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David Randolph Mercer

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STUDENT ARTICLES

A PROSPECTUS ON THE LEGISLATIVE RESPONSE TO MEDICAL WASTE¹

INTRODUCTION

We live in a "throw away" culture.² Until recent decades the expansive earth was capable of indulging our delusion that there is really such a thing as "away."³ In recent times, however, it has become inescapable that the land and sea can no longer bear the burden of an expanding population of increasingly wasteful humans without severe, and perhaps irrevocable, harm.⁴ This fact was manifestly punctuated during the summers of 1987 and 1988. In August 1987, state health officials closed fifty miles of New Jersey's public beaches after a tide of used syringes, blood vials, rubber gloves, hypodermic needles, blood bags, gauze dressings, and various other medical wastes washed ashore.⁵ The following summer medical wastes resurfaced in significant quantities and various types on the shores of northeastern states,

1. For the purposes of this article, infectious waste shall be assumed to be a subset of the more inclusive classification of "medical waste." Thus, as used by this author, "medical waste" shall incorporate infectious waste.

2. "Americans collectively toss out 160 million tons [of garbage] each year—enough to spread 30 stories high over 1,000 football fields, enough to fill a bumper-to-bumper convoy of garbage trucks halfway to the moon . . . [a]nd still the volume of garbage keeps growing—up by 80 percent since 1960, expected to mount an additional 20 percent by 2000." Beck, *Buried Alive*, NEWSWEEK, Nov. 27, 1989, at 67.

3. "[M]ost people assume that the vast oceans, which cover more than 70% of the world's surface, have an inexhaustible capacity to neutralize contaminants, by either absorbing them or letting them settle harmlessly to the sediment miles below the surface. 'People think "out of sight, out of mind,"' says Richard Curry, an oceanographer at Florida's Biscayne National Park." Toufexis, *The Dirty Seas*, TIME, Aug. 1, 1988, at 48. However, this assumption is becoming more tenuous as the quality of the coastal environment declines.

4. See generally *id.*

5. 134 CONG. REC. S10,737 (daily ed. Aug. 3, 1988)(statement of Sen. Lautenberg).

the Great Lakes states, and numerous other states on both coasts.⁶ Public outrage precipitated by these occurrences placed an immediate and continuing pressure on state and national officials to respond affirmatively to the problem.

On the federal level, Congress reacted quickly and resolutely to the immediate situation by passing The Medical Waste Tracking Act of 1988,⁷ admittedly a stopgap measure but also prospective in character. While the Medical Waste Tracking Act is only a "demonstration program"⁸ of limited scope and duration, it clearly lays the foundation for a national program of medical waste regulation. With an imminent national program, the viability of state regulation of medical waste is uncertain. Thus, it becomes important to understand both the magnitude of the medical waste problem and the interplay of federal and state regulation.

To that end, the goals of this Comment are: 1) to briefly explore the scope and significance of the environmental, economic, and sociological problems presented by medical wastes; 2) to discuss the federal legislative response to the perceived problems of the transportation and disposal of medical and infectious wastes, and 3) to analyze the existing regulatory schemes concerning medical or infectious waste in Missouri.

I. MEDICAL WASTE: GRAVE HAZARD OR GROUNDLESS HYSTERIA?

Dumping medical waste in large quantities is not a recent phenomenon.⁹ Yet, until the events of the summers of 1987 and 1988 brought the term "medical waste" into the limelight and public

6. OFFICE OF TECHNOLOGY ASSESSMENT, CONGRESS OF THE UNITED STATES, ISSUES IN MEDICAL WASTE MANAGEMENT: BACKGROUND PAPER 1 (Oct. 1988) [hereinafter ISSUES IN MEDICAL WASTE MANAGEMENT: BACKGROUND PAPER].

7. 42 U.S.C. §§ 6901-6992k (1988). See *infra* notes 45-273 and accompanying text for a full discussion of the Act.

8. See generally 42 U.S.C. § 6992g(a) (1988). The "demonstration program" was not intended by Congress to be a permanent solution to the medical waste "crisis." Instead, the focus of the program is to "demonstrate" a model for future federal legislation, to explore the nature and extent of the problem, and to examine other possible alternatives or solutions. See generally *id.*

9. As recently as 1976, the washing up of debris along the Atlantic coasts has caused beach closings, and in 1931 the cost of keeping New York beaches clean was estimated at nearly ten thousand dollars per mile. Burdick, *Hype Tide: Come on in, the Water's Fine*, THE NEW REPUBLIC, June 12, 1989, at 15. Indeed, a recent archeological find in Scotland uncovered a major medical waste dumping ground containing numerous drugs and nearly 300,000 pints of human blood that dates from the middle of the twelfth century. Bowron, *Bloodstained Mementos of Medieval Medicine*, HISTORY TODAY, Oct. 1989, at 4.

vocabulary, no significant attention was given to this class of waste.¹⁰ The problems presented by medical waste exist on two different, but equally significant planes: the quantity of waste to be disposed and the infectious qualities of the waste material.

A. Quantity

There is significant disagreement about the precise quantity of medical waste created yearly, due perhaps to inconsistent and conflicting definitions of the term "medical waste."¹¹ In regard to the major producers of medical waste, such as hospitals, the American Medical Association's House of Delegates has assessed the quantity of medical waste produced annually by American hospitals to be in the range of seven-hundred and fifty to eight-hundred million pounds.¹² Other estimates are not so optimistic and place the figure substantially higher. "The nation's hospitals . . . generate 3.2 million tons of medical waste annually."¹³ The major producers, such as hospitals, are likely to have the staff, knowledge, and finances for proper waste disposal.

The House of Delegates for the American Medical Association has noted that "[m]ost hospitals are thought to be doing an adequate job of disposal."¹⁴ Unfortunately, the major producers are not the exclusive, or perhaps even dominant, source of medical waste. "Physician's and dentist's offices, small laboratories and medical clinics are also potential sources."¹⁵ With "small quantity generators,"¹⁶ it is extremely difficult to make an exact assessment of the volume of medical waste they create nationwide because of their large numbers and diversity. Indeed,

10. See generally *infra* notes 55-62 and accompanying text discussing EPA's past and continuing reticence in regulating medical wastes.

11. Changes in the types of waste covered by the definitions of "medical waste" or "infectious waste" tremendously affects estimates of the amount of medical waste. For example, in attempting to met the "universal precautions" for handling infectious waste, which were created by the Atlanta Centers for Disease Control in Atlanta in 1976, hospitals defined any material contaminated with blood or body fluids as "infectious." This definitional shift resulted in a three to thirty percent increase in "infectious" waste. *Tracking Seaside Medical Wastes*, SCIENCE NEWS, Sept. 16, 1989, at 191.

12. Wormser, *Proprietary to the United Press International* (Dec. 7, 1988); see also Bristow, *Medical Waste: It's Not Just Garbage Anymore*, RN, Aug. 1989, at 57.

13. Tokarski, *EPA Sets Waste Tracking Plan*, MODERN HEALTH CARE, Mar. 17, 1989, at 4.

14. Wormser, *supra* note 12.

15. *Id.*

16. See 42 U.S.C. § 6992b(b) (1988). "Small quantity generators" are those that produce less than fifty pounds of medical waste per calendar month. *Id.*

in the overall scheme of total production of medical waste, small quantity generators represent an unknown quantity.¹⁷

Even accepting the conservative quantitative estimates of medical waste generated annually, there are sufficient quantities of waste produced to warrant legislative attention. When considering the potentially infectious nature of medical waste, however, proper disposal assumes a new significance.

B. Infectious Qualities

It is important to realize that not all medical waste should be classified as "infectious waste." The Environmental Protection Agency (EPA) estimates that approximately fifteen percent of all medical waste presently being generated is infectious.¹⁸ In terms of bulk tonnage, more liberal estimates contend that sources in the United States currently produce nearly five-hundred thousand tons of infectious waste per year.¹⁹ The American Medical Association contends that approximately one-hundred and twenty million pounds of infectious waste generated is per annum, or 1.5 pounds per day per hospital bed.²⁰ As with medical waste in general, the wide disparity between these figures is likely attributable to definitional differences. The EPA figure is most likely based upon a restrictive definition of "infectious waste"²¹ while

17. One source articulated:

[Few] studies have been conducted at non-hospital health-care sites, such as physicians', dentists', and veterinarians' offices, free-standing clinics, and surgical and dialysis centers. Medical waste generation by health-industry related activities, such as research universities and pharmaceutical companies is unquantified. No data are available for the generation of wastes by the home health care industry. The increasing use of "sharps" and dialysis equipment in this last category suggests that the volume of wastes produced in home health care may be significant. Finally, the extent of the invasion of the waste stream by largely unregulateable discards of "sharps" from illicit, intravenous drug use is also unknown.

NELSON A. ROCKEFELLER INST. OF GOV'T., PERSPECTIVES ON MEDICAL WASTE I.6 (June 1989) [hereinafter PERSPECTIVES ON MEDICAL WASTE].

18. Bristow, *supra* note 12, at 57.

19. *The Crisis of Infectious Waste*, HIGH TECH. BUS., Oct. 1988, at 30.

20. Wormser, *supra* note 12.

21. "EPA currently defines infectious waste as waste capable of causing infectious disease. This definition requires the consideration of several factors contributing to the risk of introduction of disease. As described in EPA's guidance manual, these factors include: (1) Presence of a pathogen of sufficient virulence; (2) dose of the pathogen; (3) portal of entry; and (4) resistance of the host. For a waste to be infectious, it must contain pathogens with sufficient

more liberal figures are derived from broad definitions of "infectious waste," incorporating any material that has come into contact with the patient.²²

Although it seems clear that the minority of medical waste is infectious, the unique nature of infectious waste tends to undermine any consolation from this fact. Unlike infectious wastes injury from other forms of hazardous or toxic wastes is predicated upon the injured person reaching a certain level of exposure. For example, a person must ingest a given amount of arsenic before harm will result. With infectious wastes, however, the harmful agents are living organisms capable of reproduction; thus, even insignificant contacts with the waste can bring about a biological magnification of the harmful agent.²³

Among the medical wastes that were found on the New York shores during the summer of 1988 were "dozens of vials of blood, three of which tested positive for hepatitis-B virus and at least six tested positive for antibodies to the AIDS virus."²⁴ One of the primary concerns of Congress in drafting the Medical Waste Tracking Act of 1988²⁵ was fear of the potential spread of infectious diseases. "While there is virtually no chance of being infected with the AIDS virus . . . there is a danger of infection from these wastes including the infection by hepatitis-B. The Centers for Disease Control have said that contaminated needles or sharps,²⁶ human blood and blood products, pathological parts, and laboratory wastes possess real potential to transmit disease."²⁷

Not surprisingly, the greatest risk of contracting a disease via infectious waste is found among those who routinely are exposed to the waste during their employment. Infectious waste potentially affects "those people who encounter these wastes from the point of generation to the point of disposal. Two occupations that regularly encounter infectious waste are hospital employees and waste disposal workers."²⁸

virulence and quantity so that exposure to the waste by a susceptible host could result in infectious disease." 134 CONG. REC. S10,740 (daily ed. Aug. 3, 1988)(statements of Rep. Lautenberg).

22. *The Crisis of Infectious Waste*, *supra* note 19, at 31.

23. See generally PERSPECTIVES ON MEDICAL WASTE, note 17 *supra*, at II.15-.16.

24. Toufexis, *supra* note 3, at 44.

25. 42 U.S.C. §§ 6992-6992j (1988). For a full discussion of this Act see *infra* notes 45-273 and accompanying text.

26. "Sharps" include various needles, hypodermic syringes, scalpels, scalpel blades, etc. See 42 U.S.C. § 6992a(a)(4) (1988); 40 C.F.R. § 259.30(a) (1989).

27. 134 CONG. REC. S10,738 (daily ed. Aug. 3, 1988) (statement of Rep. Lautenberg).

28. *Id.* at S10,740.

The Federal Centers for Disease Control have determined that each year 200 to 300 deaths occur among health care workers—often waste handlers—due to hepatitis B.²⁹ The study further concludes that "[m]any of those (deaths) can be traced to exposure to infectious materials."³⁰ These 200 to 300 deaths represent only a portion of the human suffering caused by medical waste. Each year, at least eighteen thousand people contract hepatitis B through accidental contact with medical wastes.³¹

Thus, strong evidence supports the conclusion that medical waste is a significant problem both in terms of the sheer quantity of material to be disposed and in the infectious characteristics of a substantial portion of all medical waste. Nevertheless, there are skeptics.

The American Medical Association (AMA) has acknowledged that there is currently a problem with medical waste disposal but tends to downplay its significance.³² A report issued by the AMA House of Delegates in December 1988 concluded that "a relatively small number of incidents of improper disposal of infectious waste have gained national notoriety."³³ Further, in a magazine published by the AMA, *American Medical News*, one article attributed the closing of New England beaches during the summers of 1987 and 1988 to high bacteria counts because of inadequate sewage treatment and not medical or infectious wastes washing ashore.³⁴

These skeptics are not without a factual foundation for their arguments. The amount of medical waste generated each year pales in relation to the total amount of damage Americans inflict upon the environment each day. Medical waste comprises less than one percent of the total solid waste Americans produce per year.³⁵ Compared to the thirty-two billion gallons of toxic waste and sewage the United

29. 134 CONG. REC. H9,541 (daily ed. Oct. 4, 1988) (statement of Rep. Wyden).

30. *Id.*

31. 134 CONG. REC. H9,536 (daily ed. Oct. 4, 1988) (statement of Rep. Whittaker).

32. *See generally* Wormser, *supra* note 12.

