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Infectious Waste: A Guide to State Regulation and a Cry for Federal Intervention

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INTRODUCTION

The mismanagement of infectious waste has become the focus of increasing public outrage during recent years. The problem first came into the public limelight when medical waste[1] began to wash up on the New York and New Jersey coastlines.[2] With the damage it caused to the tourist industry and the fear of possible infection it sparked in many, the populace and consequently legislators soon demanded tougher regulation of infectious waste disposal. This fear has become particularly prominent with the populace's increasing awareness of the growing AIDS epidemic and the passage of the virus by blood and infected hypodermic needles. Ironically, the health care industry that works to stop infection daily is now under fire for infecting others in the process.[3]

In the spring of 1989, it was estimated that ninety percent of the states had regulations or bills pending before their legislatures to establish infectious waste regulations.[4] In contrast, only fifty-

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1 Recent regulation of the medical waste industry has been directed towards a subset of medical waste often termed "infectious waste." The term "medical waste" refers to all waste generated in the health care industry, while "infectious waste," as generally defined, refers to waste that can infect those who are exposed to it. *See* UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, EPA GUIDE FOR INFECTIOUS WASTE MANAGEMENT 2-1 (1986) [hereinafter EPA GUIDE]. This Note, like most state regulation, is restricted to infectious waste.

2 *See generally How to Clean Up Needle Beach*, N.Y. Times, July 24, 1988, at 24, col. 1; Gross, *2 Vials Are Tainted by Hepatitis*, N.Y. Times, July 14, 1988, at B3, col. 4; Gutis, *Fear on the Beaches: What Waste May Mean*, N.Y. Times, July 12, 1988, at B4, col. 1.

Medical waste has also washed ashore on the beaches of Michigan and Ohio. *DNR Eyes Wisconsin as Source of Medical Waste*, Grand Rapids Press, Oct. 2, 1988, at A1, col. 1.

3 *See* Bleiweiss & Edwards, *A Cure for What Ails Us? Environmental Regulation of the Medical Industry*, 6 ENVTL. F. 7, 7 (1989).

4 *Id.* at 12. This author's research revealed a lower percentage. Presently forty-two out of fifty, or eighty-four percent of all states have bills pending, regulations promulgated or recommendations on the proper disposal of medical waste.

The eight states that do not are Kansas, Montana, Nevada, South Dakota, Tennessee, Utah, West Virginia and Wyoming.

Note that New Jersey, New York, Connecticut and Rhode Island are also subject to the federal medical waste tracking program and its regulations. *See infra* notes 230-252 and accompanying text. *See* Alabama - ALA. ADMIN. CODE r. 335-13-1-.03 & r. 335-13-4-.26(3) (1988); Alaska - ALASKA ADMIN. CODE tit. 18, § 60.087(g) (requires treatment before disposal) & § 60.0910(29) (infectious waste defined) (1987); Arizona - ARIZ. COMP. ADMIN R. & REGS. R9-10-220(E) (general hospitals), R9-10-320(E) (rural general hospitals), R9-10-420(special hospitals), R9-10-1220(E) (hospital/infirmaries), R9-10-921(A)(3) (supervisory care facilities), R9-14-109(20)(clinical laboratories) (1982); Arkansas - ARKANSAS DEPARTMENT OF HEALTH, DRAFT-RULES AND REGULATIONS PERTAINING TO THE MANAGE-

MENT OF SPECIAL WASTE FROM HEALTH CARE RELATED FACILITIES (Dec. 4, 1989) (adopted without change); California - CAL. ADMIN. CODE tit. 22, §§ 66835-65, 70845-47, 71649, 71651, 72643-47, 73643-45, 75068, 75069, 76655, 76657 (1985) (old regulations) and CAL. HEALTH & SAFETY CODE §§ 25015 - 99 (West 1990) (recently passed Biomedical Waste Management Act); Colorado - COLO. REV. STAT. §§ 25-15-404 - 407 (1989); Connecticut - CONN. AGENCIES REGS. §§ 22a-209-15 (1990); Delaware - DELAWARE DEPARTMENT OF NATURAL RESOURCES AND ENVIRONMENTAL CONTROL, DIVISION OF AIR & WASTE MANAGEMENT, SOLID WASTE DISPOSAL REGULATIONS §§ 4 & 11 (1989); DELAWARE DEPARTMENT OF NATURAL RESOURCES AND ENVIRONMENTAL CONTROL, DIVISION OF AIR & WASTE MANAGEMENT, AIR RESOURCES REGULATIONS §§ 1, 7, & 29 (1989); Florida - FLA. ADMIN. CODE ANN. r. 10D-104.001-008 (1989) (regulations for generators of infectious waste) and FLA. ADMIN. CODE ANN. r. 17-2 (incineration standards) & r. 17-712 (regulation of infectious waste once it leaves generator's site) (1989) ; Georgia - GA. COMP. R. & REGS. r. 391-3-4-.15 (1989); Hawaii - HAWAII DEPARTMENT OF HEALTH, MANAGEMENT AND DISPOSAL OF INFECTIOUS WASTE §§ 11-104-1 -12 (1989); Idaho - IDAHO CODE §§ 16.02.1002,19 & 16.02.1550,06 (1990) (hospitals only); Illinois - ILL. ADMIN. CODE tit. 35 §§ 809.901-.906 (1989); Indiana - IND. ADMIN. CODE tit. 410, r. 1.3 & r. 1.4 (1989); Iowa -IOWA CODE § 455B.491 (1990), (calling for an infectious waste inventory to be completed in January of 1991); Kentucky - KENTUCKY NATURAL RESOURCES & ENVIRONMENTAL PROTECTION CABINET-INFECTIOUS WASTE TASK FORCE, RECOMMENDATIONS FOR MANAGING INFECTIOUS WASTE (1989); Louisiana - 1989 La. Acts 583 (establishing standards for incinerators), La. Reg. ch. XXVII, §§ 27:020- 027 (Jan. 20, 1990) and LA. ADMIN. CODE tit. 33 § VII.13(D) (1987) (standards governing sanitary landfills); Maine - MAINE DEPARTMENT OF ENVIRONMENTAL PROTECTION, BIOMEDICAL WASTE MANAGEMENT RULES (Dec. 1989); Maryland - MD. REGS. CODE tit. 10, § 10.06.06 (1988) and MD. REGS. CODE tit. 26, §§ 26.13.11-.13 (1989); Massachusetts - MASS. REGS. CODE tit. 105, § 480 (1989); Michigan - MICHIGAN DEPARTMENT OF PUBLIC HEALTH, MEDICAL WASTE EMERGENCY RULES (April 26, 1989) (presently in rule making process); Minnesota - MINN. STAT. §§ 116.76-.83 (Supp. 1989); MINN. R. 7035.9100- .9140 (1989); Mississippi - MISSISSIPPI STATE DEPARTMENT OF HEALTH, PROPOSED STANDARDS FOR THE REGULATION OF MEDICAL WASTE (Nov. 6, 1989) (adopted Feb. 8, 1990); Missouri - MO. CODE REGS. tit. 19, §§ 20-20.010, 30-20.011, 30-20.021, 30-22.030, 30-24.040 (1988) (on-site management by hospitals only) and MISSOURI DEPARTMENT OF NATURAL RESOURCES, MANAGEMENT OF INFECTIOUS WASTE BY SMALL QUANTITY GENERATORS (May 10, 1989); Nebraska - NEBRASKA DEPARTMENT OF ENVIRONMENTAL CONTROL tit. 132, ch. 10 §§ 003 & 018 (1989); New Hampshire - N.H. CODE ADMIN. R. He-P 1901.08 (1984); New Jersey - N.J. STAT. ANN. § 13:1E-48.1 - 48.28 (West Supp. 1990) and N.J. ADMIN. CODE tit. 7, § 26-3A (1989); New Mexico - NEW MEXICO ENVIRONMENTAL IMPROVEMENT BOARD, SOLID WASTE MANAGEMENT REGULATIONS §§ 103(V) & 403 (1989); New York - N.Y. PUB. HEALTH LAW §§ 1389cc-1389gg (McKinney 1988) (governs infectious waste at site of production), N.Y. ENVR. CONSERV. LAW §§ 27-1501- 1515 (McKinney 1988) (governs infectious waste once it leaves site of generator) and N.Y. COMP. CODES R. & REGS. tit. 6, §§ 360-10.1- 10.6 (applies to all facilities which store, treat or dispose of infectious waste) & 364.1-.9 (standards for tracking and management of infectious waste) (1988); North Carolina - N.C. ADMIN. CODE tit. 10, r. 10G.1001-.1008 (Feb. 1990) (separating infectious waste into Class A and Class B medical waste); North Dakota - NORTH DAKOTA STATE DEPARTMENT OF HEALTH, STATEMENT OF POLICY: DISPOSAL OF LONG TERM CARE FACILITY WASTES (1989); Ohio - OHIO ADMIN. CODE §§ 3745-27 & 3745-37 (1990); Oklahoma - OKLAHOMA STATE DEPARTMENT OF HEALTH, BULLETIN 0524: REGULATIONS GOVERNING SOLID WASTE & SLUDGE MANAGEMENT §§ 800-890 (June 23, 1988); Oregon - OR. REV. STAT. §§ 459.386 - 459.405 (Supp. 1990); Pennsylvania - PA. STAT. ANN. tit. 35, §§ 6019.1-.6 (1989) (authorizing the promulgation of regulations and a manifest system), 25 PA. CODE §§ 271.1, 283.402, 285.132, 285.222 (1988) (regulations for the storage, containment, and

seven percent of the states had infectious waste regulations or bills pending in 1986.[5] Unfortunately, the legislation and pursuant regulations have varied immensely.[6]

Infectious waste generators and transporters ship two-thirds of all waste interstate.[7] Consequently, the diversity in state regulations has led to uncertainty and confusion for generators and transporters as to which state's regulations govern the disposal, treatment or transport of infectious waste when transported across state lines.[8] This movement across state lines also poses problems since the state receiving the waste is often unaware of the entrance of the waste or its subsequent disposal in that state.[9] Varying degrees of stringency among states has also created the incentive for "dump-shopping." In other words, an enterprising generator "shops" for the cheapest state in which disposal or treatment can be made. This is usually the state with the least amount of regulation.

This Note attempts to reconcile these divergent state regulations by presenting a guide or checklist, per se, for what most states are regulating in this area. It also recommends the implementation of minimum federal regulations to ensure that all states

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transportation of infectious and chemotherapy waste) and PENNSYLVANIA DEPARTMENT OF HEALTH ENVIRONMENTAL QUALITY BOARD, INTERIM GUIDELINES - MANIFESTING & TRANSPORTER LICENSING FOR INFECTIOUS AND CHEMOTHERAPY WASTE (July 18, 1989); Rhode Island - RHODE ISLAND DEPARTMENT OF HEALTH, RULES & REGULATIONS GOVERNING THE MANAGEMENT OF INFECTIOUS WASTE IN HEALTH CARE RELATED FACILITIES AND LABORATORIES R23-17-INF & R23-16.2-INF (April 1989); South Carolina - S.C. CODE ANN. §§ 44-93-10 - 200 (Law. Co-op. 1989) (regulations not yet promulgated); Texas - TEX. REV. CIV. STAT. ANN. art. 4437f (1986) (hospital licensing standards); TEX. ADMIN. CODE tit. 25, §§ 1.31-1.137 (1989); Utah - UTAH ADMIN. R. 450-301-1(g) (1989) (only defines infectious waste); Vermont - VT. ADMIN. PROC. COMP. Dept. of Envtl. Conserv. r. 6-802(b) (1989); Virginia - VIRGINIA DEPARTMENT OF WASTE MANAGEMENT, INFECTIOUS WASTE MANAGEMENT REGULATIONS (1990); Washington - legislation pending (H.R. 2388, which "died" in the House Rules Committee, will be used as an indication of what likely be regulated in Washington) and Wisconsin - WIS. ADMIN. CODE §§ NR 500.03 (67) & NR 506.11 (1988) (defining infectious waste and requiring treatment of infectious waste prior to landfilling); WISCONSIN DEPARTMENT OF NATURAL RESOURCES, GUIDELINES FOR THE HANDLING AND TREATMENT OF MEDICAL/INFECTIOUS WASTE (May 1989).

5 Bleiweiss & Edwards, *supra* note 3, at 7.

6 Michigan is the best illustration of this flood of legislation. As late as mid-1988, Michigan did not have any legislation proposed or planned to govern infectious waste. As of Spring 1989, Michigan had twenty-four bills pending before the legislature ranging from the general disposal of medical waste to the licensing of physicians' clinical laboratories. *Id.*

7 South Bend Tribune, Oct. 13, 1990, at 1, col. 1.

8 *See infra* notes 253-266 and accompanying text.

9 Note, *Blood on North American Soil: A Comparison of United States and Canadian Infectious Waste Disposal Regulations*, 16 SYRACUSE J. INT'L L. & COM. 129, 133 (1990).

equally protect the public and health care workers from exposure to dangerous pathogens, as well as leave open the possibility of stricter regulations, i.e. the tracking of infectious waste, for those states that have had considerable difficulty in this area.[10] Specifically, Part I of this Note introduces the infectious waste disposal problem and discusses why the problem exists. Part II focuses on state regulation with an analysis of an area of state regulation that has proven to be of considerable difficulty——the defining of infectious waste. Part III continues the state survey by focusing on state regulation of the infectious waste disposal chain including packaging, storage, treatment and ultimate disposal. Part IV concludes by arguing that minimum federal regulations are essential if there is any hope of bringing stability to the regulation of infectious waste disposal and treatment.[11]

I. INFECTIOUS WASTE DISPOSAL

A. The Problem

Infectious waste disposal is only a part of the total solid waste disposal problem created by society's disposable mind frame.[12] The Environmental Protection Agency ("EPA") estimates that of the 160 million tons of solid waste generated each year in the United States, 3.2 million tons is medical waste from hospitals alone.[13] This figure is based on an estimate of thirteen lbs./bed/day, while an independent estimate puts the generation range as high as sixteen to twenty-three lbs./bed/day.[14] Regard-

10 *See infra* notes 216-229 and accompanying text.

11 This Note should not be used as a substitute for researching a particular state's regulations. It is intended to give legal practitioners a guide for what to expect from their state's regulations and is not intended as an exclusive coverage of any state's regulations. Due to the complexity of many state regulations and the speed with which such regulations are evolving, a diligent practitioner should periodically check for recent changes to the state regulations.

12 The health care industry has certainly done its share to increase the disposable mind frame of American society. Nonetheless, while most Americans engage in quick disposal for mere convenience, the medical community has done so for safety, infection control, and cost reasons. WASHINGTON STATE DEPARTMENT OF ECOLOGY, REPORT TO THE LEGISLATURE: WASHINGTON STATE INFECTIOUS WASTE PROJECT 82 (1989) [hereinafter WASHINTON STATE INFECTIOUS WASTE PROJECT].

13 UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, ENVIRONMENTAL BACKGROUNDER: MEDICAL WASTE 1 (1989) [hereinafter ENVIORNMENTAL BACKGROUNDER].

14 Hall, *Infectious Waste Managements: A Multi-faceted Problem*, POLLUTION ENGINEERING 74, 74 (1989).

less, the EPA believes that ten to fifteen percent of this waste is potentially infectious.[15]

Although infectious waste disposal is only a part of the total problem, it should not be considered in conjunction with the general waste disposal problem. Its unique characteristics require separate treatment. Nevertheless, a few state agencies have labelled infectious waste disposal a non-problem and believe it should be considered part of the general solid waste disposal problem.[16] In support of this theory, some have suggested that the fear of danger to human health is ill-founded[17] and that the medical waste that washed up on our beaches was only a minuscule amount of the entire garbage washup.[18] This, however, ignores the danger that improper disposal poses to health care and waste disposal workers as well as to the public at large. A recent Washington state survey found twenty-one percent of its 438 waste industry employees had been stuck by hypodermic needles while five percent reported having had waste blood splashed into their faces or eyes while on the job.[19] Furthermore, the Natural Resources Defense Council found that thirty-one persons in the summer of 1989 alone were injured by hypodermic syringes at beaches in New York, New Jersey and Delaware.[20] In light of the occupational hazard that hepatitis B, a blood borne pathogen, poses to the health care worker industry[21] and the phobia over

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15 ENVIRONMENTAL BACKGROUNDER, *supra* note 13, at 1.

16 These responses, although rare, were received by the author through questionnaires sent to all state agencies that have some bearing on the infectious waste disposal problem. Since many states deal with infectious waste under different departments and many times even split the duty, questionnaires were generally sent to each state's departments of public health, environmental protection, and hazardous waste management, or the like.

17 Some studies have shown that medical waste is generally less virulent than typical domestic waste. ENVIRONMENTAL BACKGROUNDER, *supra* note 13, at 2. *See generally* CENTERS FOR DISEASE CONTROL, MORBIDITY AND MORTALITY WEEKLY REPORT (August 21, 1987).

