153. EPA FIRST INTERIM REPORT, *supra* note 21, at 6-5 to 6-6. For a more detailed discussion of steam sterilizers, see OTA REPORT, *supra* note 6, at 28.

154. EPA FIRST INTERIM REPORT, *supra* note 21, at 6-5.

155. Coon & Gilberg, *supra* note 9, at 1108.

156. OTA REPORT, *supra* note 6, at 31. Since the volume and type of medical waste will vary from load to load, the time and pressure necessary to adequately treat the waste will also vary. The most critical factor to ensure proper steam sterilization is adequate steam penetration. Shumaker, *supra* note 4, at 589-90.

157. See Shumaker, *supra* note 4, at 590. The common minimum temperature is 120 or 121 degrees Celsius; the minimum time requirement is thirty minutes; and the minimum pressure is fifteen pounds per square inch. State requirements may vary, however. *Id.* at 590-91.

158. For cost estimates of steam sterilization equipment and its operation, see OTA REPORT, *supra* note 6, at 31-32.

159. EPA FIRST INTERIM REPORT, *supra* note 21, at 6-6.

160. *Id.*

161. *Id.* Odor-controlling tablets can be added to each autoclave load. Unfortunately, documented health impacts from autoclaving do not exist. OTA REPORT, *supra* note 6, at 31.

medical waste regulations, and severe monetary penalties for non-compliance,<sup>162</sup> there is a growing need for alternative treatment methods. As the private market for medical waste disposal grows, new treatment technologies will continue to appear. As of 1992, available medical waste treatment methods included the environmentally-friendly microwave treatment,<sup>163</sup> gas sterilization,<sup>164</sup> chemical disinfection with grinding,<sup>165</sup> thermal inactivation,<sup>166</sup> irradiation,<sup>167</sup> grinding and shredding,<sup>168</sup> and compaction.<sup>169</sup> New technologies, such as the use of radio waves, are being developed to fill the niche created by the major regulatory hurdles now facing large volume generators currently using incineration and autoclaving.<sup>170</sup> Some companies are also developing waste disinfection products for direct marketing to small volume generators, such as clinics or physicians' offices.<sup>171</sup>

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162. See discussion of monetary penalties for non-compliance with medical waste disposal regulations, *supra* note 118 and accompanying text.

163. This promising new technology involves shredding and grinding the medical waste, which is then placed in a microwave to heat the waste. EPA FIRST INTERIM REPORT, *supra* note 21, at 6-10 to 6-11. A microwaving system costs about \$600,000, and is cheaper to install and operate than an incinerator. Additionally, air emission problems are avoided by the closed-loop system. The safe confetti-like residue is disposed of at a landfill. Rubin, et al., *supra* note 85, at 27.

164. Gas sterilization, an infrequently used method, involves placing the waste in an air tight chamber: air is then evacuated and the waste exposed to a disinfecting gas, such as ethylene oxide. EPA FIRST INTERIM REPORT, *supra* note 21, at 6-7.

165. Waste is initially ground and shredded and then exposed to a chemical disinfectant bath. The resulting chemical agents are then released into the sewer system and the solid waste is disposed of in a landfill. The health risks of this method may be considerable. *Id.* at 6-7 to 6-8.

166. Thermal inactivation involves heating the waste to high temperatures. This method is generally used only for large volumes of liquid wastes. *Id.* at 6-9.

167. Irradiation uses ultraviolet or ionizing radiation from a source such as Cobalt 60, to destroy infectious agents. This method is often used to sterilize medical supplies, food, and other consumer products. *Id.* at 6-9 to 6-10.

168. This process involves the grinding and shredding of medical waste to convert the waste into a more homogenous form that can be easily handled. *Id.* at 6-11.

169. Compaction is used to reduce the volume and recognizability of medical waste. This process, like grinding and shredding, does not render the medical waste less infectious. *Id.* at 6-12.

170. Winfield Industries has developed a new process that mechanically disintegrates the waste with controlled granulation. The resulting "mulch" is then automatically washed and sanitized with a liquid disinfectant. *Winfield Industries Announces New Infectious Waste Solution*, PR NEWSWIRE, Dec. 6, 1990, available in LEXIS, Nexis Library, PRNEWS File. Another company, Stericycle, has developed and is now using a medical waste treatment that uses low frequency radio waves, similar to microwaves, which causes the waste to vibrate, thereby heating the waste to disinfect it. Scott Allen, *Dealing With Our Medical Debris; To Avoid Burying the Problem, Hospitals Turning to Technology*, BOSTON GLOBE, Nov. 2, 1992, at 35, 39.