33. *Id.*

34. Somerville, *MDs, Hospitals Facing More Cost, Regulation*, AM. MED. NEWS, Aug. 25, 1989, at 1.

35. Total tonnage of solid waste created per year is approximately 160 million tons, Beck, *supra* note 2, while even the highest estimates of total medical waste produced places the amount at 3.2 million tons. *See* Tokarski, *supra* note 13, at 4. Thus, in relation to total solid waste, medical waste at a maximum represents substantially less than one percent.

States pours into the sea each day,³⁶ medical waste is seemingly insignificant. Medical waste appears minor when one considers the 10 million tons of sewage sludge New York and New Jersey have dumped into the Atlantic Ocean since 1986.³⁷ Even the medical waste that found its way to the New York and New Jersey beaches in 1987 and 1988 represented only one percent of total waste that washed ashore.³⁸ Further, many attack the true significance of the medical waste "crisis" by citing the small likelihood of infection from medical wastes.³⁹

Many of those who question the significance of medical waste contend that the "crisis" of medical waste is primarily a function of hysteria brought on by repugnance to the nature of the waste and phobia of infection.⁴⁰ In some cases, the characteristics of hysteria were manifestly displayed.

Cigar holders were reported as blood vials, animal fat and pets became human organs, household rubber gloves became surgical gloves, sewer rats became laboratory rats. . . . Thanks to AIDS hysteria, the most feared of all medical waste is the hypodermic needle. The sighting of one lone syringe was enough to close the entire Smith Point Park Beach in New York.⁴¹

Indeed, the issue of medical waste seems to strike a nerve of fear and anger in the general public.⁴²

Resolving whether medical waste is in reality a crisis is not the focus of this Comment. Instead, it is the purpose of this Comment to

36. Brownlee, *Stopping Coastline at the Sewer and the Farm*, U.S. NEWS & WORLD REP., Aug. 21, 1989, at 52.

37. Toufexis, *supra* note 3, at 44.

38. "Medical waste made up roughly 1 percent of debris washed ashore last summer, about the equivalent of one garbage bagful for every 1-ton truckload." Brownlee, *supra* note 36, at 52. "[M]ost estimates place the amount of medical debris at only one percent to ten percent of all debris that washed ashore last summer, with one DEC report comparing it to one lunch bag's worth for every two five-ton truckloads of debris." Burdick, *supra* note 9, at 16.

39. "By all accounts, there is virtually no possibility of becoming infected with AIDS or hepatitis after being stuck by a needle derived from medical or hospital waste; any such virus that did find its way onto a syringe would never survive the days of exposure to sewage, salt water, and sunlight." Burdick, *supra* note 9, at 16. See generally Brownlee, *supra* note 36, at 52.

40. Some feel that the "crisis" was a product solely of an over-reaction fueled by a "[f]ear of AIDS and general squeamishness [that] had the press and the public combing the beaches for medical waste, theorizing about legions of 'midnight dumpers,' and speculating feverishly about the health risks of wading." Burdick, *supra* note 9, at 16; see also Somerville, *supra* note 34, at 1.

41. Somerville, *supra* note 34, at 1.

42. "The public sees medical waste wash up on the beaches, and all they want to know is who the villain is and how he or she will be punished." *Hauling Infectious Waste*, BUS. DATELINE, Aug. 31, 1988, at ---.

emphasize that the perception of the public and legislators that improper disposal of medical waste is a crisis is extremely significant in itself. This perception cost New York and New Jersey at least a billion dollars in lost tourism revenues.⁴³ Further, the intensity of public pressure resulted in congressional action of uncharacteristic speed and ultimately federal legislation.⁴⁴

II. CONTROLLING FEDERAL LEGISLATION

A. Introduction

Until the recent creation of specific federal regulations governing the disposal of medical wastes in select northeastern states,⁴⁵ there was little or no assistance from the federal regulatory powers for the generator, hauler, or processor of medical waste who, in good faith, attempted proper disposal.

The [medical waste management] situation is complicated by an uncertain and incongruous regulatory climate. Inconsistencies exist in the Federal guidelines for States regarding definitions and management options suggested for medical/infectious waste. Currently, no Federal regulations exist that comprehensively address the handling, transportation, treatment, and disposal of medical waste.⁴⁶

As indicated above, federal guidelines issued by the Centers for Disease Control and EPA, which provide for proper handling and disposal techniques, are inconsistent⁴⁷ while authoritative federal control is virtually non-existent. Federal regulations provide some guidance to

43. Brownlee, *supra* note 36, at 52. Constituents obviously conveyed their displeasure over these lost revenues to legislators. *See generally* 134 CONG. REC. H10,106 (daily ed. Oct. 12, 1988)(statement of Rep. Hughes); 134 CONG. REC. E2,539 (daily ed. July 28, 1988)(statement of Rep. Florio). Both Representative Hughes and Representative Florio are from New Jersey.

44. NELSON A. ROCKEFELLER INST. OF GOVT., THE REPORT OF THE MEDICAL WASTE POLICY COMMITTEE 2 (June 1989) [hereinafter REPORT OF THE MEDICAL WASTE POLICY COMMITTEE]. The result of this legislative flurry was the Medical Waste Tracking Act of 1988, 42 U.S.C. §§ 6992-6992j (1988), discussed *infra* notes 45-273 and accompanying text.

45. Pursuant to the congressional directive of the Medical Waste Tracking Act of 1988, EPA promulgated 40 C.F.R. § 259 (1988), which exactly regulates the disposal of medical wastes in certain northeastern states. *See generally infra* notes 45-273 and accompanying text.

46. ISSUES IN MEDICAL WASTE MANAGEMENT: BACKGROUND PAPER, *supra* note 6, at 2 (footnote deleted).

47. *See id.* at 4-6.

those who handle medical waste, yet their extremely limited scope fails to bind and direct the vast majority of medical waste generators and handlers.⁴⁸ Thus, it is interesting to note that the ambiguity that exists in federal control of medical waste disposal is a result not of conflicting or inconsistent standards but of inaction on the part of federal administrative agencies.⁴⁹

Both the Secretary of Labor, under the Occupational Safety and Health Act (OSHA),⁵⁰ and the Administrator of EPA, under the Solid Waste Disposal Act,⁵¹ have express power to regulate the handling and disposal of medical (or at least infectious) waste. "[T]he Labor Secretary is given general authority to promulgate such standards in order to assure the 'attainment of the highest degree of health and safety protection of the employee.'⁵²

Although it is clear that the Secretary of Labor is authorized to promulgate regulations dictating handling and disposal of medical wastes, this power is limited by two factors: 1) the scope of OSHA encompasses only private generators of medical waste,⁵³ and 2) the predilection of the Department of Labor to confine the scope of its rulemaking power to controlling only occupational exposure to hepatitis B and AIDS.⁵⁴

Since 1975, EPA has had express power to regulate the handling and disposal of infectious medical waste under the express terms of the Solid Waste Disposal Act.⁵⁵ Much to the chagrin of Congress, however EPA has displayed a decided stubbornness concerning the regulation of medical waste disposal.⁵⁶

One of the objectives of the Solid Waste Disposal Act is the "protection of health . . . by . . . assuring that hazardous waste management practices are conducted in a manner which protects human

48. See *infra* notes 66-85 and accompanying text for discussion of the scope of 40 C.F.R. § 259 (1988).

49. ISSUES IN MEDICAL WASTE MANAGEMENT: BACKGROUND PAPER, *supra* note 6, at 23.

50. 29 U.S.C. §§ 651-678 (1982).

51. 42 U.S.C. §§ 6901-6992k (1988).

52. ISSUES IN MEDICAL WASTE MANAGEMENT: BACKGROUND PAPER, *supra* note 6, at 23.

53. See 29 U.S.C. § 652(5) (1970).

54. ISSUES IN MEDICAL WASTE MANAGEMENT: BACKGROUND PAPER, *supra* note 6, at 23.

55. 42 U.S.C. §§ 6901-6992k (1988).

56. See generally NELSON A. ROCKEFELLER INST. OF GOVT., PERSPECTIVES ON MEDICAL WASTE, SUPPLEMENT 3-7 (July 1989) [hereinafter PERSPECTIVES ON MEDICAL WASTE, SUPPLEMENT].

health and the environment."⁵⁷ "Hazardous waste" specifically includes wastes with "infectious characteristics" which may:

- (A) cause or significantly contribute to an increase in mortality or an increase in serious, irreversible, or incapacitating reversible, illness;
- or (B) pose a substantial present or potential hazard to human health or the environment when improperly treated, stored, transported, or disposed of, or otherwise managed.⁵⁸

The Solid Waste Disposal Act unequivocally empowers EPA to serve the objectives of the Act by promulgating standards that regulate infectious waste,⁵⁹ yet, until compelled by the Medical Waste Tracking Act of 1988,⁶⁰ EPA has not used this power. EPA has consistently explained its inaction by claiming there is insufficient evidence that medical or infectious waste threatens public health.⁶¹ Therefore, the ambiguity that has characterized federal control of medical waste disposal remains intact.

At present, a number of federal statutes exist which contain language that potentially could enable a federal administrative agency to regulate various facets of medical waste disposal, or the entire process.⁶² Unfortunately, this potential regulatory power had not been

57. 42 U.S.C. § 6902(a)(4) (Supp. V 1987).

58. *Id.* § 6903(5).

59. *Id.* § 6912(a)(1).

60. 42 U.S.C. §§ 6992-6992k (1988).

61. See PERSPECTIVES ON MEDICAL WASTE, *supra* note 17, at 3, 6; see also EPA GUIDE FOR INFECTIOUS WASTE MANAGEMENT vi (May 1986).

62. The Solid Waste Disposal Act, *see supra* notes 55-61 and accompanying text, holds the greatest potential for spawning comprehensive regulation of medical waste disposal. However, other federal legislation offers the possibility of regulating medical wastes in more narrow contexts. For example, the Occupational Safety and Health Act (OSHA) could be used. *See supra* notes 53-54 and accompanying text for discussion of OSHA. The Marine Protection, Research, and Sanctuaries Act of 1972 (MPRSA), 33 U.S.C. §§ 1401-1445 (1972), applies to activities on the open sea and generally makes it unlawful to dump any "material," including "chemicals [or] biological and laboratory waste" into the open sea without a permit. Specifically, section 1412(a) of MPRSA states that EPA can issue no permit to dump "medical waste," which is defined in section 1402(k), into the open sea. *Id.* § 1412(a).

Further, the Low-Level Radioactive Waste Policy Act, 42 U.S.C. §§ 2021b-2021d (1982), provides for the safe and environmentally sound disposal of low-level radioactive waste, such as that generated by medical diagnosis and treatment. Conrad, *Glowing Their Own Way: State Embargoes and Exclusive Waste Disposal Sites Under the Low-Level Radioactive Waste Policy Act of 1980*, 53 GEO. WASH. L. REV. 654, 654 (1985).

utilized. Consequently, the arrival of medical waste on the shores of New York and New Jersey was greeted by a regulatory vacuum.

B. Filling the Void: The Medical Waste Tracking Act of 1988⁶³

In November 1988, President Ronald Reagan signed into law the Medical Waste Tracking Act of 1988 ("the Act").⁶⁴ This executive action marked the culmination of four months of frenzied legislative activity as Congress responded to the strong public pressure that arose after medical wastes washed ashore in the northeast.⁶⁵ EPA also acted quickly, promulgating regulations⁶⁶ that became effective on June 22, 1989.⁶⁷

Although the Act, and its resulting regulations, became a reality within approximately one year after its introduction, immediately discernable results will be few since the Act is limited to a two-year time span⁶⁸ and covers only a meager geographic area.

As the Act was originally conceived, only a small minority of states were affected. "[T]he demonstration program . . . includes Connecticut, New Jersey, New York, and the states contiguous with the Great Lakes, which are Illinois, Indiana, Michigan, Minnesota, Ohio, Pennsylvania, and Wisconsin."⁶⁹ The coverage was subsequently broadened by EPA to include Louisiana, Rhode Island, Puerto Rico, and the District of Columbia.⁷⁰

The Act also provided an escape mechanism for states that did not desire to be included in the program.⁷¹ Therefore, an already narrow scope was even further limited by the ability of the Great Lakes states

63. 42 U.S.C. §§ 6901-6992k (1988).

64. REPORT OF THE MEDICAL WASTE POLICY COMMITTEE, *supra* note 44, at 25.

65. *Id.*

66. 40 C.F.R. § 259 (1988).

67. PERSPECTIVES ON MEDICAL WASTE, SUPPLEMENT, *supra* note 56, at 22.

68. The Act is a demonstration program, expressly limited by the enabling statute. "The demonstration program shall expire on the date 24 months after the effective date of the regulations under this subchapter." 42 U.S.C. § 6992(d) (1988). Thus, the program will terminate on June 22, 1991. However, it is possible that if the program proves to be successful the Act, or some variation of the Act, will become a permanent part of the Solid Waste Disposal Act upon reauthorization of the Solid Waste Disposal Act. PERSPECTIVES ON MEDICAL WASTE, SUPPLEMENT, *supra* note 56, at 9-10.

69. 54 Fed. Reg. 12,328 (1989).

70. 40 C.F.R. § 259.20 (1989).

