



January 1994

Environmental Regulation of Health Care Facilities: A Prescription for Compliance

Margaret M. Menicucci

Cheryl L. Coon

Recommended Citation

Margaret M. Menicucci & Cheryl L. Coon, *Environmental Regulation of Health Care Facilities: A Prescription for Compliance*, 47 SMU L. REV. 537 (1994)

<https://scholar.smu.edu/smulr/vol47/iss3/5>

This Article is brought to you for free and open access by the Law Journals at SMU Scholar. It has been accepted for inclusion in SMU Law Review by an authorized administrator of SMU Scholar. For more information, please visit <http://digitalrepository.smu.edu>.

ENVIRONMENTAL REGULATION OF HEALTH CARE FACILITIES: A PRESCRIPTION FOR COMPLIANCE

*Margaret M. Menicucci**
*Cheryl L. Coon***

TABLE OF CONTENTS

I.	INTRODUCTION.....	539
II.	MEDICAL WASTE MANAGEMENT	539
A.	FEDERAL REGULATION OF MEDICAL WASTE	539
	1. <i>Overview</i>	539
	2. <i>Lessons from the MWTA</i>	541
	3. <i>Pending Federal Legislation</i>	542
B.	STATE REGULATION OF MEDICAL WASTE.....	542
	1. <i>Overview</i>	542
	2. <i>Texas Medical Waste Regulations</i>	543
	a. <i>Generator Duties</i>	544
	b. <i>Transporter Duties</i>	545
	c. <i>Requirements for Storage Facilities</i>	546
	d. <i>Authorized Treatment, Destruction, and Disposal Technologies</i>	546

* Margaret Menicucci joined Kelly, Hart & Hallman in October 1991. She has particular experience in contested case hearings and solid waste issues, including medical waste. Margaret is a member of the Administrative Law Section and Environmental and Natural Resources Law Section of the State Bar. She has co-authored articles on environmental law topics and has spoken on the topics of environmental law concerns of building owners and federal and state pollution prevention plans. Margaret received a B.A. from Trinity University in San Antonio in 1985 and a J.D. with honors from the University of Texas School of Law in 1990. Before joining Kelly, Hart & Hallman, Margaret completed a judicial clerkship with Judge Bea Ann Smith of the Third Court of Appeals of Texas.

** Cheryl Coon joined Kelly, Hart & Hallman in August 1992. Cheryl's work in client counseling involves most environmental statutes at federal and state levels and has included lender liability issues, asbestos, hazardous waste, and recycling. She is a member of the Environmental and Natural Resources Law Section of the State Bar. Cheryl co-authored a comprehensive law review article regarding medical waste titled "The New Regulatory Horizon: Regulation of Medical Waste," in the *Southwestern Law Journal* published by Southern Methodist University. In addition, Cheryl has authored and co-authored a number of articles relating to environmental law focusing on transactional liabilities, the steel industry, hazardous waste, and emission credits. Cheryl received a B.S. in Medical Technology in 1982 from Baylor University, graduating summa cum laude, and a J.D., cum laude, from Southern Methodist University in 1989, where she was a member of the Order of the Coif. Prior to joining Kelly, Hart & Hallman, she was associated with the environmental practice group of Thompson & Knight in Dallas.

The authors are indebted to Laura Beresh, Linda Hall, Amy Melvin, and Mary Frances Simmons for their research and editing assistance.

C.	REGULATION OF HAZARDOUS AND RADIOACTIVE MEDICAL WASTE	549
	1. <i>Hazardous Medical Waste</i>	549
	2. <i>Radioactive Medical Waste</i>	550
D.	CRIMINAL PROSECUTION FOR MEDICAL WASTE VIOLATIONS	551
	1. <i>Federal Overview</i>	551
	2. <i>State Cases</i>	553
E.	LOCAL ATTEMPTS TO RESTRICT MEDICAL WASTE DISPOSAL	554
	1. <i>Overview</i>	554
	2. <i>Commerce Clause Challenges to Restrictive Ordinances</i>	554
III.	CERCLA LIABILITY	557
IV.	OCCUPATIONAL SAFETY AND HEALTH ACT	558
A.	RECORDING AND REPORTING OCCUPATIONAL INJURIES AND ILLNESSES	558
B.	GENERAL INDUSTRY SAFETY & HEALTH STANDARDS ...	559
	1. <i>Personal Protective Equipment</i>	559
	2. <i>General Environmental Controls</i>	559
	3. <i>Occupational Health and Environmental Controls</i>	560
C.	TOXIC AND HAZARDOUS SUBSTANCES	561
	1. <i>Occupational Exposure to Air Contaminants</i>	561
	2. <i>Hazard Communication</i>	561
	3. <i>Occupational Exposure to Hazardous Chemicals in Laboratories</i>	562
	4. <i>Occupational Exposure to Bloodborne Pathogens</i>	563
V.	ENVIRONMENTAL CONCERNS RELATED TO PROPERTY USE AND CONDITIONS	565
A.	LAND USE RESTRICTIONS	566
B.	CONDITIONS ON THE PROPERTY	567
	1. <i>Above Ground and Underground Storage Tanks</i>	567
	a. <i>Above Ground Storage Tanks</i>	567
	b. <i>Underground Storage Tanks</i>	568
	2. <i>Septic Tank Systems</i>	570
C.	ENVIRONMENTAL CONDITIONS IN BUILDINGS	570
	1. <i>Asbestos</i>	571
	2. <i>PCBs</i>	573
	3. <i>CERCLA Liability for On-Site Conditions</i>	574
VI.	PRACTICAL CONSIDERATIONS	575
VII.	CONCLUSION	577

I. INTRODUCTION

HEALTH care professionals and entities from nurses to research laboratories typically are subject to extensive federal and state regulation. The traditional regulations dealt with financing or administrative procedures (e.g., antitrust, disclosure, ethics). Safety issues then became an area of concern, and employers had to familiarize themselves with employment rules promulgated by the Occupational Safety & Health Administration. As technologies evolved and understanding of the environment increased, the most recent regulations came into place to protect both workers and the environment. Now, not only "smokestack" industries, but also health care facilities must be familiar with the waste management programs of the United States Environmental Protection Agency (EPA) and state regulatory agencies. In addition, health care facilities must be familiar with environmental liabilities arising from the acquisition and use of property.

This Article (1) discusses the history of federal regulation of medical waste, (2) reviews current federal and state regulations regarding medical waste, hazardous and radioactive medical waste, and worker safety, and (3) reviews environmental laws and regulations affecting property and land use. All of these areas may have a significant impact on health care industries in terms of operational costs and long-term liability. The Article concludes with a brief discussion of procedures health care professionals can use to limit the potential liabilities, which may mean the difference between the financial success or failure of an enterprise.

II. MEDICAL WASTE MANAGEMENT

A. FEDERAL REGULATION OF MEDICAL WASTE¹

1. Overview

Significant public recognition of problems involving medical waste did not begin until approximately 1988. At that time, several factors brought issues related to medical waste management to public attention. New regulations began to appear addressing medical waste. In addition, psychological responses, such as fear of contracting diseases like hepatitis B or the Acquired Immune Deficiency Syndrome (AIDS), led some businesses involved in waste storage, treatment, disposal, or transportation to stop accepting medical waste. Furthermore, diminished capacity for proper disposal and increased costs, while health care industries were generating more waste due to the increasing population,² created incentives for illegal dumping.

In 1988, Congress passed the first significant federal legislation concerning the management of medical waste, the Medical Waste Tracking Act of 1988

1. For a discussion of medical waste issues, see Cheryl L. Coon & Howard L. Gilberg, *The New Regulatory Horizon: Regulation of Medical Waste*, 45 Sw. L.J. 1099 (1991).

2. Michael K. Shumaker, Note, *Infectious Waste: A Guide to State Regulation and a Cry for Federal Intervention*, 66 NOTRE DAME L. REV. 555, 560-62 (1990).

(Mwta).³ EPA implemented regulations for the proper disposal and transportation of certain medical waste.⁴ The initial program was limited, however, in duration and scope, and mandatory only in Rhode Island, New York, Connecticut, New Jersey, and Puerto Rico.⁵ The program expired in June 1991. Also in 1988, Congress amended the Clean Water Act to expressly prohibit the discharge of medical waste into navigable waters of the United States.⁶

Generally, EPA regulations under Mwta defined "medical waste" as a solid waste generated: (1) in the diagnosis, treatment, or immunization of human beings or animals, (2) in research, or (3) in the production or testing of biologicals.⁷ "Regulated medical waste" was a subset of medical waste.⁸ Generators who transported more than fifty pounds of medical waste per month off-site had to initiate a tracking system similar to the manifest required under the hazardous waste regulations of the Resource Conservation and Recovery Act (RCRA),⁹ which tracked waste from the generator to the transporter to the final off-site disposal facility.¹⁰ The federal regulations also imposed vehicle standards and recordkeeping requirements on transporters and recordkeeping requirements on both on-site incinerators and off-site treatment, destruction, and disposal facilities (TDDs).¹¹

Many states have since adopted programs that are based on the federal system, but critics continue to suggest that a uniform federal system is required to address medical waste. If Congress adopts a new federal system in the future, it is reasonable to expect that the system would be based at least in part on the prior regulatory system.¹² Mwta system also has provided guidance to other nations, including Australia, Canada, and Japan, all of which have begun to develop medical waste programs based on the United States' example.¹³

3. 42 U.S.C. §§ 6992-6992k (Supp. IV 1992).

4. 40 C.F.R. § 259 (1990).

5. 42 U.S.C. § 6992(a) (Supp. IV 1992).

6. 33 U.S.C. § 1311(f) (1988). In addition, Congress restricted ocean-disposal of medical waste. First, Congress passed the "United States Public Vessel Medical Waste Anti-Dumping Act of 1988," which prohibits vessels, owned or operated by the United States government, from disposing of "potentially infectious medical waste" into ocean waters within fifty nautical miles of land. 33 U.S.C. § 2503 (1988). Second, Congress passed the "Ocean Dumping Ban Act of 1988," which prohibits the issuance of a permit for the disposal of medical waste in the territorial seas of the United States. 33 U.S.C. §§ 1402(k), 1412(a) (1988).

7. 40 C.F.R. § 259.10 (1990).

8. *Id.* § 259.30.

9. 42 U.S.C. §§ 6901-6992k (1988 & Supp. IV 1992).

10. 40 C.F.R. § 259.52, .74-.75, .81, .90-.91 (1990).

11. *Id.* § 259.60-.62, .70-.79, .83-.84.

12. See Honohan, *Growing Medical Waste Market Needs More Uniform Regulations*, ENVIRONMENTAL ENGINEERING E-52 (1993); Scott B. Goldie, 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 (1989); Shumaker, *supra* note 2, at 596-601.

Since the expiration of Mwta, several bills have been presented in Congress. See, e.g., Medical Waste Management Act of 1991, H.R. 1816, S. 1083, 102d Cong., 2d Sess. (1992).

13. H.R. 1304, 103d Cong., 1st Sess. (1993) (introduced by Rep. Pete Stark); see also Stark's *Anti-Needlestick Bill Wins Support from Health Care Groups During House Hearing*, [Current Report] O.S.H. Rep. (BNA) 140-41 (July 7, 1993) [hereinafter *Anti-Needlestick Bill*].

The federal program also was important because it authorized EPA to actively enforce medical waste regulations.¹⁴ EPA could seek civil or administrative penalties, issue compliance orders, or initiate actions for injunctive relief.¹⁵ Additionally, for activities such as knowingly violating MWTA requirements,¹⁶ MWTA provided for criminal penalties of up to \$50,000 per day, imprisonment for up to two years, or upon subsequent convictions, up to twice the specified penalties.¹⁷ Persons who knowingly violated a provision of MWTA and who knew that such action placed another person in imminent danger of death or serious bodily injury could be found guilty of knowing endangerment and subject to a fine of up to \$250,000, imprisonment for not more than fifteen years, or both.¹⁸ If the defendant was an organization, such as a corporation, the maximum fine was \$1,000,000.¹⁹

EPA appeared more than willing to use its enforcement authority. During the first year, EPA conducted approximately 510 inspections, brought eleven administrative enforcement actions, issued 257 warning letters or notices of violation, and assessed approximately \$690,000 in penalties.²⁰

2. Lessons from the MWTA

MWTA required EPA to provide three reports on medical waste.²¹ According to the second EPA report, some currently unregulated activities contribute in part to the illegal medical waste disposal problem. Specifically, EPA cited illegal intravenous drug users and home health care facilities as potential generators of improperly disposed medical waste.²² EPA also noted that household medical waste, such as syringes from allergy and insulin shots and home health care services, which was excluded from the federal program's definition of regulated medical waste, constitutes a large portion of improperly disposed medical waste.²³ Future federal or state programs, therefore, may begin to address these concerns.

EPA also prepared a list of issues it recommended for further evaluation, including (1) whether to develop a uniform definition of "medical waste," (2) whether aesthetics is a proper criteria to use in regulating medical waste, (3) whether to maintain the current exclusions or expand the regulations to in-

14. 42 U.S.C. § 6992d (Supp. IV 1992).

15. *Id.* § 6992d(a)(1). The administrative penalty was up to \$25,000 per day per violation. *Id.* § 6992d(a)(2).

16. *Id.* § 6992d(b).

17. *Id.*

18. *Id.* § 6992d(c).