18 The New York State Department of Health stated that the amount of medical waste washup was of "minor amounts . . . perhaps capable of filling three basic leaf bags." NEW YORK STATE DEPARTMENT OF HEALTH, A STATEWIDE PLAN FOR TREATMENT AND DISPOSAL OF REGULATED MEDICAL WASTE iv (1989) [hereinafter NEW YORK STATEWIDE PLAN]. The EPA studies indicate that the most likely sources of the medical waste washup in the summer of 1988 were not medical facilities, but rather sewage overflows containing wastes from home health care and illegal drug use. Bleiweiss & Edwards, *supra* note 3, at 7.

19 WASHINGTON STATE INFECTIOUS WASTE PROJECT, *supra* note 12, at ii.

20 *Phantom Incinerators for Medical Waste*, Newsday, Sept. 24, 1989, at 11.

21 The Center for Disease Control's Hepatitis Branch estimates that twelve thousand infections occur annually among health care workers due to occupational exposure to

AIDS contraction,[22] there is little doubt that improper infectious waste disposal poses a danger to many and is of general consequence to the public at large.[23]

Infectious waste sightings, furthermore, are not confined to our beaches. Infectious waste has been found on suburban street curbs,[24] in major metropolitan parks,[25] in residential neighborhoods,[26] in front of schools,[27] and even on the bottom of

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blood. It further estimates that these infections will result in 2,500 to 3,000 cases of clinical acute hepatitis, 500 to 600 hospitalizations and over 200 deaths. The hepatitis B virus ("HBV") can spread through breaks in the skin (e.g., cuts or needlestick injuries), mucous membranes (e.g., eyes and mouth), sexual contact and from mother to infant. One milliliter of blood from an HBV positive individual may contain up to 100 million infectious doses of the virus. The risk of acquiring HBV infection due to a needlestick injury from an HBV carrier ranges between six to thirty percent within healthcare settings. HBV is known for its resiliency in surviving in infective doses on dried surfaces for up to one week or longer at room temperature. WASHINGTON STATE INFECTIOUS WASTE PROJECT, *supra* note 12, at 43-45.

22 The actual danger that the AIDS or human immunodeficiency virus poses to health care workers and the public is less than commonly perceived. The HIV virus survives poorly outside of the human body and is far less hardy and infective than the hepatitis B virus. Nonetheless, there are reports of up to twenty-five health care workers having been infected with HIV while working in a health care setting. *Id.* at 47. Estimates show that HIV positive needlestick injuries result in infection at a rate of 3-5 infections per 1000 persons injured. *Id.* at 47-48.

23 One example of the danger mismanaged infectious waste and the viruses it can carry pose to the public at large is the case where a group of school children found fifty-one illegally dumped blood vials on Penny Beach in Staten Island, N.Y. The hepatitis virus was still active and contagious in five of the vials when the kids found them. Newsday, May 18, 1989, at 17. None of the children was injured. In Indianapolis, a small group of children found and smashed several small bottles containing blood samples from a nearby clinic. One of the bottles contained blood from an individual diagnosed with AIDS. Clark, Williams, McKillon & Turque, *The Garbage Health Scare*, NEWSWEEK, July 20, 1987, at 56. In Boardman Township, Ohio, some youngsters discovered syringes in a dumpster and spent the afternoon "jabbing each other in the arm in a game of doctor." *Id.*

24 One doctor was fined $3,000 for leaving medical waste on a curb, *Medical Waste Put on Curb*, Newsday, Sept. 18, 1989, at 27, while residents in Roosevelt, N.Y. awoke one day to find eighteen bags of infectious waste on their curbside. *Bags of Medical Waste on Streets*, Newsday, January 21, 1989, at 7. An eyewitness stated that he had seen an unmarked white van drop off the bags at about 1:30 a.m. *Id.*

25 Police found several pounds of medical waste in Washington Circle in Northwest, Washington D.C. Police believed that the waste was carried there by street people. The waste was discovered at 1:00 P.M. At 4:45 P.M., the health association clean-up crew, which was notified immediately, had still not arrived. *Medical Waste Brings Park Closing*, The Washington Times, August 22, 1989, at B3.

26 A medical laboratory in a residential, Queens, N.Y. neighborhood that was under investigation for illegal ocean dumping was found to be illegally storing infectious waste in a plywood shack. Community residents stated that they had seen workers from the laboratory dump bloody materials and other medical waste on the street. The owner alleged that the waste was not his and that he was the subject of ethnic attacks from competitors trying to put him out of business. This incident occurred after medical waste

riverbeds.[28] Regardless of the position one takes, "[w]hether it is syringes and bandages washing up on the beach or children playing with vials of blood they have found in a dumpster, people are outraged when they feel there is even a possibility of contracting a disease from the improperly managed wastes."[29]

B. The Incentive

The recently created incentive for generators, treatment facilities and waste disposers to improperly dispose of infectious waste is a topic that is often ignored, but is one that is nonetheless essential to the consideration of improper infectious waste disposal. Only recently has infectious waste disposal become a major problem, and only within the last few years has medical waste begun to appear on our beaches and in a variety of other unusual places.[30] Where did it all begin?

The problem likely began with the ever-increasing use of disposable products in the health care industry.[31] This increase

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that washed up on New Jersey beaches was linked to the laboratory. *Medical Waste Illegally Stored*, Newsday, May 22, 1989, at 3.

Similarly, residents of a New York suburb complained of an offensive odor coming from a nearby warehouse. Hanley, *The Danger of Dumping Medical Wastes Are Under Scrutiny*, N.Y. Times, Aug. 24, 1987, at B1, col. 2. Investigating health officers found about five tons of medical waste, including body parts. *Id.* In 1986, Brooklyn firefighters discovered about 1400 bags of medical waste in a smoldering warehouse. *Id.* There was evidence indicating that vagrants had rummaged through and slept on the bags. *Id.*

27 A five-cubic-yard mound of infectious waste was illegally dumped in front of a grade school in Brockton, Massachusetts. *Medical Waste Spills in Front of Grade School*, The Boston Globe, November 8, 1988, at 18.

28 In probably the most "bizarre" medical waste disposal episode ever, state officials in Connecticut found twenty concrete blocks containing hypodermic needles, syringes, bandages and vials at the bottom of the Connecticut River. Boston Globe, July 6, 1989, at 11.

29 IOWA DEPARTMENT OF NATURAL RESOURCES & IOWA DEPARTMENT OF PUBLIC HEALTH, INFECTIOUS WASTE MANAGEMENT: A REPORT TO THE IOWA GENERAL ASSEMBLY 1 (1989) [hereinafter IOWA INFECTIOUS WASTE REPORT]. This has been termed the "yuck factor" by some people involved in state health departments. Los Angeles Times, Nov. 11, 1988, § 7, at 1, col. 4.

30 *See supra* notes 23-28 for examples of unusual scenarios. In addition to these, infectious waste has been inadvertently discovered in such unlikely situations as drug busts, L.A. Times, Nov. 4, 1989, at B2, col. 1; in robbery investigations, Newsday, May 18, 1989, at 36 (stolen van turned up eighty-one cartons of infectious waste and medical group to which the van belonged would not comment on why the van contained the waste or where the waste was going to be disposed); and in fighting fires, Harmon v. Pennsylvania, 119 Pa. Commw. 1, 546 A.2d 726 (1988) (fire fighters discovered infectious waste on the site of a fire when one fire fighter's boot was pierced by a needle and other firemen found two to three dozen needles in the truck tires and hose).

31 *See supra* note 12 and accompanying text.

eventually led to an increased demand for ways to dispose of the waste and correspondingly a rise in the price of disposing of such waste. The incentive to cut costs, which exists in every business, soon led to improper disposal. It was simply easier to cheat.

With the appearance of infectious waste on the beaches and in open dumpsters, states soon began to regulate the industry. Increased regulation often leads to increased expense for those being regulated.[32] This correlates into increased profits for illegal as well as legal waste disposers. The BFI Medical Waste Systems Inc., believed to be the nation's largest handler of medical waste, increased its revenues from $ 3.5 million in 1986 to $ 15 million in 1988.[33] One report of an illegal waste handler estimated that the parties involved had made nearly $ 2.5 million in profits based on fees they charged over a five month period.[34] The incentive to "cheat" had certainly become substantial.

The incentive to improperly dispose of infectious waste soon magnified when waste disposal handlers began to refuse to accept infectious waste.[35] This reluctance was partly due to their recognition of the possibility of accidentally contracting hepatitis B,[36] but was more likely due to their fear of contracting the socially stigmatizing AIDS virus. Regardless of the reasoning, waste disposal handlers rejected the infectious waste, often with no consideration of alternative disposal.[37]

In sum, each event fed the other: the health care industry increased its production of disposables; this increase resulted in

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32 Mr. L.D. Thurman, P.E., the Associate Commissioner for Environmental and Consumer Health Protection in Texas expressed his concerns in this regard. He stated that the increasing expense involved in further regulation of the industry threatened substantial harm to those "small hospitals in Texas [that] are barely hanging on now." Texas, unfortunately, leads the nation in hospital closures. Letter from L.D. Thurman, P.E. to Michael Shumaker (Jan. 9, 1990) (letter on file with the *Notre Dame Law Review*).

33 N.Y. Times, June 27, 1989, at C4, col. 4.

34 Washington Post, June 16, 1989, at A18, col. 2. The violators were indicted. *Id.*

35 In New York, none of the eleven municipal incinerator operators accepted infectious waste as of August, 1989. They noted their concern with the risk of worker exposure to pathogenic agents as their reason for refusing to accept any waste generated by a health care facility. The New York Department of Health recognized that this increased the cost of handling infectious waste off-site for treatment and disposal because a significant portion was then transported to special facilities out of the state. NEW YORK STATEWIDE PLAN, *supra* note 18, at viii & 22.

36 *See supra* note 21 and accompanying text.

37 In Indiana, where landfill disposal of infectious waste is prohibited, one landfill operator stated: "In the last month we rejected forty-five to forty-eight loads [of infectious waste]." Chicago Trib., Nov. 7, 1989, at 1, col. 1. When asked where the rejected loads go, the operator replied: "It's out of my hands; it's not my worry." *Id.*

higher demand for proper disposal; the higher demand for disposal increased the price for disposal; high prices led unscrupulous generators, transporters, and disposers to improperly dispose of the waste; state and federal regulators responded with regulations that were often only "knee jerk" reactions to public outcry; increased regulation led to increased expenses for the health care industry and, in some cases, opposition to any further regulation. This is where we stand in 1990.

The incentive to improperly dispose of infectious waste, however, is not confined to those who improperly dispose of the waste to avoid the expense of regulation or to make a profit. The incentive for individuals practicing home health care (e.g., diabetics) and illicit drug users to improperly dispose of infectious wastes is generally one of convenience. Regulators must also consider these groups of generators in getting a "grasp" on the problem.[38] Their output is certainly significant; diabetics alone discard up to one billion disposable needles a year.[39]

II. STATE RESPONSE: THE DEFINITION OF INFECTIOUS WASTE

Unfortunately, states have no uniform definition for infectious waste.[40] A letter from the American Hospital Association ("AHA") to the EPA dated August 1, 1988 indicates the importance of properly defining infectious waste.[41] It states that, "lack

38 Some studies have found these generators to be the most likely sources of medical waste washups in New York and New Jersey. *See supra* note 14.

39 N.Y. Times, June 27, 1989, at 29, col. 4. In New York City alone it is believed two million diabetic needles are disposed annually. *Id.* The New York harbor is often the chief conduit of beach washups in New York and New Jersey. *Id.*

40 This section is not an attempt to ascertain what should be considered infectious waste. As stated by the EPA, the "proper" definition of infectious waste has been debated for years." EPA GUIDE, *supra* note 1, at 2-1. This is only a summary of what most states have defined as infectious wastes and is geared towards the legal practitioner. The proper definition of what should constitute infectious waste is best left to the health care professionals and those responsible for the waste's proper disposal. For this reason, this Note limits itself only to sensible, not technical, recommendations.

41 There is no universally accepted definition for "infectious waste." As there is inconsistency in the definition of "infectious waste," there is similar inconsistency in the terminology used to define these wastes. Infectious waste has almost as many names as there are states. They include: infectious, biohazardous (Florida), biomedical (Georgia, Connecticut), medically hazardous (Iowa), regulated medical waste (New Jersey, New York), infectious medical waste (Indiana), physically dangerous medical or biological waste (Massachusetts), hazardous (infectious) hospital waste (Illinois), hazardous waste (California-new Act will consider it biomedical waste), special waste (Texas, Delaware), special medical waste (Maryland), potentially infectious medical waste (Louisiana), nonhazardous infectious waste (Mississippi), and special waste from health care related facilities (Arkansas).

of a consistent and rational definition of infectious waste for use by federal, state, and local agencies creates the most significant obstacle to efficient waste management and contributes to public apprehension about the effectiveness of current practices."[42] The AHA went on to say that a hospital could classify between five and seventy percent of its waste stream as infectious depending on the criteria used.[43]

Most infectious waste definitions can be divided into two parts: the general and the specific.[44] The EPA definition is a good example for both since it is the definition often followed by state regulators. It defines infectious waste in general as waste that "contain[s] pathogens with sufficient virulence and quantity so that exposure to the waste by a susceptible host could result in an infectious disease."[45]

The EPA then lists six specific categories that constitute infectious waste. These include: (1) contaminated sharps; (2) cultures and stocks of infectious agents and associated biologicals; (3) human blood and blood products; (4) pathological wastes; (4) contaminated animal carcasses, body parts and bedding; and (6) isolation wastes.[46] The EPA also lists additional materials that it suggests may pose a health hazard because of their potential infectiousness and may require infectious waste treatment. These include surgery and autopsy wastes, contaminated equipment, laboratory wastes, and dialysis unit wastes.[47] These specific types of infectious waste serve as a good reference point for a survey of

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42 IOWA INFECTIOUS WASTE REPORT, *supra* note 29, at 6 (citing Letter from the AHA to the EPA (Aug. 1, 1988)).

43 *Id.*

44 Utah is an exception in that it only provides a general definition of infectious waste. It provides: "'[i]nfectious waste' means a solid waste that contains or may reasonably be expected to contain pathogens of sufficient virulence and quantity that exposure to the waste by a susceptible host could result in an infectious disease." UTAH ADMIN. R. 450-301-1(g) (1989). Utah, however, has no specific regulations for the disposal of infectious waste.

45 EPA GUIDE, *supra* note 1, at 2-1 (1986). The EPA also lists four factors to be considered in defining waste as infectious:

a) presence of a pathogen of sufficient virulence;
b) dose;
c) portal of entry;
d) resistance of host.

Id. This definition was eventually incorporated into the Federal Medical Waste Tracking Act. 42 U.S.C. § 6992a (1988). *See infra* notes 230-252 and accompanying text.

46 EPA GUIDE, *supra* note 1, at 2-2.

47 *Id.* These specific wastes were eventually incorporated into the Medical Waste Tracking Act. *See infra* notes 230-252 and accompanying text.

state definitions and for illustrating points on which states agree and those on which some have deviated.[48]