71. *See generally* 42 U.S.C. § 6992(b) (1988).

to "opt out" of the demonstration program without any justification.⁷² In fact, all of the Great Lakes states exercised this option and removed themselves from the program.⁷³ Further, the remaining states could opt out upon a showing that state regulations existed that were at least as strict as those promulgated by EPA.⁷⁴ As of August 1989, Louisiana and the District of Columbia had exercised this option⁷⁵ leaving only five states: New York, New Jersey, Rhode Island, Connecticut, and Puerto Rico.⁷⁶ In addition, New Jersey and New York currently have regulations as strict as those promulgated by EPA and can successfully opt out of the program if they desire.⁷⁷

Congress acknowledged that, in terms of geographic scope, the problem of improper medical waste disposal is "[l]ike a disease traveling across America . . . erupting in dozens of disparate communities without warning or explanation."⁷⁸ It expressly chose, however, to limit the Act to "[t]he manifestations of the emerging crisis—the symptoms of the disease."⁷⁹ Why, if the problem is as pervasive as indicated, did Congress choose to treat only the "symptoms" and not the "disease?" A report by the Nelson A. Rockefeller Institute of Government concluded that a number of factors contributed to the temporal nature of the Act's scope: insufficient support to override "resistance from the hospital and medical establishment,"⁸⁰ a perception that the problem was "primarily an 'East Coast problem',"⁸¹ and, perhaps most significantly, that a program of limited duration and geographical scope would allow

72. Section 6992(b)(1) of the Act provides:

If the Governor of any State covered under subsection (a) of this section (which defines the "covered states") which is not contiguous to the Atlantic Ocean notifies the Administrator that such State elects not to participate in the demonstration program, the Administrator shall remove such State from the program.

Id. § 6992(b)(1).

Section 6992(b)(3) states that notification of opting out shall be submitted no later than thirty days after promulgation of the implementation regulations.

Id. § 6992(b)(3).

73. PERSPECTIVES ON MEDICAL WASTE, SUPPLEMENT, *supra* note 56, at 9 n.12.

74. See 42 U.S.C. § 6992(b)(2) (1988).

75. Herubin, *State News Service* (Aug. 25, 1989).

76. *Id.*

77. PERSPECTIVES ON MEDICAL WASTE, SUPPLEMENT, *supra* note 56, at 9 n.13.

78. 134 CONG. REC. H9,536 (daily ed. Oct. 4, 1988)(statement of Rep. Luken).

79. *Id.*

80. PERSPECTIVES ON MEDICAL WASTE, SUPPLEMENT, *supra* note 56, at 9.

81. *Id.*

Congress to view a scale model in operation before committing to a national program.⁸²

While the scope of the Act is admittedly small, its true significance lies not in its ability to make extensive changes immediately, but in the impact it will have as a paradigm of future regulation. The data gathered and the lessons learned from the operation of this scale model will assume great significance when the next Congress faces the reauthorization of the Solid Waste Disposal Act⁸³ and the questions of how to regulate medical waste on a national level.⁸⁴ Therefore, close examination of the Act's provisions is warranted. These provisions fall roughly into categories that attempt to effectuate four purposes: 1) the definitional purpose, 2) "cradle-to-grave"⁸⁵ tracking of medical wastes, 3) enforcement, and 4) information gathering.

1. Toward a Definition of Medical Waste

One of the greatest obstacles to effective regulation of medical wastes has been the lack of a standardized definition:

Despite the attention given to medical waste by the public and by all levels of government, the term "medical waste" remains poorly defined. No standard, uniform definition exists and there

82. *Id.* at 9-10.

83. 42 U.S.C. §§ 6901-6992k (1988).

84. A report by the Nelson A. Rockefeller Institute of Government stated:

Our interviews on Capital Hill suggest that in addition to political considerations involved in getting a medical waste bill out of Congress before its adjournment, some members and staffers felt that a limited demonstration bill would allow the Congress to have a 'second shot' at the medical waste problem in the context of RCRA [Resource Conservation and Recovery Act of 1975 which is also commonly known as the Solid Waste Disposal Act, 42 U.S.C. §§ 6901-6992k (1988)] reauthorization when, hopefully, they would have more information from the MWTA [Medical Waste Tracking Act of 1988] demonstration projects and the various reports required from EPA under the act.

PERSPECTIVES ON MEDICAL WASTE, SUPPLEMENT, *supra* note 56, at 9-10.

It is also evident from the comments of those sponsoring the Act that its purpose is not fleeting. After citing examples that indicated the national scope of the problem, Representative Luken, one of the House sponsors of the bill, commented: "Today we are voting on a bill . . . that takes a critically important *first step* toward controlling the spread of medical waste." 134 CONG. REC. H9,536 (daily ed. Oct. 4, 1988)(statement of Rep. Luken) (emphasis added).

85. 134 CONG. REC. S10,738 (daily ed. Aug. 3, 1988) (statement of Sen. Lautenberg).

seems to be as many definitions in use as there are government agencies and other groups concerned with medical waste.⁸⁶

Effective and consistent regulation of medical waste obviously is predicated upon a uniform definition. To this end, Congress designed the Act to directly and indirectly remove the ambiguities from the regulatory scheme.⁸⁷

The Act's language itself goes far toward directly honing the operative definition by enumerating ten specific classifications of "medical waste."⁸⁸ Congress included in section 6992a(a) of the Act those materials thought to be most problematic and in need of regulation.⁸⁹ Summarized, they are as follows:

- (1) Cultures and stocks of infectious wastes;
- (2) Pathological wastes;
- (3) Waste human and blood and blood products;
- (4) Used sharps (needles, syringes, scalpels, etc.);
- (5) Animal carcasses and wastes used for research or production of biologicals or pharmaceuticals;
- (6) Surgery and autopsy wastes;
- (7) Laboratory wastes;
- (8) Dialysis wastes;
- (9) Discarded medical equipment; and
- (10) Biological waste and discarded wastes contaminated with blood, excretion, exudates, or secretion.⁹⁰

The Act, however, does not give a functioning definition of "medical waste" in absolute, immutable terms.⁹¹ Rather, the Act indirectly provides for further clarification of the meaning of "medical waste" by allowing EPA to refine the term to include any other material related to the "administration of medical care" that is found to "pose a threat

86. PERSPECTIVES ON MEDICAL WASTE, *supra* note 17, at I.2; *see also* ISSUES IN MEDICAL WASTE MANAGEMENT: BACKGROUND PAPER, *supra* note 6, at 4-8.

87. One of the selling points relied upon by Representative Luken was that "[t]here has been great confusion about what is and is not 'medical waste.'" 134 CONG. REC. H9,537 (daily ed. Oct. 4, 1988)(statement of Rep. Luken). Representative Luken stated: "The bill resolves this issue, I believe. It precisely defines 10 categories of wastes that must be tracked and handled under EPA regulations." *Id.*

88. 42 U.S.C. § 6992a(a)(1)-(10) (1988).

89. *Id.*

90. *Id.* The language of this section goes into great detail regarding the types of materials contemplated to be within the Act.

91. Section 6992a ultimately relies on the EPA to issue a concrete definition of "medical waste." *See id.* § 6992a.

to human health or the environment."⁹² In addition, the Act gives EPA the power to exclude any or all of items (6) through (10) listed in section 6992a(a) if it determines that these materials "do not pose a substantial present or potential harm to human health or the environment."⁹³ In essence, the Act merely set the parameters by which EPA is to carry out the congressional directive to "promulgate regulations listing the types of medical waste to be tracked under the demonstration program."⁹⁴

Responding to this directive, EPA both defined "medical waste" in general terms and explicitly listed the materials it contemplated to be

92. *Id.* § 6992a(a)(11).

93. *Id.* § 6992a(b).

94. *Id.* § 6992a(a).

within this definition.⁹⁵ "Medical waste," as generically defined by the

95. "Medical waste" is generally defined by 40 C.F.R. § 259.10(b) (1989). However, the response of EPA to the congressional mandate to "list the types of medical wastes to be tracked" under the Medical Waste Tracking Act, 42 U.S.C. § 6992a(a) (1988), is found in 40 C.F.R. § 259.30 (1989), which defines "regulated medical waste" as:

(a) A regulated medical waste is any solid waste, defined in § 259.10(a) of this part, generated in the diagnosis, treatment, (e.g., provision of medical services), or immunization of human beings or animals, in research pertaining thereto, or in the production or testing of biologicals, that is not excluded or exempted under paragraph (b) of this section and that is listed in the following table

40 C.F.R. § 259.30 (1989).

The table, titled "Regulated Medical Waste," divides covered wastes into waste classes and gives a detailed description of each class. It is summarized as follows:

- (1) Cultures and stocks of infectious agents and associated biologicals;
- (2) All human pathological wastes (i.e. tissues, organs, body parts and fluids) resulting from medical procedures;
- (3) Human blood and blood products which fall into four classes: liquid blood, blood products, items saturated with blood, and items containing dried blood;
- (4) Used sharps used in human or animal care;
- (5) Animal waste exposed to infectious agents;
- (6) Isolation wastes containing blood, excretions, exudates, or secretions from humans isolated to protect others from highly communicable diseases; and
- (7) Unused Sharps.

See id.

EPA has explained the relationship between this table and the ten items listed in 42 U.S.C. § 6992a(a)(1)-(10): "Of the seven (7) waste classes listed [in the above table], the first six parallel six (6) of the first 10 waste types identified in section 11002 of the statute (§ 6992a(a)). The seventh has been added by EPA under the authority of section 11002(a)(11)(§ 6992a(a)(11))." 54 Fed. Reg. 12,340 (1989).

Further, based on its authority under section 6992a(b), EPA concluded that "wastes in sections . . . (6) through (9) (of § 6992a(a)) that are not already included in EPA classes 1 through 7 should not be included in the demonstration program." *Id.* at 12,342.

Item (10) of section 6992a(a) is accounted for in class six of the EPA which is nearly identical to the original item (10). *Id.* at 12,341. Section 259.30(b)(1) of the federal regulation also lists specific exclusions to the term "medical wastes:"

(b)(1) Exclusions.

(i) Hazardous waste identified or listed under the regulations in Part 261 of this chapter is not regulated medical waste. Note to paragraph (b)(1)(i): Mixtures of regulated medical waste and

resulting EPA regulations means:

any solid waste⁹⁶ which is generated in the diagnosis, treatment (e.g., provision of medical services), or immunization of human beings or animals, in research pertaining thereto, or in the production or testing of biologicals.⁹⁷ The term does not include any hazardous waste identified or listed under Part 261 of this chapter⁹⁸ or any household

hazardous waste are subject to Part 259, except as provided in § 259.31(b) of this subpart.

(ii) Household waste, as defined in § 261.4(b)(1) of this Chapter is not regulated medical waste.

(iii) Ash from incineration of regulated medical waste is not regulated medical waste once the incineration process has been completed.

(iv) Residues from treatment and destruction processes are no longer regulated medical waste once the waste has been both treated and destroyed.

(v) Human corpses, remains, and anatomical parts that are intended for interment or cremation are not regulated medical waste.

40 C.F.R. § 259.30 (1989).

Section 259.30(b)(2) exempts certain testing and monitoring activities of EPA, U.S. Department of Transportation, and U.S. Department of Health and Human Services. *Id.* § 259.30.

96. Section 259.10(a) of the federal regulations states that "solid waste" means a solid waste as defined in Section 1004(27) of RCRA." 40 C.F.R. § 259.10(a) (1989). The Resource Conservation and Recovery Act of 1976 (RCRA) was revised and is now codified as the Solid Waste Disposal Act at 42 U.S.C. §§ 6901-6987 (1982). Section 1004(27) of RCRA, now codified at 42 U.S.C. § 6903(27) (1982), reads:

The term 'solid waste' means any garbage, refuse . . . and any other discarded material, including solid, liquid, semisolid, or contained gaseous material resulting from industrial, commercial, mining, and agricultural operations, and from community activities, but does not include solid or dissolved material in domestic sewage . . . or byproduct material as defined by the Atomic Energy Act of 1954

Id.

97. Section 259.10(a) of the federal regulations defines "biologicals" as meaning "preparations made from living organisms and their by-products, including vaccines, cultures, etc., intended for use in diagnosing, immunizing or treating humans or animals or in research pertaining thereto." 40 C.F.R. § 259.10(a) (1989).

98. Section 259.10(b) clearly delineates "medical waste" from the "hazardous materials" dealt with in section 261.20. *See id.* § 259.10(b). "Hazardous materials" must exhibit one or more of four characteristics: ignitability, reactivity, corrosivity, and EP toxicity. *Id.* § 261.20.

waste as defined in § 261.4(b)(1) of this chapter.⁹⁹ Note to this definition: Mixtures¹⁰⁰ of hazardous waste and medical waste are subject to this part except as provided in § 259.31.¹⁰¹

There is a notable silence in both the provisions of the Act itself and EPA regulations made pursuant to the Act concerning low-level radioactive materials that are the waste products of medical diagnosis, treatments, and research.¹⁰² While the definition of "solid waste," as set out in the Solid Waste Disposal Act¹⁰³ and incorporated into part

99. "Household waste" means any material (including garbage, trash, and sanitary wastes in septic tanks) derived from households (including single and multiple residences, hotels and motels, bunkhouses, ranger stations, crew quarters, campgrounds, picnic grounds and day-use recreation areas)." *Id.* § 261.4(b)(1).

100. Section 259.31(a) is applicable to all mixtures of "regulated medical waste," *see supra* note 95, and solid waste, *see supra* note 96, "except as provided in paragraph (b) of this section." *See id.* § 259.31(a).

"Mixtures of solid waste and regulated medical waste . . . are a regulated medical waste." *Id.* It is important to realize that the regulation does not quantify any minimum proportion of regulated medical waste to solid waste. Thus, it is conceivable that no amount of dilution of medical waste with solid waste will remove the mixed waste from the provisions of part 259.

Section 259.31(b) provides that mixtures of "hazardous wastes," *see supra* note 98 for definition, and "regulated medical wastes," *see supra* note 95 for definition, are subject to the provisions of this section. *Id.* § 259.31(b). Section 259.31(b) and the note that follows it clearly indicate that any mixture of regulated medical waste and hazardous waste is subject to the manifest requirements of part 259 unless the resulting mixture is otherwise subject to the manifest requirements of part 262 ("standards applicable to generators of hazardous waste") or part 266 ("standards for the management of specific hazardous wastes and specific types of hazardous waste management facilities). *Id.* § 259.30(b).