19. *Id.* The MWTA also gave EPA other enforcement-related authority, including the ability to request information concerning the generation, storage, treatment, disposal, or handling of medical waste, the power to conduct monitoring or take samples, and access to facility medical waste records. *Id.* § 6992c.

20. U.S. EPA, MEDICAL WASTE MANAGEMENT IN THE UNITED STATES, SECOND INTERIM REPORT TO CONGRESS PB91-130187, at 34 (1990) [hereinafter SECOND INTERIM REPORT].

21. 42 U.S.C. § 6992g (Supp. IV 1992). According to the EPA, the third and final report required by the MWTA has not been issued and has been delayed indefinitely. Telephone interview with Superfund/RCRA Hotline (Feb. 8, 1994).

22. SECOND INTERIM REPORT, *supra* note 20, at 10-11.

23. *Id.*

clude exempt areas such as home health care and household medical waste, (4) whether to implement a different tracking and reporting system, (5) whether the EPA should develop uniform standards for TDDs based on objective measures rather than the current general definitions, and (6) whether to implement a uniform program addressing all aspects of medical waste similar to the hazardous waste program.²⁴ In particular, EPA acknowledged that generators, transporters, and TDDs may encounter conflicting or overlapping requirements because of the independent development of state and local programs.²⁵ Additionally, EPA noted that because states lack the power to regulate medical waste traveling through interstate commerce, a federal program may be necessary.²⁶

3. Pending Federal Legislation

After expiration of MOWTA, there have been a number of bills before Congress concerning medical waste. One pending bill would impose a ten cent tax on "unsafe" needles that do not comply with existing standards; the intent is to reduce the risk of needlesticks.²⁷ The bill aims at protecting those persons potentially exposed to needlesticks, including laboratory workers, nurse's aides, and sanitation workers. Another bill, entitled "Pollution Prevention and Incineration Alternatives Act of 1993,"²⁸ would require permit applicants seeking permits after December 31, 1996 to conduct, among other things, a waste composition analysis of the solid waste generated in the area for the year and annually thereafter.²⁹ To continue to operate, each incineration facility would be required to show that each year it diverted eighty percent of medical waste to waste management methods other than incineration.³⁰ Furthermore, the bill would require permit applicants to provide a grant of at least \$50,000 to local groups to participate in the permit approval process.³¹ This bill also would impose a moratorium on new incineration permits until the year 1997.³²

B. STATE REGULATION OF MEDICAL WASTE

1. Overview

As of 1993, forty-three states have enacted various regulations controlling medical or infectious waste.³³ States with laws similar to the federal pro-

24. *Id.* at 26-29.

25. *Id.* at 29.

26. *Id.*

27. H.R. 1304, 103d Cong., 1st Sess. (1993) (introduced by Rep. Pete Stark); *see also Anti-Needlestick Bill*, *supra* note 13, at 140-41.

28. H.R. 2488, 103d Cong., 1st Sess. (1993) (introduced by Rep. Bill Richardson, June 22, 1993).

29. *Id.*

30. *Id.*

31. *Id.* In addition to the public participation process, construction must be approved by the local government. *Id.*

32. *Id.*

33. Colorado, Michigan, and Montana have enacted statutes governing infectious waste management, but have not developed regulations. *See* COLO. REV. STAT. ANN. § 25-15-401

gram include Texas, New Mexico, Minnesota, Oregon, California, Delaware, Louisiana, Maine, North Carolina, and Ohio.³⁴ The state laws, however, differ significantly in terminology used and regulatory controls imposed. For example, the term "regulated medical waste" ranges from infectious waste, biohazardous waste, biomedical waste, medically hazardous waste, and regulated medical waste to special waste.³⁵ This variation creates a burden on the regulated community and may impose conflicting obligations, making compliance difficult.³⁶ In addition to the inconsistent requirements, the varied state legislation also may lead to "forum shopping," where parties search for the state with the least expensive regulatory system to dispose of their wastes or to establish businesses.³⁷

2. Texas Medical Waste Regulations

Under the Texas Solid Waste Disposal Act (SWDA),³⁸ health care waste is defined as "medical waste," which includes both "special waste from health care related facilities" and "other medical waste."³⁹ "Special waste" includes sharps (e.g., needles, blades), pathological waste, microbiological waste, animal waste, and bulk blood and blood products.⁴⁰ Household medical wastes are excluded from regulation.⁴¹ "Other medical waste" is defined as waste from health care facilities excluding garbage and rubbish from offices, kitchens, or non-health care activities, subject to special handling requirements.⁴² The Solid Waste Division of the Texas Department of Health (TDH), a predecessor to the Texas Natural Resource Conservation Commission (TNRCC), which now has primary jurisdiction over medical waste, developed a regulatory system for medical waste that is almost identical to the former federal MMTA program.⁴³ TDH has retained jurisdiction over on-

to -407 (West 1990 & Supp. 1993); MICH. COMP. LAWS ANN. § 333.13801-.16100 (West 1992); and MONT. CODE ANN. § 75-10-1001 to -1006 (1993). Wisconsin and Wyoming have developed guidelines regarding certain aspects of infectious waste management. Guidelines for the Handling and Treatment of Medical/Infectious Waste, Solid and Hazardous Waste Management Bureau, Wisconsin Department of Natural Resources, May 1991, November 1, 1993 Letter from J.C. Kleinschmidt P.G., Environmental Analyst, Solid Hazardous Waste Division, Wyoming Department of Environmental Quality. Kentucky and Washington have regulations governing only the incineration of infectious waste and sharps. 401 KY. ADMIN. REGS. 59:023, 61:013 (1988); 902 KY. ADMIN. REGS. 20:016 (1992); WASH. REV. CODE ANN. § 70.95D (West 1992).

34. Shumaker, *supra* note 2, at 556-57.

35. *Id.* at 564 n.41.

36. Goldie, *supra* note 12, at 132, 134-38.

37. Shumaker, *supra* note 2, at 598-99.

38. TEX. HEALTH & SAFETY CODE ANN. § 361.001-.345 (Vernon 1992 & Supp. 1994).

39. 30 TEX. ADMIN. CODE § 330.5 (West Supp. 1993-94). Medical waste generally may include: animal waste, blood and blood products, microbiological waste, pathological waste, and sharps. Sharps include needles, scalpel blades, razor blades, pasteur pipettes, and broken glass from laboratories. *Id.*; 25 TEX. ADMIN. CODE § 1.132 (West Supp. 1993-94).

40. 30 TEX. ADMIN. CODE § 330.5. "Special waste" is any waste which is improperly treated or handled or for which disposal may pose a present or potential danger to human health or the environment. *Id.*

41. 25 TEX. ADMIN. CODE § 1.132, .134.

42. 30 TEX. ADMIN. CODE § 330.5.

43. *Id.* § 330.1001-.1009.

site pretreatment of medical waste. As a consequence, regulations describing medical waste and the pretreatment requirements are found in title 25 of the Texas Administrative Code, rather than with TNRCC rules.⁴⁴ Collectively, the Texas regulations set forth very specific medical waste treatment requirements, impose specific waste management duties on generators and transporters, set forth the acceptable methods of medical waste storage and disposal, and implement a medical waste tracking system.

a. Generator Duties

In April 1990, requirements applicable to generators of "special wastes" became effective. The regulations require, among other things, waste segregation, use of a specified method for any on-site treatment, recordkeeping relating to on-site waste treatment and off-site shipments, and meeting specified disposal requirements.⁴⁵ The specified methods of disposal include chemical disinfection, incineration, encapsulation (for sharps in containers), steam sterilization, and thermo-inactivation.⁴⁶ Medical waste treated using one of these methods may be landfilled, but the regulations prohibit landfilling of *untreated* medical waste when the generator is located within seventy-five miles of a treatment facility.⁴⁷ Additionally, generators must observe packaging and labeling rules for any off-site shipment of "untreated" special waste, use only TNRCC-registered transporters, initiate the tracking system, and maintain shipping records for a period of at least three years.⁴⁸ The range of potential generators is broad — covering blood banks, research centers, home health care agencies, and even funeral establishments.⁴⁹

Perhaps the most important duty for generators is identifying wastes. Generators must be aware of the rules for special wastes, solid waste such as garbage, and hazardous waste. Some states regulate certain chemotherapy and pharmaceutical wastes as medical waste.⁵⁰ Such wastes, however, also may be deemed hazardous waste under federal rules.⁵¹ Mixtures of special waste and hazardous waste constitute hazardous waste under the Texas sys-

44. See 25 TEX. ADMIN. CODE § 1.131-.137 (Definition, Treatment and Disposition of Special Waste from Health Care Related Facilities).

45. 30 TEX. ADMIN. CODE § 330.1004(b)-(c).

46. *Id.* § 330.1004(c)(1).

47. See 25 TEX. ADMIN. CODE § 1.136; 30 TEX. ADMIN. CODE § 330.1004(d).

48. 30 TEX. ADMIN. CODE § 330.1004(h).

49. 25 TEX. ADMIN. CODE § 1.135. The regulations apply to special waste generated by publicly and privately owned or operated health care related facilities including "but not limited to" ambulatory surgical centers, abortion and birthing clinics, blood banks, clinics including medical, dental, and veterinary clinics, clinical, diagnostic, pathological or biomedical research laboratories, educational institutional health center laboratories, emergency medical services, in-stage renal dialysis facilities, funeral establishments, home health care agencies, hospitals, long-term care facilities, mental health and retardation clinics, pharmacies, pharmaceutical and research laboratories, professional offices including physicians and dentists, special residential care facilities, and veterinary clinics. *Id.*

50. See, e.g., 35 PA. CODE § 271.1 (1988). Waste such as chemotherapy waste is not "medical waste" even if the facility was a health care provider, but could be a "hazardous waste" or "special waste" under state laws or RCRA.

51. 40 C.F.R. § 259.30(b)(1) (1990). The EPA has listed several chemotherapeutic agents as "hazardous waste," such as mitomycin C, uracil mustard, and chlorambucil. *Id.* § 261.33.

tem, the same as under the federal system.⁵² Mixtures of special waste and other regulated waste are deemed to be special waste.⁵³

b. Transporter Duties

The Texas medical waste transporter regulations provide that any person who collects for transport, or who transports, "untreated" medical waste from health care related facilities must comply with the regulations.⁵⁴ Transporters of "treated" waste, such as waste ash or ground sterilized residues, therefore, are exempt from medical waste regulation.

Transporters must register with TNRCC and pay an annual registration fee.⁵⁵ The regulations also establish standards for transportation vehicles and require transporters to deliver medical waste only to properly licensed disposal or treatment facilities.⁵⁶ Additionally, the regulations prevent "backhauling" and require transporters, after completing a shipment of medical waste, to clean and disinfect their vehicles before any other cargo is carried.⁵⁷ Moreover, transporters must provide evidence of financial responsibility, currently through a general liability policy, a performance bond, or a letter of credit.⁵⁸ After receipt of a shipment of medical waste, a transporter must furnish the generator with a signed receipt that includes the address, telephone number, and registration number of the transporter and identifies the generator with the same information.⁵⁹ Transporters must maintain a copy of transport documents for at least three years.⁶⁰ The regulations also govern transfer of medical waste between vehicles.⁶¹ As an industry practice, many transporters will provide generators with certificates of destruction after medical waste is treated and disposed.

Generators of less than fifty pounds of special waste per month may transport their own untreated medical waste to a licensed transfer station, storage or treatment facility without complying with TNRCC transporter rules.⁶² Generators of more than fifty pounds per month may transport their own medical waste without registering with TNRCC, but they must comply with

52. Under the federal definitions, the definition of medical waste expressly excluded hazardous waste. *Id.* § 259.30(b)(1). Thus, a waste was either medical waste or hazardous waste; by definition it could not be both under the federal system. If a mixture contained both medical waste and solid waste, EPA regulations treated the mixture as a regulated medical waste. The same is true of a mixture of regulated medical waste and hazardous waste, meaning it is treated as medical waste *unless* the mixture is subject to the hazardous waste manifest requirements in Part 262 or Part 266 of 40 C.F.R. Chapter 1. Once one deciphers this exemption, it is narrow, and most mixtures were treated as hazardous waste. Only mixtures transported solely on-site or mixtures produced by conditionally exempt small quantity generators are treated as medical waste. *Id.*

53. 30 TEX. ADMIN. CODE § 330.1004(b).

54. *Id.* § 330.1005(a).

55. *Id.* §§ 330.643, 330.1005(q).

56. *Id.* § 330.1005(g).

57. *Id.* § 330.1005(h).

58. *Id.* § 330.1005(j).

59. *Id.* § 330.1005(k).

60. *Id.* § 330.1005(l).

61. *Id.* § 330.1006.

62. *Id.* § 330.1005(p).