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48 All forty-two states that regulate infectious waste or have a policy regarding infectious waste have defined infectious waste. *See* Alabama - ALA. ADMIN. CODE r. 335-13-1-.03 (1988); Alaska - ALASKA ADMIN. CODE tit. 18, § 60.910(29) (1989); Arizona - ARIZ. COMP. ADMIN & REGS. R9-10-220(E) (general hospitals), R9-10-320(E) (rural general hospitals), R9-10-420 (special hospitals), R9-10-1220(E) (hospital/infirmaries), R9-10-921(A)(3) (supervisory care facilities), R9-14-109(20)(clinical labs) (1982); Arkansas - ARKANSAS DEPARTMENT OF HEALTH, DRAFT-RULES AND REGULATIONS PERTAINING TO THE MANAGEMENT OF SPECIAL WASTE FROM HEALTH CARE RELATED FACILITIES § III(c) (Dec. 4, 1989); California - CAL. HEALTH & SAFETY CODE § 25-15-25020(b) (West 1990) (recently passed Biomedical Waste Management Act) and CAL. HEALTH & SAFETY CODE § 25117.5 (West 1985) (old definition); Connecticut - CONN. AGENCIES REGS. §§ 22a-209-15 (1990); Delaware - DELAWARE DEPARTMENT OF NATURAL RESOURCES AND ENVIRONMENTAL CONTROL, DIVISION OF AIR & WASTE MANAGEMENT, SOLID WASTE DISPOSAL REGULATIONS § 11, Part I (B)(1) (1989); Florida - FLA. ADMIN. CODE ANN. r. 10D-104.002(2) (1989); Georgia - GA. COMP. R. & REGS. r. 391-3-4-.15(1) (1989); Hawaii - HAWAII DEPARTMENT OF HEALTH, MANAGEMENT AND DISPOSAL OF INFECTIOUS WASTE § 11-104-2 (1989); Idaho - IDAHO CODE § 16.02.1002,19 (1990); Illinois - ILL. ADMIN. CODE tit. 35, § 809.901 (1989); Indiana - IND. ADMIN. CODE tit. 410, r. 1.3-10 (1989); Iowa - IOWA CODE § 455B.501(1)(b) (1989); Kentucky - KENTUCKY DEPARTMENT OF HEALTH, NATURAL RESOURCES & ENVIRONMENTAL PROTECTION CABINET - INFECTIOUS WASTE TASK FORCE, RECOMMENDATIONS FOR MANAGING INFECTIOUS WASTE 1 (1989); Louisiana -La. Reg. ch. XXVII § 27:020(g) (Jan. 20, 1990); Maine - MAINE DEPARTMENT OF ENVIRONMENTAL PROTECTION, BIOMEDICAL WASTE MANAGEMENT RULES ch. 900, §§ 6(c), 7 (Dec. 1989); Maryland - MD. REGS. CODE tit. 10, § 10.06.06.02(14) (1988) and MD. REGS. CODE tit. 26, § 26.13.11.02(10) (1989); Massachusetts - MASS. REGS. CODE tit. 105, § 480.010 (1989); Michigan - MICHIGAN DEPARTMENT OF PUBLIC HEALTH, MEDICAL WASTE EMERGENCY RULES r. 1(i) (April 26, 1989) (presently in rule making process); Minnesota - MINN. STAT. § 116.76(12) (Supp. 1989); MINN. R. 7035.0300 (48)(1989); Mississippi - MISSISSIPPI STATE DEPARTMENT OF HEALTH, PROPOSED STANDARDS FOR THE REGULATION OF MEDICAL WASTE 1 (Nov. 6, 1989); Missouri - MO. CODE REGS. tit. 19, § 20-20.010 (1988) (definition relating to communicable diseases), MO. CODE REGS. tit. 19, § 30-20.011 (1988) (definitions relating to hospitals), and MISSOURI DEPARTMENT OF NATURAL RESOURCES, MANAGEMENT OF INFECTIOUS WASTE BY SMALL QUANTITY GENERATORS 2 (May 10, 1989) (all three definitions are consistent); Nebraska - NEBRASKA DEPARTMENT OF ENVIRONMENTAL CONTROL tit. 132, ch. 10 §§ 003 & 018 (1989); New Hampshire - N.H. CODE ADMIN. R. He-P 1901.08(a) (1984); New Jersey - N.J. STAT. ANN. § 13:1E-48.1 (1989) and N.J. ADMIN. CODE tit. 7, § 26-3A.5 - 6 (1989) (definitions are consistent); New Mexico - NEW MEXICO ENVIRONMENTAL IMPROVEMENT BOARD, SOLID WASTE MANAGEMENT REGULATIONS § 103(V) (1989); New York - N.Y. PUB. HEALTH LAW §§ 1389aa (a)-(j) (McKinney 1988) (governs infectious waste at site of production), N.Y. ENVTL. CONSERV. LAW § 27-1501 (a)-(j) (McKinney 1988) (governs infectious waste once it leaves site of generator) and N.Y. COMP. CODES R. & REGS. tit. 6, § 360-1.2(b)(8) & tit. 6, § 364.1(c) (definition for the tracking of waste) (1986) (all definitions are consistent); North Carolina - N.C. ADMIN. CODE tit. 10, r. 10G.1001(15) (1990); North Dakota - NORTH DAKOTA STATE DEPARTMENT OF HEALTH, STATEMENT OF POLICY: DISPOSAL OF LONG TERM CARE FACILITY WASTES 1 (1989); Ohio - OHIO ADMIN. CODE § 3745-27-01(V) (1990); Oklahoma - OKLAHOMA STATE DEPARTMENT OF HEALTH, BULLETIN 0524: REGULATIONS GOVERNING SOLID WASTE & SLUDGE MANAGEMENT § 811 (June 23, 1988); Oregon - OR. REV. STAT. § 459.386(2) (Supp. 1990); Pennsylvania - PA. STAT. ANN. tit. 35, § 6019.1 (1989) and 25 PA. CODE § 271.1 (1988); Rhode Island - RHODE ISLAND DEPARTMENT OF HEALTH, RULES & REGULATIONS GOVERNING THE MANAGEMENT OF INFECTIOUS

A. Contaminated Sharps

At present, forty of the forty-two states defining infectious waste include "sharps" in their infectious waste definition.[49] A "sharp" is generally considered a hypodermic needle or a syringe used in giving injections. This, however, is only the tip of the iceberg for this category. It often includes pasteur pipettes, scalpel blades, broken glass and any other medical wastes that can cut or puncture the skin. State regulators are obviously concerned about the disposal of sharps due to the sharps' "ability to puncture the human body's first line of defense against invading microorganisms, the skin."[50]

The word "contaminated" suggests that generators may exclude some sharps if they are found uncontaminated. The EPA initially stated specifically that only sharps "which have come into contact with infectious agents during use" are to be regulated.[51] In light of the difficulty of determining what is "contaminated" and what is not, and the particular danger this waste poses to handlers and those exposed to it, the better position is to treat as infectious all sharps that have been used and are marked for disposal.[52] A number of states have already made this deci-

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WASTE IN HEALTH CARE RELATED FACILITIES AND LABORATORIES R23-17-INF & R23-16.2-INF, § 1.3 (April 1989); South Carolina - S.C. CODE ANN. § 44-93-20 (Law. Co-op. 1989); Texas - TEX. ADMIN. CODE tit. 25, § 1.321 (1989); Utah - UTAH ADMIN. R. 450-301-1(g) (1989); Vermont - VT. ADMIN. PROC. COMP. Dept. of Envtl. Conserv. r. 7-103(26) (1988) (as defined in hazardous waste regulations); Virginia - VIRGINIA DEPARTMENT OF WASTE MANAGEMENT, INFECTIOUS WASTE MANAGEMENT REGULATIONS §§ 3.3 - .4 (1990); Washington - Washington House Bill 2388 (Infectious waste bill that died in House Rules Committee); Wisconsin - WISCONSIN DEPARTMENT OF NATURAL RESOURCES, GUIDELINES FOR THE HANDLING AND TREATMENT OF MEDICAL/INFECTIOUS WASTE Part II (May 1989); WIS. ADMIN. CODE § NR 500.03(67) (Feb. 1986).

Colorado has not specifically defined infectious waste, but has stated that it will follow the EPA's guidelines. COLO. REV. STAT. §§ 25-15-404- 407 (1989).

New Jersey, New York, Connecticut, and Rhode Island must also follow the Medical Waste Tracking Act's definition of infectious waste. *See supra* notes 45-47 and accompanying text.

49 Arizona, Nebraska, New Hampshire, and New Mexico are the four states that do not include sharps in their regulations. Illinois does not include contaminated sharps specifically, but does provide that they would be considered infectious if used in the care of a patient with an infectious disease. ILL. ADMIN. CODE. tit. 35, § 809.901 (1989). *See supra* note 48 and accompanying citations.

50 WASHINGTON STATE INFECTIOUS WASTE PROJECT, *supra* note 12, at 50.

51 EPA GUIDE, *supra* note 1, at 2-4.

52 The EPA recommends that all sharps used in *patient care* be considered infectious waste because of the possibility of undiagnosed blood-borne diseases (e.g., hepatitis B and AIDS). *Id.* The consideration of all sharps destined for disposal as "contaminated"

sion,[53] and the EPA removed these qualifying words in the enactment of the Medical Waste Tracking Act of 1988.[54]

B. Cultures and Stocks of Infectious Agents

Cultures and stocks of infectious agents is the most common type of infectious waste included in state definitions.[55] Presently forty-one of the forty-two states defining infectious waste include "cultures and stocks" in their infectious waste definition.[56] States designate these wastes as infectious because high concentrations of pathogenic organisms are typically present.[57] For this reason, their inclusion is essential to any definition of infectious waste.

C. Human Blood & Blood Products

Forty-one states include human blood and blood products[58] in their definitions of infectious waste.[59] Some states restrict the definition to only liquid forms of blood,[60] while others expand it to include any material that is soaked or contaminated with dried

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encompasses this concern.

53 Alabama, Alaska, Connecticut, Delaware, Florida, Idaho, Kentucky, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, North Carolina, North Dakota, Ohio, Oregon, Pennsylvania, South Carolina, Vermont, Virginia, Wisconsin. *See supra* note 48 and accompanying citations.

54 42 U.S.C. § 6992(a)(4) (1988).

55 Not all states entitle this category "cultures and stocks of infectious agents." Oregon has termed it "biological waste"; New Mexico includes "fomites and disposable fomites" in its definition; and a number of states term the waste "microbiologicals." These include Kentucky, North Carolina, and North Dakota. New Hampshire also calls cultures and stocks "microbiologicals," but also adds "petri dishes." *See supra* note 48, and accompanying citations.

56 Alaska, Arizona and Nebraska are the lone dissenters, but the term "lab wastes and the like" in Arizona's definition will often encompass these wastes. ARIZ. COMP. ADMIN. R. & REGS. R9-10-220(E), R9-10-320(E), R9-10-1220(E) (1982)(these cover general hospitals, rural general hospitals and hospital infirmaries, respectively). This definition comes from the Arizona Department of Health Services regulations. The Arizona Department of Environmental Quality is in the process of rule making.

57 Laboratories grow microbiological agents on artificial media for a number of purposes such as vaccine production, clinical analysis and research. They are grown in high concentrations to achieve this purpose. WASHINGTON STATE INFECTIOUS WASTE PROJECT, *supra* note 12, at 49.

58 The term "blood products" includes such matter as serum, plasma and other blood components.

59 Nebraska, New Hampshire, and North Dakota are the three states that do not include human blood and blood products in their definitions of infectious waste. NEBRASKA DEPARTMENT OF ENVIRONMENTAL CONTROL tit. 132, ch. 10 § 018 (1989); N.H. CODE ADMIN. R. He-P 1901.08 (1984); NORTH DAKOTA STATE DEPARTMENT OF HEALTH, STATEMENT OF POLICY: DISPOSAL OF LONG TERM CARE FACILITY WASTES (1989).

60 *See, e.g.*, IND. ADMIN. CODE tit. 410, r. 1.3-10 (1989).

or dripping blood or body fluids.[61] Some state infectious waste definitions describe or include human blood and blood products in such terms as "biological products"[62] or "biological waste."[63]

D. Pathological Wastes

Pathological waste generally consists of human tissues, organs, and body parts removed during surgery and autopsy. The EPA has stated that generators should consider pathological waste infectious "because of the possibility of unknown infection in the patient or corpse."[64] Nonetheless, one of the main reasons for considering this waste infectious is its unaesthetic appeal, i.e. when body parts are recognizable and destined for treatment or disposal.[65] Some states have found pathological waste of such significance that they include it as a separate category distinct from infectious waste.[66] Illinois, on the other hand, has chosen to regulate only pathological waste that has been contaminated by an infectious agent.[67] Regardless, all forty-two states have chosen to regulate pathological waste as infectious waste in some manner.[68]

E. Contaminated Animal Carcasses and Bedding

Another type of infectious waste includes contaminated animal carcasses, animal body parts, and bedding of animals that

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61 *See, e.g.*, CONN. AGENCIES REGS. § 22a-209-15 (1990).

62 *See, e.g.*, GA. COMP. R. & REGS. r. 391-3-4-.15 (1989).

63 *See, e.g.*, ALA. ADMIN. CODE r. 335-13-1-.03 & r. 335-4-.26(3) (1988) (biological liquid waste); DELAWARE DEPARTMENT OF NATURAL RESOURCES AND ENVIRONMENTAL CONTROL, DIVISION OF AIR & WASTE MANAGEMENT, SOLID WASTE DISPOSAL REGULATIONS Section 11, Part I (B)(1) (1989) (biological liquid waste).

64 EPA GUIDE, *supra* note 1, at 2-4.

65 Wisconsin has even restricted its regulation of pathological waste to "recognizable human tissue." WISCONSIN DEPARTMENT OF NATURAL RESOURCES, GUIDELINES FOR THE HANDLING AND TREATMENT OF MEDICAL/INFECTIOUS WASTE 1 (May 1989); WIS. ADMIN. CODE § NR 500.03(67) (1988).

66 *See, e.g.*, CONN. AGENCIES REGS. § 22a-209-15 (1990); MINN. STAT. § 116.76(12), (14) (Supp. 1989); MINN. R. 7035.0300(48) (1989).

67 ILL. ADMIN. CODE tit. 35, § 809.901 (1989).

68 North Dakota and Arizona are the dissenters. *See supra* note 48 and accompanying citations. Minnesota and Oregon have excluded teeth from this category to avoid regulating the dental profession. MINN. STAT. § 116.76 (14) (Supp. 1989); MINN. R. 7035.0300 (48) (1989); ORE. REV. STAT. § 459.386(2) (Supp. 1990). In the recently passed California biomedical waste management act, pathological wastes would not be included unless they were deemed contaminated. CAL. HEALTH & SAFETY CODE § 25073 (1990). This of course ignores one of the main reasons for including these wastes in the definition—its unaesthetic appeal.

generators intentionally exposed to pathogens.[69] The primary concern in regulating this category is the possible exposure of the populace to human pathogens to which generators often expose animals for research.[70] The final tally shows thirty-nine states include it in their infectious waste definitions.[71]

F. Isolation Wastes

Isolation wastes are wastes generated by hospitalized patients who have been isolated to protect others from communicable diseases. The EPA recommends that generators consult the Centers for Disease Control ("CDC") guidelines[72] to determine what diseases should be considered communicable and what patients require isolation.

In the EPA's Guide to Infectious Waste Management, isolation waste is the first waste type listed as infectious.[73] This indicates the importance that the EPA attaches to the proper disposal of this type of waste. This top priority reflects the renewed importance this category has received with the recent fear of AIDS contraction.[74]

Nevertheless, there are problems with the inclusion of such waste in an infectious waste definition. The state of Washington's Department of Ecology, in recommending the exclusion of isola-

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69 Reasons for intentional exposure include research, the production of biologicals, and the *in vivo* testing of pharmaceuticals. EPA GUIDE, *supra* note 1, at 2-5.

70 A number of states have included animal carcasses, body parts and bedding of animals intentionally exposed to pathogens in waste categories that have already been discussed or in other broad categories. Mississippi considers it a part of "cultures and stocks"; Oregon includes it in "pathological wastes"; Connecticut defines it under "animal carcasses and bedding"; Texas simply considers it "animal waste." Maryland includes both pathological and animal waste in the general category "Anatomical Material." *See supra* note 48 and accompanying citations.

71 Alaska, Illinois, North Carolina, Nebraska and North Dakota constitute the minority. California presently includes such waste, but as in the case of pathological waste, the new act pending will include it only if it is contaminated. *See supra* note 48 and accompanying citations.

72 CENTERS FOR DISEASE CONTROL, GUIDELINES FOR ISOLATION PRECAUTIONS IN HOSPITALS (1983).

73 *See supra* note 1, at 2-3.

74 The fear of AIDS is reflected in some states' coverage of isolation wastes. For example, rather than use the term "isolation waste" in its infectious waste definition, Idaho's regulations cover "items contaminated with blood or body fluids from patients known to be infected with diseases transmitted with body fluid contact." IDAHO CODE § 16.02.1002,19(f) (1990). Although AIDS is not the only disease transmitted by body fluids, it is certainly the most well known and more than likely influenced the drafters wording of their definition.

tion wastes from their infectious waste definition described some of these problems:

> A weakness with this system is the need for an infectious disease diagnosis, which is often difficult to determine. People with specific infections may shed the causative microorganisms whether diagnosed or not, or whether at home or in a medical facility. Many people never exhibit signs of overt infectious disease, yet may be chronic carriers of an infectious disease agent. For these reasons the CDC [Center for Disease Control] is urging health care professionals to consider every patient as a potential source of infection and practice "universal precautions;" a system designed to protect health care professionals from potential infection from any patient, with or without [a] diagnosed infectious disease. The CDC also cautions that the universal precautions system was developed specifically for health care worker protection, and not be applied to waste disposal . . . . There is no evidence to suggest that isolation waste poses any more infection hazard than general waste.[75]

Consequently, only twenty-five states find that the advantages outweigh the disadvantages and presently regulate such waste.[76] This dramatic drop in state regulation indicates the states' reluctance to sweeping regulation without proof of any recognizable danger to the public or health care workers.

G. Optional Miscellaneous Wastes

The EPA's suggestion that wastes from surgery and autopsy, contaminated equipment, laboratory wastes, and dialysis wastes

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75 WASHINGTON STATE INFECTIOUS WASTE PROJECT, *supra* note 12, at 53. Kentucky concurs with the Washington's view. In Ketucky's definition, isolation waste is not to be included unless it specifically falls within one of the four major categories: microbiologicals, blood and blood products, discarded sharps or pathologicals. KENTUCKY DEPARTMENT OF HEALTH, INFECTIOUS WASTE TASK FORCE RECOMMENDATIONS FOR MANAGING INFECTIOUS WASTE (1989).

76 These states include: Alabama, Alaska, Arizona, California, Colorado, Connecticut, Florida, Hawaii, Idaho, Illinois, Louisiana, Minnesota, Mississippi, Missouri, Nebraska, New Hampshire, New Mexico, New York, Ohio, Oklahoma, Pennsylvania, Rhode Island, South Carolina, Vermont, and Washington. *See supra* note 48 and accompanying citations.