The bottom line of section 259.31 is that any mixture of a regulated medical waste with a solid waste, regardless of the degree of concentration, must be covered by either the manifest requirements of part 259, of part 262, or of part 266. *See id.* §§ 259, 262, 266.

101. *Id.* § 259.10(b) (1988).

102. The Low-Level Radioactive Waste Policy Act of 1980, 42 U.S.C. §§ 2021b-2021d (1982), "defines low-level waste negatively; it comprises all radioactive waste that is not high-level waste, spent nuclear fuel, transuranic waste, or byproduct material. Although much of the low-level waste is generated by the nuclear power industry, much is generated by other forms of private industry and research, most notably medical research and diagnosis." Conrad, *supra* note 62, at 654 (citations omitted). *See generally* Hart & Glaser, *infra* note 108.

103. *See supra* note 96 for the definition of "solid waste."

259¹⁰⁴ of EPA regulations, does mention that radioactive wastes are excluded from solid wastes, it expressly limits this exclusion to "by-products" of nuclear activities which are by definition not low-level radioactive wastes.¹⁰⁵

Although the enabling Act and the resulting EPA regulations fail to deal expressly with low-level radioactive wastes, this material implicitly falls within the language of both. Section 6992a(b) of the Act makes it mandatory that the list of medical wastes created by EPA regulations include "[s]uch other waste material that results from the administration of medical care to a patient by a health care provider and is found by the Administrator to pose a threat to human health or the environment."¹⁰⁶ The regulations promulgated by EPA apply to "any solid waste . . . generated in the . . . provision of medical services [or] . . . research."¹⁰⁷ Given the potential threat to human health posed by concentrations of low-level radioactive wastes,¹⁰⁸ it appears probable that radioactive wastes generated by medical care and research will be included in the definition of medical wastes.

Doubtless there are those who criticize the definition of "medical waste" established in the Act and the regulations promulgated by EPA pursuant to the Act or both. The significance and value of the definition, however, is not due to any degree of objective accuracy, but rather to the regulatory standardization it will provide.

2. "Cradle-to-Grave" Tracking of Medical Waste

One of the purposes of the Medical Waste Tracking Act of 1988 was to insure the proper handling and disposal of such wastes before and after leaving the source of generation.¹⁰⁹ Indeed, EPA contends that

104. 40 C.F.R. § 259 (1989).

105. See 42 U.S.C. § 2021d (1982). This language should be compared to that contained in 42 U.S.C. § 6903(27) (1982) and adopted by 40 C.F.R. § 259.10(a) (1989).

106. 42 U.S.C. § 6992a(a)(11) (1988). This provision is not among the items that EPA is allowed to omit at its discretion in section 6992a(b). See *id.* § 6992a(b).

107. 40 C.F.R. §§ 259.10(b), 259.30(a) (1989).

108. See generally Hart & Glaser, *A Failure to Enact: A Review of Radioactive Waste Issues and Legislation Considered by the Ninety-Sixth Congress*, 32 S.C.L. REV. 639, 650-51, 655, 772-85 (1981).

109. 134 CONG. REC. H9,536 (daily ed. Oct. 4, 1988) (statement of Rep. Luken). A study done by the Nelson A. Rockefeller Institute of Government points to two essential purposes of the Act. "The MWTA [Medical Waste Tracking Act of 1988] envisions EPA performing two distinct sets of tasks: creating and administering a tracking system for medical waste in order to promote proper handling and disposal, and generating a series of reports or

"[t]he core of the demonstration program . . . is the requirement to track medical wastes from the site of generation to the treatment or disposal facility."¹¹⁰ To this end, EPA regulations put into place a comprehensive tracking system¹¹¹ which creates a paper trail of "tracking forms"¹¹² and "records."¹¹³ The perception in Congress was that:

[T]he tracking system will work like a burglar alarm. It will force the generator to alert the EPA headquarters whenever medical waste doesn't make it to the designated incinerator or landfill-thus sounding the alarm that puts law enforcement officials on the trail of the midnight dumper.¹¹⁴

C. Who is Covered by the Regulations

While these provisions are extensive in regard to those falling within their scope, deciding who is within the regulations is dependant upon two threshold determinations: a) whether the party is the type sought to be monitored, and b) whether the party is producing, transporting, or disposing of a material that is contemplated by the regulations.

studies to inform Congress about the nature and seriousness of the national medical waste problem." PERSPECTIVES ON MEDICAL WASTE, SUPPLEMENT, *supra* note 56, at 23. See *infra* notes 269-73 and accompanying text for discussion of the information gathering aspect of the Act.

110. 54 Fed. Reg. 12,350 (1989).

111. See 40 C.F.R. §§ 259.50-.91 (1989).

112. A "tracking form" is defined as "the Federal Medical Waste Tracking Form that must accompany all applicable shipments of regulated medical wastes generated within one of the Covered States." *Id.* § 259.10(b). See *infra* notes 182-91 and accompanying text for a more detailed explanation of these forms.

113. Generators, transporters, and those who process medical wastes are required by the regulations to create records that account for all waste shipped, transported, or disposed and which must be retained for at least three years. See 40 C.F.R. §§ 259.54, 259.77, 259.83 (1989).

114. 134 CONG. REC. H9,536 (daily ed. Oct. 4, 1988) (statement of Rep. Luken). The mechanics of this regulatory "burglar alarm" are contained in 40 C.F.R. § 259 (1989), titled "Standards for the Tracking and Management of Medical Waste."

1. Regulated "Persons"¹¹⁵

The express purposes of the regulations clearly state those "persons" who are to be regulated: "Generators, transporters, and owners or operators of intermediate handling facilities (e.g. treatment or destruction facilities) or destination facilities (e.g. disposal facilities) . . ."¹¹⁶ A closer examination of the characteristics of these persons will prove helpful in determining to whom, precisely, the regulations are applicable.

a. *Generators of Medical Waste*

"The universe of potential generators of medical waste is quite large: hospitals, physicians' offices, dental offices, veterinary practices, funeral homes, research laboratories, nursing homes, hospices, etc."¹¹⁷ EPA has defined generators as "any person,¹¹⁸ by site, whose act or process produces regulated medical waste¹¹⁹ . . . or whose act first causes a regulated medical waste to become subject to regulation."¹²⁰ Coupling this definition with the broad spectrum of wastes enumerated in the regulations¹²¹ yields a vast array of prospective "generators."

b. *Post-Generation Entities*

The remaining persons covered by EPA regulations, other than generators, are those who process medical waste as it progresses along a chain of custody to its ultimate disposal. These persons include transporters, destruction facilities, intermediate handlers and destination facilities.

Transporters of medical wastes include any "person[s] engaged in the off-site transportation of regulated medical waste by air, rail, highway, or water."¹²² Two aspects of this definition need clarifica-

115. Within the terms of the regulations, a "person" is defined as "an individual, trust, firm, joint stock company, corporation (including a government corporation), partnership, association, State, municipality, commission, political subdivision of a State, and interstate body, or any department, agency, or instrumentality of the United States." 40 C.F.R. § 259.10(a) (1989).

116. *Id.* § 259.1(c).

117. PERSPECTIVES ON MEDICAL WASTE, SUPPLEMENT, *supra* note 56, at 20.

118. *See supra* note 115 for the definition of "person."

119. *See infra* notes 135-45 and accompanying text for a full discussion of what constitutes a "regulated medical waste."

120. 40 C.F.R. § 259.10(a) (1989).

121. *See supra* notes 88-108 and accompanying text.

122. 40 C.F.R. § 259.10(a) (1989).

tion. First, "off-site" refers only to transportation away from the generating person or facility; not to merely moving the waste about the generating facility.¹²³ Second, "transportation" means any "shipment or conveyance" of medical waste.¹²⁴

The final phase of proper disposal is found at "destination facilities,"¹²⁵ which take the form of a "disposal facility . . . incineration facility or . . . facility that both treats and destroys regulated medical waste."¹²⁶ There are, however, other "facilities"¹²⁷ that possibly exist along the route to the "destination facility."¹²⁸ Some facilities, known as "intermediate handlers," either "treat"¹²⁹ or destroy medical wastes but not both.¹³⁰ Finally, the scope of the regulations include "destruction facilities" which mechanically or thermally reduce materials into a form that "is no longer generally recognizable as medical waste."¹³¹ The regulations allow for numerous conceivable routes from generation to final disposal,¹³² all of which are covered by the regulatory language.

In order for the provisions of the regulations to be applicable, a "person" must fit into one of the above categories.¹³³ There is, however, a second threshold determination that must be made before the regulatory scheme can be imposed upon any "person:" the generation,

123. *Id.* § 259.70(b).

124. *Id.* § 259.10(a).

125. *Id.* § 259.10(b).

126. *Id.*

127. The definition of "facilities" is contained in 40 C.F.R. § 259.10(a) (1989).

128. *See generally* 54 Fed. Reg. 12,357-59 (1989).

129. Medical waste that has been "treated" has been processed so as to "substantially reduce or eliminate its potential for causing disease, but has not yet been destroyed." 40 C.F.R. § 259.10(b) (1989).

130. *Id.*

131. *Id.* "Destruction" does not include the process of compaction. *Id.*

132. For example, within the scope of the regulations, the following represent only a few possible routes that would fall within the regulatory scheme:

- 1) Generator to Transporter to Destination facility;
- 2) Generator to Transporter to Intermediate handler to Transporter to Destination facility;
- 3) Generator to Transporter to Intermediate handler to Transporter to Destruction facility to Transporter to Destination facility;
- 4) Intermediate handler to Transporter to Destination facility.

133. Notice that the structure of 40 C.F.R. § 259 (1989) is set up in such a way that a "person" must be a generator, transporter, or some type of processing facility for the regulations to apply: subpart F governs "generators," subpart G covers "generators" that incinerate on-site, subpart H governs "transporters," and subpart I controls facilities that process medical waste. *Id.*

transportation, or processing must involve a "regulated medical waste."¹³⁴

2. Regulated Medical Waste

Regardless of the capacity or role in which one generates, transports, or processes medical wastes, for the activity to come within the bounds of EPA's "Standards for the Tracking and Management of Medical Waste"¹³⁵ the material in question must be a "regulated medical waste."¹³⁶

Deciding whether the material being generated, transported, or processed is a "regulated medical waste" requires a four-step evaluation¹³⁷ that proceeds from very broad classifications of waste to the very narrow classification of "regulated medical waste." First, it must be determined if the material is a "solid waste" as defined by Section 1004 of the Solid Waste Disposal Act.¹³⁸ If not, the material cannot be a "regulated medical waste."¹³⁹ Second, the material must satisfy the general definition of "medical waste" listed in EPA regulations.¹⁴⁰ The third step acts in conjunction with the second step and requires that, in addition to satisfying the general definition of "medical waste," the material also must appear expressly in the more specific table of "regulated medical wastes."¹⁴¹ The final question is whether the material is specifically excluded or exempted under the regulations.¹⁴² The "exclusions" include hazardous wastes,¹⁴³ household

134. See generally *infra* notes 135-45 and accompanying text for a discussion of the meaning of the term "regulated medical waste" under EPA regulations.

135. 40 C.F.R. § 259 (1989).

136. See *id.* §§ 259.30, 259.10(b).

137. 54 Fed. Reg. 12,338 (1989).

138. 42 U.S.C. §§ 6901-6992k (1988). This Act was originally known as the RCRA, or Resource Conservation and Recovery Act of 1976, and is now commonly called the Solid Waste Disposal Act.

The definition of "solid waste" found in the Solid Waste Disposal Act is codified at 42 U.S.C. § 6903(27) (1988). See *supra* note 96, for the definition of "solid waste."

139. Sections 259.10(b) and 259.30(a), taken together, require that all "regulated medical wastes" also be "solid wastes," as the term is used in 42 U.S.C. § 6903(27) (1988). See 40 C.F.R. §§ 259.10(b), 259.30(a) (1989); see also 54 Fed. Reg. 12,338 (1989).

140. 40 C.F.R. § 259.10(b) (1989).

141. *Id.* § 259.30(a). This section reiterates the exact language of the general definition of "medical waste" found in section 259.10(b), but adds the important qualification that for a material to be a "regulated medical waste," it must appear on the provided table. *Id.*

142. 54 Fed. Reg. 12,338 (1989).

waste, ash from regulated medical waste incinerators, residue from the treatment of regulated medical wastes, and human corpses or remains intended for cremation or interment.¹⁴⁴ "Exemptions" covers etiologic agents being transported interstate by federal agencies and samples of regulated medical waste taken by EPA.¹⁴⁵

Thus, a profile of the entities that are subject to the regulatory structure of EPA's provisions concerning disposal of medical waste would appear as follows: A "person"¹⁴⁶ who produces, causes to be produced,¹⁴⁷ transports,¹⁴⁸ or processes¹⁴⁹ a material that is at once a "solid waste,"¹⁵⁰ a "medical waste,"¹⁵¹ and specifically listed on the table in 40 C.F.R. § 259.30(a) (1989) but not expressly excepted or exempted by the regulations.¹⁵² The activities of any entity that meets the above profile will be regulated by EPA, although the degree of regulation will vary with the amount of waste produced and how it is disposed.

D. Duties of Persons Regulated

1. Duties of Generators

There are two initial affirmative obligations incumbent upon generators: first, to determine if the material or materials generated are in fact a "regulated medical waste,"¹⁵³ and second, to determine the quantity of waste generated "in a calendar month, and . . . transported or offered for transport off-site for treatment, destruction, or disposal."¹⁵⁴ A finding by the generator that the material is not a "regulated medical waste" will remove that person from the control of

143. 40 C.F.R. § 259.30(b)(1)(i) (1989). "Hazardous materials" are covered in 40 C.F.R. § 261 (1989), although any mixture of a hazardous waste with a medical waste is covered by medical waste tracking provisions. *See id.* § 259.30(b).