171. Allen, *supra* note 170, at 39. Ecomed of Indianapolis sells a \$4,000 machine that pulverizes medical waste and soaks it in the surgical scrub iodophor. *Id.* Another product sold to small volume generators is the "Thermal Activated Plastic Sanitizer," a 15-inch high, on-site machine which disinfects medical waste. *Fifteen-Inch, On Site Medical Waste Processor Benefits*

All of the treatment methods discussed above require ultimate disposal of the waste in a landfill or through the public sewer system, although they transform the medical waste into a less hazardous and more easily transportable form. Several companies are now attempting to transform medical waste into reusable products, such as glass, through new technology at their recycling plants.<sup>172</sup> As a chief executive of a pioneering medical waste recycling company recently noted, medical waste treatment must “make a fundamental shift away from landfill and incineration.”<sup>173</sup> At least one state, Wisconsin, has recognized the benefits of recycling and waste reduction by enacting legislation to encourage such policies.<sup>174</sup>

### CONCLUSION

Once perceived as a “crisis” situation and debated in the popular press, medical waste management today receives scant attention from the public and regulatory agencies. In the last two years, state and federal agencies have delayed any sweeping new medical waste regulations and remained content with existing laws. Nonetheless, there has been a great deal of research and information gathering on medical waste management, both on the federal and state level. Even considering the recent increase in knowledge regarding medical waste, there is room for improvement, both in terms of effective regulation and management methods. Setting minimum packaging, storage and transportation standards applicable to all medical waste management situations would eliminate much of the conflict among local, state and federal medical waste regulations.<sup>175</sup> While overarching federal regulation may be the most effective way to achieve harmonization—and the EPA may suggest such a course of action in its to-be-released Third Report to Congress—industry leaders in medical waste management, as well as organizations like the American Hospital Association, could formulate uniform guidelines in the absence of such federal legislation. States could revise their current medical waste regulations to implement such uniform guidelines.

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*Physicians and Dentists*, BUS. WIRE, Nov. 4, 1992, available in LEXIS, Nexis Library, BWIRE File.

172. Biomedical Waste Systems of Boston has proposed such a plant. Allen, *supra* note 170, at 35. In Washington State, American Environment Management Corporation plans to build a pilot waste processing plant to convert medical waste into glass through a process known as “vitrification,” which uses heat fusion. *Richland Plant to Convert Medical Waste to Glass*, J. OF BUS.-SPOKANE, Apr. 23, 1992, at B6. Yet another company is recycling patient monitoring equipment. Laura Evenson, *Helping Hospitals Cut Waste; Nellcor Recycling Monitoring Devices*, S.F. CHRON., Nov. 3, 1992, at B1.

173. Allen, *supra* note 170, at 35.

174. See WIS. STAT. ANN. § 159.07(8) (West 1992) (Medical Waste Source Reduction Policy).

175. Assuming the federal government were to take regulatory responsibility over medical waste disposal, a problem of coordination among the regulatory agencies is likely to persist. The EPA, OSHA, the Postal Service, and the Department of Transportation, among others, would have to eliminate any inconsistencies in their medical waste regulations.

The first step in establishing uniform medical waste regulations or guidelines is to define "regulated medical waste" in an exact, uniform and comprehensive fashion. After setting the appropriate scope for the regulation, an enforcement mechanism using state environmental or other agencies could be established. In addition, a national registration and coding system could be used to help identify medical waste generators, transporters, handlers and treatment facilities, each with their own identification number, possibly as part of a national manifest system.<sup>176</sup>

Because small volume medical waste generators are unlikely to be governed under federal or state medical waste regulation, education and viable medical waste disposal services must be provided to generators by state and local agencies. For example, local governments could provide community needle depositories for home health users, such as diabetics or cancer patients.

The heart of the medical waste treatment problem does not lie with the lack of a uniform federal regulation. Rather, increasing reluctance of landfill owners to accept medical waste and increasing treatment costs produce incentives to improperly dispose of medical waste, creating the greatest public health risk. As large volume medical waste generators shift away from on-site incineration, regional state-of-the-art incineration facilities or alternative treatment and recycling technologies must fill the gaps. Market forces and forward-looking regulatory schemes will likely encourage the development of alternative medical waste technologies on their own. However, in order to expedite such research and development, both federal and state governments should take an active role through tax incentives or research and development grants. The cost of such assistance will be offset by savings associated with reduced landfill dumping due to new technologies. Some states are already encouraging development of alternative medical waste technologies through a uniform and simplified process for approving new methods.<sup>177</sup> An additional benefit of reducing the reliance on on-site incineration is enhanced clean air regulatory compliance.

The current medical waste management situation is not one of "crisis." Almost all states now have some form of regulation addressing proper medical waste treatment. Furthermore, various federal agencies have developed worker protection laws to guard against the occupational health hazards posed by medical waste treatment. In addition, state and federal enforcement agencies are currently prosecuting those who improperly dispose of medical waste when abuse is discovered. An occasional syringe will likely wash up on a beach in

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176. See *Some See Time Right For Renewed Effort Toward Developing Uniform Manifest*, MED. WASTE NEWS, Dec. 31, 1992, available in LEXIS, Nexis Library, NWLTRS File. Such a cradle-to-grave manifest system would be similar to the methods established by RCRA.

177. See, e.g., *California Offers National Model for Approving Alternative Technologies*, MED. WASTE NEWS, Nov. 5, 1992 available in LEXIS, Nexis Library, NWLTRS File (discussing California's *Guide and Application for Alternative Medical Waste Treatment Technology Approval*).



the future, again arousing great public discomfort due primarily to concern about AIDS. However, such isolated incidents are hardly cause for alarm, even if today's confusing patchwork of medical waste regulations remains intact. We can avert the possibility that a real medical waste "crisis" will develop by pursuing technological advances and more comprehensive and uniform medical waste legislation.



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