California's inclusion of this category is only in the proposed act's definition and not in its old infectious waste definition. Some other distinguishable states are Missouri, which includes waste from Class I or II diseases transmitted by blood and body fluids; Washington, which limited its coverage to "biosafety level 4 disease wastes" in its most recently introduced legislation; and Florida, which covers only isolated waste from "AIDS, hepatitis B or other diseases requiring strict isolation." *See supra* note 48 and accompanying citations.

may pose a health hazard and therefore generators should treat them as infectious waste[77] has met with little favor in state regulations. Laboratory wastes have met the most favorable acceptance with thirteen states including it in their definitions,[78] while surgery and autopsy wastes have met the least favorable acceptance with only six states including it in their definition.[79] The remaining two optional wastes, dialysis unit wastes and contaminated equipment, round out the list with nine[80] and seven states[81] regulating them respectively.

This lack of acceptance primarily reflects the health care industry's distaste for overregulation when no clear showing of danger to the public health or environment has been shown. Further, many of the other categories included in state regulations cover the most infectious parts of these rather general categories. For example, cultures and stocks of infectious agents is a rather large subset, and also the most infectious subset, of laboratory wastes. Also, sharps and blood products definitions is a subset of dialysis wastes. This is the part of dialysis waste that poses the greatest danger of infection to the public. Similarly, autopsy and surgery wastes is a substantial subset of pathological wastes. Health care officials, taking into account the expenses involved, and justifiably so, respond by favoring specific regulation rather than such broad categories.[82] In Alabama, the infectious waste

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77 *See supra* note 47 and accompanying text.

78 These states include Alabama, Alaska, Arizona, California, Delaware, Florida, Maryland, Nebraska, New Hampshire, New York, Ohio, Oklahoma, and Vermont. *See supra* note 48 and accompanying citations.

79 Those states are Alabama, Illinois, Nebraska, New York, Oklahoma, and California (the new Biomedical Waste Management Act gives discretion to the attending physician to decide what is autopsy and surgery waste). *See supra* note 48 and accompanying citations.

80 Alabama, Delaware, Florida, New York, North Dakota, Oklahoma, Pennsylvania, Vermont, and California (old regulations only). *See supra* note 48 and accompanying citations.

81 Georgia, Maryland, Nebraska, New Mexico, Pennsylvania, Vermont, and California (present regulations). *See supra* note 48 and accompanying citations.

82 The distaste for broad categories is reflected in the states that do include some of these categories in their definition by limiting language. Surgery/autopsy wastes has been restricted to instances where the case is infectious (Alabama), contaminated (the new Biomedical Waste Management Act), or the patient is in isolation (New York). Laboratory wastes has been restricted to wastes that come in contact with "pathogenic organisms" (Alabama), "human disease causing agents" (Florida), and "infectious agents" (Ohio). In Florida, dialysis wastes has been limited to cases where "blood or body fluids are visible in the tubing." *See supra* note 48 and accompanying citations.

Rhode Island has vested the generator with discretion to decide whether these wastes should be considered infectious. *See supra* note 48 and accompanying citations.

regulatory agency is presently reviewing the infectious waste regulations because the health care industry has found them to be too stringent. The primary difficulty appears to be the overbreadth of its definition. Alabama presently includes surgery/autopsy wastes, laboratory wastes and dialysis unit wastes in their infectious waste definition.[83]

This desire for a restricted definition of infectious waste is evident in the recently passed California Biomedical Waste Act.[84] California included all four categories in its old regulations, but has decided to limit them in the proposed act. The new act rejects inclusion of dialysis wastes entirely, and limits surgery and autopsy wastes to only those thought contaminated by the attending physician, and restricts contaminated equipment to only equipment contaminated with blood.[85] Laboratory waste is the only optional EPA category that California has carried over completely to the new act.[86]

H. Chemotherapy Waste

Of recent concern in infectious waste disposal, and in particular the defining of infectious waste, is the role of chemotherapy waste. Chemotherapy is generally the use of drugs or medications to treat disease,[87] but it is best known as a treatment for cancer. Chemotherapy often involves the use of antineoplastic agents and cytotoxic drugs which are introduced into the body to disrupt the uncontrolled manner in which cancer cells reproduce.[88] Improper disposal of the waste from such procedures poses substantial health concerns to those handling it. There are strong indications that chemotherapeutic agents are fetotoxic and carcinogenic in humans.[89] Proper disposal is accordingly of great concern.

A few states have addressed this concern in their infectious waste regulations. Pennsylvania treats chemotherapy waste as a special waste in itself,[90] while Alabama, Connecticut and Georgia, consider chemotherapy waste a subset of infectious waste.[91]

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83 ALA. ADMIN. CODE r. 335-13-.03 (1989).

84 CAL. HEALTH & SAFETY CODE § 25020(b) (1990).

85 *Id.*

86 *Id.*

87 Taking penicillin is a simplified form of chemotherapy. NATIONAL CANCER INSTITUTE, CHEMOTHERAPY AND YOU: A GUIDE TO SELF HELP DURING TREATMENT (August 1985) (reprinted 1986).

88 *Id.*

89 *Id.*

90 25 PA. CODE § 271.1 (1988).

91 ALA. ADMIN. CODE r.335-13.03 (1989); CONN. AGENCIES REGS. § 22a-209-15 (a)

Maine, defines chemotherapy waste in its recently adopted regulations and provides that a generator "may" manage chemotherapy waste as biomedical waste, but does not require it.[92] Oklahoma takes a different approach to the problem and splits its definition of infectious waste into two types: Type A-infectious waste and Type B-chemotherapy and chemical waste.[93] Despite little attention from state regulators, the dangerous nature of such waste strongly supports inclusion of such waste in future state regulations.[94]

III. STATE RESPONSE: THE INFECTIOUS WASTE DISPOSAL CHAIN

A. Storage & Segregation of Infectious Waste

State regulation is virtually unanimous in recognizing the propriety of segregating infectious waste from the general waste stream. Segregation serves three functions: (1) it avoids contamination of larger quantities of waste in the general waste stream;[95] (2) it assures that waste that is dangerous to human health and the environment will be specially treated in comparison with normal health care waste;[96] and (3) it assures that the added costs of special handling will not be applied to non-infectious waste thereby keeping the total cost of such a plan to a minimum.[97] While most states only require that generators segregate infectious waste from the general waste stream, New York also requires that generators segregate "regulated medical waste" into "sharps, fluids and other regulated medical waste."[98]

Since same day treatment is not always practical, storage of infectious waste is often required. Most states have recognized this and have regulations governing storage duration, temperature and

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(1990); GA. COMP. R. & REGS. r. 391-3-4-.15(1)(f) (1989).

92 MAINE DEPARTMENT OF ENVIRONMENTAL PROTECTION, BIOMEDICAL WASTE MANAGEMENT RULES ch. 900, § 7 (Dec. 1989).

93 OKLAHOMA STATE DEPARTMENT OF HEALTH, BULLETIN 0524: REGULATIONS GOVERNING SOLID WASTE & SLUDGE MANAGEMENT § 811 (June 23, 1988).

94 Certain chemotherapy agents may also require disposal as hazardous wastes. Seven antineoplastic agents are listed by the EPA as hazardous wastes. They are Chlorambucil, Cyclophosphamide, Daunomycin, Melphalan, Mitomycin C, Streptozotocin, and Uracil mustard. 40 C.F.R. § 261.33 (1990). A generator must also determine whether it is a regulated generator of hazardous waste by determining the total volume of hazardous wastes generated in a month. 40 C.F.R. § 261 (1990).

95 IOWA INFECTIOUS WASTE REPORT, *supra* note 29, at 12.

96 EPA GUIDE, *supra* note 1, at 3-5 & 3-6.

97 *Id.* at 3-13.

98 N.Y. COMP. CODES R. & REGS. tit. 6, § 364.9(2)(d)(1)(i)(b) (1986). Fluid segregation is limited to quantities greater that twenty cubic centimeters. *Id.*

location of the storage area. Although there is no unanimity of opinion on optimum storage time and temperature, most states have established storage requirements as a function of time and temperature.[99] For example, in California a generator cannot store infectious waste for more than four days above a temperature of zero degrees Celsius (32° Fahrenheit) unless approved, but can be kept at a temperature below zero degrees Celsius for up to ninety days.[100] In Delaware, a generator can store infectious waste for up to ninety days in a freezer (-20° to -18° Celsius, -4° to -1° Fahrenheit) forty-five days in a refrigerator (2° to 7° Celsius, 36° to 45° Fahrenheit), and fourteen days at room temperature (12° to 18° Celsius, 54° to 64° Fahrenheit).[101] Pennsylvania and Maine require different time and temperature storage for different kinds of infectious wastes.[102] These examples illustrate

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99 These are important considerations since, as temperature and time increases, the sites of putrefaction and microbial growth increase often resulting in unpleasant odors. *See generally* EPA GUIDE, *supra* note 1, at 3-13; IOWA INFECTIOUS WASTE REPORT, *supra* note 29, at 12.

100 CAL. ADMIN. CODE tit. 22, § 66840(d) (1986). These requirements are included in the new Biomedical Waste Management Act. CAL. HEALTH & SAFETY CODE § 25061(f) (1990).

101 DELAWARE DEPARTMENT OF NATURAL RESOURCES & ENVIRONMENTAL CONTROL, DIVISION OF AIR AND WASTE MANAGEMENT, SOLID WASTE DISPOSAL REGULATIONS § 11(F)(5)(c) (1989). *See also, e.g.,* Mississippi - MISSISSIPPI STATE DEPARTMENT OF HEALTH, PROPOSED STANDARDS FOR THE REGULATIONS OF MEDICAL WASTE (Nov. 6, 1989) (infectious waste can not be stored for more than seven days above a temperature of six degrees Celsius (43° Fahrenheit) and no longer than ninety days at or below a temperature of zero degrees Celsius (32° Fahrenheit); Ohio - OHIO ADMIN. CODE § 3745-27-34(A)(1) (1990); Idaho - IDAHO CODE § 16.02.1550,06 (b)(ii) (1990) (no longer than seven days unless stored at a temperature below 32 degrees Fahrenheit, but in any event no longer than ninety days); North Carolina - N.C. ADMIN. CODE tit. 10, r. 10G.1006(4) (1990) (no longer than seven calendar days unless refrigerated (35 to 45° Fahrenheit) for class A medical waste); Rhode Island - RHODE ISLAND DEPARTMENT OF HEALTH, RULES & REGULATIONS GOVERNING THE MANAGEMENT OF INFECTIOUS WASTE IN HEALTH CARE RELATED FACILITIES AND LABORATORIES R23-16.2-INF & R23-17-INF § 6.1.2 (April 1989) (storage can not exceed nine days in a refrigerator (35° to 45° Fahrenheit) or ninety days in a freezer); Virginia - VIRGINIA DEPARTMENT OF WASTE MANAGEMENT, INFECTIOUS WASTE MANAGEMENT REGULATIONS Part V, § 5.3 (1990) (storage can never exceed thirty days, but if held longer than seventy-two hours it must be frozen within seventy-two hours of generation).

102 Pennsylvania prohibits the storage of infectious waste at a generator for longer than:

> (1) [t]wenty-four hours at room temperature (18° to 28° Celsius for blood, body fluids, body parts and cultures andstocks of etiologic agents;
>
> (2) [t]hree days at room temperature (18° to 28° Celsius) forinfectious waste other than blood, body fluids, body parts andcultures and stocks of etiologic agents;
>
> (3) [f]ive days in a refrigerator (2° to 7° Celsius) notused for food or patient related items; [and]

the large deviation in state time and temperature storage requirements.

In contrast to providing set time and temperature storage requirements, the EPA and some states have only mandated that storage of infectious waste be done in a non-putrescent state or in such a manner as to avoid putrefaction of the waste.[103] Although such generalized regulations are beneficial, they fail to provide the certainty that the health care industry desires and receives in specific time and temperature storage requirements.

In contrast to not enough instruction or guidance, states such as Florida, New York and Arizona are unyielding in their rather strict standards. Florida requires that generators not store infectious waste longer than thirty days,[104] while New York limits generators to a five day storage maximum.[105] In Arizona's recommendations, seventy-two hours is the limit for infectious waste storage.[106] These regulations definitely provide the consistency

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(4) [n]inety days in a freezer (-20° to -18° Celsius) notused for food or patient related items.

25 PA. CODE § 285.132(c) (1988).

Pennsylvania does not make a distinction in terms of time and temperature storage for particular infectious wastes at off-site treatment centers. In such cases, infectious waste may not be stored for more than twenty-four hours at room temperature (18° to 28° Celsius), for five days in a refrigerator (2° to 7° Celsius) or for thirty days in a freezer (-20° to -18° Celsius). *Id.* at § 285.132 (d).

Maine requires pathological waste, animal carcasses, cultures and body parts that are to be stored longer than twenty-four hours be refrigerated at a temperature of forty-five degrees Fahrenheit or below in a refrigerator used only for biomedical waste. MAINE DEPARTMENT OF ENVIRONMENTAL PROTECTION, BIOMEDICAL WASTE MANAGEMENT RULES ch. 900, § 12(D) (Dec. 1989). Maine also provides that all biomedical waste "shall be stored in a manner that . . . is not conducive to microbial growth and/or putrefaction." *Id.* at § 12(D)(3).

103 The EPA recommends that storage time be kept as short as possible. EPA GUIDE, *supra* note 1, at 3-12. The regulations promulgated pursuant to the Medical Waste Tracking Act require infectious waste to be maintained "in a non-putrescent state using refrigeration when necessary." 40 C.F.R. § 259.42(b) (1990). *See infra* notes 230-252 and accompanying text. State regulation examples include: Arkansas - ARKANSAS DEPARTMENT OF HEALTH, DRAFT- RULES AND REGULATIONS PERTAINING TO THE MANAGEMENT OF SPECIAL WASTE FROM HEALTH CARE RELATED FACILITIES § 7(H) (December 4, 1989) (storage of infectious waste is to be kept to a minimum and if infectious waste must be stored it should be kept in a cool, secure location); Connecticut - CONN. AGENCIES REGS. § 22a-209-15(c)(4) (1990) (infectious waste must be maintained in a non-putrescent state and may be refrigerated); Indiana - IND. ADMIN. CODE tit. 410, r. 1.3, § 25(2) (1989) (infectious waste shall be protected from putrefaction); Wisconsin - WISCONSIN DEPARTMENT OF NATURAL RESOURCES, GUIDELINES FOR THE HANDLING AND TREATMENT OF MEDICAL/INFECTIOUS WASTE Part IV(C) (May 1989) (infectious waste shall be maintained in a non-putrescible state and may be refrigerated when appropriate).

104 FLA. ADMIN. CODE ANN. r. 10D-104.004(1) & r. 17-712.420(6) (1989).

105 N.Y. COMP. CODES R. & REGS. tit. 6, § 360-10.5(a) (1988).

106 Westell, *Summary of Medical Waste Management in Arizona* 4 (August 1989) (copy

and certainty that the generalized storage regulations do not provide, but the standards' inflexibility on refrigeration and freezing outweigh these advantages.

Other state regulation of storage areas include: limiting access of on-site storage areas to authorized employees;[107] posting of the universal biohazard symbol or other indicator on storage areas to ward off unsuspecting intruders;[108] maintaining storage areas to assure that they are protected from the weather and are free of rodents and vermin;[109] and placing locks on outside storage areas including dumpsters, sheds, and tractor trailers.[110] The

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on file at the *Notre Dame Law Review*).

107 The following states include the regulation: Idaho, Indiana, Maine, Minnesota, New York, and Ohio. IDAHO CODE § 16.02.1550.06(b)(1) (1990); IND. ADMIN. CODE tit. 410, r.1.3 §25(1)(a) (1989); MAINE DEPARTMENT OF ENVIRONMENTAL PROTECTION, BIOMEDICAL WASTE MANAGEMENT RULES ch. 900, §12(D)(2) (Dec. 1989); MINN. STAT. §116.78(6) (Supp. 1989); N.Y. COMP. CODES R. & REGS. tit. 6, §360-10.5(c) (1988); OHIO ADMIN. CODE § 3745-27-35(A)(4) (1990).

The regulations promulgated to the Federal Medical Waste Tracking Act also provide for limited access. 40 C.F.R. § 259.42(d) (1990).

108 The following states include the regulation: California, Idaho, Indiana, Maine, Mississippi, New York and Rhode Island. CAL. ADMIN. CODE tit. 22, §66840 (1985) (old regulations); CAL. HEALTH & SAFETY CODE § 25065 (1990) (Biomedical Waste Management Act); IDAHO CODE § 19.02.1550,06 (1990); IND. ADMIN. CODE tit. 410, r. 1.3 § 25(1)(c) (1989); MAINE DEPARTMENT OF ENVIRONMENTAL PROTECTION, BIOMEDICAL WASTE MANAGEMENT RULES ch. 900, § 12(d)(6) (Dec. 1989); MO. CODE REGS. tit 19, § 30-20.021(3) (1988); N.Y. COMP. CODES R. & REGS. tit. 6, § 360-10.5(c) (1986)(warning signs must be visible from twenty-five feet).

California's new Biomedical Waste Management Act is rather unusual in that it requires the signs to be in English and Spanish or other language. The term "other language" was added in the proposed biomedical waste management act to provide for the high number of Gaelic speaking individuals in the health care industry. CAL. HEALTH & SAFETY CODE § 25065 (1990).