144. *Id.* § 259.30(b)(1)(i)-(v).

145. *Id.* § 259.30(b)(2).

146. *See supra* note 115.

147. *See supra* note 119.

148. *See supra* note 122.

149. *See generally supra* notes 125-32 and accompanying text.

150. *See supra* note 96.

151. *See supra* notes 95, 101.

152. *See supra* note 95.

153. 40 C.F.R. § 259.50(b) (1989) states: "A person who generates a medical waste . . . must determine if that waste is a regulated medical waste." *See supra* note 95 for the definition of "regulated medical waste."

154. 40 C.F.R. § 259.50(e) (1989).

the regulations entirely.¹⁵⁵ A conclusion that a generator produces, transports, or offers for transport, more or less than fifty pounds of regulated medical waste per month will be determinative of the extent that specific tracking requirements will be applicable to individual generators.¹⁵⁶

Regardless of the quantity of waste generated, however, all generators who rely on transportation of regulated medical wastes off-site must meet the "Pre-Transport Requirements"¹⁵⁷ of the regulations.¹⁵⁸ The "Pre-Transport Requirements" set out four procedures that must be accomplished by the generator before transportation of regulated medical wastes can occur:¹⁵⁹ segregation, packaging, labeling, and marking.¹⁶⁰

Segregation involves the separation of "sharps"¹⁶¹ (including sharps containing residual fluids), fluids (quantities greater than twenty cubic centimeters), and other regulated medical waste.¹⁶² Mixing regulated medical wastes with other forms of solid waste does not relieve the generator of the responsibilities under the "Pre-Transport Requirements."¹⁶³

The packaging requirements impose minimum container standards that generators must use in preparing regulated medical wastes for transport.¹⁶⁴ Specifically, the regulations require generators to package wastes in containers that are:

- (1) Rigid;
- (2) Leak-resistant;
- (3) Impervious to moisture;
- (4) Sufficient to prevent tearing or bursting under normal conditions of use or handling; and
- (5) Sealed to prevent leakage during transport.¹⁶⁵

155. *See id.* § 259.

156. *See generally id.* §§ 259.50-.51.

157. *See generally id.* §§ 259.39-.45.

158. *See id.* § 259.50(e).

159. *See id.* § 259.39.

160. *See generally id.* § 259.39-.45.

161. "Sharps" include used and new hypodermic needles, syringes, scalpel blades, etc., as set forth in Class 4 and 7 in section 259.30(a). *See id.* § 259.30(a).

162. *Id.* § 259.40(a)(2).

163. *Id.*

164. *See id.* § 259.41.

165. *Id.* § 259.41(a).

Further, sharps must be packaged in such a fashion that prevents punctures¹⁶⁶ and fluids of more than 20 cubic centimeters must be placed in containers which are "break-resistant and tightly lidded or stoppered."¹⁶⁷

The labeling requirements of the regulations impose a duty upon the generator to label all "packages"¹⁶⁸ of "untreated regulated medical waste"¹⁶⁹ by affixing to the outside of the container a water resistant label that contains the words "Medical Waste," or "Infectious Waste," or "the universal biohazard symbol."¹⁷⁰

Finally, the packages or containers¹⁷¹ of regulated medical waste must be "marked" by the generator or intermediate handler¹⁷² before transportation can occur.¹⁷³ "Marking" requires the generator to place a "water-resistant identification tag [on] [t]he outermost surface of each package"¹⁷⁴ which states the name of the generator or intermediate handler and the transporter,¹⁷⁵ the state permit or identification number for the generator or intermediate handler and the transporter,¹⁷⁶ the date of the shipment,¹⁷⁷ and an identification of the contents as medical waste.¹⁷⁸ Further, any inner containers (those within a package) must display a marking which contains the generator's or intermediate handler's name and state identification or permit

166. *Id.* § 259.41(b)(1).

167. *Id.* § 259.41(b)(2).

168. As "package" and "container" are not defined in the regulations, there is an ambiguity as to the precise meaning of the terms. While both seem to be used interchangeably in sections 259.41 and 259.44, it is unclear if "containers" are placed within "packages" or vice versa, or neither. Thus, it is unclear if packages and containers, although one may enclose the other, both must be labeled. Section 259.45 seems to imply that, for purposes of marking, containers are within packages but such a conclusion is uncertain in terms of the other sections. *Id.* § 259.45. Section 259.44(a) does, however, state that "[r]ed plastic bag(s) used as inner packaging need not display a label." *Id.* § 259.44(a).

169. "Untreated regulated medical waste" includes all "regulated medical waste that has not been treated to substantially reduce or eliminate its potential for causing disease." *Id.* § 259.10(b).

170. *Id.* § 259.44(a).

171. *See supra* note 168 as to the interchangeability of these terms.

172. *See supra* note 129-30 and accompanying text for discussion of "intermediate handlers."

173. 40 C.F.R. § 259.45 (1989).

174. *Id.* § 259.45(a).

175. *Id.* § 259.45(a)(1), (3).

176. *Id.* § 259.45(a)(2), (4).

177. *Id.* § 259.45(a)(5).

178. *Id.* § 259.45(a)(6).

number (or address if the State does not require an identification number or permit).¹⁷⁹

The "Pre-Transport Requirements" contained in subpart E of 40 C.F.R. § 259 (1989) are applicable to all generators of regulated medical waste who ship wastes off-site to be processed.¹⁸⁰ The EPA regulations also compel generators to initiate a rigorous system of documentation to track the waste from generation to disposal. The requirements under the medical waste tracking regulations for generators, however, are dependent upon whether the mass of regulated medical waste generated and transported, or offered for transport, is less than fifty pounds per month.¹⁸¹

Appropriately, those who generate, transport, or offer for transport in excess of fifty pounds of regulated medical waste bear the heaviest burden of documentation. Before a transporter is permitted to accept a shipment of medical waste from a generator in this category, the generator must prepare a "tracking form."¹⁸² Acquisition of the required forms by the generator is based upon a hierarchy of available tracking forms with a preference towards the forms supplied by either the state of generation or the state of disposal.¹⁸³ While the regula-

179. *Id.* § 259.45(b).

180. Sections 259.42 and 259.43 dictate the proper procedure for generators who either store regulated medical wastes before transportation or decontaminate on-site. *Id.* §§ 259.42, 43.

181. *Id.* § 259.50(e). Section 259.50(e) delineates between two weight dependent regulatory schemes. *Id.*

Section 259.50(e)(2)(i) states that "[g]enerators who generate and transport or offer for transport off-site less than 50 pounds of regulated medical waste in a calendar month are subjected to the requirements of Subpart E of this Part [section 259.39-.45] and §§ 259.50, 259.51, and 259.54(b) of this subpart." *Id.* § 259.50(e)(2)(i).

The other regulatory scheme is created in section 259.50(e)(2)(ii), which requires generators who generate less than fifty pounds per month but *offer more than fifty pounds in any one shipment* to comply with both subpart E and all other requirements of the subpart *for that shipment*, and section 259.50(e)(1), which states that generators of fifty pounds or more must also comply with subpart E and all other requirements of the subpart. *See id.* § 259.50(e)(1), (2)(ii).

182. *Id.* § 259.52(a). "Tracking forms" are the "Federal Medical Waste Tracking Form that must accompany all applicable shipments of regulated medical wastes." *Id.* § 259.10(b). *See also* § 259.71(b). There is an exception from the requirement of using tracking forms for generators that produce, transport, or offer for transport, more than fifty pounds of waste per month if the generator is merely shipping the waste to another of the generator's facilities. *Id.* § 259.51(b).

183. *Id.* § 259.52(b); 54 Fed. Reg. 12,326, 12,350 (1989) (interim final rule effective June 22, 1989).

tions permit individual states to print their own tracking forms, all must conform strictly to the forms provided in the regulations.¹⁸⁴

Before the waste leaves the site of generation, the generator must prepare sufficient copies of the tracking form to provide one copy for the generator, one for each transporter and each intermediate handler, and two for the destination facility.¹⁸⁵ In addition, the generator must sign the form by hand, obtain the initial transporter's handwritten signature, place the date of acceptance on the form, and retain a copy.¹⁸⁶

The contents of the form are roughly analogous, though somewhat more detailed, to the information contained in the marking tags to be attached to the outer surface of each package.¹⁸⁷ Perhaps the greatest significance of the form is found in the cycle of paper work it creates from generator to transporter or transporters to the destination facility back to generator.¹⁸⁸ Any break in the cycle of tracking forms,¹⁸⁹ or

184. 54 Fed. Reg. 12,326, 12,350 (1989). This form is printed at 40 C.F.R. § 259, App. I (1989).

185. 40 C.F.R. § 259.52(c) (1989).

186. *Id.* § 259.52(d).

187. *See supra* notes 173-79 and accompanying text for the contents of the marking tag. The tracking form further calls for the mailing address and phone number of the generator, transporter, intermediate handler, and destination facility, as well as, a full description of the type of medical waste, the total number of containers for each type of waste, and the total weight or volume of each type. There are also certifications to be signed for the generator, transporters, intermediate handlers, and destination facilities. 40 C.F.R. § 259, App. I (1989).

188. 40 C.F.R. § 259, App. I (1989). Notice that the form shown in Appendix I implicitly mandates such a cycle.

189. Any generator that produces, transports, or offers for transport in excess of fifty pounds of regulated medical waste per month or transports more than fifty pounds in a single shipment "must contact the owner or operator of the destination facility, transporter(s), and intermediate handler(s), as appropriate, to determine the status of any tracked waste if he does not receive a copy of the completed tracking form . . . within 35 days of the date the waste was accepted by the initial transporter," *Id.* § 259.55(a), and if the completed tracking form has not been received within 45 days the "generator must submit an Exception Report . . . to the State and EPA Regional Administrator." *Id.* § 259.55(b).

other "discrepancy,"¹⁹⁰ triggers the "burglar alarm"¹⁹¹ that indicates improper or non-compliance handling.

The generator also must keep complete records of all transactions involving the transportation or processing of regulated medical waste.¹⁹² Specifically, generators must keep a copy of all tracking forms for at least three years after acceptance by an initial transporter¹⁹³ and a copy of all exception reports¹⁹⁴ for an indefinite period of time.¹⁹⁵ While generators who transport regulated medical wastes between their own facilities are exempted from these recordkeeping requirements,¹⁹⁶ the regulations do require that a "shipment log" be maintained at the point of generation for three years after the waste is shipped.¹⁹⁷

For generators who produce, transport, or offer for transport less than fifty pounds of medical waste per calendar month the documentation requirements are less demanding.¹⁹⁸ Generators in this class are expressly exempted from the use of tracking forms,¹⁹⁹ dealing with a transporter who has notified EPA,²⁰⁰ and any transporter requirements²⁰¹ upon a showing that proper disposal standards are followed and records properly kept.²⁰²

190. "Discrepancies" are any irregularities in a shipment of regulated medical waste in count, condition, or lack of tracking form detected by the owner or operator of an intermediate handler or destination facility. *See id.* § 259.82. Unless "resolved" by the owner or operator of such facilities within 15 days, discrepancies must be reported to the EPA Regional Administrator. *Id.* § 259.82(b). *See infra* notes 248-54 and accompanying text for a more comprehensive discussion of discrepancies.

191. *See supra* text accompanying note 114.

192. *See* 40 C.F.R. § 259.54 (1989).

193. *Id.* § 259.54(a)(1)(i).

194. *Id.* § 259.55.

195. *Id.* § 259.54(a)(1)(ii).

196. *Id.* § 259.51(b).

197. *Id.* § 259.54(a)(2).

198. *Compare id.* § 259.50(e)(2)(i) with *id.* § 259.50(e)(2)(ii) and *id.* § 259.50(e)(1).

199. *See generally supra* notes 179-97 and accompanying text.

200. *See infra* notes 209-15 and accompanying text.

201. 40 C.F.R. § 259.51(a) (1989).

202. Section 259.51(a) provides for exemption if it is shown that the regulated medical waste will ultimately arrive at a proper disposal site:

(1)(i) The regulated medical waste is transported to a health care facility, an intermediate handler, or a destination facility with which the generator has a written agreement to accept the regulated medical waste; or

The documentation required for generators in this class depends on whether the generator chooses to use a third party transporter or to personally transport the waste.²⁰³ If the third party transporter is used, a "shipment log" containing the transporter's name, address, and state permit or identification number, the quantity of waste shipped, the date of shipment, and the transporter's signature is required and must be kept for three years from the date of shipment.²⁰⁴ Generators that decide to transport their own regulated medical waste must maintain a shipment log with the same general information as the above log.²⁰⁵ Express provisions that dictate the procedures to be followed in the event that irregularities occur in the transportation or disposal of regulated medical wastes from this class of generators are curiously absent.

2. Transporters

"The central purpose of Subtitle J²⁰⁶ is to track the movement of medical waste from places of generation to the destination facility."²⁰⁷ With this central purpose in mind, it is no surprise that EPA placed

(ii) The generator is transporting the regulated medical waste from the original generation point to the generator's place of business

....

Id. § 259.51(a)(1).

Further, the generator must show a means of transport under his direct control: "(2) The regulated medical waste is transported by the generator (or an authorized employee) in a vehicle owned by the generator or authorized employee . . ." *Id.* § 259.51(a)(2).

Finally, it must be shown that adequate documentation will be kept! (3) The generator must compile a shipment log and maintain records as required by § 259.54(b)(2)." *Id.* § 259.51(a)(3).