TNRCC vehicle, waste tracking, and financial assurance requirements.⁶³ Finally, generators located in a structure contiguous to a permitted facility may transport their own waste to this facility and receive an exemption from the transporter rules as long as they meet certain conditions, including not transporting the waste along a public road or right of way.⁶⁴

Because the regulations are so recent, they raise a number of questions of interpretation. For example, is a home health care provider that transports waste from a home to the health care center a "transporter" under the regulations? Because of the exclusion for household medical waste,⁶⁵ the nurse or other provider is not a transporter. Any transport from the central health care center to a TDD, however, will be subject to the transporter rules.⁶⁶

In sparsely populated areas, TNRCC regulations allow a licensed hospital to register as a medical waste collection station and to accept untreated medical waste for storage and consolidation from facilities that generate less than fifty pounds of waste per month.⁶⁷ Hospitals that act as collection stations may not *treat* the collected waste even if the hospital treats its own medical waste on-site.⁶⁸ TNRCC will consider a health care facility that treats third party waste to be a "commercial" infectious waste treatment facility subject to the full gamut of regulations, including the solid waste and air quality permit requirements for commercial TDDs.⁶⁹ Failure to comply with the regulations may result in an administrative penalty of up to \$10,000 per day of violation and civil penalties of not less than \$100 or more than \$25,000 per day per violation, based on the SWDA.⁷⁰

c. Requirements for Storage Facilities

Facilities storing off-site generated medical waste must obtain a TNRCC permit unless they qualify as a registered medical waste collection station.⁷¹ All storage must be in a secure location with protection from vandalism and the elements (rain, wind).⁷² Any transfer or storage facility must maintain a storage temperature of less than forty-five degrees fahrenheit if waste is held for seventy-two hours or longer.⁷³

d. Authorized Treatment, Destruction, and Disposal Technologies

The present means for treatment and disposal of medical waste are essentially the methods that the health care profession has used for several years.

63. *Id.*

64. *Id.*

65. 25 TEX. ADMIN. CODE § 1.134(a)(1).

66. 30 TEX. ADMIN. CODE § 330.1005(a).

67. *Id.* § 330.1008.

68. *Id.* § 330.1008(c)(5).

69. *See id.* § 101.1 (West Supp. 1993-94) (defining commercial medical waste incinerator); *id.* § 330.4(i) and (l) (providing a permitting exemption to on-site medical and pathological waste treatment facilities for the disposal of on-site generated wastes only).

70. TEX. HEALTH & SAFETY CODE ANN. § 361.223, .251 (Vernon 1992).

71. 30 TEX. ADMIN. CODE § 330.1009(b)-(c).

72. *Id.*

73. *Id.* § 330.1009(d).

The most common of these include incineration and steam sterilization or autoclaving, with incineration being the primary treatment method.⁷⁴ In Texas, for example, every licensed hospital must have an on-site incinerator or a contract for authorized off-site disposal of its medical waste.⁷⁵ Most treatment technologies may be used on-site or at an off-site commercial facility.

Incineration is the process of using heat combustion to convert a material into a non-infectious or non-hazardous ash.⁷⁶ The benefits of on-site incineration include waste volume reduction, conversion to a more aesthetic waste, effective pathogen destruction, compatibility with most waste types, and familiarity with the process. When incineration is performed on-site, the volume reduction reduces off-site waste disposal costs. Heat recovered from the incineration process may be used as energy offsetting electricity costs for the health care facility.⁷⁷ Off-site incineration facilities may become more common due to the significant capital cost of incineration and air pollution control systems.⁷⁸ Commercial incineration facilities must obtain a TNRCC solid waste permit and a TNRCC air quality permit. Under the federal Clean Air Act,⁷⁹ the EPA must promulgate new source performance standards (NSPS) for medical waste incinerators.⁸⁰ Although the EPA has gathered substantial data regarding these NSPS, it does not expect to issue a notice of proposed rulemaking until June 1994.⁸¹

Incineration poses some potential risks. The combustion of medical waste containing chlorinated plastics can result in the emission of air pollutants such as dioxins and furans.⁸² Furthermore, incineration of medical waste may cause increased emissions of hydrogen chloride, sulphur dioxide, nitrous oxides, particulates, carbon monoxide, and trace metals.⁸³ A large percentage of these pollutants can be controlled, however, by using air pollution equipment and properly operating the entire incineration and air pollution control system.⁸⁴ State-of-the-art incineration requires well-trained operation and maintenance personnel.⁸⁵ Finally, trace metals in incinerator

74. See HOSPITAL WASTE COMBUSTION STUDY DATA GATHERING PHASE FINAL DRAFT REPORT (1987) (prepared by Radian Corporation for EPA) [hereinafter DRAFT REPORT].

75. 25 TEX. ADMIN. CODE § 133.5 (West Supp. 1993-94).

76. U.S. EPA, OFFICE OF SOLID WASTE - EMERGENCY RESPONSE, EPA GUIDE FOR INFECTIOUS WASTE MANAGEMENT, PB86-199130, at 4-7 (1986) [hereinafter EPA GUIDE].

77. *Id.* at 4-7; *Medical Waste Treatment Technologies*, F-D-C REP., Apr. 9, 1990, at I & W-10 [hereinafter *Waste Treatment*]; DRAFT REPORT, *supra* note 74, at 1-2.

78. *Waste Treatment*, *supra* note 77, at I & W-10.

79. The Act is codified at 42 U.S.C. §§ 7401-7671q (1988, Supp. I 1989, Supp. II 1990, Supp. IV 1992).

80. *Id.* §§ 7411, 7429.

81. 56 Fed. Reg. 56,998, 57,061-62 (1993) (Notice, EPA Unified Regulatory Agenda).

82. *Waste Treatment*, *supra* note 77, at I & W-10.

83. DRAFT REPORT, *supra* note 74, at 3-1 to 3-30; Stephan K. Hall, *Infectious Waste Management: A Multi-faceted Problem*, POLLUTION ENGINEERING, Aug. 1989.

84. Shumaker, *supra* note 2, at 586-87 n.165.

85. See U.S. EPA, OFFICE OF AIR QUALITY AND PLANNING STANDARDS, CONTROL TECHNOLOGY CENTER: OPERATION AND MAINTENANCE OF HOSPITAL MEDICAL WASTE INCINERATORS, EPA-450/3-89-002 (Mar. 1989); HOSPITAL INCINERATOR OPERATOR

fly-ash may cause ash to be regulated as hazardous waste under RCRA.

Another disposal technique for infectious medical waste is steam sterilization or autoclaving. Autoclaving is well-adapted for treating microbiological cultures and stocks, clothing or other types of waste or material easily penetrable by steam or chemicals, or for instruments where the full exterior of the item is reachable. The advantages of autoclaving include effectiveness in killing pathogens, familiarity with the method, ease of operation, compatibility with many types of medical wastes, and low capital costs.⁸⁶ Autoclaving does not reduce the waste volume, so the remains must be disposed of in landfills or used as waste fuel. The process is not effective for all types of medical waste and the process may result in unpleasant odors.⁸⁷ Additionally, autoclaving uses ethylene oxide, which has a potential adverse effect on the ozone layer and is a probable carcinogen.⁸⁸ Moreover, several factors influence the effectiveness of autoclaving, including temperature, exposure time, waste container, presence of water, and waste volume and density.⁸⁹

Any on-site TDD that emits air contaminants must qualify for a standard exemption⁹⁰ or have an air quality permit from the TNRCC air quality division.⁹¹ All commercial medical waste disposal facilities must have a TNRCC solid waste disposal permit with either authority to emit air contaminants or a separate air quality permit.⁹²

New techniques beginning to emerge for disposal and treatment include microwave technologies. Microwave disposal units promise zero or reduced air emissions, volume reduction, and non-hazardous residue.⁹³ Several states have approved the microwave technology or are evaluating it, including California, North Carolina, New Jersey, Ohio, New York, Massachusetts, Pennsylvania, and Texas.⁹⁴ Additionally, plastics and resin producers in the medical market are beginning to focus on alternative treatment means such as gamma radiation.⁹⁵ Other less-used but authorized on-site technologies include thermal inactivation and chemical disinfection followed by discharge into public sewer systems or disposal in landfills.⁹⁶

Because of the increasing regulation and expense of managing medical waste, new management practices and disposal technologies also are begin-

TRAINING COURSE: Volumes I-III, EPA-450/3-89-003, EPA-450/3-89-004, EPA-450/3-89-010 (Mar. 1989).

86. *Waste Treatment*, *supra* note 77, at I & W-10.

87. *Id.*

88. EPA GUIDE, *supra* note 76, at 4-13; *Waste Treatment*, *supra* note 77, at I & W-10; Elizabeth Keische, *Waste and Costs High Among Medical Plastics Concerns*, CHEMICAL WK., June 19, 1991, at 14.

89. Hall, *supra* note 83, at 76.

90. 30 TEX. ADMIN. CODE § 116.211 (West Supp. 1993-94), Standard Exemptions 89 and 90.

91. *Id.* § 116.110(a).

92. *Id.* §§ 116.110(a), 330.4(a).

93. *Connecticut Company Cooks up a Solution for Hospital Waste*, CHI. TRIB., Jan. 6, 1991, at 9C.

94. *Id.*

95. Keische, *supra* note 88, at 14.

96. 25 TEX. ADMIN. CODE § 1.136 (West Supp. 1993-94).

ning to develop. New medical waste consultant companies are developing to assist health care providers in addressing medical waste issues.⁹⁷ Recycling components of the medical waste stream is receiving new emphasis. A recycling program in Vermont was cited as one of the first in the nation to address the issue of recycling medical waste.⁹⁸ A ton of medical waste was recycled in the first two weeks of the pilot plant's operation, consisting primarily of paper and plastics. Under the program, wastes are sorted, removing the hazardous and infectious medical waste for separate disposal.⁹⁹ Hospital employees received training on the recycling program to ensure success. One article noted that the effort reduced the medical waste from the hospital by seventy-five to eighty percent.¹⁰⁰

C. REGULATION OF HAZARDOUS AND RADIOACTIVE MEDICAL WASTE

Hazardous and radioactive wastes generated as a result of medical treatment and research must be segregated from the medical waste stream and managed separately.¹⁰¹ In Texas, health care facilities must manage hazardous medical waste in accordance with RCRA requirements as administered by the state.¹⁰² RCRA imposes a cradle-to-grave system of waste management requiring generators to manifest all hazardous wastes before transportation and disposal so that wastes may be traced back to the generator well after disposal.¹⁰³ Health care facilities must manage radioactive medical waste in accordance with the Occupational Safety and Radiation Control regulations.¹⁰⁴ Both programs create independent bases for liability.

1. Hazardous Medical Waste

A solid waste is hazardous under RCRA if (1) the waste has one of four characteristics of hazardous wastes—ignitability, corrosivity, reactivity, or toxicity,¹⁰⁵ or (2) EPA has listed the waste as hazardous waste on one of three lists.¹⁰⁶ Certain cytotoxic agents used for chemotherapy are listed as hazardous wastes. These chemotherapy wastes include cyclophosphamide (U058), daunomycin (U059), melphalan (U150), mitomycin C (U010), streptozotcin (U206), and uracil mustard (U237).¹⁰⁷ RCRA generally re-

97. *Arima Is Formed to Provide Medical Waste Consulting Services*, INTEGRATED WASTE MGMT., June 12, 1991, at 5.

98. *A Medical Waste Recycling Program Tested in Vermont*, REUTERS, June 5, 1991.

99. *Id.*

100. *Id.*; see also *Study Looks at Ways to Recycle Medical Waste*, AP DOMESTIC NEWS, May 29, 1991.

101. See 30 TEX. ADMIN. CODE § 330.1002, .1005(i) (West Supp. 1993-94).

102. See TEX. HEALTH & SAFETY CODE ANN. § 361.001-.510 (Vernon 1992); 31 TEX. ADMIN. CODE § 335.1-.480 (West Supp. 1993-94) (incorporating by reference several portions of 40 C.F.R. §§ 260-268).

103. 40 C.F.R. §§ 260-268 (1990).

104. 25 TEX. ADMIN. CODE § 289.111-.126 (West Supp. 1993-94) (incorporating by reference the Texas Regulations for Control of Radiation (TRCR)).

105. 40 C.F.R. § 261.20-.24 (1993).

106. *Id.* § 261.30-.35.

107. *Id.* § 261.33. The alpha-numeric classification following each waste name is a RCRA listing classification.

quires permits for facilities treating, storing, or disposing of hazardous waste, but provides certain exemptions based on quantity of waste generated. Most health care facilities will be classified as either conditionally exempt small quantity generators (CESQG) or small quantity generators (SQG) under RCRA and, therefore, will not be required to obtain a RCRA permit to manage and store these hazardous wastes.¹⁰⁸ A CESQG is a facility that generates less than 100 kilograms (220 pounds) of hazardous waste per month.¹⁰⁹ A SQG is a facility that generates more than 100 kilograms but less than 1000 kilograms (2,200 pounds) of hazardous waste per month.¹¹⁰

Both CESQGs and SQGs are subject, however, to waste management regulations. They must perform hazardous waste determinations on the solid waste they produce,¹¹¹ label and mark the waste as hazardous before offering it for transportation,¹¹² prepare a hazardous waste manifest,¹¹³ and dispose of the waste at a RCRA authorized facility.¹¹⁴ Facilities that are SQGs also must comply with limited recordkeeping requirements primarily involving records of manifests and waste analyses,¹¹⁵ container marking and labeling requirements involving hazardous waste identification and the waste accumulation date,¹¹⁶ container and tank management practices such as inspections and providing secondary containment,¹¹⁷ and emergency preparedness and prevention, which includes the designation of an emergency coordinator and emergency response procedures.¹¹⁸

2. Radioactive Medical Waste

Radiopharmaceuticals may be used in diagnostic studies involving measurements of uptake, dilution, and excretion or in diagnostic studies involving imaging and tumor location. For example, iodine-125 is used for studies of fat absorption and kidney functioning; fluorine-18 is used for bone imaging; and gallium-67 is used for tumor imaging.¹¹⁹ In addition, certain radioactive materials are used for cancer treatment. The use of radiopharmaceuticals by health care facilities can produce radioactive medical waste. Radioactive medical waste is federally regulated by the Nuclear Regulatory Commission (NRC) and the United States Department of Transportation (DOT), through packaging and transportation requirements. By agreement, NRC may transfer regulatory authority to a state agency. In Texas, the TDH Bureau of Radiation Control licenses equipment producing

108. A CESQG may accumulate up to 1000 kilograms of hazardous waste on-site without a RCRA permit. *Id.* § 261.5(b). An SQG may accumulate up to 6000 kilograms of hazardous waste on-site in a 180-day period without a RCRA permit. *Id.* § 262.5(d).