109 This regulation is rather popular. The following states include the regulation: Arkansas, California, Delaware, Hawaii, Georgia, Idaho, Indiana, Minnesota, New York, Ohio, Pennsylvania, and South Carolina. ARKANSAS DEPARTMENT OF HEALTH, DRAFT - RULES AND REGULATIONS PERTAINING TO THE MANAGEMENT OF SPECIAL WASTE FROM HEALTH CARE RELATED FACILITIES § VII(a) (Dec. 4, 1989) (adopted without change); CAL. ADMIN. CODE tit. 22, § 66840(b) (1985); CAL. HEALTH & SAFETY CODE § 25065 (1990); DELAWARE DEPARTMENT OF NATURAL RESOURCES & ENVIRONMENTAL CONTROL, DIVISION OF AIR & WASTE MANAGEMENT § 11, Part 1, F(5)(a) (1)&(3) (1989); HAWAII DEPARTMENT OF HEALTH, MANAGEMENT AND DISPOSAL OF INFECTIOUS WASTE § 11-104-8(a) (1989); IDAHO CODE § 16.02.1550,06 (b)(1) (1990); GA. COMP. R. & REGS. r. 391-3-4-.15(3) (1989); IND. ADMIN. CODE tit. 410, r.1.3 § 25(1)(b) (1989); MINN. STAT. § 116.78(6) (Supp. 1989); N.Y. COMP. CODES R. & REGS. tit. 6, § 360-10.5(b) (1988); OHIO ADMIN. CODE §3745-27-35(A)(5) (1990); 25 PA. CODE § 285.132(a) (1988); S.C. CODE ANN. § 44-93-60 (Law. Co-op. 1989).

The federal program also requires protection from vermin and the weather. 40 C.F.R. § 259.42(a) & (e) (1990).

110 Connecticut, Michigan, New York, Ohio, Pennsylvania and South Carolina. CONN. AGENCIES REGS. § 22a-209-15(c) (1990); MICHIGAN DEPARTMENT OF PUBLIC HEALTH,

regulatory agencies formulate these provisions to avoid public exposure to, and further transfer of, any pathogenic organisms. For example, limited access to authorized employees attempts to avoid inadvertent exposure of people to dangerous waste, while locked-outside storage chambers prevent curious children and desperate street people from endangering themselves.[111] Such regulations are common, sensible and serve a vital function in deterring the spread of dangerous microorganisms from waste storage sites.

B. The Packaging and Containment of Infectious Waste

Infectious waste packaging and containment is vitally important to ensure the protection of infectious waste handlers and the public from inadvertent exposure to pathogenic organisms, and in particular, the accidental "sticking" of individuals by sharps. In order to minimize exposure and accidental "sticking," generators and handlers should contain infectious waste from the generation point to the treatment and disposal point.[112] Accordingly, handlers must preserve the integrity of packaging through handling, storage, transportation and treatment.[113] In regulating packaging, state regulators have generally addressed three areas: (1) the type of infectious waste; (2) package identification; and (3) the treatment technique.

1. Waste Type

Handlers of infectious waste commonly segregate infectious waste into containers designed for each particular waste type. States generally require solid and semi-solid wastes to be placed into disposable, leak-proof containers or plastic bags. These containers and plastic bags are usually red or orange to indicate to handlers that they are dealing with infectious waste. This practice has led waste disposal workers to refer to infectious waste as "red

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MEDICAL WASTE EMERGENCY RULES Rule 2(4) (April 26, 1989); N.Y. COMP. CODES R. & REGS. tit. 6, § 360-10.5(b) (1988); OHIO ADMIN. CODE §3745-27-35(A)(5) (1990); 25 PA. CODE § 285.132(a) (1988); S.C. CODE ANN. § 44-93-60 (Law. Co-op. 1989).

States subject to the Medical Waste Tracking Act are also required to lock storage areas. 40 C.F.R. § 259.42(c) (1990).

111 *See supra* note 25, for an example of street people going through infectious waste garbage.

112 EPA GUIDE, *supra* note 1, at 3-8.

113 *Id.*

bag waste."[114] The increased danger sharp waste poses to waste handlers because of its ability to puncture a handler's skin, has led to the use of rigid, leak-proof, puncture-resistant, and break-resistant containers. Handlers can tightly lid these containers for storage, handling and transport to avoid spillage. The final waste packaging category is liquid wastes. The states that regulate such waste have generally required generators to segregate the wastes into leakproof containers that can be transported off-site without spillage.

(a) Non-Sharp Wastes.—States vary in the degree to which they regulate bag strength. Some states only require that the bag be impervious, burst-proof, and leak-proof.[115] Other states require bags to meet certain durability tests. For example, Virginia requires non-sharp waste to be bagged in two red plastic bags that satisfy the American Society for Testing and Materials ("ASTM") 125 pound drop-weight test or one bag satisfying the test placed inside a double-walled corrugated fiberboard box.[116] California, Minnesota, Ohio, and Wisconsin, on the other hand, use a 165 gram dropped-dart-impact test to test the durability of bags.[117] In addition, Ohio requires all bags to pass a "water test."[118] Each bag must be able to hold twenty-five pounds of water for thirty seconds. Florida is likely the most stringent state in testing bag durability. It requires generators to use red polyethylene or polypropylene bags that meet the 165 gram ASTM impact-resistance test and the 480 gram ASTM resistance test.[119] In

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114 Garvin, *Reducing Infectious Waste Volumes*, WASTE AGE, July, 1990, at 67.

115 *See, e.g.*, Westell, *Summary of Arizona Medical Waste Management in Arizona* 4 (August 1989); ARKANSAS DEPARTMENT OF HEALTH, DRAFT - RULES AND REGULATIONS PERTAINING TO THE MANAGEMENT OF SPECIAL WASTE FROM HEALTH CARE RELATED FACILITIES § VII(b) (Dec. 4, 1989) (adopted without change); GA. COMP. R. & REGS. r. 391-3-4.15(3)(b)(1) (1989); HAWAII DEPARTMENT OF HEALTH, MANAGEMENT AND DISPOSAL OF INFECTIOUS WASTE § 11-104-8 (1989); IDAHO CODE § 16.02.1550,06(b)(i), (ii) (1990); IND. ADMIN. CODE tit. 410, r. 1-3-24(c) (1989); N.Y. COMP. CODES R. & REGS. tit. 6, § 360-10.5(e) (1988); NORTH DAKOTA STATE DEPARTMENT OF HEALTH, STATEMENT OF POLICY: DISPOSAL OF LONG TERM CARE FACILITY WASTES 1 (1988).

116 VT. ADMIN. PROC. COMP. Dept. of Envtl. Conserv. § 4.2(B)(1) (1990). Virginia also requires that if the waste is to be steam sterilized in an autoclave, orange bags with autoclave tape must be used. *Id.*

117 California used this test under the earlier regulations and has incorporated it in the Biomedical Waste Management Act.

118 OHIO ADMIN. CODE § 3745-27-34(A)(1) (1990).

119 FLA. ADMIN. CODE ANN. r. 17-712.400(3)(a) (1989) (off-site biohazardous waste transport).

addition, all generators must keep the manufacturer's testing results on file.[120]

Unlike the states that use performance tests for durability, such as ASTM tests, some states require minimum thickness requirements. North Carolina, for example, requires handlers to package non-sharp waste in two bags each of which must be at least three mils (.003 inches) thick.[121] In contrast, Mississippi requires handlers to package non-sharp waste in bags that are only 1.5 mils thick.[122] A generator in Mississippi can also choose between single or double bagging.[123] Nonetheless, in terms of effectiveness, the Washington State Infectious Waste Project,[124] concluded that an ASTM or other performance test, rather than any millage requirement was the most appropriate form for insuring durability since "millage or bag thickness [has] no bearing on a plastic bag's durability."[125] Proper performance, rather than bag thickness, should be the minimum required of all bags.

In addition to non-sharp waste bagging, a number of states require handlers to place bags in rigid exterior containers if the waste will be transported off-site.[126] Some states offer the use of

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120 *Id.* r. 17-712.400(3)(a)(2).

121 Delaware, Maryland, Massachusetts, New Hampshire, and Rhode Island are some other states that require bags to be at least three mils thick although not all require two bags. DELAWARE DEPARTMENT OF NATURAL RESOURCES AND ENVIRONMENTAL CONTROL, DIVISION OF AIR & WASTE MANAGEMENT § 11(F)(2)(a) (1989); MD. REGS. CODE tit. 26, § 13.12.05(A)(2) (1989) (bag or bags must have combined thickness of three mils); MASS. REGS. CODE tit. 105, § 480.100(D) (1989) (three mils or greater single bagged); N.C. ADMIN. CODE tit. 10, r. 10G.1004(a)(1) (Class A Medical Waste) & r. 10G.1008(a)(1) (Class B Medical Waste) (1990); N.H. CODE ADMIN. R. He-P 1901.08(b)(3) (1984) (two bags separately sealed); RHODE ISLAND DEPARTMENT OF HEALTH, RULES & REGULATIONS GOVERNING THE MANAGEMENT OF INFECTIOUS WASTE IN HEALTH CARE RELATED FACILITIES AND LABORATORIES R23-17-INF & R23-16.2-INF § 5.2.1 (April 1989); 25 PA. CODE §§ 285.132(f)(1) & 285.133(d)(1)(chemotherapy waste) (1988) (two bags with a combined thickness of at least three mils).

122 MISSISSIPPI STATE DEPARTMENT OF HEALTH, PROPOSED STANDARDS FOR THE REGULATION OF MEDICAL WASTE § I(E) (Nov. 6, 1989).

123 *Id.*

124 *See supra* note 12.

125 WASHINGTON STATE INFECTIOUS WASTE PROJECT, *supra* note 12, at 56-57.

126 *See, e.g.*, CAL. HEALTH & SAFETY CODE § 25061(c), (d) (1990) (requiring exterior containers for all storage, handling or transport of infectious waste); DELAWARE DEPARTMENT OF NATURAL RESOURCES AND ENVIRONMENTAL CONTROL, DIVISION OF AIR & WASTE MANAGEMENT, SOLID WASTE DISPOSAL REGULATIONS § F(2)(d) (1989) (requiring bags to be placed in a double-walled corrugated, fiberboard box); FLA. ADMIN. CODE r. 17-712(2)(h) (1989) (requiring bags to be placed in a "rigid type container"); MASS. REGS. CODE tit. 105, § 480.300(B)(1)(a) (1989); OHIO ADMIN. CODE § 3745-27-34(A)(4) (1990) (requiring bags to be put in a second bag meeting the 165 gram dropped-dart-impact test or a rigid container if infectious waste is transported off-site); 25 PA. CODE § 285.222(b) (1988) (granting an option of two bags with six mils total thickness, two bags

the rigid container as an alternative to the bagging of non-sharp waste,[127] while other states require handlers to bag the waste and to place it in a rigid, exterior container.[128] The most popular container is the double-walled, corrugated, fiberboard or cardboard box. Rigid or semi-rigid plastic drums that can be reused after decontamination[129] are also popular.

As in the case with bags, some states have required the exterior container to meet minimum standards. North Carolina requires its fiberboard box to have a 175 pound burst-strength.[130] Florida's Department of Health and Rehabilitative Services, which regulates infectious waste at the site of generation, initially required bagged biohazardous waste that was to be transported off-site prior to final treatment or disposal to be placed in a fiberboard box with a 275 pound burst-strength. The Agency eventually found the box too costly for transporters and reduced the minimum strength to 200 pounds.[131] Florida's Department of Environmental Regulation, which regulates off-site infectious waste handling and disposal, however, still requires a 275 pound burst-strength box.[132] State regulators will likely correct this inconsistency, but it illustrates the problems created by splitting regulatory authority between state agencies.[133]

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with total thickness of three mils and a fiberboard container, or a leakproof rigid container that is tightly lidded).

127 *See, e.g.*, ORE. REV. STAT. § 459.390 (Supp. 1990); 25 PA. CODE § 285.132(f) (1988); S.C. CODE ANN. § 44-93-60(c) (Law Co-op 1989).

128 *See, e.g.*, La. Reg. ch. XXVII § 27:020(f) (Jan. 20, 1990); MD. REGS. CODE tit. 26, § 13.12.05(A)(2) (1989) (anatomical materials only); N.J. ADMIN. CODE tit. 7, § 26-3A.11(b) (1989); N.C. ADMIN. CODE tit. 10, r. 10G.1004(a)(1)(Class A) & r. 10G.1008(a)(1) (Class B) (1990) (both regulations require handlers to place bags in 175 lb. burst strength corrugated fiberboard boxes); VIRGINIA DEPARTMENT OF WASTE MANAGEMENT, INFECTIOUS WASTE MANAGEMENT REGULATIONS § 4.2(B)(1) (1990) (requiring handlers to double bag waste and place the bags in a "double walled corrugated fiberboard box or equivalent rigid container").

129 Many states do not require disinfection if a red bag liner is used. *See, e.g.*, IDAHO CODE § 16.02.1002,19 (1990); MAINE DEPARTMENT OF ENVIRONMENTAL PROTECTION, BIOMEDICAL WASTE MANAGEMENT RULES (Dec. 1989).

130 N.C. ADMIN. CODE tit. 10, r. 10G.1004(a)(1) (Class A Medical Waste) & r. 10G.1008(a)(1) (Class B Medical Waste) (1990).

131 FLORIDA DEPARTMENT OF HEALTH AND REHABILITATIVE SERVICES, SUMMARY OF CHAPTER 10D-104 DRAFT 1 (1989) (copy on file at the *Notre Dame Law Review*). The Florida Department of Health and Rehabilitative Services estimated that this reduction would decrease costs by forty percent and still ensure safety. *Id. See* FLA. ADMIN. CODE ANN. r. 10D-104.006(8) (1989).

132 FLA. ADMIN. CODE ANN. r. 17-712.400(h) (1989).

133 Maine concurs with Florida in requiring a 200 pound burst-strength. MAINE DEPARTMENT OF ENVIRONMENTAL PROTECTION, BIOMEDICAL WASTE MANAGEMENT RULES ch. 900, § 12(A)(6) (Dec. 1989).

(b) Sharp Wastes.—One area of unanimity in the health care and waste management industry is the propriety of using rigid or semi-rigid, puncture-resistant containers in the packaging of sharp wastes. These containers eliminate the hazard of physical injury, most notably accidental sticking.[134] Suitable containers include glass, metal, rigid plastic, wood and heavy cardboard.[135] These containers are usually required to be taped closed or tightly lidded. It is also common practice to prohibit the clipping, bending or breaking of needles to prevent the possible release of airborne pathogens and aerosols into the environment.[136] There is some unusual state regulation in this area. For example, New Hampshire requires generators and handlers to place sharps in polyethylene bags *before* they are encased in rigid containers.[137] In contrast, Virginia requires generators and handlers to place sharps in a non-sharp waste bag *after* they are enclosed in a puncture-resistant container.[138]

(c) Liquid Wastes.—States that regulate the disposal of liquid or semi-liquid wastes such as blood and other body fluids require the packaging of fluids in tightly lidded or stoppered flasks.[139] States predominantly require these containers to be leakproof and break-proof.[140] These states often restrict regulation of such

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134 *See* WASHINGTON STATE INFECTIOUS WASTE PROJECT, *supra* note 12, at 57. *See also* EPA GUIDE, *supra* note 1, at 3-8.

135 Coffee cans are particularly well-suited for home health care patients.

136 *See, e.g.*, MAINE DEPARTMENT OF ENVIRONMENTAL PROTECTION, BIOMEDICAL WASTE MANAGEMENT RULES ch. 900, § 12(A)(4) (Dec. 1989); RHODE ISLAND DEPARTMENT OF HEALTH, RULES & REGULATIONS GOVERNING THE MANAGEMENT OF INFECTIOUS WASTE IN HEALTH CARE RELATED FACILITIES AND LABORATORIES R23-17-INF & R23-16.2-INF, § 10.3.1(a) (April 1989). *See generally* ENVIRONMENTAL PROTECTION AGENCY, MEDICAL WASTE MANAGEMENT IN THE UNITED STATES - FIRST INTERIM REPORT TO CONGRESS 6-12 (May 1990) [hereinafter EPA'S FIRST REPORT].

137 N.H. CODE ADMIN. R. He-P 1901.08(b)(3) (1984).

138 VIRGINIA DEPARTMENT OF WASTE MANAGEMENT, INFECTIOUS WASTE MANAGEMENT REGULATIONS § 4.2(B)(1) (1990).

139 *See, e.g.*, CONN. AGENCIES REGS. § 22a-209(15)(b)(4)(C) (1990); MAINE DEPARTMENT OF ENVIRONMENTAL PROTECTION, BIOMEDICAL WASTE MANAGEMENT RULES ch. 900, § 12(A)(6) (Dec. 1989); N.J. ADMIN. CODE tit. 7, § 26-3A.11(c)(2) (1989); OKLAHOMA STATE DEPARTMENT OF HEALTH, BULLETIN 0524: REGULATIONS GOVERNING SOLID WASTE & SLUDGE MANAGEMENT § 872 (June 23, 1988) (applies specifically to chemical wastes); RHODE ISLAND DEPARTMENT OF HEALTH, RULES & REGULATIONS GOVERNING THE MANAGEMENT OF INFECTIOUS WASTE IN HEALTH CARE RELATED FACILITIES AND LABORATORIES R23-17-INF & R23-16.2-INF, § 5.2.3 (April 1989).