See infra notes 224-53 and accompanying text for a discussion of the documentation requirements of section 259.54(b)(2).

203. 40 C.F.R. § 259.51(a)(1) (1989). *See generally* 54 Fed. Reg. 12,351 (1989).

204. 40 C.F.R. § 259.54(b)(1) (1989).

205. *Id.* § 259.54(b)(2). The federal regulation requires a generator that ships its own waste to include in a log the names and addresses of the intermediate handlers, destination facility, or health care facility to which the waste has been transported, the quantity of treated and untreated waste transported, the date of shipment, and the signature of the generator or his agent. *Id.*

206. The Medical Waste Tracking Act of 1988 added Subtitle J to the Resource Conservation and Recovery Act of 1976. *See* 54 Fed. Reg. 12,328 (1989).

207. *Id.*

significant emphasis on regulating those entities responsible for carrying regulated medical waste from generator to processor.²⁰⁸

The initial responsibility of a transporter of regulated medical waste is to notify EPA and "each . . . State in which the transporter intends to accept regulated medical waste directly from a generator [If] from another transporter, they must also submit a notification for each . . . State where the waste originated."²⁰⁹ From EPA's view, the notification requirement is an expedient to both federal and state implementation of the program and monitoring transporters' activities for compliance with regulations.²¹⁰

Transporters must notify EPA and the states either by a letter or using the form appended to the regulations.²¹¹ Upon proper notification, EPA will issue an "EPA medical waste identification number" to the transporter²¹² to be used on the tracking form.²¹³ Without proper notification, transporters are prohibited from handling regulated medical waste.²¹⁴

Assuming proper notification, the transporter is permitted to receive regulated medical wastes. Proper acceptance procedures are dictated by the "weight" class into which the generator falls.²¹⁵

208. "EPA believes monitoring of waste movement is essential, and the transporter, as the central actor, is in the best position to collect, compile, and report this information." *Id.* at 12,356.

209. *Id.* This duty of notification is contained within the language of 40 C.F.R. § 259.72(a) (1989). The proper parties to whom notification must be sent is found in section 259.72(a)(3). *Id.* § 259.72(a)(3).

210. 54 Fed. Reg. 12,353 (1989).

211. *Id.* An illustration of the notification form is found at 40 C.F.R. § 259, App. IV (1989). Regardless of whether a letter or the above form is used, the regulations mandate that the notification contain at a minimum:

- (1) The transporter's name, address, and EPA hazardous waste identification number (if applicable);
- (2) The name, address, and telephone number of all transportation or transfer facility at which the transporter will operate;
- (3) The number(s) of State permits or license required to handle such waste; and
- (4) A signed certification statement acknowledging that the transporter has read 40 C.F.R. § 259 (1989) and understands the penalties for non-compliance.

See id. § 259.72(b).

212. 40 C.F.R. § 259.72(c) (1989).

213. *See id.* § 259, App. I for a sample form.

214. 40 C.F.R. § 259.72(a)(1) (1989).

215. Section 259.74 carefully delineates between the requirements applicable to the transporter arising from the two classes of generators: 1) those producing fifty or more pounds of regulated medical waste per month and those who offer

For those generators who produce per month, or offer for shipment, more than fifty pounds of regulated medical waste, there are two mandatory requirements for proper "acceptance." First, proper acceptance requires that "all applicable requirements,"²¹⁶ namely, the "Pre-Transport Requirements" found in subpart E of 40 C.F.R. § 259 (1989),²¹⁷ be met: "Before accepting any regulated medical waste for transport, the transporter must make certain through *visual inspection* that the waste is packaged, labeled, and marked in accordance with all applicable requirements."²¹⁸ Second, the transporter must find that the generator has supplied²¹⁹ "a properly completed tracking form."²²⁰

When accepting regulated medical waste from a generator required to use a tracking form,²²¹ it is the duty of the transporter, during the acceptance process, to certify through signing: 1) that the tracking form supplied by the generator is a true and accurate reflection of the amount of waste in the shipment, 2) the date of shipment, and 3) that the transporter has accepted the waste from the generator.²²² The final act of acceptance is providing to the generator "a signed copy of the tracking form before leaving the generator's site."²²³

When transporting waste for a generator who is exempted from using tracking forms, the acceptance process is somewhat simplified. The transporter is required to keep, and carry while transporting waste, a log listing the generators from which waste was accepted, the quantity accepted, and the date of acceptance.²²⁴ Finally, the transporter must sign and date the log book held by the generator.²²⁵ It is interesting to note that a generator, without a tracking form, can offer for transport a package of regulated medical waste weighing less than fifty pounds. But, for the transporter to pass this same package on to a third party,

for transport more than fifty pounds of medical waste in a single shipment, and 2) those producing less than fifty pounds of waste per month. *Id.* § 259.74. *See infra* notes 216-34 and accompanying text. Additional acceptance requirements exist if the waste is to be transported by more than one transporter. *See id.* § 259.71(c).

216. 54 Fed. Reg. 12,354 (1989).

217. *See supra* notes 180-81 and accompanying text for treatment of these requirements.

218. 54 Fed. Reg. 12,354 (1989)(emphasis added).

219. 40 C.F.R. §§ 259.74, 259.71(b) (1989).

220. *Id.* § 259.71(b); *see also id.* § 259.74(a).

221. *See supra* note 182.

222. 40 C.F.R. § 259.74(b)(1) (1989).

223. *Id.* § 259.74(b)(2).

224. *Id.* § 259.74(g).

225. *Id.* § 259.74(g)(3).

the package must be accompanied by a tracking form initiated by the transporter.²²⁶ To reduce the paperwork transporters must complete, the regulations allow for "consolidation" and "remanifesting" of smaller packages into larger packages with a single tracking form.²²⁷

Upon delivery to a subsequent transporter, an intermediate handler, or a destination facility, the initial transporter should obtain the signature and date of delivery to the subsequent transporter or processor, retain a copy of the tracking form, and pass the remaining copies of the form onto the other party.²²⁸ The transporter is charged with delivering to the subsequent holder the entire amount of waste accepted from the generator or other party.²²⁹ Completion of a transporter's obligations under the regulations requires that all relevant records be kept for three years²³⁰ and reports be issued to EPA and the appropriate state agencies.²³¹

3. Processors of Regulated Medical Waste

The regulations promulgated by EPA in regards to processors of regulated medical waste differentiate between "destination facilities"²³² and "intermediate handlers."²³³²³⁴ The degree to which each of these processors changes the characteristics of the received regulated medical waste is the distinguishing factor between the two processors.²³⁵ Although not all regulations governing processors are

226. *Id.* § 259.76(a); *see also* 54 Fed. Reg. 12,354 (1989).

227. 40 C.F.R. § 259.76(b) (1989). A consolidated package appearing on a single tracking form must weigh less than 220 pounds. *Id.* Consolidation must be recorded in a "consolidation log." *Id.* § 259.76(c)(4).

228. *Id.* § 259.74(d).

229. *Id.* § 259.75. Section 259.75(b) provides that if the transporter cannot deliver all items contained in the tracking form, he must contact the generator for instructions, revise the tracking form, and delivery the entire quantity following the generator's instructions. *Id.* § 259.75(b).

230. *See id.* § 259.77.

231. *See id.* § 259.78. The form for these reports is found in Appendix III following section 259. *Id.* § 259, App. III.

232. *See supra* note 125.

233. *See supra* notes 129-30.

234. 40 C.F.R. § 259.80(a) (1989).

235. "Destination facilities" change regulated medical waste so that it meets the conditions listed in 40 C.F.R. § 259.30(b)(1)(iii), (iv) (1989). *See id.* § 259.80(a)(1). "Intermediate handlers" do not change the received medical waste so that it fits these two categories. Intermediate facilities are, in essence, new generators of regulated medical wastes, often with characteristics or in a form different than the received waste. *See generally* 54 Fed. Reg. 12,359 (1989).

different,²³⁶ the above distinction is used as the basis for deciding how each facility is to properly use the tracking form.

The destination facility is the last place the waste will exhibit the characteristics of a regulated medical waste.²³⁷ Accordingly, it is at this point that the tracking form is returned to the generator, thus completing the cycle.²³⁸ Before the form is returned to the generator, the owner or operator of the destination facility must sign and date the form as an indication that the waste received conforms with the tracking form,²³⁹ give one copy immediately to the transporter, keep one for herself,²⁴⁰ and note any discrepancies on the tracking form.²⁴¹

"Intermediate handlers" are subjected to very different tracking form requirements because the regulated medical waste they process will be passed on to subsequent holders as regulated medical waste.²⁴² The regulations tend to treat intermediate handlers as new generators, requiring that they fulfill all pre-transport requirements²⁴³ and generator standards,²⁴⁴ including the requirement to complete an initial tracking form.²⁴⁵ A log which accounts for both tracking forms must be kept by the intermediate handler²⁴⁶ and a copy of both the original tracking form and the form signed by the destination facility must be returned to the generator.²⁴⁷

Both intermediate handlers and destination facilities share a common responsibility to deal with "tracking form discrepancies."²⁴⁸ Such discrepancies can be of four types which may occur concurrently:

236. For example, the recordkeeping requirements are identical for the two entities. See 40 C.F.R. § 259.83 (1989). Further, these recordkeeping requirements roughly match those found for generators and transporters. See *id.* § 259.77.

237. See *supra* note 125.

238. 40 C.F.R. § 259.81(a)(4) (1989). The processor must return the tracking form within fifteen days of delivery. *Id.*

239. *Id.* § 259.81(a)(1); see also 54 Fed. Reg. 12,358 (1989).

240. 40 C.F.R. § 259.81(a)(3), (5) (1989).

241. *Id.* § 259.81(a)(2). See *infra* notes 248-52 and accompanying text for a discussion of discrepancies.

242. See generally 54 Fed. Reg. 12,359 (1989).

243. 40 C.F.R. §§ 259.39-.45 (1989).

244. *Id.* §§ 259.50-.56.

245. *Id.* § 259.81(b)(1).

246. *Id.* § 259.81(b)(2).

247. *Id.* § 259.81(b)(3). The federal regulation requires that this be accomplished within fifteen days of receipt by the intermediate handler of her own tracking form. *Id.*

248. *Id.* § 259.82.

1) discrepancies as to the count within a container, 2) discrepancies as to the count for each category of waste,²⁴⁹ 3) disrupted packaging, and 4) waste without a proper tracking form.²⁵⁰ The first responsibility of the handler or facility that discovers a discrepancy is to seek resolution from any or all preceding holders.²⁵¹ If a resolution is not reached within fifteen days the handler or facility must contact the EPA Regional Administrator.²⁵²

E. Enforcement

The enforcement provisions of the Act grant EPA formidable powers for effectuating the Act and the resulting regulations. The Act's enforcement scheme was modeled directly from the enforcement provisions found in the hazardous waste statutes in the Solid Waste Disposal Act²⁵³ and grants EPA full inspection and enforcement powers against violators.²⁵⁴

The strict enforcement provisions are founded upon the authority given to EPA to inspect "any person who generates, stores, treats, transports, disposes of, or otherwise has handled medical waste."²⁵⁵ The purposes of such inspections are two-fold: to gather information useful to the development of regulations or reports, and for the enforcement of the Act or EPA regulations.²⁵⁶ The power to inspect is limited in that the inspection must be made at a reasonable time at a place where "medical wastes are or have been generated, stored,

249. Section 259.82(a)(2) indicates that "untreated" and "treated" are the two "categories" contemplated. *Id.* § 259.82(a)(2).

250. *Id.* § 259.82(a).

251. *Id.* § 259.82(b).

252. *Id.*

253. The Solid Waste Disposal Act is codified at 42 U.S.C. §§ 6901-6992k (1988). The sections covering hazardous wastes are generally found in Subchapter III of the Solid Waste Disposal Act, 42 U.S.C. §§ 6921-6939b (1988), while the specific provisions governing inspections and enforcement are at 42 U.S.C. §§ 6927-6928 (1988).

A close reading of the enforcement and inspection provisions of the Medical Waste Tracking Act discloses obvious similarities to the language and structure of the provisions covering hazardous waste. *Compare id.* § 6992c(a) with *id.* § 6927(a) and *id.* §§ 6992d(a)-(c) with *id.* §§ 6928(a)-(e).

254. "The bill . . . authorizes EPA to use the full inspection and enforcement powers established for hazardous wastes to track down and prosecute anyone who violates the new Federal requirements for medical waste." 134 CONG. REC. H9,537 (daily ed. Oct. 4, 1988) (statement of Rep. Luken).

255. 42 U.S.C. § 6992c(a) (1988).

256. *Id.*

treated, disposed of, or transported from²⁵⁷ and must be conducted for the purposes of "monitoring or testing"²⁵⁸ or obtaining samples of wastes, containers, or labels.²⁵⁹

Assuming that a violation of the Act or EPA regulations has occurred, the Administrator of EPA has two avenues of redress: either to issue an order directly against the violator, or to proceed against the violator in a United States district court.²⁶⁰ An administrative order can assess civil penalties not to "exceed 25,000 dollars per day of noncompliance for each violation,"²⁶¹ and require immediate compliance.²⁶² Remedy by administrative order allows for a public hearing on the matter upon the alleged violator's request.²⁶³ If the Administrator opts to file an action in district court, both criminal and civil remedies are available.²⁶⁴ For criminal remedies to be available to EPA, the defendant must have knowingly violated the Act or regulations, knowingly misrepresented or falsified information in the documentation process, knowingly handled a medical waste contrary to the provisions of the Act or regulations, or knowingly endangered the health or safety of another person in.²⁶⁵ While these remedies are ostensibly quite strict, there are those who claim they are for political

257. *Id.* § 6992c(a)(1).

258. *Id.* § 6992c(a)(2).