109. *Id.* § 261.5(a).

110. *Id.* § 260.10.

111. *Id.* §§ 261.5(g)(1), 262.11.

112. *Id.* §§ 262.30-.33.

113. *Id.* §§ 262.20-.23.

114. *Id.* §§ 261.5(g)(3), 262.12(c).

115. *Id.* § 262.44.

116. *Id.* §§ 261.31-.33, .34(d).

117. *Id.* § 262.34(d)(2), (3).

118. *Id.* § 262.34(d)(4), (5).

119. TRCR, *supra* note 104, app. 41-B.

radionuclides such as x-ray machines and activities such as using radiopharmaceuticals in laboratories and diagnosis or processing and storing radioactive waste.¹²⁰ Health care facilities must obtain a TDH license to use radioactive materials. TNRCC also regulates the disposal of radioactive substances.¹²¹

Most radioactive materials used for diagnosis and therapy have extremely short half-lives. As a consequence, a health care facility may store radioactive medical waste for a short period of time, such as eight days, to allow the material to decay to the point that it does not require management and disposal as a radioactive material. The TDH license obtained by a health care facility should address management activities such as temporary storage of radioactive medical waste.

Laboratories may use radioactive materials in liquid scintillation counters and for *in vitro* testing and cancer research. TDH allows the disposal of .05 microcuries or less of hydrogen-3, carbon-14, or iodine-125, per gram of medium, used in these testing procedures in an authorized municipal solid waste landfill, so long as the waste is not mixed with hazardous waste.¹²² A facility licensed to conduct testing procedures with radioactive substances may use the disposal authority in TRCR Section 21.307 if it submits for TDH approval procedures for (1) delivering waste to the disposal site, (2) conducting surveys of wastes generated to assure radioactivity limits are not exceeded, (3) labeling and marking radioactive materials, and (4) record-keeping.¹²³ In rare circumstances, a health care facility or laboratory may generate waste that must be packaged and transported in accordance with DOT requirements and stored, processed, or disposed of in accordance with TDH and TNRCC requirements for low-level radioactive materials.

D. CRIMINAL PROSECUTION FOR MEDICAL WASTE VIOLATIONS

1. Federal Overview

Several recent cases involving medical waste emphasize that the failure to know and follow the law can be a serious mistake, not only for waste management entities such as medical waste transporters, but also for physicians and other health care providers.¹²⁴ Health care providers should be familiar with medical waste laws and the business practices and regulatory compliance status of the companies used to transport and dispose of their medical waste. The statutes relating to medical waste generally do not require any degree of culpability or improper conduct by a health care provider or others in the chain of handling waste for liability to accrue. The Justice Department echoes EPA's aggressive enforcement sentiment.¹²⁵ The challenge for

120. 25 TEX. ADMIN. CODE § 289.116, .124.

121. 30 TEX. ADMIN. CODE § 361.1-.4.

122. TRCR, *supra* note 104, § 21.307.

123. *Id.* § 21.307(c)-(d).

124. See *infra* notes 125-46 and accompanying text.

125. *Criminal Enforcement, Doctor Convicted of Water Act Violations for Dumping Medical Waste Into Hudson River*, [Current Developments] Env't Rep. (BNA) 1812-13 (Feb. 8, 1991) [hereinafter *Criminal Enforcement*].

health care professionals is to stay abreast of emerging laws relating to medical waste and to familiarize themselves with reputable and experienced transporters and TDD facilities.

One of the largest and most serious fraud cases in the United States, *United States v. Paccione*,¹²⁶ involved medical waste management. Three defendants were convicted of mail fraud, conspiracy, and several Racketeer Influenced and Corrupt Organizations Act (RICO)¹²⁷ charges based on environmental crimes.¹²⁸ The defendants submitted false information to state agencies to obtain permits and licenses to transport and dispose of hazardous and medical wastes. The defendants then illegally disposed of the wastes. According to the *Paccione* court, the doctors and hospitals who entrusted medical waste to the defendants are potentially liable for both civil and criminal fines.¹²⁹ The court further noted that this liability existed even though the defendants had attempted to ensure the generators that they were duly licensed.¹³⁰

In *United States v. Villegas*¹³¹ a New Jersey doctor was convicted for the improper disposal of medical waste. The physician dumped, or ordered other employees to dump, vials of blood and other medical waste contaminated with hepatitis into the Hudson River. A jury found Villegas guilty of several criminal violations of the Clean Water Act, which carried a maximum sentence of a \$1,000,000 fine and thirty-six years imprisonment.¹³² State investigators tracked the waste to the physician and laboratory by coded labels on the blood vials.

The convictions were based on two Clean Water Act provisions: (1) the knowing endangerment provision, which makes it unlawful to knowingly place another in danger of death or serious bodily injury; and (2) the provision relating to knowingly discharging pollutants into waters of the United States without a permit or other authorization.¹³³ The district court reversed counts I and II of the conviction regarding knowing endangerment because it found there was insufficient evidence to prove the physician knew with a substantial certainty or a high probability that an exposure would lead to serious illness or death.¹³⁴ The Second Circuit Court of Appeals reversed the conviction, which was based on the unlawful discharge of a pollutant into water of the United States, holding that a human being is not a point source under the Clean Water Act.¹³⁵

126. 751 F. Supp. 368 (S.D.N.Y. 1990).

127. 18 U.S.C. §§ 1961-1968 (Supp. IV 1992).

128. *Paccione*, 751 F. Supp. at 371.

129. *Id.* at 372.

130. *Id.*

131. 784 F. Supp. 6 (E.D.N.Y. 1991). No opinion is available because of the rules concerning publication of criminal opinions. Such opinions are apparently not published unless a jury verdict has been overruled or there was a ruling on a preliminary motion. Telephone Interview with Michelle Roker, Court Docket Clerk (July 30, 1991).

132. *See United States v. Plaza Health Labs., Inc.*, 3 F.3d 643, 37 E.R.C. 1265, 1266 (2d Cir. 1993).

133. *See* 33 U.S.C. §§ 1311(a), 1319(c)(2), 1319(c)(3) (Supp. III 1991).

134. *Villegas*, 784 F. Supp. at 14-15.

135. *Plaza Health Labs.*, 37 E.R.C. at 1271.

In a related case, the laboratory associated with the physician, Plaza Health Laboratories, Inc., also was indicted based on the same provisions.¹³⁶ Despite the laboratory's allegation that it had no knowledge of or did not authorize the physician's actions, the New York Department of Social Services notified the laboratory that pending the outcome of the criminal action, the laboratory would be suspended from participation in the Medicaid program.¹³⁷ The Department based the suspension on the occurrence of crimes "relating to the furnishing or billing for medical care, services, or supplies."¹³⁸ Although the laboratory appealed this decision and sought an injunction to prevent the suspension, the court denied the request, finding that the disposal of waste was sufficiently related to the provision of services to permit the suspension.¹³⁹

2. State Cases

Recently, the state of California alleged that a San Francisco attorney and his law firm violated several provisions relating to the proper disposal of medical waste because of advice allegedly given relating to the waste disposal and abandonment of rental property.¹⁴⁰ This case provokes interest for several reasons. It marks perhaps the first time California prosecuted for the violation of its medical waste disposal provisions and is one of the first times it charged an attorney with responsibility for a client's alleged violations. The state alleged that the attorney informed its client's landlord that the client would not clean up medical waste at a laboratory, in part because of pending bankruptcy proceedings.¹⁴¹ When the tenant vacated the leased premises, it removed only equipment and personal belongings, leaving the medical waste in place. The tenant told a representative of the landlord that it had been advised by its attorney not to remove any medical waste.

Even though the attorney and the law firm were dismissed from the case, the case is worthy of review.¹⁴² The case demonstrates the difficulties that attorneys may face under competing laws. For example, in a bankruptcy proceeding, attorneys may violate bankruptcy law principles by advising a party to clean up or dispose of waste based on the misuse of assets of a bankruptcy estate.¹⁴³ On the other hand, attorneys might be charged with a criminal violation of environmental law if they advise clients to abandon the waste.

Also worth noting is the scope of parties charged by the state. The state

136. *Plaza Health Labs., Inc. v. Perales*, 702 F. Supp. 86 (S.D.N.Y.), *aff'd*, 878 F.2d 577 (2d Cir. 1989).

137. *Id.* at 88.

138. *Id.*

139. *Id.* at 91.

140. See First Amended Complaint at 10-11, *People v. Infergene Co.*, No. 96,922 (Solano County Mun. Ct. Cal., filed June 21, 1991).

141. *Id.*

142. Telephone Interview with Ramona Gordon, Administrative Court Clerk (July 30, 1991).

143. Bankruptcy law imposes a fiduciary duty on debtors in possession and trustees to preserve the value of the assets. See 11 U.S.C. §§ 1106(a), 1107(a) (1988).

charged various individuals associated with the laboratory with the violations: the chief operating officer, an investment banker, the general counsel, a related corporation of the CEO, the law firm, and the attorney.¹⁴⁴ Parties should be aware that criminal law does not always require the government to prove actual knowledge that an act violates the law. Rather, the state only need prove that the defendants "should have known" that an unlawful disposal or act would occur from their actions.¹⁴⁵

This discussion of federal and state enforcement actions provides only some highlights. Many other enforcement cases are pending or reaching settlement.¹⁴⁶

E. LOCAL ATTEMPTS TO RESTRICT MEDICAL WASTE DISPOSAL

1. Overview

Not unlike other waste disposal facilities, medical waste disposal facilities frequently face community opposition. Although community members agree that medical waste must be disposed of in a manner that complies with regulatory requirements and enables the total destruction of the dangerous components of the waste, communities often respond to a facility with the not-in-my-backyard phenomenon. Due to the substantial cost of retrofitting on-site medical waste disposal facilities with state-of-the-art air pollution control equipment, centralized medical waste disposal at large regional facilities is becoming more common. Permit applicants for new facilities consistently face community opposition at the permitting stage. Other communities have enacted ordinances to limit local disposal of medical waste generated outside the community. Although some ordinances have been struck down as unconstitutional under the Commerce Clause, others have been upheld. The ordinances and individual opposition to medical waste disposal facilities have the potential to significantly limit medical waste disposal capacity in the future.

2. Commerce Clause Challenges to Restrictive Ordinances

Recently, several cases regarding statutes and ordinances that restrict the importation of waste into states, counties, and cities have been decided. In *Medical Waste Associates Ltd. Partnership v. Mayor & City Council of Baltimore*¹⁴⁷ and *BFI Medical Waste Systems, Inc. v. Whatcom County*,¹⁴⁸ different ordinances restricting medical waste disposal were challenged as violations of the Commerce Clause. The Ninth Circuit struck down the Whatcom County ordinance,¹⁴⁹ but the Fourth Circuit upheld the

144. First Amended Complaint at 1-2, *Infergene* No. 96,922.

145. Ruling on Demurrers at 4-5, *Infergene* No. 96,922.

146. See, e.g., *EPA Collects \$15,000 for Medical Waste Tracking Act Violation*, P.R. NEWSWIRE ASS'N, Apr. 22, 1991.

147. 966 F.2d 148 (4th Cir. 1992).

148. 983 F.2d 911 (9th Cir. 1993).

149. *Id.* at 911.

Baltimore ordinance.¹⁵⁰

The “Negative” or “Dormant” Commerce Clause prohibits a state from curtailing commerce to advance the state’s own interest.¹⁵¹ Where simple economic protectionism is effected by a state political subdivision, a virtual *per se* rule of constitutional invalidity has been applied.¹⁵² Where other legislative objectives, such as the health and safety of state citizens, forms the basis of the ordinance, and there is no patent discrimination against interstate trade, the court may apply the balancing test set forth in *Pike v. Bruce Church, Inc.*¹⁵³ Under the *Pike* balancing test, the court must determine whether the ordinance (1) effectuates a legitimate local public interest, (2) has only an incidental effect on interstate commerce, and (3) does not impose a burden on commerce that is clearly excessive in relation to the putative local benefits.¹⁵⁴

Whatcom County enacted an ordinance prohibiting the disposal of infectious medical waste generated outside the territorial limits of Whatcom County at any waste disposal facility within Whatcom County.¹⁵⁵ BFI Medical Waste Systems, Inc. (BFI) had the exclusive right to use up to four tons per day of medical waste capacity at a commercial incinerator inside Whatcom County for disposal of medical waste from Vancouver, British Columbia, Washington, and Oregon. BFI challenged the constitutionality of the Whatcom County ordinance as a violation of the Commerce Clause. The Ninth Circuit Court of Appeals affirmed summary judgment in favor of BFI, holding that the ordinance violated the Commerce Clause.¹⁵⁶

The court of appeals followed the United States Supreme Court holding that out-of-county waste bans are *per se* unconstitutional.¹⁵⁷ To avoid a *per se* violation of the Commerce Clause, the court stated that Whatcom County must demonstrate that its discrimination was “justified by a valid factor unrelated to economic protectionism.”¹⁵⁸ Whatcom County based its ordinance on a concern for the health and safety of its citizens due to medical waste transportation and disposal, but failed to demonstrate that medical waste generated outside the county was more dangerous to its citizens than medical waste generated within the county. The court reasoned that the ordinance was no more than a preference for local waste.¹⁵⁹

Without addressing the United States Supreme Court decisions in *Fort Gratiot* and *Chemical Waste Management, Inc. v. Hunt*,¹⁶⁰ the Fourth Cir-

150. *Medical Waste Assoc.*, 966 F.2d at 153.