140 *See id.*

waste by setting a minimum volume that is subject to regulation.[141]

2. Labeling

The labeling of infectious waste is an important feature of any packaging regulation since it informs individuals to be particularly careful with the handling or disposal of the waste. Although the color of bagged waste and sharp containers, red or orange, is the most noticeable and common feature of packaged infectious waste, many states have required additional labeling. These regulations commonly require the printing of the words "infectious waste," "biohazardous waste," or "medical waste" or more commonly the printing of the universal biohazardous symbol[142] on the bag or exterior container. Some states require one or the other, while other states require both. Connecticut, for example, requires a water-resistant label displaying a biohazardous symbol or the words "medical" or "infectious waste."[143] In contrast, Maine affirmatively requires the biohazardous symbol and the words "infectious" or "biohazardous waste." Delaware requires the words "infectious waste" or, in the alternative the word "biohazard" and the universal biohazard symbol.[144]

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141 *See, e.g.*, CONN. AGENCIES REGS. § 22a-209(15)(b)(4)(C) (1990); N.J. ADMIN. CODE tit. 7, § 26-3A.11(c)(2) (1989) (twenty cubic centimeters).

142 *See* EPA GUIDE, *supra* note 1, at 3-7 for an illustration of the biohazardous symbol.

143 CONN. AGENCIES REGS. § 22a-209-15(b)(7) (1990). Other states that give an option include: Delaware - DELAWARE DEPARTMENT OF NATURAL RESOURCES AND ENVIRONMENTAL CONTROL, DIVISION OF AIR & WASTE MANAGEMENT, SOLID WASTE DISPOSAL REGULATIONS § 11(F)(5)(f) (1989); Minnesota - MINN. R. § 7035.9120(1)(E) (1989) (biohazardous symbol or infectious waste); Missouri - MISSOURI DEPARTMENT OF NATURAL RESOURCES, MANAGEMENT OF INFECTIOUS WASTE BY SMALL QUANTITY GENERATORS 3 ("infectious waste" or "biohazard"); and Georgia - GA. COMP. R. & REGS. r. 391-3-4-.15(3)(d) (1989) (biohazardous symbol and biohazardous waste). Some states that require a specific label include: Massachusetts - MASS. REGS. CODE tit. 105, § 480.300 (A)(1) (1989) (requiring biohazardous symbol and an indication that the package contains sharps); New York - N.Y. COMP. CODES & REGS. tit. 6, § 360-10.5(d) & (f) (1986) (must be labelled "infectious"); N.Y. ENVTL. CONSERV. LAW § 27-1505(3) (McKinney 1988) (permitting the words "infectious" or "regulated medical waste"); Oklahoma - OKLAHOMA STATE DEPARTMENT OF HEALTH, BULLETIN 0524: REGULATIONS GOVERNING SOLID WASTE & SLUDGE MANAGEMENT § 871 (biohazardous symbol); Pennsylvania - 25 PA. CODE § 285.132(h) (1988) ("infectious waste," "biohazard," or biohazardous symbol); Rhode Island - RHODE ISLAND DEPARTMENT OF HEALTH, RULES & REGULATIONS GOVERNING THE MANAGEMENT OF INFECTIOUS WASTE IN HEALTH CARE RELATED FACILITIES AND LABORATORIES R23-17-INF & R23-16.2-INF (April 1989) (biohazardous symbol); and Wisconsin - WISCONSIN DEPARTMENT OF NATURAL RESOURCES, GUIDELINES FOR THE HANDLING AND TREATMENT OF MEDICAL/INFECTIOUS WASTE Part III, (B) & (C) (May 1989) (biohazardous symbol).

144 DELAWARE DEPARTMENT OF NATURAL RESOURCES AND ENVIRONMENTAL CONTROL,

A labeling technique that has recently received increased acceptance is the placing of tags directly on or affixing them to bags, sharp containers, or exterior containers. These tags usually contain such relevant information as the generator's name, the amount or weight of the waste, and the ultimate destination or disposal facility. A typical tag is 3 x 5 inches and requires the use of indelible ink in filling out the tag.[145]

An unusual form of labeling exists in New York. Although passed for enforcement purposes rather than for the protection of handlers, New York's regulation requires all generators to *insert* two floatable identification tags into all red bagged waste.[146] These tags must have the generator's name and address imprinted on them.[147] The regulators apparently hope that any waste found illegally disposed, whether separated from the initial container or not, will include the violating generator's identification tags. The tags are required to float as a result of the recent problems that New York and New Jersey have had with beach washups of medical waste.[148] Oddly, at the time this regulation was originally enacted, there were no vendors that manufactured or distributed such tags.[149]

3. The Treatment of Infectious Waste

In developing packaging regulations, state regulators have also considered the treatment technique used to render waste non-infectious. As will be discussed later,[150] the most common procedures for rendering infectious waste non-infectious are incineration and steam sterilization. Both, however, have different packag-

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DIVISION OF AIR & WASTE MANAGEMENT, SOLID WASTE DISPOSAL REGULATIONS § 11(F)(5)(f) (1989). *See also, e.g.*, MAINE DEPARTMENT OF ENVIRONMENTAL PROTECTION, BIOMEDICAL WASTE MANAGEMENT RULES ch. 900, § 12(A)(2) (Dec. 1989). *See also* VIRGINIA DEPARTMENT OF WASTE MANAGEMENT, INFECTIOUS WASTE MANAGEMENT REGULATIONS § 4.2(c) (1990) (requiring "infectious waste" and the biological hazard symbol); and N.Y. COMP. CODES R. & REGS. tit. 6, § 360-10.5(d) & (f) (1986) (requiring the word "infectious").

145 *See, e.g.*, DELAWARE DEPARTMENT OF NATURAL RESOURCES AND ENVIRONMENTAL CONTROL, DIVISION OF AIR & WASTE MANAGEMENT, SOLID WASTE DISPOSAL REGULATIONS § 11(F)(3) (1989); MAINE DEPARTMENT OF ENVIRONMENTAL PROTECTION, BIOMEDICAL WASTE MANAGEMENT RULES ch. 900, § 12(B) (Dec. 1989); VIRGINIA DEPARTMENT OF WASTE MANAGEMENT, INFECTIOUS WASTE REGULATIONS § 4.2(c) (1990).

146 N.Y. COMP. CODES R. & REGS. tit. 6, § 364.9(b) (1986).

147 *Id.*

148 *See supra* note 1 and accompanying text.

149 Leland, *State Legislation on Disposal of Infectious Waste*, 200 N.Y.L.J., at 1, col. 1 (Dec. 1, 1988).

150 *See infra* notes 156-209 and accompanying text.

ing considerations. Incineration requires containers to be combustible, while effective steam sterilization requires that packaging allow sufficient steam penetration and evacuation of air.[151] Accordingly, a single packaging technique may not suit all treatment processes. High density plastics, for example, prevent effective treatment of infectious waste by trapping air within the bags and by impeding steam penetration.[152] Substitution of a low density plastic, however, often results in less bag strength.[153] The EPA, therefore, recommends that handlers place low density bags within heat-resistant containers to prevent waste seepage during steam sterilization.[154]

Despite the EPA's proper packaging discussion and its correlation to effective treatment, state regulators have apparently ignored these concerns.[155] Bag strength has received much more attention. Although proper containment, i.e. bag strength, protects the public from pathogenic organisms and accidental sticking by sharps, state regulators should not view bag strength as a substitution for proper disinfection of the waste.

C. The Treatment and Disposal of Infectious Waste

Infectious waste treatment and its final disposal has been and must continue to be, a primary concern of all state regulators. Improper disposal of infectious waste is the major contributor to the recent medical waste controversy, while improper treatment is a fundamental consideration in deterring the spread of infectious disease from mismanaged infectious waste. Accordingly, this part of the Note, discusses the varying treatment methods as well as their advantages and disadvantages.

1. Incineration

Incineration or combustion is the process whereby infectious waste is converted by fire or intense heat into non-combustible residue or ash.[156] Properly designed and operated incinerators

151 EPA GUIDE, *supra* note 1, at 3-10.

152 *Id.*

153 *Id.*

154 *Id.* at 3-11.

155 Oklahoma is an exception in that it requires that incineration be done in a combustible container. OKLAHOMA STATE DEPARTMENT OF HEALTH, BULLETIN 0524: REGULATIONS GOVERNING SOLID WASTE & SLUDGE MANAGEMENT § 870 (June 23, 1988).

156 *See generally* EPA GUIDE, *supra* note 1, at 4-7. A generator that operates an on-site incinerator or any incinerator that accepts infectious waste for treatment should be

have been found effective in killing the pathogenic organisms present in infectious waste.[157] It is presently the preferred form of treatment for generators.[158] The AHA recently estimated that sixty-seven percent of the nearly 6,900 hospitals in the country use on-site incinerators.[159]

There are a number of reasons for incineration's popularity. First, incinerators reduce the volume and mass of material that generators must dispose of in landfills by eighty to ninety-five percent.[160] Second, incineration often transforms unaesthetic waste into a less recognizable form.[161] Third, as the AHA statistic illustrates, incineration is often an on-site treatment method thus reducing the cost of transporting infectious waste off-site for treatment. A final advantage of incineration, and one that generators and treatment facilities will see increased use of, is the recovery of heat from the incineration process.[162] The treatment facility can use the recovered heat from the process to generate steam which in turn can be converted into electricity.[163] This is an advantage that usually only large systems can recognize.[164]

There are, however, disadvantages to the incineration of infectious waste. First, incinerators often emit dangerous pollutants in the process. Infectious waste contains up to thirty percent more plastics than municipal solid wastes, which correlates to more dangerous pollutants.[165] Second, proper operation of an

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aware that the residue ash may be a hazardous waste and subject to federal and state regulations. The regulation of residual ash, however, is outside the scope of this Note.

157 *Id.*

158 In a recent survey reported by the AHA, approximately sixty-seven percent of United States hospitals incinerate their infectious waste, sixteen percent use only autoclave systems and fifteen percent use off-site treatment. Hall, *Infectious Waste Management: A Multi-faceted Problem*, POLLUTION ENGINEERING, Aug., 1989, at 76.

159 Etter, Kiser, and Shuler, *Medical Waste Combustion: Current and Future Prospects*, WASTE AGE 77, 77 (July 1990).

160 EPA'S FIRST REPORT, *supra* note 136, at 6-4. The Washington State Task Force found that the weight of waste was reduced by seventy-five percent while volume was reduced by ninety percent. WASHINGTON STATE INFECTIOUS WASTE PROJECT, *supra* note 12, at 85.

161 EPA'S FIRST REPORT, *supra* note 136, at 6-4.

162 *Id.*

163 *Id.*

164 Etter, Kiser, and Shuler, *supra* note 159, at 77.

165 The primary pollutants of concern, according to the EPA's Air and Energy Engineering Research Laboratory, are particulate matter, hydrogen chloride, sulfur dioxide, trace organics (dioxans and furans), and trace metals. Etter, Kiser, and Shuler, *supra* note 159, at 77-78. In response, the Washington State Infectious Waste Project has estimated that air emissions can be reduced by more than ninety-nine percent for properly designed and maintained incinerators that have been fitted with appropriate air

incinerator is difficult.[166] Accordingly, in order to ensure proper treatment and complete waste reduction, trained operators are required.[167] Third, incinerators present a "moderate risk" to operators due to the high operating temperatures and potential for fires associated with operation.[168] Fourth, incinerators create monitoring problems due to the difficulty of testing the effectiveness of an incinerator in destroying pathogens.[169] Finally, incinerator ash may be a hazardous waste subject to federal and state hazardous waste disposal regulations.[170]

The EPA has identified three factors to consider when infectious waste is to be incinerated: (1) variation in waste composition; (2) waste feed rate; and (3) combustion temperature.[171] Variation in waste composition affects incineration conditions due to variations in moisture content.[172] Waste feed rate is important since overloading of an incinerator will result in incomplete incineration and unsatisfactory treatment.[173] Therefore, it is important to adjust loading rate and incineration temperature to ensure proper incineration and destruction of pathogenic organisms. Incineration temperature is important in ensuring proper combustion of all infectious waste in the chamber.[174] Adjustments in the amount of air and fuel used are often necessary as the composition of waste changes.

Every state in the nation presently allows some incineration of infectious waste. Maine requires all biomedical waste, except pathological waste, which may also be interred, and blood and body products, which may be discharged into a public sewer system, to be incinerated.[175] Texas has gone so far as to require each

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pollution equipment and which are run by trained operators. WASHINGTON STATE INFECTIOUS WASTE PROJECT, *supra* note 12, at 85.

166 There are generally three kinds of incinerators: controlled air, multiple chamber air, and rotary kiln. All three vary in complexity, but a discussion of the individual features of each is outside the scope of this Note. *See generally* EPA'S FIRST REPORT, *supra* note 136, at 6-2 to 6-4; Etter, Kiser, and Shuler, *supra* note 159, at 77-78.

167 EPA'S FIRST REPORT, *supra* note 137, at 6-5.

168 *Id.*

169 The most popular way to ensure proper destruction of all pathogens is the running of a test treatment utilizing the very resilient *Bacillus Sterothermophilus*. If a test is successful, an operator is ensured that most if not all dangerous pathogens have been destroyed. Many states require periodic tests of effectiveness under this test.

170 EPA'S FIRST REPORT, *supra* note 136, at 6-5.

171 EPA GUIDE, *supra* note 1, at 4-8.

172 *Id.*

173 *Id.*

174 *Id.*

175 MAINE DEPARTMENT OF ENVIRONMENTAL PROTECTION, BIOMEDICAL WASTE MAN-

each hospital to have an on-site incinerator.[176] Nonetheless, regulation of the incineration process, especially incineration temperature, is as inconsistent as any state regulations on infectious waste.[177]

State regulation of incineration temperature usually requires a minimum temperature and time requirement for the two separate chambers in an incinerator. States have generally required the secondary chamber, which heats all aerosols and gases emitted by the primary chamber, to have a higher minimum temperature than the primary chamber. This temperature has ranged from as low as 1600 degrees Fahrenheit[178] to as high as 2,000 degrees Fahrenheit,[179] with 1800 degrees Fahrenheit being the average.[180] The minimum temperature in the primary chamber, for those states that regulate it, ranges from 1200 degrees Fahrenheit in Ohio,[181] 1400 degrees Fahrenheit in Oklahoma[182] and Virginia,[183] and 1600 degrees Fahrenheit in North Carolina.[184]

States also require a minimum residence time in the secondary chamber to ensure proper destruction of all pathogens within the waste. These range from as low as one-half second[185] to as high as two seconds[186] with one second being the average.[187]

AGEMENT RULES ch. 900, § 10(A) - (C) (Dec. 1989).

176 TEX. REV. CIV. STAT. ANN. art. 4437f, ch. 2. § 11.1.3 (1986).

177 State regulators often require infectious waste incinerators to obtain a permit from a state regulatory agency before they can accept infectious waste for combustion. Although this is outside the scope of this Note, a diligent practitioner should check that a client who desires to incinerate infectious waste has received such a permit if it is required.

178 OHIO ADMIN. CODE § 3745-27-32(A)(1) (1990).

179 OKLAHOMA STATE DEPARTMENT OF HEALTH, BULLETIN 0524: REGULATIONS GOVERNING SOLID WASTE & SLUDGE MANAGEMENT § 841 (June 23, 1988).

180 GA. COMP. R. & REGS. r. 391-3-4.15(5)(A)(1)(i) (1988); MAINE DEPARTMENT OF ENVIRONMENTAL PROTECTION, BIOMEDICAL WASTE MANAGEMENT RULES ch. 900, § 18(F)(1) (Dec. 1989); MINN. R. 7005.0630 (1989); MO. CODE REGS. tit. 19, § 30-20.021(5)(D)(4) (1988); N.C. ADMIN. CODE tit. 10, r. 10G.1007(2)(a) (1990) (1850 degrees Fahrenheit); VIRGINIA DEPARTMENT OF WASTE MANAGEMENT, INFECTIOUS WASTE MANAGEMENT REGULATIONS § 7.1(A) (1990); WISCONSIN DEPARTMENT OF NATURAL RESOURCES, GUIDELINES FOR THE HANDLING AND TREATMENT OF MEDICAL/INFECTIOUS WASTE app. A (May 1989).

181 OHIO ADMIN. CODE § 3745-27-30(A)(1) (1990).

182 OKLAHOMA STATE DEPARTMENT OF HEALTH, BULLETIN 0524: REGULATIONS GOVERNING SOLID WASTE & SLUDGE MANAGEMENT § 841 (June 23, 1988).

183 VIRGINIA DEPARTMENT OF WASTE MANAGEMENT, INFECTIOUS WASTE MANAGEMENT REGULATIONS § 7.1(A) (1990).

184 N.C. ADMIN. CODE tit. 10, r. 10G.1007(2)(a) (1990).

185 MO. CODE REGS. tit. 19, § 30-20.021(5)(D)(4) (1988).

186 GA. COMP. R. & REGS. r. 391-3-4-.15(5)(a)(1)(i) (1989) (two seconds for chemotherapy waste only—other waste only to the point "sufficient to destroy infectious

States have not required a minimum residence time in the primary chamber.