259. *Id.* § 6992c(a)(3).

260. *Id.* § 6992d(a)(1).

261. *Id.* §§ 6992d(a)(1)-(2). An order assessing civil penalties must be tempered with a consideration of the "seriousness" of the transgression and "good faith efforts to comply." *Id.*

262. *Id.* § 6992d(a)(1). Section 6992d(a)(4) states that in the event that the compliance order is violated, it is within the discretion of the EPA Administrator to assess civil penalties not to exceed twenty-five thousand dollars. *Id.* § 6992d(a)(4).

263. *Id.* § 6992d(a)(3).

264. *Id.* §§ 6992d(b)-(d). As stated in section 6992d(a)(2), civil penalties imposed by a district court under section 6992d(d) cannot exceed twenty-five thousand dollars. *Id.* § 6992d(a)(2). Section 6992d(b) provides for possible sentences ranging from two years to five years and fines up to fifty thousand dollars per day per violation for knowingly violating provisions of the Act or regulations. *Id.* § 6992d(b). Section 6992d(c) provides for sentences of up to fifteen years and fines of two-hundred and fifty thousand dollars per violation for individuals, and one million dollars per violation for organizations, for knowingly placing "another person in imminent danger of death or serious bodily injury." *Id.* § 6992d(c).

265. *Id.* §§ 6992d(b)-(c).

show and more smoke than fire.²⁶⁶ In response to this contention, one must realize that the true importance of the Act is found not in its immediate remedies to the medical waste problems, but in the model it will provide for future legislation.²⁶⁷

F. Information Gathering

The Medical Waste Tracking Act of 1988 charges EPA (and the Agency for Toxic Substances and Disease Registry) with the duty of providing Congress with extensive factual reports before and after the demonstration program is completed.²⁶⁸ The information required for the EPA reports is quite detailed and seeks answers to questions concerning:

- (1) The types, number, and size of generators, the types and amounts of medical waste generated, and the current methods used to handle, store, transport, treat and dispose of medical waste;
- (2) The present or potential threat to human health and the environment posed by medical waste;
- (3) The balance between the present or potential costs to local economies, persons, and the environment from improper handling and disposal versus the costs to generators, transporters, and processors for compliance with the tracking regulations;
- (4) The success of the demonstration program, changes in disposal practices attributable to the program, and advantages and disadvantages to alternative tracking programs;
- (5) Advantages and disadvantages of alternative handling and disposal methods;
- (6) Current and possible treatment methods;
- (7) Factors affecting the effectiveness of treatment;

266. "The severity of the sanctions is remarkable, if not unique, in the environmental area. Given the almost voluntary nature of the act's application to individual states, its limited two-year duration, and the failure to provide either funds or statutory provisions to insure compliance and enforcement, it is difficult to view the violations section as anything other than an exercise in symbolic politics." PERSPECTIVES ON MEDICAL WASTE, SUPPLEMENT, *supra* note 56, at 12.

267. *Id.* at 31.

268. 42 U.S.C. §§ 6992g-6992h (1988). Section 6992g(b) requires that EPA file two "interim reports" with Congress during the span of the demonstration program. *Id.* § 6992g(b). Section 6992g(a) requires that a "final report" be supplied to Congress at the end of the program. *Id.* § 6992g(a).

- (8) State and local controls on handling and disposal of medical waste;
- (9) The "appropriateness of using any existing State requirements or the requirements contained in subchapter III of this chapter²⁶⁹ as nationwide requirements to monitor and control medical waste;"²⁷⁰
- (10) The appropriateness of the enforcement provisions in the Act;
- (11) The effects of excluding from regulation small quantity generators and producers of household waste, and possible regulations for these categories;
- (12) Current and possible recycling technologies for medical waste.²⁷¹

The Agency for Toxic Substances and Disease Registry must prepare a report for Congress by November 1, 1990 that speaks to the issues of potential health risks from handling and disposal of medical waste, the number of people injured or infected and the degree of harm caused by sharps per year, the number of persons infected per year by medical waste handling and disposal, and the annual number of cases of disease, including AIDS and hepatitis B, attributable to medical waste.²⁷²

This immense task of data gathering is not without a reason. Indeed, it is in the information gathering sections of the Act that it becomes most evident that the Medical Waste Tracking Act is not transitory relief to a fleeting crisis, but rather a prototype for permanent federal legislation controlling all aspects of medical waste.²⁷³

269. See generally *id.* §§ 6921-6939(b) (entitled "Hazardous Waste Management").

270. *Id.* § 6992g(a)(9) (emphasis added).

271. *Id.* § 6992g(a).

272. *Id.* § 6992(h).

273. "Regardless of the state of the nation's beaches and dumpsters, there are several upcoming events that will guarantee the return of some degree of Congressional attention to the medical waste issue: the submission of the various reports by EPA describing the results of the demonstration tracking program and answers to the technical questions posed in the statute, and the reauthorization of RCRA. Our interviews on Capital Hill indicate that medical waste is not currently at the top of the Congressional environmental agenda. But there was [a] clear expectation when the MWTA was passed that Congress would have a 'second shot' at the issue sometime within the following two years. Of course, a major incident involving medical waste, or another summer of despoiled beaches, would undoubtedly accelerate that review." PERSPECTIVES ON MEDICAL WASTE, SUPPLEMENT, *supra* note 56, at 32.

III. THE MISSOURI APPROACH TO TRACKING INFECTIOUS WASTE²⁷⁴

A. Introduction

As recently as 1986, two statutory schemes concurrently controlled the disposal of infectious waste in Missouri: that of hazardous waste disposal and solid waste management.²⁷⁵ Treatment, transportation, and disposal of infectious waste in Missouri, however, currently is governed by The Missouri Solid Waste Management Law (SWML).²⁷⁶ SWML required that two administrative agencies, The Missouri Department of Health (MDOH) and the Missouri Department of Natural Resources (MDNR), promulgate regulations to control the transportation and disposal of infectious waste.²⁷⁷

While Missouri hazardous waste statutes are no longer viable in regard to infectious waste, they do offer a definition of "infectious waste."²⁷⁸ Still, given that SWML is now the dominant legislation, it is logical to conclude that its definition will be of most importance. SWML states that infectious waste:

means waste in quantities and characteristics as determined by the department²⁷⁹ by rule, including isolation wastes,

274. Missouri statutes do not recognize the term "medical waste." Instead, all relevant statutes concentrate on those wastes that display infectious qualities. See MO. REV. STAT. §§ 260.200(8), 260.360(13) (Supp. 1990).

275. As of 1987, infectious waste fell within the express language of both the Solid Waste Management Law (SWML) and provisions governing hazardous waste management. See generally *id.* §§ 260.203, 260.378. In 1988, Senate Bill 535 removed infectious waste from the provisions controlling "hazardous waste management" by repealing section 260.378, thus placing control of infectious wastes exclusively within the Missouri Solid Waste Management Law. See *id.* § 260.378.

276. *Id.* §§ 260.200-281. See WASTE MGMT. PROGRAM OF THE MO. DEP'T OF NAT. RESOURCES, MANAGEMENT OF INFECTIOUS WASTE BY SMALL QUANTITY GENERATORS, TECHNICAL BULLETIN 1 (May 10th, 1989) [hereinafter MANAGEMENT OF INFECTIOUS WASTE BY SMALL QUANTITY GENERATORS].

277. MO. REV. STAT. § 260.203(2) (Supp. 1990); see also *id.* § 260.225. These regulations are found at MO. CODE REGS. tit. 10, § 80-7.010 (1989) and MO. CODE REGS. tit. 19, § 20-20.010 (1989).

278. See MO. REV. STAT. §§ 260.360(13) (Supp. 1990). While there are minor wording differences, the content of this definition and that found in SWDL are nearly identical. The major difference is that the definition offered in the hazardous waste provisions covers chemotherapeutic materials while the SWML does not. *Id.*

279. *Id.* § 260.200(5).

cultures and stocks of etiologic agents, blood and blood products, pathological wastes, other wastes from surgery and autopsy, contaminated laboratory wastes, sharps, dialysis unit wastes, [and] discarded biologicals known or suspected to be infectious.²⁸⁰

This skeletal definition is fully fleshed out through the effectuating regulations created by MDNR.²⁸¹

Equipped with a working definition of infectious waste, it is now possible to explore those entities that are within the scope of SWML and the accompanying regulations, and their various responsibilities under these regulations.

The provisions of SWML create three general classes of regulated entities, matching those found in the federal regulations: generators, transporters, and processors.²⁸² Within the classification of generators, there are three subclasses: small quantity generators,²⁸³ hospitals,²⁸⁴ and by default, all large quantity generators that are not hospitals.²⁸⁵ While each of these classes and subclasses share some of the general regulatory requirements, there are also unique requirements for each. Thus, it is vital to properly classify the entity to be regulated.

B. Regulated Entities and Applicable Requirements

1. Generators

Before delving into the unique requirements for the subclasses of generators, it is important to point out the regulations that are categorically applicable to generators of infectious waste in Missouri. All generators have the option of treating infectious waste "on-site," and

280. *Id.* § 260.200(8). The "department" referred to in this statute is the Missouri Department of Natural Resources.

281. *See* MO. CODE REGS. tit. 10, § 80-7.010(1)(A)(3) (1989). Notice that section 80-7.010(1)(A)(2) alludes to the special definition of infectious waste created by the Department of Health in MO. CODE REGS. tit. 19, § 20-20.010 (1989). *See infra* notes 292-94 and accompanying text.

282. MO. REV. STAT. § 260.203 (Supp. 1990) implies that those who generate, transport, or process infectious waste will be subject to the statute.

283. *Id.* § 260.203(10).

284. *Id.* § 260.203(9). "Hospital" is defined in section 197.020(2). *Id.* § 197.020(2).

285. *See generally id.* § 260.203. While small quantity generators and hospitals are subject to express sections of the statute, large quantity generators are subject to the full requirements of the statute.

thus avoid most of the regulations dealing with transporting and disposing of actively infectious waste.²⁸⁶ If, however, any generator decides to remove actively infectious waste from the site of generation, additional requirements are triggered. Every generator transporting infectious waste "off-site" must complete all packaging and labeling requirements prior to shipping.²⁸⁷ Further, tracking forms, transportation procedures, and fees may be required for proper transportation of infectious waste, depending on who transports the waste²⁸⁸ and its ultimate destination.²⁸⁹

a. Small Quantity Generators and Hospitals as Generators

The term "small quantity generators" (SQG) is not expressly contained within the definition section of SWML.²⁹⁰ It is, however, implicitly defined in later sections as "[p]ersons generating one hundred kilograms or less of infectious waste per month."²⁹¹ Within the context of SWML, the "infectious waste" to be weighed seems to point to the definition contained in the statute itself.²⁹² Interestingly, the state regulations promulgated by MDNR point to a potentially different definition of "infectious waste." As in the statute, SQGs are defined by MDNR regulations as those "person[s] generating one hundred kilograms (100 kg) or less per month of infectious waste."²⁹³ But the MDNR regulations base SQG determination not on the definition of "infectious waste" contained within the statute, but on the definition of "infectious waste" in regulations promulgated by the MDOH.²⁹⁴

286. MO. CODE REGS. tit. 10, § 80-7.010(1)(C)(1) (1989); *see also* MO. CODE REGS. tit. 10, § 80-7.010(1)(B)(1) (1989). The note to this section states that treated infectious waste is not subjected to the transportation requirements of later sections. *Id.*

287. MO. CODE REGS. tit. 10, § 80-7.010(2) (1989). This section specifies packaging and labeling requirements quite similar to those found in the federal regulations. *See supra* notes 158-78 and accompanying text.

288. *See infra* 329-33 and accompanying text.

289. *See infra* notes 334-39 and accompanying text.

290. MO. REV. STAT. § 260.200 (Supp. 1990).

291. *Id.* § 260.203(10). One hundred kilograms is approximately equal to two hundred and twenty pounds.

292. *See supra* notes 279-80 and accompanying text.

293. MO. CODE REGS. tit. 10, § 80-7.010(1)(C)(3) (1989); *see also id.* § 80-7.010(1)(A)(2).

294. The MDOH has defined "infectious waste" in terms of SQGs as: [W]aste capable of producing an infectious disease. For a waste to be infectious, it must contain pathogens with sufficient virulence and quantity so that exposure to the waste by a susceptible human host could result in an infectious disease . . . [and] shall include the

While these two definitions of SQG are ostensibly congruous, any ambiguities could lead to inconsistent findings as to whether an entity qualifies as a SQG. As a practical matter, it is clear that the MDNR, the agency with the greatest authority over the day-to-day implementation of SWML, views the latter definition of SQG controlling.²⁹⁵ Therefore, who qualifies as a SQG should be determined using the MDNR definition which is founded upon the definition of "infectious waste" created by the MDOH.

Small quantity generators, like all other generators, have the option of treating infectious waste "on-site," thus avoiding most of the requirements of the regulations.²⁹⁶ If, however, the waste is treated at a place other than the site of generation, regulations to monitor the movement of infectious waste are triggered. As with all generators that transport off-site, the packaging and labeling regulations must be met before transportation.²⁹⁷ The mode of transportation and the ultimate destination of infectious waste generated by a SQG is determinative of further applicable requirements.

The SQG that chooses to transport its own infectious waste can escape all "transportation requirements"²⁹⁸ and "fees"²⁹⁹ upon a showing that the vehicle used for transport is "closed and secured" and owned and operated by the SQG.³⁰⁰ The SQG is also relieved of the

following categories:

- (A) Sharps—all discarded sharps including hypodermic needles, syringes and scalpel blades. Broken glass or other sharp items that have come in contact with material defined as infectious are included;
- (B) Cultures and stocks of infectious agents and associated biologicals—included in this category are all cultures and stocks of infectious organisms as well as culture dishes and devices used to transfer, inoculate and mix cultures; and
- (C) Other wastes—those wastes designated by the medical authority responsible (physician, podiatrist, dentist, veterinarian) for the care of the patient which may be capable of producing an infectious disease.