151. *Fort Gratiot Sanitary Landfill, Inc. v. Michigan Dep’t of Natural Resources*, 112 S. Ct. 2019, 2022 (1992).

152. *City of Philadelphia v. New Jersey*, 437 U.S. 617, 627 (1978).

153. 397 U.S. 137 (1970).

154. *Id.* at 142.

155. *BFI Medical Waste Sys., Inc. v. Whatcom County*, 756 F. Supp. 480, 482 (W.D. Wash. 1991), *aff’d in part & rev’d in part*, 983 F.2d 911 (9th Cir. 1993).

156. *BFI Medical Waste Sys.*, 983 F.2d at 913.

157. *Id.* (citing *Fort Gratiot Sanitary Landfill, Inc.*, 112 S. Ct. at 2022).

158. *Id.* (quoting *New Energy Co. v. Limbach*, 486 U.S. 269, 274 (1988)).

159. *Id.* at 913.

160. 112 S. Ct. 2009 (1992).

cuit Court of Appeals upheld a Baltimore ordinance that restricted the use of a new medical waste incinerator to medical waste generating facilities participating in the Northeast Maryland Waste Disposal Authority, which covered Baltimore City and County, Anne Arundel County, and Hartford County, Maryland.¹⁶¹ In affirming summary judgment in favor of the Mayor and City Council of Baltimore, the court held that the ordinance did not violate the Commerce Clause under the *per se* rule because the ordinance restricted only the disposal of imported waste at one facility.¹⁶² The court went on to create a "single facility" exception to the *per se* rule, which would allow a city to restrict a single facility's use to its residents, in order to solve a regional waste management problem. This exception was derived from an exception that allows a governmental entity to build and operate a waste disposal facility reserving its entire capacity to its residents.¹⁶³ This exemption, however, ignores the distinction between a private commercial facility, ostensibly operated for profit, and a public facility, constructed with taxpayer resources and operated as a community service.

Once the court found that the *per se* rule did not apply, it used the *Pike* balancing test to hold the ordinance constitutional.¹⁶⁴ The court stated that the ordinance furthered a legitimate local public interest: compliance with state emergency regulations and the prevention of improper medical waste disposal in the Baltimore and Chesapeake Bay area.¹⁶⁵ Because the ordinance restricted disposal at only one facility, the court found no burden on interstate commerce, noting that the ordinance did not prevent construction of other medical waste disposal facilities in Baltimore capable of receiving medical waste generated outside of the community.¹⁶⁶

Considering *Fort Gratiot*, which was decided nearly seven weeks before the Fourth Circuit amended its decision in *Medical Waste Associates*, the Fourth Circuit decision may be wrong. The *Fort Gratiot* case addressed amendments to the Michigan Solid Waste Management Act, which enabled Michigan counties to prohibit the disposal of out-of-county waste at a particular facility based on a desire to preserve the capacity of local disposal facilities for locally generated wastes. These amendments required each Michigan disposal facility seeking to receive out-of-county waste to obtain explicit authorization under the county's solid waste management plan. The amendments did not ban all out-of-county or out-of-state waste from Michigan's borders nor would their application necessarily prohibit every disposal facility within a county from receiving out-of-county waste. When the Fort Gratiot sanitary landfill was denied authorization to dispose of out-of-county waste, it sued the state contending that requiring a private landfill operator to limit business to the acceptance of local waste constituted impermissible

161. *Medical Waste Assoc.*, 966 F.2d at 148.

162. *Id.* at 150-51.

163. *Id.*

164. *Id.* at 151.

165. *Id.*

166. *Id.* at 151-52.

discrimination against interstate commerce. The Supreme Court agreed.¹⁶⁷

The Supreme Court held that such restrictions violated the Commerce Clause because the statute afforded local waste producers complete protection from competition of out-of-state waste producers who seek to use local waste disposal facilities. Furthermore, the Court could find no valid health and safety reason for limiting the amount of waste that a disposal facility operator may accept from out-of-state, but not the amount of waste the operator may accept from inside the state.¹⁶⁸ As a consequence, the Court found that the amendments, which do not ban *all* out-of-state waste from a county, unambiguously discriminated against interstate commerce.

Under *Fort Gratiot* the government cannot force a single commercial facility to reserve all of its capacity for local users. Therefore, the decision abrogates the Fourth Circuit's "single facility" exception to the *per se* rule. Had the Fourth Circuit followed the holding in *Fort Gratiot*, it likely would have found the ordinance a *per se* violation of the Commerce Clause and would not have reached the *Pike* balancing test.

The *BFI Medical Waste Systems* and *Medical Waste Associates* cases demonstrate the manner in which a community may attempt to restrict medical waste disposal through an ordinance. Due to the *Fort Gratiot* and *Chemical Waste Management* decisions, restrictions on private facilities may not be successful. Nonetheless, these attempts at restrictions and local concerns for adequate capacity may constrict the disposal market in the future, increasing disposal costs for medical waste generators.

III. CERCLA LIABILITY

Hazardous wastes and radioactive wastes are "hazardous substances" under the Comprehensive Environmental Response Compensation and Liability Act¹⁶⁹ (CERCLA or Superfund). As a result, a medical waste generator can be a potentially responsible party (PRP) at a facility where its wastes are disposed if there has been a release or threat of release of hazardous substances.¹⁷⁰ Although CERCLA does not use the term "generator" when identifying PRPs, a generator whose wastes have been disposed at an off-site facility subject to CERCLA could be an "arranger" under CERCLA — one who has arranged for the treatment or disposal of hazardous substances at a site from which there has been a release.¹⁷¹ CERCLA liability is strict: Compliance with the law or the use of due care does not preclude the imposition of liability.¹⁷² CERCLA liability generally may also be joint and several,¹⁷³ meaning the government or a private party can sue any PRP for the

167. *Fort Gratiot*, 34 E.R.C. at 1734.

168. *Id.* at 1732, 1734.

169. 42 U.S.C. § 9601(14) (Supp. IV 1992).

170. *See id.* § 9607.

171. *Id.*

172. *See id.* § 9607(b).

173. *But see* *Bell Petroleum Serv., Inc. v. Sequa Corp.*, 3 F.3d. 889, 902 (5th Cir. 1993) (holding that CERCLA does not mandate joint and several liability, rather it should be imposed only when appropriate, applying common-law principles).

entire cost of remediation and damages, leaving that PRP to seek contribution from others.¹⁷⁴ CERCLA provides for sanctions for failure to comply with reporting requirements or with agency orders, but liabilities for investigation and remediation are a PRP's most serious costs.¹⁷⁵

IV. OCCUPATIONAL SAFETY AND HEALTH ACT

Congress enacted the Occupational Safety and Health Act of 1970¹⁷⁶ (the Act) to assure "safe and healthful working conditions and to preserve our human resources" by encouraging employers and employees to institute new programs and perfect existing programs for providing safe and healthy working conditions.¹⁷⁷ Under the Act, employers have a duty to provide a place of employment "free from recognized hazards that are causing or are likely to cause death or serious physical harm to . . . employees."¹⁷⁸ The Act authorized the Occupational Safety & Health Administration (OSHA) to promulgate occupational safety and health regulations, to provide medical criteria to assure employee health, and to develop recordkeeping and reporting procedures on employee training, hazard information, and injuries.¹⁷⁹

Certain OSHA standards are of specific interest to health care facilities, such as the OSHA Industry and Illness Recordkeeping and Reporting Requirements, the General Industry Safety and Health Standards, and the Occupational Exposure to Bloodborne Pathogens Standard (Bloodborne Pathogens Rule). The General Industry Safety & Health Standards, which apply to all types of employers, require programs to protect against and keep records of common workplace injuries from mechanical hazards, chemical hazards, air contaminants, and physical strains such as lifting and repetitive motion.¹⁸⁰ The Bloodborne Pathogens Rule, which became effective March 6, 1992, applies to all occupational exposure to blood and other potentially infectious materials and is an effort to minimize occupational exposure to the Hepatitis B virus (HBV), the Human Immunodeficiency Virus (HIV), and other bloodborne pathogens.¹⁸¹

A. RECORDING AND REPORTING OCCUPATIONAL INJURIES AND ILLNESSES

OSHA regulations require recordkeeping and reporting "as necessary or appropriate for enforcement of the Act, for developing information regard-

174. 42 U.S.C. § 9613(f) (1988).

175. *See id.* § 9613(f)(1).

176. 29 U.S.C. §§ 651-678 (1988).

177. *Id.* § 651.

178. *Id.* § 654(a).

179. *Id.* § 655.

180. *Id.* § 654(a).

181. 29 C.F.R. § 1910.1030(a) (1993). The Bloodborne Pathogens Standard does not apply to volunteers, public sector employees, sole practitioners with no employees, first aid responders, and good samaritans. The Bloodborne Pathogens Rule does apply to remediation and emergency response activities, such as operation of medical waste incinerators and spill responses. *See U.S. EPA, THE EFFECT OF OSHA'S BLOODBORNE PATHOGENS STANDARD ON HAZARDOUS WASTE CLEANUP ACTIVITIES (Fact Sheet) (1993).*

ing the causes and prevention of occupational accidents and illnesses, and for maintaining a program of collection, compilation, and analysis of occupational safety and health statistics."¹⁸² OSHA recordkeeping requirements apply to most private sector employers and involve maintaining a Log of Occupational Injuries and Illnesses, a Supplementary Injury and Illness Record, completing and posting an Annual Summary of Injuries and Illnesses, and reporting fatalities and multiple hospitalization accidents.¹⁸³ Employers must retain these records for five years.¹⁸⁴ Employers with less than ten employees and employers in low-hazard industries are exempt from all injury and illness recordkeeping requirements except reporting fatalities and multiple hospitalization accidents.¹⁸⁵ Low-hazard industries are identified and categorized according to their Standard Industrial Classification (SIC) code and their average lost work-day case injury rate. Health services under SIC 80 were not included among the exempt industries because of the average lost work-day case injury rate.

B. GENERAL INDUSTRY SAFETY & HEALTH STANDARDS

1. *Personal Protective Equipment*

Personal protective equipment for eyes, face, head, and extremities, protective clothing, respiratory devices, and protective shields and barriers must be provided when employees encounter a process, environmental hazard, chemical hazard, radiological hazard, or mechanical irritant in a manner capable of causing injury or impairment in the function of any part of the body due to absorption, inhalation, or physical contact.¹⁸⁶ Employers must maintain protective equipment in a sanitary and reliable condition.¹⁸⁷ For health care facilities, personal protective equipment will include, among other things, gloves, eye protection, and barriers to protect against radiation. Prior to the establishment of the Bloodborne Pathogens Rule, OSHA urged employers to minimize occupational exposure to infections through the use of gloves and protective gowns.

2. *General Environmental Controls*

The regulations regarding general environmental controls include two components that specifically affect health care facilities: a sanitation requirement and accident prevention tags. OSHA requires employers to keep all places of employment clean to the extent the nature of the work allows.¹⁸⁸ At health care facilities, this requirement may be construed to require the use of disinfectants to sanitize areas exposed to infectious materials. OSHA requires employers to use hazard tags as a method of preventing accidental

182. 29 C.F.R. § 1904.1 (1993).

183. *Id.* § 1904.2, .4, .5, .8.

184. *Id.* § 1904.6.

185. *Id.* § 1904.15(a)-(b).

186. 29 C.F.R. § 1910.132(a) (1993).

187. *Id.*

188. 29 C.F.R. § 1910.141(a)(3) (1993).

injury or illness to employees who are exposed to hazardous conditions, equipment, or operations that are out-of-the-ordinary, unexpected, or not readily apparent.¹⁸⁹ The rules require employers to use biological hazard tags to identify the actual or potential presence of a biological hazard and to identify equipment, containers, rooms, or laboratory animals that contain or are contaminated with hazardous biological agents.¹⁹⁰

3. *Occupational Health and Environmental Controls*

The Occupational Health and Environmental Control rules contain requirements regarding the control of ionizing radiation, a component of the health care workplace.¹⁹¹ OSHA regulations provide that no employer may possess, use, or transfer sources of ionizing radiation in a manner that may cause any adult individual in a restricted area to receive in any single calendar quarter a radiation dose in excess of the prescribed OSHA limits.¹⁹² Exposure limits for individuals under eighteen years old are ten percent of the adult dosage.¹⁹³ Health care facilities providing radiology services must comply with these regulations.¹⁹⁴ When appropriate, employers must evaluate the workplace for ionizing radiation by conducting a physical survey of the location of the materials and equipment and measurements of levels of radiation or concentrations of radioactive material present.¹⁹⁵ The employer also must supply and require the use of appropriate personnel monitoring equipment, such as film badges, pocket chambers, pocket dosimeters, or film rings.¹⁹⁶

Employers affected by these rules must:

- (1) post appropriate caution signs, caution labels, and signals;¹⁹⁷
- (2) inform all employees working in or frequenting any portion of a radiation area of the occurrence of radioactive materials or of radiation in those areas;¹⁹⁸
- (3) instruct employees regarding the safety problems associated with exposure to radioactive materials or radiation, precautions or devices to minimize exposure, the applicable provisions of the regulations for the protection of employees from exposure to radiation or of radioactive materials;¹⁹⁹

189. *Id.* § 1910.145(f)(3).