States have recognized that incineration is particularly appropriate for pathological waste since combustion turns recognizable, unaesthetic body parts into ash. Accordingly, many states have required or recommended the incineration of such waste.[188]

2. Steam Sterilization or Autoclaving

Steam sterilization or autoclaving is a process whereby saturated steam within a pressurized vial is used to kill dangerous pathogens.[189] The term "sterilization" is misleading since the waste is not actually sterilized in all cases, but health care facilities use the same process for sterilizing equipment, hence the name.[190] Decontamination is a function of the temperature of the steam, the length of time the waste is in contact with the steam and the degree of steam penetration into the waste.[191]

The most critical factor in ensuring proper steam sterilization is steam penetration. Accordingly, the operator must ensure proper steam penetration through the entire waste load.[192] Since there is no standard load, the operator must make adjustments to

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agents"); WISCONSIN DEPARTMENT OF NATURAL RESOURCES, GUIDELINES FOR THE HANDLING AND TREATMENT OF MEDICAL/INFECTIOUS WASTE app. A (May 1989). Wisconsin's guidelines are particularly stringent in this area. They require complete combustion of all material such that the fixed carbon content remaining does not exceed 7.5 percent. *Id.* In addition, Wisconsin requires that there be no "visible unburned combustibles." *Id.* The operator is also required to take a minimum of twenty readings at fifteen second intervals. *Id.*

187 1989 La. Act 583 § 2180(D)(2)(f) (1 - 1 1/2 seconds); N.C. ADMIN. CODE tit. 10, r. 10G.1007(a)(2) (1990); OHIO ADMIN. CODE § 3745-27-32(A)(1) (1990); VIRGINIA DEPARTMENT OF WASTE MANAGEMENT, INFECTIOUS WASTE MANAGEMENT REGULATIONS § 7.1(A) (1990).

188 *See, e.g.*, CONN. AGENCIES REGS. § 22a-209-15(f)(3)(B) (1990) (incineration or internment); MAINE DEPARTMENT OF ENVIRONMENTAL PROTECTION, BIOMEDICAL WASTE MANAGEMENT RULES ch. 900, § 10(A) (Dec. 1989) (incineration or internment); N.H. CODE ADMIN. R. He-P 1901.08(b)(4) (1984); N.C. ADMIN. CODE tit. 10, §10G.1003(a)(3) (1984); NORTH DAKOTA STATE DEPARTMENT OF HEALTH, STATEMENT OF POLICY: DISPOSAL OF LONG TERM CARE FACILITY WASTES 2 (1989) (incineration unless requested otherwise); RHODE ISLAND DEPARTMENT OF HEALTH, RULES & REGULATIONS GOVERNING THE MANAGEMENT OF INFECTIOUS WASTE IN HEALTH CARE RELATED FACILITIES AND LABORATORIES R23-17-INF & R23-16.2-INF, § 8.3.4 (April 1989); VIRGINIA DEPARTMENT OF WASTE MANAGEMENT, INFECTIOUS WASTE MANAGEMENT REGULATIONS § 4.5(c) (1990) (incineration must be used).

189 NEW YORK STATEWIDE PLAN, *supra* note 18, at 34.

190 EPA'S FIRST REPORT, *supra* note 136, at 6-5.

191 NEW YORK STATEWIDE PLAN, *supra* note 18, at 34.

192 EPA GUIDE, *supra* note 1, at 4-4.

the time and temperature cycles to account for the varying types of waste and load compactness.[193] In addition, the operator must allow complete displacement of all residual air after treatment.[194] The presence of left-over residual air in the sterilization chamber will prevent effective sterilization by reducing the temperature throughout the chamber regardless of pressure. This can cause variations in temperature throughout the chamber prolonging the time needed to attain the maximum temperature and inhibiting steam penetration into the waste itself.[195]

Steam sterilization is the second most popular form of infectious waste treatment, primarily due to its simplicity and familiarity within the health care industry.[196] The process is particularly well-suited for treatment of microbiological cultures and stocks,[197] but is capable of decontaminating most waste classes.[198] Accordingly, states recognize the method as effective and regulate its operation.

Like incineration, states have commonly chosen to set minimum time, temperature and pressure levels for steam sterilizers. The common minimum temperature is 120 or 121 degrees Celsius (248-250° Fahrenheit).[199] Similarly, most states have a minimum time requirement of thirty minutes,[200] and a minimum

193 NEW YORK STATEWIDE PLAN, *supra* note 18, at 34. *See generally* EPA GUIDE, *supra* note 1, at 4-4.

194 EPA GUIDE, *supra* note 1, at 4-4.

195 *Id.*

196 *See* EPA'S FIRST REPORT, *supra* note 136, at 6-6.

197 NEW YORK STATEWIDE PLAN, *supra* note 18, at 34.

198 EPA'S FIRST REPORT, *supra* note 136, at 6-6.

199 ARKANSAS DEPARTMENT OF HEALTH, DRAFT-RULES AND REGULATIONS PERTAINING TO THE MANAGEMENT OF SPECIAL WASTE FROM HEALTH CARE RELATED FACILITIES § VI(A)(2) (Dec. 4, 1989) (120° Celsius) (adopted without change); CAL. ADMIN. CODE tit. 22, § 66845(a)(4)(B) (1985) (old regulations - 120° Celsius); CAL. HEALTH & SAFETY CODE § 25080(c)(2) (1990) (Biomedical Waste Management Act - 121° Celsius); GA. COMP. R. & REGS. r. 391-3-4-.15(5)(a)(2)(i) (1989) (121° Celsius); La. Reg. ch. XXVII § 27:024-2 (Jan. 20, 1990) (120° Celsius); MINN. R. 7035.9120(3)(B) (1989) (250° Fahrenheit); OHIO ADMIN. CODE § 3745-27-32(A)(2)(a) (1990) (121° Celsius); N.C. ADMIN. CODE tit. 10, § 10G.1007(1)(a) (1990) (250° Fahrenheit); TEX. ADMIN. CODE tit. 25, § 1.132 (1989) (121° Celsius).

200 ARKANSAS DEPARTMENT OF HEALTH, DRAFT-RULES AND REGULATIONS PERTAINING TO THE MANAGEMENT OF SPECIAL WASTE FROM HEALTH CARE RELATED FACILITIES § VI(A)(2) (Dec. 4, 1989) (adopted without change); CAL. ADMIN. CODE tit. 22, § 66845(a)(4)(B) (1985) (former regulations - at least thirty minutes); CAL. HEALTH & SAFETY CODE § 25080(c)(2) (1990) (Biomedical Waste Management Act - requiring a half hour or longer "depending on quantity and compaction"); GA. COMP. R. & REGS. r. 391-3-4-.15(5)(a)(2)(i) (1989); La. Reg. ch. XXVII § 27:024-2 (Jan. 20, 1990); OHIO ADMIN. CODE § 3745-27-32(A)(2)(a) (1990) (thirty minute minimum); TEX. ADMIN. CODE tit. 25, § 1.132 (1989).

pressure requirement of fifteen pounds per square inch ("psi").[201] Nonetheless, some states that have set more stringent minimums. Connecticut and Minnesota require treatment centers to treat the waste at 250 degrees Fahrenheit at fifteen psi for at least an hour,[202] while North Carolina requires the same temperature and pressure requirements, but requires a forty-five minute residence time.[203] Connecticut makes a distinction between gravity flow and vacuum type sterilizers. Vacuum types are required to meet minimums of 270 degrees Fahrenheit (152° Celsius) at twenty-seven psi for forty-five minutes.[204] These different types of sterilizers also account for the differences and options allowed in Delaware and Wisconsin. These states allow treatment centers and generators to treat infectious waste at 250 degrees Fahrenheit at fifteen psi for ninety minutes or 272 degrees Fahrenheit at twenty-seven psi for forty-five minutes.[205]

In addition to minimum time, temperature, and pressure requirements, a number of states require the use of autoclave or heat sensitive tape on bags.[206] On reaching the minimum temperature, the tape will discolor, thereby indicating to the operator that the target temperature has been reached.

Despite the advantages and popularity of steam sterilization, there are disadvantages to the treatment process. First, the process does not reduce the mass of material that the generator must

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201 ARKANSAS DEPARTMENT OF HEALTH, DRAFT-RULES AND REGULATIONS PERTAINING TO THE MANAGEMENT OF SPECIAL WASTE FROM HEALTH CARE RELATED FACILITIES § VI(A)(2) (Dec. 4, 1989) (adopted without change); CONN. AGENCIES REGS. § 22a-209-15(f)(6)(A) (1990); La. Reg. ch. XXVII § 27:024-2 (Jan. 20, 1990); MINN. R. 7035.9120(3)(B) (1989); N.C. ADMIN. CODE tit. 10, § 10G.1007(1)(a) (1990); TEX. ADMIN. CODE tit. 25, § 1.132 (1989).

202 CONN. AGENCIES REGS. § 22a-209-15(f)(6)(A) (1990) (gravity flow sterilizers only); MINN. R. 7035.9120(3)(B) (1989).

203 N.C. ADMIN. CODE tit. 10, r. 10G-.1007(1)(a) (1990).

204 CONN. AGENCIES REGS. § 22a-209-15(f)(6)(B) (1990).

205 DELAWARE DEPARTMENT OF NATURAL RESOURCES AND ENVIRONMENTAL CONTROL, DIVISION OF AIR & WASTE MANAGEMENT, AIR RESOURCES REGULATIONS § 11(M)(2)(a) (1989); WISCONSIN DEPARTMENT OF NATURAL RESOURCES, GUIDELINES FOR THE HANDLING AND TREATMENT OF MEDICAL/INFECTIOUS WASTE § V(B) (May 1989).

206 CAL. ADMIN. CODE tit. 22, § 66845(a)(4)(c) (1985) (old regulations); CAL. HEALTH & SAFETY CODE § 25080(c)(3) (1990) (Biomedical Waste Management Act); DELAWARE DEPARTMENT OF NATURAL RESOURCES AND ENVIRONMENTAL CONTROL, DIVISION OF AIR & WASTE MANAGEMENT, SOLID WASTE DISPOSAL REGULATIONS § 11(M)(2)(b)(1) (1989); FLA. ADMIN. CODE r. 17-712.430(1)(b)(3) (1989); N.C. ADMIN. CODE tit. 10, r. 10G.1007(1)(g) & (h) (1990) (Class A Medical Waste only); RHODE ISLAND DEPARTMENT OF HEALTH, RULES & REGULATIONS GOVERNING THE MANAGEMENT OF INFECTIOUS WASTE IN HEALTH CARE RELATED FACILITIES AND LABORATORIES R23-17-INF & R23-16.2-INF, § 8.1.1 (April 1989) (tape or bag must discolor).

dispose.[207] Second, the process often produces extremely offensive odors.[208] Third, the process does not render unaesthetic waste, such as anatomical remains, unrecognizable.[209]

3. Other Treatment Methods

There are a variety of treatment methods other than steam sterilization and incineration. In the past, generators and treatment centers have made minimal use of the treatment methods, but they have recently received increased attention due to the disadvantages inherent in incineration and steam sterilization. These methods include thermal inactivation,[210] chemical disinfection,[211] irradiation,[212] microwave treatment,[213] and grinding and shredding.[214] For the most part, states have left these procedures unregulated because of their minimal use. Nonetheless, with the increased recognition of the disadvantages and the danger incineration and steam sterilization pose, these methods will continue to receive increased attention. Some states already recognize

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207 EPA'S FIRST REPORT, *supra* note 136, at 6-6.

208 *Id.*

209 *Id.*

210 This method involves heating the waste, usually large volumes of liquid infectious waste, to a temperature that destroys the infectious agents. The process exposes the waste to a gaseous sterilizing agent such as ethylene oxide or formaldehyde after the air is evacuated from the chamber. It has rarely been used for treatment of infectious waste. EPA'S FIRST REPORT, *supra* note 136, at 6-7. Those states that authorize use of the process require that the method be approved by the regulatory agency prior to use. Louisiana and Texas, however, have chosen to specifically regulate the process. Both require treatment centers to treat the waste at a minimum temperature of 160 degrees Celsius (320° Fahrenheit) for at least two hours at atmospheric pressure. La. Reg. ch. XXVII § 27:024-4 (Jan. 20, 1990); TEX. ADMIN. CODE tit. 25, § 1.132 (1989).

211 This treatment method involves exposing infectious waste to liquid chemical disinfectants. EPA'S FIRST REPORT, *supra* note 136, at 6-7. The main concern of this method is the risk the used chemical disinfectants present to operators and personnel. The solution often exhibits characteristics that make it unsuitable for disposal in municipal sewer systems. *Id.*

212 This procedure involves exposing the waste to ultraviolet or ionizing radiation. The EPA finds the method promising because of the small amount of energy it utilizes and the fact that no heat is required. The main problem is replacement and disposal of the radiation source after decay. *Id.* at 6-10.

213 This method does exactly what it says. The infectious waste, after being ground first, is exposed to microwaves. The procedure has yet to be used commercially in the United States. *Id.* at 6-10 to 6-11.

214 This process entails breaking up the infectious waste into smaller particles. A form of this process includes needle-clipping, which most states have banned due to the fear of propelling particles from the clipping into the operator's face. Generators have used the process in the past for the disintegration of unaesthetic body parts, but it has increasingly met with disfavor in the industry because of the process' potential for forming a pathogenic aerosol thereby endangering the operator. *See generally id.*

the advent of these procedures by authorizing the use of treatment methods other than those present in the regulations if approval is received from the regulatory agency.[215]

D. The Disposal and Tracking of Infectious Waste

Generators and waste disposers commonly dispose infectious waste, whether treated or not, in a landfill. In the past, states commonly allowed the landfilling of infectious wastes without treatment, but there are few today that allow such a practice.[216] Also, states commonly allow the treatment of blood and other body fluids by the local municipal waste treatment plant.[217]

Although the actual disposal methods for infectious waste have remained relatively unchanged, the most revolutionizing development in the disposal of infectious waste is the "tracking" of infectious waste by states. "Tracking" involves the monitoring of infectious waste from the time it leaves the generator to the point at which it is treated and ultimately disposed.[218] The

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215 *See, e.g.*, Louisiana - La. Reg. ch. XXVII § 27:024 (Jan. 20, 1990) (incineration, sterilization, chemical disinfection, irradiation, thermal disinfection or any other approved method is allowed — chemical disinfection and irradiation require written approval); Massachusetts - MASS. REGS. CODE tit. 105, § 480.100(F) (1989) (incineration, steam sterilization, gas sterilization, chemical disinfection or other approved method); Minnesota - MINN. R. 7035.9120(3) (1989) (incineration, steam sterilization or other approved method); Missouri - MO. CODE REGS. tit. 19, § 3-20.021(4) (1988); New Hampshire - N.H. CODE ADMIN. R. He-P 1901.08(b)(2) (1984) (need prior written approval for methods other than incineration); Ohio - OHIO ADMIN. CODE § 3745-27-32 (1990) (incineration, steam sterilization, chemical treatment for cultures and other treatments approved by the Director); South Carolina - S.C. CODE ANN. § 44-93-80(B) (Law Co-op 1989) (incineration, steam sterilization, chemical disinfection and any other Department approved method); and Virginia - VIRGINIA DEPARTMENT OF WASTE MANAGEMENT, INFECTIOUS WASTE MANAGEMENT REGULATIONS § 4.5(A) (1990) (all waste must be incinerated or steam sterilized unless approved under special circumstances).

216 States that have infectious waste regulations or guidelines but still allow landfilling without treatment are Alabama, Arizona, Michigan (blood and animal waste only), Nevada, Texas and Utah. ALA. ADMIN. CODE r. 335-13-4-.26(3) (1988); ARIZ. COMP. ADMIN. R. & REGS. R9-10-320(E) & R9-10-1220(E) (1982) (if only one autoclave is available and an incinerator is not, the waste may be landfilled if double-bagged and clearly marked); MICHIGAN DEPARTMENT OF PUBLIC HEALTH, MEDICAL WASTE EMERGENCY RULES r. 2(7) & (10) (April 26, 1989) (blood and animal waste only); TEX. ADMIN. CODE tit. 25, § 1.136(a) (5)(A)(iv), 5(B)(iv), 5(C)iv) (1989) (sharps only). Utah and Nevada do not prohibit landfilling.

217 *See, e.g.*, N.Y. COMP. CODES R. & REGS. tit. 6, § 360-10.6(b)(3) (1986); TEX. ADMIN. CODE tit. 25, § 1.136(4)(iv) (1989); VIRGINIA DEPARTMENT OF WASTE MANAGEMENT, INFECTIOUS WASTE MANAGEMENT REGULATIONS § 4.5(c) (1990).