Id. tit. 19, § 20-20.010(13).

295. See MANAGEMENT OF INFECTIOUS WASTE BY SMALL QUANTITY GENERATORS, *supra* note 276, at 2.

296. See *supra* note 286 and accompanying text.

297. See *supra* note 287 and accompanying text.

298. MO. CODE REGS. tit. 10, § 80-7.010(4) (1989); MO. REV. STAT. § 260.203.3 (Supp. 1990).

299. MO. REV. STAT. § 260.203(8) (Supp. 1990); MO. CODE REGS. tit. 10, § 80-7.010(5)(D) (1989).

300. MO. CODE REGS. tit. 10, § 80-7.010(1)(C)(3) (1989); MO. REV. STAT. § 260.203(3) (Supp. 1990).

"tracking forms requirement"³⁰¹ if the ultimate destination of the waste is an in-state hospital approved to treat transported infectious waste.³⁰² The accepting hospital cannot gain "approval" from the MDNR and MDOH unless there is some system in place to account for and "track" the waste.³⁰³ If the waste is transported to a "Permitted Infectious Waste Processing Facility"³⁰⁴ in lieu of an approved hospital the tracking forms must be used.³⁰⁵ Finally, if the SQG transports the waste out of Missouri, all laws and regulations of the destination state must be followed,³⁰⁶ although during transportation in Missouri the vehicle must be "closed and secured."³⁰⁷

If the SQG decides not to transport the infectious waste itself, a licensed transporter must be used.³⁰⁸ Further, choosing to use a transporter apparently triggers the applicability of tracking form requirements.³⁰⁹ A transporter hauling infectious waste from a SQG to a processing facility that is not a hospital are subject to the appropriate fees,³¹⁰ although this fee will probably be passed on to the customer.

In the current regulatory structure, hospitals³¹¹ are accorded certain exemptions despite the fact that most hospitals will fall within the definition of a generator³¹² of infectious waste in significant quantities. The exemptions available to hospitals are the same as those available to SQGs.³¹³ Hospitals have the option of treating their own

301. See MO. CODE REGS. tit. 10, § 80-7.010(3) (1989).

302. *Id.* § 80-7.010(1)(C)(5); see also MANAGEMENT OF INFECTIOUS WASTE BY SMALL QUANTITY GENERATORS, *supra* note 276, at 3. Approval for a hospital to accept SQG infectious waste must come from the MDNR and the MDOH. See MO. CODE REGS. tit. 10, § 80-7.010(1)(C)(5)(A) (1989).

303. MO. CODE REGS. tit. 10, § 80-7.010(1)(C)(5)A(III) (1989).

304. See *id.* § 80-7.010(5).

305. *Id.* § 80-7.010(3)(A).

306. *Id.* § 80-7.010(4).

307. *Id.*

308. *Id.*

309. See *id.* §§ 80-7.010(3)(A), 80-7.010(3)(B). Section 80-7.010(3)(A) implies that tracking documents are only necessary if the destination is a "permitted infectious waste processing facility." *Id.* § 80-7.010(3)(A). Section 80-7.010(3)(B) makes it unclear, however, if a transporter can receive infectious waste from a SQG unless accompanied by a tracking document regardless its' destination. *Id.* § 80-7.010(3)(B). Caution would suggest that tracking forms should accompany all infectious waste hauled by a transporter.

310. *Id.* § 80-7.010(5)(D).

311. See *supra* note 284 and accompanying text.

312. See MO. CODE REGS. tit. 10, § 80-7.010(1)(A)(1) (1989).

313. See *supra* notes 296-307 and accompanying text.

infectious waste on-site³¹⁴ and avoiding most of the requirements of the regulations. As with SQGs, a hospital that transports its own waste from the site of generation will be exempted from the application of the "transportation requirements"³¹⁵ and "fees,"³¹⁶ and may be exempted from the use of "tracking documents" provided the destination of the waste is a Missouri hospital "approved" to accept infectious waste.³¹⁷ A hospital electing not to process on-site or transport its own infectious waste must use a licensed transporter³¹⁸ and should also use tracking forms.³¹⁹

b. Large Quantity Generators

Large quantity generators (LQG) are those generators that fall neither into the classification of SQGs or Missouri hospitals.³²⁰ In

314. See *supra* note 286 and accompanying text.

315. See *supra* note 298 and accompanying text.

316. Mo. CODE REGS. tit. 10, § 80-7.010(1)(C)(5)(B) (1989).

317. Section 80-7.010(1)(C)(5)(A) of the Missouri regulations allows one hospital to treat the waste of another if the accepting hospital is either "approved" or "permitted." Hospitals accepting from SQGs must, at the minimum, obtain "approval" from the MDNR and MDOH under the requirements of section 80-7.010(1)(C)(5)(A). *Id.* § 80-7.010(1)(C)(5)(A). As with a SQG transporting its own waste, "tracking documents" are not required but the accepting hospital must have some tracking system to obtain approval. See notes 299-308 and accompanying text.

An accepting hospital must obtain a "processing facility permit" if waste is accepted from 1) generators other than SQGs or other Missouri hospitals, 2) out-of-state hospitals, and 3) "off-site quantities as provided in 19 CSR 30." Mo. CODE REGS. tit 10, § 80-7.010(1)(C)(5)C (1989). Section 30-20.020(5)(D)7 of the Missouri regulations specifies that an accepting hospital receiving quantities of infectious waste that exceed fifty percent of the infectious waste generated on-site shall obtain a MDNR permit as a processing facility. *Id.* tit. 19, § 30-20.020(5)(d)7. The amount of infectious waste generated on site is calculated by multiplying 1.5 per day by the number of hospital beds in the facility. *Id.*

If the waste's destination is designated as a "permitted infectious waste processing facility," *Id.* tit. 10, § 80-7.010(3)(A), requires the use of tracking documents.

318. See *supra* note 308 and accompanying text.

319. As with an SQG using a transporter, hospitals using a transporter must comply with the requirements of Mo. CODE REGS. tit. 10, §§ 80-7.010(3)(A), 80-7.010(3)(B) (1989). These regulations may necessitate the use of tracking forms. See *supra* note 309 and accompanying text.

320. As stated previously, the characteristics of large quantity generators are not expressed, but implied, in the SWML and the ensuing regulations. See generally Mo. REV. STAT. § 260.203 (Supp. 1990); Mo. CODE REGS. tit. 10, § 80-7.010(1), (1989).

essence, LQGs represent the default status in the statute and MDNR regulations. In other words, exemptions are available only to SQGs and Missouri hospitals; thus the full gambit of regulatory powers falls upon LQGs.³²¹

The only possibility the LQG has for avoiding the requirements of the SWML and MDNR regulations is found in "on-site" treatment.³²² If the LQG transports the infectious waste off-site, all requirements of the regulations must be met: 1) all packaging and labeling requirements,³²³ 2) a licensed transporter must be used,³²⁴ and 3) all tracking documents and fees are required,³²⁵ unless the waste is being transported out-of-state.³²⁶ It is important to note that LQGs do not have the option available to SQGs of transporting infectious waste to Missouri hospitals.³²⁷ Thus, LQGs must transport their infectious waste out-of-state or to a licensed Missouri processing facility.³²⁸

2. Transporters

"Transporter" is not defined expressly by the statute or the regulations, but seems to include any entity that moves infectious waste from a site of generation to an approved treatment facility.³²⁹ The tracking duties of a transporter flow mainly from properly documenting the transportation of infectious waste through the use of tracking forms.³³⁰

A transporter cannot accept a shipment of infectious waste from a generator unless it is accompanied by a properly completed tracking

Missouri hospitals are defined in MO. REV. STAT. § 197.020(2) (1986).

321. See generally MO. REV. STAT. § 260.203 (Supp. 1990); MO. CODE REGS. tit. 10, § 80-7.010(1) (1989).

322. MO. CODE REGS. tit. 10, § 80-7.010(1)(B)(1) (1989). Infectious waste properly treated can be disposed of like any other solid waste if the generator certifies that it has been rendered innocuous. *Id.*; see also *supra* note 286 and accompanying text; MO. REV. STAT. § 260.203(2) (Supp. 1990).

323. See *supra* note 287 and accompanying text.

324. See *supra* note 308 and accompanying text.

325. MO. CODE REGS. tit. 10, § 80-7.010(4) (1989).

326. *Id.* Even if the waste is bound for another state, the transporting vehicle must be "closed and secured." *Id.*

327. See MO. REV. STAT. § 260.203(9) (Supp. 1990); MO. CODE REGS. tit. 10, § 80-7.010(5) (1989).

328. MO. CODE REGS. tit. 10, §§ 80-7.010(4)-(5)(A) (1989).

329. See *id.* § 80-7.010(5).

330. Section 80-7.010(4) of the Missouri regulations also specifies the vehicle characteristics and maintenance requirements for transporters. *Id.* § 80-7.010(4).

form that correctly reflects the quantity and types of waste.³³¹ Upon delivery of the waste to the receiving facility, the transport must obtain the signature of an authorized agent for the facility³³² and deliver the entire quantity received from the generator.³³³

3. Processors

Treatment facilities are defined in the MDNR regulations as those facilities that have received a permit to process or treat infectious waste.³³⁴ Although some facilities effect only intermediate treatment of infectious waste, treatment facilities or processors are generally the final link in the chain of custody of infectious waste. Therefore processors also have duties in tracking infectious wastes. A treatment facility is prohibited from accepting infectious waste without the proper documentation.³³⁵ Further, the facility must sign the tracking form and note any discrepancies on all copies of the tracking document.³³⁶ Finally, the processing facility must, within thirty-five days of the date the waste was accepted by the transporter, send a copy of the completed tracking form to the generator.³³⁷

The regulations also specify in detail the treatment procedures to be used by the facility in rendering the waste innocuous.³³⁸ Interestingly, the regulations do not specify treatment procedures for on-site treatment.³³⁹

C. Summary of Infectious Waste Tracking in Missouri

The SWML and the resulting MDNR and MDOH regulations provide both a concrete definition of the types of wastes to be regulated and "cradle-to-grave" tracking provisions for waste that leaves the site of generation. Thus, if and when the federal government promulgates national regulations based on the results of the Medical Waste Tracking Act of 1988,³⁴⁰ Missouri will not be without its own regulatory scheme. Therefore, provided that Missouri's regulations are "no less stringent"

331. *Id.* § 80-7.010(3)(B)(1).

332. *Id.* § 80-7.010(3)(B)(4)(A).

333. *Id.* § 80-7.010(3)(B)(5).

334. *Id.* § 80-7.010(5)(A).

335. *Id.* § 80-7.010(3)(C)(1).

336. *Id.* § 80-7.010(3)(C)(2).

337. *Id.* § 80-7.010(3)(C)(6).

338. *See generally id.* § 80-7.010(5).

339. *See id.* § 80-7.010(1)(B). The only requirement for on-site disposal is that the waste be rendered "innocuous." *Id.*

340. 42 U.S.C. §§ 6992-6992k (1988).

than the federal regulations, there will be no mandatory implementation of federal standards or requirements in Missouri.³⁴¹

IV. CONCLUSION

There has been a distinct pattern over the last few decades in federal environmental regulation. The standards and regulations in the federal regulatory scheme will be put into place if a state fails to promulgate regulations at least as strict as the federal standards.³⁴² It is likely that any national regulation of medical waste will also predicate approval of state regulations upon a showing that these regulations are no less stringent than the federal regulations.³⁴³

The Missouri program should fare well if the coming federal legislation is similar to the Medical Waste Tracking Act. The definitions used, the entities covered, and the duties imposed by the Missouri regulations are the functional equivalents to the regulations promulgated by EPA under the Act. Indeed, the only significant disparity found in the two regulatory schemes is the degree to which infectious waste must be treated³⁴⁴ and the sanctions imposed upon violators. The Medical Waste Tracking Act imposes severe criminal and civil liabilities on violators.³⁴⁵ The only enforcement provision in the Missouri enabling statute makes violations a class A misdemeanor.³⁴⁶

In the Medical Waste Tracking Act, Congress has taken the first tentative step toward pervasive national regulation of the disposal of medical and infectious waste. The Missouri Legislature also has recognized the social significance of controlling the disposal of infectious

341. *Id.* § 6992(b)(2).

342. *See* 30 U.S.C. § 1254(a) (1982) (Surface Mining Control and Reclamation Act, 30 U.S.C. §§ 1201-1202, 1211, 1221-1328 (1986 & Supp. 1989)); 42 U.S.C. § 7410(c) (1982) (Clean Air Act, 42 U.S.C. §§ 7401-7642 (1982)); 42 U.S.C. 6926(e) (1982) (Solid Waste Disposal Act, 42 U.S.C. 6901-6992k (1988)).

343. Indeed, the demonstration program of the Medical Waste Tracking Act applies this standard to states covered by the program. 42 U.S.C. § 6992(b)(2) (1988).

344. Missouri requires only that the waste be rendered "innocuous," *see supra* note 339, while federal regulations require that medical waste "destination facilities" treat waste and destroy waste so that "it is no longer generally recognizable as medical waste." 40 C.F.R. § 259.10(b) (1989).

345. *See* notes 253-67 *supra* and accompanying text.

346. MO. REV. STAT. § 260.203(6) (Supp. 1990).

wastes and has legislated accordingly. Thus, while the problems of medical waste disposal remain objectively undefined, state and federal powers have acted with decisiveness to cure a perceived social ill.

DAVID RANDOLPH MERCER