190. *Id.* § 1910.145(f)(8).

191. 29 C.F.R. § 1910.96 (1993).

192. *Id.* § 1910.96(b)(1). Table G-18 of the rule identifies the following limits per calendar quarter: whole body: head and trunk, active blood-forming organs, lens of eyes, or gonads — 1/4 rems; hands and forearms, feet and ankles — 18 3/4 rems; skin of whole body — 7 1/2 rems. *Id.*

193. *Id.* § 1910.96(b)(2)(3).

194. *See id.* § 1910.96(c)(1)-(2) (the law applies to any facility using radiation and radioactive material).

195. *Id.* § 1910.96(a)(1).

196. *Id.* § 1910.96(d)(2).

197. *Id.* § 1910.96(e).

198. *Id.* § 1910.96(i)(2).

199. *Id.*

- (4) advise employees of reports of radiation exposure;²⁰⁰
- (5) post a current copy of the provisions and operating procedures applicable to the work area or keep the provisions and operating procedures available for examination by employees upon request;²⁰¹ and
- (6) provide notice to the Secretary of Labor regarding excessive occupational exposure.²⁰²

Additionally, storage of radioactive materials, which can include medical waste, in a non-radiation area must be secured against unauthorized removal.²⁰³

C. TOXIC AND HAZARDOUS SUBSTANCES

1. Occupational Exposure to Air Contaminants

OSHA regulates occupational exposure to hazardous and toxic air contaminants by setting permissible exposure limits (PELs). These PELs are based either on ceiling concentrations to which an employee may be exposed or concentrations developed as an eight hour time-weighted average. These rules may be relevant in dentist offices or other health care facilities depending on the chemicals used such as nitrous oxide, barium, and formaldehyde. In addition, an employer must prevent or reduce skin absorption of hazardous and toxic substances by its employees through the use of gloves, coveralls, goggles, or other appropriate personal protective equipment, engineering controls, or work practices.²⁰⁴

OSHA also has established a workplace PEL for airborne asbestos, which could be released from asbestos-containing materials such as insulation or ceiling and floor tiles. If an employer determines that airborne asbestos exceeds 0.2 fibers per cubic centimeter, the employer must conduct monitoring and comply with OSHA notification requirements.²⁰⁵

2. Hazard Communication

The OSHA Hazard Communication Standard addresses the evaluation of potential hazards of chemicals and the communication of chemical hazard information and appropriate protective measures to employees.²⁰⁶ "Hazardous chemicals" include any element, chemical compound, or mixture of elements or compounds that cause a physical hazard²⁰⁷ or a health hazard.²⁰⁸ If a commercial product is a "hazardous chemical," then the manufacturer

200. *Id.*

201. *Id.* § 1910.96(i)(3).

202. *Id.* § 1910.96(i).

203. *Id.* § 1910.96(j).

204. 29 C.F.R. § 1910.1000(e) (1993).

205. *Id.* § 1910.1001(c)-(d).

206. 29 C.F.R. § 1910.1200(a)(2) (1993).

207. Chemicals that create a physical hazard are those for which there is scientifically valid evidence that the chemical is a combustible liquid, a compressed gas, an organic peroxide, an oxidizer, or explosive, flammable, pyrophoric, reactive, or water-reactive. *Id.* § 1910.1200(c).

208. Chemicals that cause a health hazard are those for which there is statistically significant evidence that acute or chronic health effects may occur in exposed employees. These chemicals include carcinogens, toxic agents, reproductive toxins, irritants, corrosives, sensitiz-

must prepare a Material Safety Data Sheet (MSDS) describing the chemical's hazard classification and its hazardous characteristics.²⁰⁹ Employers must have an MSDS for each chemical used and must provide to their employees information about the hazardous chemicals to which employees are exposed.²¹⁰ Generally, information is provided by means of a hazard communication program, package labels and warnings, MSDS, and training programs regarding chemical hazards and protective measures.²¹¹

In addition to hazardous chemicals brought into the workplace, the Hazard Communication Standard also applies to any chemical that is known to be present in a workplace in a manner that employees may be exposed under normal conditions of use or in a foreseeable emergency.²¹² If employees only handle chemicals in sealed containers that are not opened under normal conditions, employers must (i) ensure that labels on incoming containers of hazardous chemicals are not removed or defaced, (ii) maintain copies of the appropriate MSDS in an area readily accessible to employees, and (iii) provide employees with information and training necessary to protect the employees in the event of a spill or leak of a hazardous chemical from a sealed container.²¹³

Employers also must develop, implement, and maintain at the workplace a written hazard communication program that describes how the employer will meet the criteria specified for labels and other forms of warning, MSDS, and employee information and training.²¹⁴ The written hazard communication program also must include a list of the hazardous chemicals known to be present in the workplace and the methods the employer will use to inform employees of the hazards of non-routine tasks and the hazards associated with chemicals contained in unlabeled pipes in their work areas.²¹⁵

3. Occupational Exposure to Hazardous Chemicals in Laboratories

The Occupational Exposure to Hazardous Chemicals in Laboratories Standard (the Laboratory Standard)²¹⁶ applies to all employers who use multiple hazardous chemicals on a laboratory scale in non-production process laboratories.²¹⁷ The Laboratory Standard supersedes all other OSHA standards for Toxic and Hazardous Substances, such as the Hazard Communication Standard, but does not supersede PELs (found at table 1910.1000, table Z-1-A) and any prohibition against eye and skin contact.²¹⁸ Clinical-

ers, hepatotoxins, nephrotoxins, neurotoxins, agents that act on the blood formation system, and agents that damage lungs, skin, eyes, or mucous membranes. *Id.*

209. *Id.* § 1910.1200(g)(1).

210. *Id.* § 1910.1200(g)(2).

211. *Id.* § 1910.1200(e)-(h).

212. *Id.* § 1910.1200(a)(2).

213. *Id.* § 1910.1200(b)(4).

214. *Id.* § 1910.1200(e).

215. *Id.*

216. 29 C.F.R. § 1910.1450 (1990).

217. *Id.* § 1910.1450(a)(1), (b). The Laboratory Standard does not apply to laboratory uses of hazardous chemicals that provide no potential for employee exposure. *Id.* § 1910.1450(a)(3)(ii).

218. *Id.* § 1910.1450(a)(2).

pathological type laboratories that accept unknown tissue samples and cultures for identification and verification must comply with the Laboratory Standard,²¹⁹ whereas quality-assurance laboratories, such as those preparing pharmaceuticals, must comply with the Hazard Communication Standard, among others.²²⁰

Employers must develop and implement a written Chemical Hygiene Plan that is capable both of protecting employees from health hazards associated with hazardous chemicals in the laboratory and of keeping exposures below regulatory limits.²²¹ The Chemical Hygiene Plan must be available to employees and, upon request, to an OSHA representative.²²² At the time of an employee's initial assignment to a work area where hazardous chemicals are present and before assignments involving new exposure situations, the employer must provide employees with information and training to ensure they are apprised of the hazards of chemicals present in their workplace.²²³ Employers also are required to establish and maintain for each employee an accurate record of any measurements taken to monitor employee exposures and any medical consultation and examinations, including tests or written opinions required by this standard.²²⁴

With respect to materials coming into the laboratory, employers must insure that labels on canisters of hazardous materials are not removed or defaced. Employers must maintain MSDS associated with incoming materials in a place easily accessible to laboratory employees.²²⁵

4. Occupational Exposure to Bloodborne Pathogens

In promulgating the Bloodborne Pathogens Rule, OSHA determined that employees face a significant health risk as a result of occupational exposure to blood and other potentially infectious materials that may contain bloodborne pathogens.²²⁶ OSHA further concluded that this exposure can be minimized or eliminated using a combination of universal precautions, engineering and work practice controls, personal protective clothing and equipment, training, medical surveillance, Hepatitis B vaccine, signs and labels, and other provisions.²²⁷ The Bloodborne Pathogens Rule affects nearly every aspect of the health care industry in attempting to eliminate or minimize exposure to HBV, HIV, and other bloodborne pathogens. The Seventh Circuit Court of Appeals has held, however, that the Bloodborne Pathogens rule did not apply in situations where an employer could not control the site of the health care activity, such as the in-home provision of

219. *Id.* § 1910.1450(h)(2)(ii).

220. *Id.* § 1910.1450(h)(2)(iii).

221. *Id.* § 1910.1450(e)(1).

222. *Id.* § 1910.1450(e)(2).

223. *Id.* § 1910.1450(f).

224. *Id.* § 1910.1450(j).

225. *Id.* § 1910.1450(h).

226. Occupational Exposure to Bloodborne Pathogens, 56 Fed. Reg. 64,004 (1991) (preamble).

227. *Id.*

health care services.²²⁸

Before promulgating the Bloodborne Pathogens Rule, OSHA could protect against exposure to pathogens through use of the "general duty clause" and miscellaneous provisions of the General Industry Safety and Health Standard requiring protective gowns and gloves as personal protective equipment,²²⁹ requiring the use of disinfectants to promote a sanitary workplace,²³⁰ prohibiting the recapping of needles by hand and mandating the use of puncture-resistant sharps containers,²³¹ and requiring biological hazard tags and the use of redbags for medical waste as hazard identification.²³² These broadly written standards made enforcement difficult for OSHA because it had to prove that a reasonable person familiar with the circumstances surrounding an allegedly hazardous condition would recognize a hazard warranting the use of personal protective equipment and other precautionary measures.²³³

Under the Bloodborne Pathogens Rule, OSHA mandates three types of protective activities to prevent contact with blood and/or other potentially infectious materials: universal precautions, workplace controls, and personal protective equipment.²³⁴ "Universal precautions" are defined as the assumption that all human blood and body fluid is treated as if known to be infected with HBV, HIV, and other bloodborne pathogens.²³⁵

Workplace controls take the form of either engineering controls or work practice controls. Engineering controls affect the source of the hazard, often omitting it. Engineering controls can include (1) process or equipment redesign, such as self-sheathing needles; (2) enclosures, such as biosafety cabinets; or (3) employee isolation.²³⁶ Work practice controls alter the manner in which a task is performed, and as a result, their success depends on employee behavior.²³⁷ Work practice controls include handwashing or prescribing methods for encapsulating needles for disposal.

In a circumstance of occupational exposure, the employer must provide appropriate personal protective equipment including, but not limited to, gloves, gowns, face shields or masks, eye protection, resuscitation bags, and other ventilation devices.²³⁸ Only personal protective equipment that does not permit blood or other potentially infectious materials to pass through to or reach the employee's clothing, skin, eyes, mouth, or other mucous membranes under normal conditions of use and for the duration of the time that

228. *American Dental Ass'n v. Martin*, 984 F.2d 823 (7th Cir.), *cert. denied*, 114 S. Ct. 172 (1993).

229. 29 C.F.R. § 1910.132(a) (1992).

230. *Id.* § 1910.22(a).

231. *Id.* § 1910.145(f).

232. *Id.*

233. 56 Fed. Reg. 64,004 (1991) (preamble); *see also* *General Dynamics Corp. v. Occupational Safety & Health Review Comm'n*, 599 F.2d 453, 467 (1st Cir. 1979).

234. "Other potentially infectious material" includes body fluids, organs and tissues, and HIV-containing tissue cultures or cells. 29 C.F.R. § 1910.1030(b) (1993).

235. *Id.*

236. 56 Fed. Reg. 64,004, 64,114 (1991) (preamble).

237. *Id.*

238. 29 C.F.R. § 1910.1030(d)(3).

the protective equipment will be used will be considered "appropriate."²³⁹ Employers must ensure that personal protective equipment is accessible and sanitary.²⁴⁰ All personal protective equipment must be removed before leaving a work area to minimize broadcasting an exposure throughout the facility.²⁴¹

Employers that have employees with occupational exposure must establish a written Exposure Control Plan designed to eliminate or minimize employee exposure.²⁴² The Exposure Control Plan must contain an exposure determination, a schedule for implementing the requirements of the rule, and the procedures for evaluating the circumstances surrounding exposure incidents.²⁴³ Exposure Control Plans must be updated annually and available to employees and agency personnel.²⁴⁴ For each employee with an occupational exposure, employers must establish and maintain an employee training record as well as a record of the general medical status including, among other things, the employee's vaccination status, results of medical testing, and medical opinions.²⁴⁵

Well before the enactment of the Bloodborne Pathogens Rule, several health care employee unions requested that the agency promulgate a standard that, at a minimum, made workers aware of the benefits of a vaccine against HBV.²⁴⁶ As a consequence of this history, the Bloodborne Pathogens Rule directs employers to make available to employees the hepatitis vaccine and vaccination series and to provide post-exposure evaluation and follow-up to all employees involved in an HBV exposure incident.²⁴⁷

OSHA regulations affecting health care facilities are numerous. Many regulations, however, involve practical protective measures that are not difficult to incorporate in the workplace. To assist regulated facilities in achieving and maintaining compliance, OSHA has developed several compliance kits and has representatives available in most larger communities to answer questions. Obtaining information and assistance from the agency will minimize the possibility of an adverse enforcement action due to non-compliances.