218 States that have implemented tracking programs include New York, Pennsylvania, Massachusetts, Illinois, Delaware, Ohio, Connecticut, Missouri, New Jersey, Rhode Island, Maine, and California (Biomedical Waste Management Act). CAL. HEALTH & SAFETY

tracking form is designed to ensure that the infectious waste, which is being transported off-site for treatment or disposal, is not being illegally disposed and released into the environment where it could possibly wash up on beaches or find its way into the hands of curious children.[219]

New Jersey and New York were the first states to initiate such a program, but the practice received national attention only after Congress passed the Medical Waste Tracking Act of 1988.[220] Since then, tracking programs have increased in popularity. These tracking programs have taken a variety of forms but all have followed a paper based system.[221] They generally require the generator to fill out a form, usually termed a "manifest," indicating the amount of waste to be treated or disposed, the generator's name, address and the date transported off-site. Each link in the chain, i.e. transporter, treatment facility, and landfill, must sign the manifest form before delivering the waste to its next handler to verify that the amount of waste indicated by the originating generator is still present. In addition, their signatures indicate to all entities in the chain that they have properly completed their service, whether it be treatment, disposal or transportation, and properly transported the waste to the next destination, or notified the originating generator that the waste

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CODE § 25072 (1990); CONN. AGENCIES REGS. § 22a-209-15(h) (1990); DELAWARE DEPARTMENT OF NATURAL RESOURCES AND ENVIRONMENTAL CONTROL, DIVISION OF AIR & WASTE MANAGEMENT § 11(N) (1989); ILL. ADMIN. CODE tit. 35, 809.501 (1989) (hospitals only); MAINE DEPARTMENT OF ENVIRONMENTAL PROTECTION, BIOMEDICAL WASTE MANAGEMENT RULES ch. 900, § 12(E) (Dec. 1989); MASS. REGS. CODE tit. 105, § 480.500 (1989); MO. CODE REGS. tit. 10, § 80-7.010 (1988); N.J. ADMIN. CODE tit. 7, § 26-3A (1989); N.Y. COMP. CODES R. & REGS. tit. 6, § 364.9 (1986); PENNSYLVANIA DEPARTMENT OF HEALTH ENVIRONMENTAL QUALITY BOARD, INTERIM GUIDELINES - MANIFESTING & TRANSPORTER LICENSING FOR INFECTIOUS AND CHEMOTHERAPY WASTE (July 18, 1989); RHODE ISLAND DEPARTMENT OF HEALTH, RULES & REGULATIONS GOVERNING THE MANAGEMENT OF INFECTIOUS WASTE IN HEALTH CARE RELATED FACILITIES AND LABORATORIES R23-17-INF & R23-16.2-INF, § 7.3 (April 1989). Florida is in the process of developing a tracking program.

219 In a recent report to Congress, the EPA stated that the primary objective of the Medical Waste Tracking Act is "to ensure that regulated medical wastes, which are generated and which may pose environmental (including aesthetic) problems, are delivered to disposal or treatment facilities with a minimum of exposure to waste management workers and the public." EPA'S FIRST REPORT, *supra* note 136, at 4-1.

220 42 U.S.C. §§ 6992 - 6992k (1988); 40 C.F.R. §§ 259.1 - 259.91 (1990) (regulations promulgated pursuant to the Act). *See infra* notes 229-252 and accompanying text for a discussion of the federal response to the infectious waste problem.

The EPA's tracking forms are based on, and consistent with, the New York and New Jersey medical waste tracking forms. The EPA, in fact, modeled the federal program after these two state programs.

221 EPA'S FIRST REPORT, *supra* note 136 at 8-19.

has been properly disposed. Each link in the chain is often required to keep a copy of the manifest or detach a receipt from a multi-part carbon copy form.[222] Ultimately, the generator is required to obtain a final copy and verification of the final disposal within a certain period of time. If no copy is received or no verification made, the generator must notify the regulatory agency.[223]

In contrast to the common manifest form system, Ohio has implemented a shipping paper based system.[224] Under this system there are two different papers. The generator sends the first paper to the treatment facility, while the treatment facility sends the second to the waste's ultimate disposal destination.[225] The papers have two different colors for identification purposes.

The EPA states that the main disadvantage of paper based systems is the susceptibility to human error either in completion of the form or in its handling.[226] In addition, large manifest forms and yearly summaries of infectious waste shipments are labor-intensive and time-consuming.[227] In response to these problems, computers and the use of bar codes, similar to the grocery checkout procedure, have been tried, but have not been implemented to any significant degree in a regulatory capaci-

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222 There are a variety of forms being used by states that require tracking of infectious waste. Pennsylvania requires a four-part manifest form for generators and an eight-part manifest form for hospitals. PENNSYLVANIA DEPARTMENT OF HEALTH ENVIRONMENTAL QUALITY BOARD, INTERIM GUIDELINES - MANIFESTING & TRANSPORTER LICENSING FOR INFECTIOUS AND CHEMOTHERAPY WASTE (July 18, 1989). New Jersey has a four-part manifest form. N.J. ADMIN. CODE tit. 7, § 26-3A.19 (1989). Illinois, which requires only tracking for hospitals, uses a six-part form. ILL. ADMIN. CODE tit. 35, § 809.50 (1989). In Illinois, the treatment or disposal facility must send copies of the manifest both to the generator and the Illinois Environmental Protection Agency. *Id.* Delaware uses a five-part form. DELAWARE DEPARTMENT OF NATURAL RESOURCES AND ENVIRONMENTAL CONTROL, DIVISION OF AIR & WASTE MANAGEMENT, SOLID WASTE DISPOSAL REGULATIONS § 11(N) (1989). New York's regulation has no set number, but states that "[t]he generator must prepare at least the number of tracking form copies that will provide the generator, each transporter(s), and each intermediate handler with one copy, and the owner or operator of the destination facility with two copies . . . ." N.Y. COMP. CODES R. & REGS. tit. 6, § 364.9(e)(3)(iii) (1986).

223 In New York and New Jersey copies of the completed tracking form must be sent back to the generator within thirty-five days of shipment. If a copy is not received within forty-five days, the generator must notify the regulatory agency. N.J. ADMIN. CODE tit. 7, § 26-3A.22(a) (1989); N.Y. COMP. CODES R. & REGS. tit. 6, § 364.9(e)(3)(iii) (1986).

224 OHIO ADMIN. CODE § 3745-27-33 (1990).

225 *Id.*

226 EPA'S FIRST REPORT, *supra* note 136, at 4-20.

227 *Id.*

ty.[228] Nonetheless, these systems will become more popular in the future since they provide the user and the regulatory official with immediate status reports of shipments and can save time if corrective or enforcement action becomes necessary.[229]

IV. THE FEDERAL RESPONSE AND THE NEED FOR MINIMUM REQUIREMENTS

A. What Has Been Done?

In response to the medical/infectious waste problem, the EPA initially planned to classify infectious waste as a hazardous waste thereby subjecting the waste to the hazardous waste "cradle to grave" program. But, by the time these rules were adopted in 1980, the EPA had decided to create separate guidelines for infectious waste management.[230] The first draft of these guidelines appeared in 1982,[231] but the EPA did not finalize them until 1986.[232] In response to increased public concern about improperly managed medical wastes, Congress enacted the Medical Waste Tracking Act ("MWTA") of 1988.[233]

The Medical Waste Tracking Act added Subtitle J to the Resource Conservation and Recovery Act and established a system of tracking medical waste, as the Act defines the term.[234] The EPA eventually developed and published regulations that specified standards for tracking, packaging, labeling, storage, treatment and segregation.[235] Under the Act, generators of more than fifty pounds of infectious waste per month,[236] within a regulated state, are required to ship all waste that is to be transported offsite with an EPA authorized transporter, accompanied by a tracking form.[237] All generators within a regulated state, even

228 *Id.*

229 *Id.*

230 WASHINGTON STATE INFECTIOUS WASTE PROJECT, *supra* note 12, at 63.

231 *Id.*

232 *See* EPA GUIDE, *supra* note 1.

233 Pub. L. No. 100-582, 102 Stat. 2951 (1988) (codified at 42 U.S.C. §§ 6692-6692k (1988)).

234 *See* 42 U.S.C. § 6992(a) (1988)(definition of infectious waste under the Act).

235 40 C.F.R. §§ 259.1-259.91 (1990). The Washington State Infectious Waste Project commented that the regulations were developed with very little public input. WASHINGTON STATE INFECTIOUS WASTE PROJECT, *supra* note 12, at 63.

236 The term "generators" includes hospitals, physician's offices, dental offices, veterinary practices, funeral homes, research laboratories and nursing homes. 40 C.F.R. § 239.10(a) (1989).

237 *See* 40 C.F.R. § 259.50-.56 (1989).

those generating less than fifty pounds per month, are required to comply with all segregation, packaging, labeling, and storage requirements.[238] Generators who incinerate regulated medical waste by on-site incineration, sewer disposal or burial are not subject to the tracking requirements.[239] Those who incinerate, however, are required to keep records and submit reports to the EPA and the state waste management agency.[240]

The MWTA was originally designed for states that had had difficulty with mismanaged medical waste. Accordingly, the Act initially applied to "New York, New Jersey, Connecticut [and] the States contiguous to the Great Lakes."[241]All of the Great Lakes states, however, opted out of the program under a provision in the Act authorizing a state to opt out on notification of the EPA by the Governor of the state and a finding by the EPA that the state program was "no less stringent than the demonstration program."[242] The Act further provides for any interested state to opt into the demonstration program.[243] Rhode Island and Puerto Rico joined the program through this procedure. As a result of these actions, four states (Connecticut, New Jersey, New York, and Rhode Island) and Puerto Rico are participants in the program.

Violators of the Medical Waste Tracking Act are subject to civil penalties of up to $25,000 a day per violation.[244] In addition, violators are subject to criminal penalties of up to $50,000 a day per violation and a prison term of up to five years.[245]

The MWTA also requires the EPA to report on a number of topics to Congress within three months after the demonstration program.[246] These topics include the potential threat infectious

238 *See id.*
239 *See id.* § 259.50(c).
240 40 C.F.R. 259.60-.62 (1990).
241 42 U.S.C. § 6692(a) (1988).
242 *Id.* § 6992(b).
243 *Id.* § 6992(c).
244 *Id.* § 6992(d).
245 *Id.*
246 Since the MWTA provides for a limited two year duration and the rules became effective at different times in different states due to the opt-in procedure, see *supra* notes 204 - 206 and accompanying text, there was confusion over the precise time period during which the rules were effective. 55 Fed. Reg. 127 (July 2, 1990). Recent amendments to the regulations have established that the program is effective for the period June 22, 1989 to June 22, 1991 in Connecticut, New Jersey and New York, and from July 24, 1989 to June 22, 1991 in Rhode Island and Puerto Rico. *Id.* at 27,231 (codified at 40 C.F.R. § 259.12 (1990)). This printing also amended the MWTA by clarifying certain definitions and requirements under the Act. *Id.*

waste poses to human health, the effectiveness of the demonstration program, and existing state and local controls. The first of these reports was made final in May 1990,[247] although the demonstration program has not officially ended for any of the participating states.[248] This report concluded that the tracking requirement imposed an average annual cost compliance of twelve million dollars or twenty-four million dollars for the two years the program would be run.[249] In comparison, the EPA estimated that New York, New Jersey, and Connecticut alone would lose thirty million dollars in mismanaged medical wastes.[250] The EPA obtained this figure by estimating the economic value of lost beach days due to medical waste.[251] Note that this figure does not include any allotment for expenses derived from infection contracted from mismanaged infectious waste.[252]

B. What Needs To Be Done

As the previous discussion illustrates, state regulation of infectious waste treatment and disposal is far from consistent. Deviations in packaging, tracking, disposal and treatment regulations between states is far from uncommon. In an industry where much of the nation's infectious waste is shipped across state lines,[253] such deviations increase the probability of infectious waste mismanagement. Specifically, the movement of infectious waste across state lines[254] poses a problem to the state receiving the waste since the state is often unaware of the entrance of the waste or its subsequent disposal.[255] Even if the states share a similar infectious waste disposal policy, one state may suffer from the other's lax enforcement.[256] In addition, stringent regulations of infectious waste in one state compared to a neighboring state's regulation creates the incentive for an enterprising, yet unscrupu-

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247 EPA'S FIRST REPORT, *supra* note 136.

248 *See supra* note 246.

249 EPA'S FIRST REPORT, *supra* note 136, at 3-9.

250 *Id.* at 3-16.

251 *Id.*

252 *See supra* notes 16-28 and accompanying text for a discussion of the actual and perceived threat mismanaged infectious waste poses to the public and its handlers.

253 The National Resources Defense Council ("NRDC") has emphasized this point and believes that only a national program administered by the EPA can adequately address the issue. *See* Kass and Gerrard, *Regulation of Medical Waste*, 200 N.Y.L.J. at 3, col. 1 (1988).

254 *See supra* note 7 and accompanying text.

255 Note, *supra* note 9, at 33.

256 *Id.*

lous generator to ship waste to the less stringent state to avoid treatment and disposal cost due to increased regulation.[257] Nevertheless, with the exception of the five states presently "participating" in the Medical Waste Tracking Act, the fact remains that there is not an enforceable federal program for the effective and safe disposal of infectious waste.

The most common argument against federal regulation of infectious waste is the increased expense such regulation would create. This concern, however, arises primarily from reaction to the Medical Waste Tracking Act by states that have not had great difficulty with mismanaged infectious waste and that find any tracking program to be overkill.[258] This argument ignores the fact that federal regulation need not consist of a cradle to grave tracking program as exists under the MWTA. Simply put, Montana does not have the same needs as New Jersey. For example, a tracking program in New Jersey would be beneficial, but would be overkill in Montana. But, improperly packaged infectious waste, improperly treated waste, and improperly stored infectious waste poses the same hazards to health care workers and the public in Montana as it does in New Jersey. Accordingly, regulation by the federal government should not consist of a nationwide tracking program, but should instead provide minimum regulation in such areas as packaging,[259] storage,[260] treatment,[261] and disposal.[262] In addition, the federal regulations should include a voluntary tracking program with an opt in provision for those states which desire such a program and have found current state programs beneficial.

In response to the increased expense argument, the fact that states are largely unanimous in recognizing the propriety of cer-

257 Note, *supra* note 9, at 132-33 ("Neighboring state's infectious waste policies often clash and contribute to each other's failures."). *Id. See infra* notes 33-34 and accompanying text for a discussion of the profits medical waste disposal and transport companies have recognized.

258 *See infra* note 32 for Texas' concern.

259 Examples are double bagging of infectious waste, performance standards for such bags, rigid or semi-rigid containers for sharps, use of the universal biohazard symbol, and a designated color for bags, i.e. red or orange.

260 Examples include segregation, locked outdoor containers, and admittance to authorized employees only.

261 This may be in the form of required procedures so long as future treatment methods such as chemical disinfection and irradiation are allowed to be used if proven effective.

262 For example, requiring treatment of infectious waste before disposal.

tain infectious waste management techniques[263] will serve to keep increased expense from federal regulation to a minimum. This Note assumes that federal regulation would not dramatically alter any of the techniques that states presently employ in the management of infectious waste. This is not a far-fetched assumption since the EPA has been a guide for state infectious waste management plans since 1982.[264] Accordingly, expense would be kept at a minimum, while consistency and uniformity would be gained.[265]

Granted, those states that presently have no or limited infectious waste management guidelines will face increased expense in some areas, but the expense is necessary to bring them "up to speed" with the rest of the country. As stated earlier, mismanaged infectious waste poses the same danger in these states as they do in New York and New Jersey. New York's problem today will be Nebraska's problem tomorrow. An infectious waste handler or curious child can as easily be stuck by an improperly packaged or managed infected needle in Kansas as in Washington.[266] Ignorance can not be an alternative.

CONCLUSION

State regulation of infectious waste is far from consistent. Consequently, in an area where consistency and efficiency is of utmost importance, individuals who are responsible for the disposal of infectious waste are faced with confusion and uncertainty. In addition, this inconsistency combined with the amount of waste that is transported interstate[267] has increased the possibility of mismanaged infectious waste.

The answer to the problem is simple. Federal regulation of infectious waste management, establishing minimum regulations and a set definition of infectious waste, would bring consistency and uniformity to the industry. Federal regulation in the areas of packaging, storage, treatment, and disposal would result in all state generators and infectious waste handlers being in national

263 *See supra* notes 259-260 for examples of these practices.

264 *See supra* notes 45-46 and accompanying text.

265 Note, *supra* note 9, at 133 ("Without a consistent basis for state regulatory behavior and its enforcement, interstate waste conflict and illegal dumpings will continue to be a problem"). *Id.*

266 *See supra* note 19 and accompanying text for a discussion of the danger mismanaged sharps pose to infectious waste handlers.

267 *See supra* note 7 and accompanying text.

conformity, thereby increasing protection for the general populace and health care workers. In addition, the regulations this Note advocates would leave open the option of promulgating stricter standards for those states that have had considerable difficulty in this area. For example, a state could implement a tracking program or continue an existing tracking program as long as the state follows all minimum federal regulations. Finally, any argument that the regulation would drastically increase the expense of infectious waste management is unfounded since most states have already implemented similar, although far from consistent, regulation in these areas.[268]

Regardless of the expense involved, consistency, uniformity, and efficiency can only be obtained through a national program. Only through the attainment of these goals will the populace and infectious waste handlers be ensured the optimum protection from the danger infectious waste poses.

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268 *See supra* notes 259-262 and accompanying text.