V. ENVIRONMENTAL CONCERNS RELATED TO PROPERTY USE AND CONDITIONS

In addition to environmental issues arising in the areas of waste management and employee safety, environmental issues can affect health care facilities through facility location and construction. Land use restrictions and prohibitions may limit the development of a new facility or the expansion of

239. *Id.*

240. *See id.* § 1910.1030(d)(3)(iii)-(iv), (4)(i).

241. *Id.*

242. *Id.* § 1910.1030(c).

243. *Id.* § 1910.1030(c)(ii)(A)-(C).

244. *Id.*

245. *Id.* §§ 1910.1030(g)(2), .1030(h).

246. 56 Fed. Reg. 64,004 (1991) (preamble).

247. 29 C.F.R. § 1910.1029(f) (1993).

an existing facility. Prior land uses, sources of on-site contamination, and certain building fixtures such as asbestos insulation and PCB-contaminated capacitors and transformers may create substantial liabilities for health care facilities. The final section of this article addresses these concerns.

A. LAND USE RESTRICTIONS

Certain environmental statutes regulate land use directly, requiring a permit or other authorization for development or prohibiting development altogether. For example, a health care facility may be required to obtain a permit for dredge or fill activities in wetlands when it decides to develop a property for a new facility. EPA and the Army Corps of Engineers (Corps) regulate wetlands under section 404 of the Clean Water Act.²⁴⁸ "Wetlands" are defined as areas inundated or saturated by surface or groundwater at a frequency and duration sufficient to support a prevalence of vegetation typically adapted to life in saturated soil conditions under normal circumstances and include such areas as swamps, marshes, and bogs.²⁴⁹ The Corps, in conjunction with EPA and the Fish & Wildlife Service, has established three characteristics to define wetlands: hydrophytic vegetation, hydric soils, and wetlands hydrology.²⁵⁰ Because wetlands are regulated without regard to whether they are man-made or naturally occurring, even man-made watering tanks or former gravel pits can be deemed wetlands if wetlands characteristics develop.

In order to develop property, parties may be required to create or enhance wetlands or dedicate nearby land for wetland use. Discharges into wetlands, which may result from grading and filling properties, must be authorized under a general or specific permit issued by the Corps.²⁵¹ If a permit is issued, a facility may be subject to use restrictions such as seasonal discharge prohibitions, monitoring requirements, or limits on the location of any fill activity.

Violators of Clean Water Act section 404 may be subject to civil and/or criminal penalties of as much as \$25,000 per day per violation.²⁵² If there is any question about whether an area constitutes a wetland, the prudent action is to involve the Corps or a consultant with sufficient expertise and experience for a wetlands determination regarding the property to be developed.

Other lesser-known statutes also may affect land use and should be considered. These statutes include the National Flood Insurance Program,²⁵³ regulating development in floodplains and the Endangered Species Act,²⁵⁴

248. 33 U.S.C. § 1344 (1988). The Corps has jurisdiction under Section 404 to issue dredge and fill permits; EPA retains independent enforcement authority.

249. See 33 C.F.R. § 328.3(b) (1993).

250. See FEDERAL MANUAL FOR IDENTIFYING AND DELINEATING JURISDICTIONAL WETLANDS (1987).

251. 33 U.S.C. § 1311 (1988); see 33 C.F.R. § 330.1-6 (1993) (nationwide permit program).

252. 33 U.S.C. § 1319(b), (c)(1) (1988).

253. 42 U.S.C. §§ 4001-4129 (1988).

254. 16 U.S.C. §§ 1531-1544 (1988).

restricting development of critical habitats or other areas where endangered species may be present.

B. CONDITIONS ON THE PROPERTY

1. Above Ground and Underground Storage Tanks

a. Above Ground Storage Tanks

Regulation of above ground storage tanks (ASTs) will affect only those health care facilities that own or operate large fuel containing ASTs. EPA has promulgated regulations that indirectly regulate ASTs under the Clean Water Act²⁵⁵ and the Oil Pollution Act of 1990.²⁵⁶ Under these acts, owners and operators must prepare and submit spill prevention, control, and countermeasure (SPCC) plans when the AST is located so that a discharge of oil in harmful quantities could reasonably be expected to affect navigable waters.²⁵⁷ Facilities with above ground storage capacity of 1320 gallons or less, with no single container having a capacity in excess of 660 gallons, are exempt from these regulations.²⁵⁸

SPCC plans must be reviewed and certified by a registered professional engineer after the engineer examines the facility.²⁵⁹ Owners and operators must maintain copies of the plans at the facility or in the nearest field office.²⁶⁰ Among other things, the SPCC plans must meet good engineering practices and have the full approval of management. The plan also must include a prediction of the direction, rate of flow, and total quantity of oil that could be discharged from the facility, provide for appropriate containment or diversionary structures to prevent any discharged oil from reaching navigable waters, and provide for adequate site security.²⁶¹ Plans must be updated every three years or when there is a significant change in facility design.²⁶² EPA recommends that because the plans must be certified by engineers, parties should verify the sufficiency of a facility plan after an acquisition.

In addition to or instead of environmental regulation, states may regulate ASTs through their health departments or fire marshals. In many instances, state and local departments have adopted the National Fire Prevention Association (NFPA) rules for ASTs containing flammable or combustible liquids (such as diesel, gasoline, and oil).²⁶³ NFPA rules address tank structure, location, marking, supervision, and monitoring. For example, unsupervised or isolated ASTs must be marked in a manner to identify the tank

255. 33 U.S.C. §§ 1251-1387 (1988).

256. 33 U.S.C. §§ 2701-2761 (1988).

257. 40 C.F.R. § 112 (1993). Navigable water can include almost any waters of the United States, including inland rivers and streams. *Id.* § 112.2(h).

258. *Id.* § 112.1(d)(2).

259. *Id.* § 112.3(d).

260. *Id.* § 112.3(e).

261. *Id.* § 112.7.

262. *Id.* § 112.5.

263. NFPA maintains customer service and technical assistance lines (800-735-0100).

contents and potential fire hazards.²⁶⁴ NFPA rules also regulate ASTs that have been taken out of service or abandoned.²⁶⁵

In Texas, TNRCC regulates ASTs if they contain a "petroleum product."²⁶⁶ An "above ground storage tank" is defined as:

[a] non-vehicular device (including any associated piping) that is made of nonearthen materials; located on or above the surface of the ground, or on or above the surface of the floor of the structure below ground, such as a mineworking, basement, or vault; and designed to contain an accumulation of petroleum products.²⁶⁷

Certain ASTs are excluded from regulation. ASTs used for storing heating oil for consumptive use on the premises where stored, ASTs with less than 1100 gallons of capacity, emergency spill or overflow containment tanks, tanks containing dilute concentrations of petroleum products, and electrical equipment such as transformers are not regulated.²⁶⁸

The owner or operator of a regulated AST is subject to certain obligations including registration, notification of installation, fee assessments, release reporting, investigation, corrective action rules, and certain record keeping requirements.²⁶⁹ All existing ASTs should have been registered by March 1, 1990; new or replacement ASTs should be registered within thirty days from the date any petroleum product is placed in the tank.²⁷⁰

In a transactional context, owners of ASTs must provide written notice to TNRCC of any change to the tank or additional information concerning the status of the regulated tank.²⁷¹ For example, a facility must notify TNRCC of a change in ownership within thirty days of the occurrence of the change or within thirty days of the date on which the owner first became aware of the change.²⁷²

b. Underground Storage Tanks

Under Subtitle I of RCRA,²⁷³ Congress required EPA to promulgate reg-

264. See NFPA 30 § 2-9.2; NFPA 704.

265. NFPA 30 §§ 2-3.8.1, 2-4.4.1.

266. "Petroleum product" is defined to include motor vehicle fuel, specifically:

A petroleum substance obtained from distilling and processing crude oil that is liquid at standard conditions of temperature and pressure, and that is capable of being used as a fuel for the propulsion of a motor vehicle or aircraft, including, but not necessarily limited to, motor gasoline, gasohol, other alcohol blended fuels, aviation gasoline, kerosene, distillate fuel oil, and #1 and #2 diesel. The term does not include naphtha-type jet fuel, kerosene-type jet fuel, or a petroleum product destined for use in chemical manufacturing or feedstock of that manufacturing.

30 TEX. ADMIN. CODE § 334.122(b)(12) (West Supp. 1993-94).

267. *Id.* § 334.122(b).

268. *Id.* § 334.123-.124. Several types of ASTs that may contain petroleum products are not regulated. These ASTs include storm water or waste water collection systems and flow-through process tanks.

269. *Id.* § 334.126-.132.

270. *Id.* § 334.127(b)-(c).

271. *Id.* § 334.127(d).

272. *Id.*

273. 42 U.S.C. §§ 6991-6991i (1988).

ulations for underground storage tanks (USTs) containing "regulated substances."²⁷⁴ States can receive a delegation of authority to oversee and implement the federal UST program. TNRCC has promulgated UST regulations for Texas.²⁷⁵

The Texas UST provisions generally are similar to the AST regulations noted above, but more expansive. For example, owners and operators must register the tanks, provide notification in the event of major construction activity, report releases, and adequately investigate and remediate if necessary, pay annual fees, and observe technical requirements relating to spill and overfill prevention and control, leak detection, and reporting and recordkeeping requirements.²⁷⁶ Under both the federal and state definitions, "owners" are persons who hold legal possession or ownership of a total or partial interest in an underground storage tank system.²⁷⁷ Under the state definition, however, if the actual ownership of the UST system is uncertain, unknown, or in dispute, the fee simple owner of the surface estate where the UST is located will be deemed the owner unless the person can demonstrate with adequate proof that others own the UST system.²⁷⁸

Both the federal and state regulations require the seller of a tank intended to be used as a UST to notify the purchaser of the UST owner's certification requirements and obligations.²⁷⁹ In Texas, the notification must include the names and addresses of the seller and purchaser, the number of tanks involved with a description of each tank, and the facility identification number. The notification requirement applies not only to transfers or conveyances of new or used tanks, but also to sales of real property where underground storage tanks are located.²⁸⁰ The written notification must be provided before the actual conveyance of the tanks or before the real property closing date.²⁸¹ Both federal and Texas regulations require that owners provide written notice to the TNRCC of relevant status changes including a change in ownership or ownership information, such as a change in mailing address or telephone number and tank closure.²⁸²

USTs containing petroleum products are regulated under the Clean Water Act and Oil Pollution Act of 1990 in the same manner as ASTs, but the capacity threshold triggering regulation is significantly higher. Only owners of USTs with storage capacity exceeding 42,000 gallons must comply with the oil pollution prevention regulations.²⁸³

274. See 40 C.F.R. § 280.10-.112 (1993). "Regulated substance" means any substance defined in CERCLA § 9601(14), except RCRA regulated hazardous wastes, and petroleum and petroleum-based substances comprised of complex-blend hydrocarbons derived from crude oil through processes of separation, conversion, upgrading, and finishing. *Id.* § 280.12.

275. 30 TEX. ADMIN. CODE § 334.

276. 40 C.F.R. § 280.22, .34, .50, .52, .53 (1993); 30 TEX. ADMIN. CODE § 334.6, .7, .10, .21, .41, .42.

277. 40 C.F.R. § 280.12; 30 TEX. ADMIN. CODE § 334.2.

278. 30 TEX. ADMIN. CODE § 334.2.

279. 40 C.F.R. § 280.22(g); 30 TEX. ADMIN. CODE § 334.9.

280. 30 TEX. ADMIN. CODE § 334.9.

281. *Id.*

282. 40 C.F.R. § 280.34(a)(4), .71(a) (1993); 30 TEX. ADMIN. CODE § 334.7(d).

283. 40 C.F.R. § 112.1 (1992).

2. *Septic Tank Systems*

Smaller health care facilities, especially those in suburban or rural communities, may use septic tank systems for sanitary sewage disposal. Most state regulatory agencies do not regulate septic tanks as USTs.²⁸⁴ Instead, septic tanks generally are regulated by state and/or local health departments.

Septic tanks that receive any non-sanitary wastes, however, are regulated pursuant to the Safe Drinking Water Act²⁸⁵ (SDWA) as underground injection wells. Specifically, Class V wells include septic tank systems used for wastes from business establishments or industrial facilities.²⁸⁶ Discharge to a regulated septic system is prohibited if it allows the movement of fluid containing any contaminant into an underground source of drinking water (USDW) and if the presence of contaminants may cause a violation of any primary drinking water regulation or otherwise adversely affect human health.²⁸⁷ USDW is any aquifer that contains fluids with less than 10,000 mg/l total dissolved solids *and* that either (1) currently supplies any public water system or (2) contains sufficient amounts of groundwater to supply a public water system.²⁸⁸ Permits are required for operation of any class of underground injection wells.²⁸⁹

Additionally, states may have more general laws aimed at protecting groundwater supplies. In Texas, for example, persons may not cause, suffer, or allow discharges to "waters of the state" without a permit or authorization.²⁹⁰ Because "waters of the state" include groundwater,²⁹¹ there may be a general prohibition against any activity or structure, such as septic tanks, that could affect or pollute groundwater, or a generic prohibition against the maintenance of a nuisance.

C. ENVIRONMENTAL CONDITIONS IN BUILDINGS

Environmental concerns can arise due to building fixtures such as asbestos-containing building materials and electrical transformers and capacitors contaminated with polychlorinated biphenyls (PCBs). Asbestos and PCBs were commonly used in commercial buildings until it was determined that, when not enclosed or contained, they may pose a threat to human health and the environment. Health care facilities located in buildings containing these materials may be subject to several regulatory responsibilities and may have exposure to common law and CERCLA liability.

284. Texas regulations exclude septic tanks from coverage under the UST and AST regulations. 30 TEX. ADMIN. CODE § 334.3(3).

285. 42 U.S.C. §§ 300f-300j-11 (1988).

286. 40 C.F.R. § 146.5(e)-(g). Septic tank systems used solely for the disposal of sanitary waste and with a capacity to serve fewer than twenty people per day are not regulated. *Id.*

287. *See* 40 C.F.R. § 144.12(a) (1993).

288. *Id.* § 144.3.

289. *Id.* § 144.11.

290. TEX. WATER CODE ANN. § 26.121 (Vernon 1988 & Supp. 1994).

291. *Id.* § 26.001(5).

1. *Asbestos*

Before the late 1970s, asbestos was used in a variety of building materials, especially insulation, fire proofing, and sound proofing. Its physical properties, including high thermal and electric resistivity and tensile strength, made it well-suited for these purposes. Asbestos generally is found in two states: friable (easily crushed) and non-friable.²⁹² EPA has estimated that asbestos is present in twenty percent of public and commercial buildings in the United States.²⁹³

Asbestos-containing materials (ACM)²⁹⁴ can be found in ceiling and floor tiles, wall board, duct work, pipe insulation, fire proofing textiles, and materials used in high heat areas. Asbestos is a risk to public health because it can cause or exacerbate certain lung diseases such as mesothelioma or asbestosis. The primary danger from asbestos is through inhalation. Therefore, the environmental regulatory agencies seek to control conditions that may disturb asbestos and ACM and thus create a dust that can be inhaled. Because of the prevalence of asbestos and ACM in buildings, it is likely that a health care facility, large or small, may encounter regulatory responsibilities associated with these products.

EPA and Texas regulations, however, impose minimal requirements on property owners, at least until property is demolished or renovated, and then only if the property has friable asbestos.²⁹⁵ Under the Clean Air Act, Section 112, National Emission Standards for Hazardous Air Pollutants (NESHAP),²⁹⁶ EPA regulates asbestos exposure in commercial buildings during demolition or renovation activities.²⁹⁷ The owner or operator of the demolition or renovation activity must comply with notice requirements and procedures for controlling emissions of asbestos.²⁹⁸ Owners and operators in this context include any person who owns, leases, operates, controls, or supervises the facility being demolished or renovated or the entity doing the work.²⁹⁹ Based on the type of work and the amount of ACM involved, notice requirements may vary from ten days notice before the demolition and renovation activity to ten days before the end of the calendar year for the planned renovation operation.³⁰⁰ Finally, the owner of the facility from which asbestos or ACM is removed must ensure that the material is trans-

292. 40 C.F.R. § 61.141 (1992).

293. U.S. ENVIRONMENTAL PROTECTION AGENCY, EPA STUDY OF ASBESTOS-CONTAINING MATERIALS IN PUBLIC BUILDINGS: A REPORT TO CONGRESS, Feb. 1988, at 10.

294. Any material containing more than one percent asbestos is considered to be an asbestos-containing material. 40 C.F.R. § 61.141.

295. Applicability of the requirements may be limited by the amount of asbestos involved in the demolition or renovation activity. For example, eighty linear meters of pipe or fifteen square meters of other components must be disturbed. *Id.* § 61.121; 30 TEX. ADMIN. CODE § 101.2(2).

296. 42 U.S.C. § 7412 (1988).

297. 40 C.F.R. §§ 60.140-61.157 (1992). The asbestos emission standards apply to any "institutional, commercial, public, industrial or residential building containing five or more dwelling units." *Id.* § 61.141.

298. *Id.* § 61.145; 30 TEX. ADMIN. CODE § 101.20(2).

299. 40 C.F.R. §§ 61.141, 61.145.

300. *See id.* § 61.145(a), (b)(1), (b)(3).

ported and disposed of in accordance with EPA regulations.³⁰¹ EPA requires that waste be wet and sealed before transport in marked vehicles and disposed of at a site operated in accordance with EPA standards.³⁰² The building owner must use a licensed contractor for the removal of asbestos or ACM.³⁰³ Often ACMs are not in the friable state and need to be managed in place rather than removed.³⁰⁴ EPA has published guidelines for managing asbestos in place, which, if followed, can minimize a facility's regulatory liability and potential common law liability.

The Texas Asbestos Health Protection Act and the regulations promulgated thereunder regulate the removal or encapsulation of asbestos in buildings open to the public.³⁰⁵ The Act and regulations require all asbestos abatement or demolition contractors to be licensed and to adhere to all EPA and state standards regarding asbestos-related work.³⁰⁶ Building owners are responsible for the presence, condition, disturbance, and disposal of any asbestos encountered in the construction, operations, maintenance, or furnishing of a building.³⁰⁷ Responsibilities include conducting an asbestos survey prior to any partial or total demolition activities, notifying employees and contractors of the presence and condition of any asbestos and ACMs in the building, and controlling asbestos and ACM through abatement or an Operations and Maintenance Plan.³⁰⁸ The Texas Asbestos Health Protection Act authorizes civil, administrative, and criminal penalties for violations of the Act and regulations.³⁰⁹ TDH may impose administrative penalties of up to \$10,000 per day for each violation.³¹⁰ Persons who remove asbestos or ACM without a license or who fail to keep records of asbestos-related activities commit a misdemeanor with a fine of up to \$25,000 and up to two years in jail or both.³¹¹

OSHA has established standards applicable to maintenance and repairs involving asbestos for both short duration, small scale projects, such as routine maintenance and repairs, and for larger projects, such as demolition or renovation.³¹² OSHA also has proposed, but not finalized, regulations that would require building owners to notify workers and tenants if asbestos is present in commercial property.³¹³ Implementation of an asbestos Opera-

301. *Id.* § 61.145(c).

302. *Id.* § 61.145(c)(1)(ii).

303. *Id.* § 61.141.

304. See EPA, *MANAGING ASBESTOS IN PLACE: A BUILDING OWNER'S GUIDE TO OPERATIONS AND MAINTENANCE PROGRAMS FOR ASBESTOS-CONTAINING MATERIALS* (July, 1990).

305. TEX. REV. CIV. STAT. ANN. art. 4477-3a, § 2(11) (Vernon Supp. 1994); 25 TEX. ADMIN. CODE § 295.31-.70 (West Supp. 1993-94).

306. TEX. REV. CIV. STAT. ANN. art. 4477-3a, § 4 (Vernon Supp. 1994).

307. 25 TEX. ADMIN. CODE § 295.34(b).

308. *Id.* § 295.34(b)-(d).

309. TEX. REV. CIV. STAT. ANN. art. 4477.31, §§ 15, 16, 17 (Vernon Supp. 1994).

310. *Id.* art. 4477-3a, § 16(b); 25 TEX. ADMIN. CODE § 295.70(b).

311. TEX. REV. CIV. STAT. ANN. art. 4477-3a, § 17 (Vernon Supp. 1994).

312. See 29 C.F.R. §§ 1926.58 (construction standards), 1910.1001 (general standards) (1993).

313. 55 Fed. Reg. 29,712 (1990) (to be codified at 29 C.F.R. §§ 1910, 1926) (proposed July 20, 1990); 57 Fed. Reg. 49,657 (1992).

tion and Maintenance Plan, although not mandatory, is highly recommended by OSHA.

2. PCBs

Dielectric fluid found in electrical equipment and heat transfer and hydraulic systems manufactured from the 1930s through the late 1970s may contain PCBs. EPA began regulating PCBs because they are believed to pose significant risks to public health and the environment. Specifically, exposure to PCBs may cause chloracne and have carcinogenic and other health effects.³¹⁴ The primary danger from PCBs occurs as a result of fire, where PCBs can be converted into dioxin. Dioxin is a carcinogen and also may cause teterogenic effects. PCBs are regulated primarily under the Toxic Substances Control Act (TSCA).³¹⁵ TSCA prohibits the manufacture, processing, distribution in commerce, or use of PCBs, other than in a totally enclosed manner, unless specifically exempted by regulation.³¹⁶ EPA gradually has been phasing out the use of PCBs.³¹⁷ Facilities may use certain in-service PCB items for the remainder of their useful lives if the following conditions are satisfied:

- (1) The PCB items, and in some cases, the areas in which the PCB items are located, are marked, and are identified according to the regulations;
- (2) The item is registered with the local fire department;
- (3) The item is registered with the building owner;
- (4) The person responsible for the PCB item conducts quarterly inspections;
- (5) The responsible party maintains records regarding those inspections; and
- (6) The responsible parties comply with TSCA requirements relating to the storage, removal, transportation, and disposal of PCB items.³¹⁸

EPA regulates the disposal of items contaminated with PCBs in concentrations of fifty parts per million (ppm) and above.³¹⁹ PCB-contaminated materials may be disposed in a chemical waste landfill, an authorized incinerator, a high efficiency boiler, or another EPA-approved method.³²⁰ If a PCB-contaminated item, such as a transformer, begins to leak the fluid containing PCBs, then the owner of the PCB-contaminated item must take action to contain the spill and remediate the site immediately and must take action to prevent any further spills from occurring.³²¹ Spills of PCB-contaminated fluid at concentrations exceeding fifty ppm are considered dispo-

314. 47 Fed. Reg. 37,342, 37,344-45 (1982) (preamble).

315. 15 U.S.C. §§ 2601-2671 (1988).

316. *Id.* § 2604(a), (h).

317. *See, e.g.*, 40 C.F.R. § 761.30(1)(iv)(D) (1992). As of October 1, 1993, all lower secondary voltage PCB transformers located in sidewalk vaults in use near commercial buildings must be removed from service. *Id.*

318. *See id.* § 761.

319. *Id.* § 761.60(a).

320. *Id.* § 761.60.

321. *Id.* § 761.123-.125. Often an electrical utility rather than the building owner will own a PCB contaminated item such as a transformer, and therefore, the health care facility should not have liability associated with that item.

sal³²² and may lead to EPA enforcement if not properly addressed.

It is highly likely that large health care facilities have transformers on their property. The health care facility first must verify whether the transformer is owned by the property owner or by the local electrical utility and second must determine whether the transformer is leaking. The party responsible for the transformer should regularly inspect the transformer and may consider, as a preventive measure, having the existing fluid emptied and replaced with non-PCB containing fluid to avoid any potential for a release of the hazardous substance.

In addition to federal regulations, potential buyers or other parties involved in real estate transactions should realize that state regulations also may apply to PCBs. Federal regulations are applicable only to PCB items, equipment, or wastes with a concentration of fifty ppm or more. Thus, states are free to regulate items or wastes with a concentration of less than fifty ppm. The state may have separate PCB regulations that require registration or notification or impose special disposal or storage requirements. Some states may have more than one set of regulations, such as a two-tiered system. Under the two-tiered system, concentrations of less than fifty ppm but more than a minimal amount are regulated as PCB waste, whereas items or waste with less than the minimal concentration (such as five ppm or less PCBs) are regulated as waste oil.³²³ States also may regulate PCB wastes or items as "special wastes."³²⁴

3. CERCLA Liability for On-Site Conditions

Under CERCLA,³²⁵ both asbestos and PCBs are classified as hazardous substances. Accordingly, property owners may be liable for any release or threatened release of asbestos or PCBs from a facility during their period of ownership and for previous releases that have caused contamination if the court defines "disposal" to include passive releases.³²⁶ A release of asbestos could result from demolition or other destruction of an area having asbestos-containing material. A release of PCBs could result from leaking transformer fluid or an explosion. In addition, a release of asbestos or PCBs could occur at a disposal facility after the health care facility has had the substances lawfully removed from its building. In that situation, the health care facility could become liable under CERCLA as an arranger, i.e. one who arranged for the disposal of hazardous substances. Therefore, the health care facility should thoroughly investigate the disposal facility used for any asbestos and PCBs removed from its property and request certificates of destruction or disposal.

Moreover, some cases suggest that, in certain circumstances, a seller of a

322. *Id.* § 761.60(d).

323. *Id.*

324. See 30 TEX. ADMIN. CODE § 330.2 (West Supp. 1993-94) (defining *special waste* to include light ballasts and/or small capacitors containing PCB compounds).

325. 42 U.S.C. §§ 9601-9675 (1988).

326. *Id.* § 9607.

building containing asbestos or PCBs may become liable under CERCLA as an arranger for the disposal of hazardous substances as a consequence of the building sale. In *Sanford St. Local Development Corp. v. Textron, Inc.*³²⁷ the seller did not remove PCB-contaminated transformers from the building, nor did it generate PCB waste or arrange for the disposal of PCBs. The court held, however, that based on the extremely discounted price of the building, it could be inferred that the seller intended for the buyer to dispose of the PCB-contaminated transformers and thus was an arranger.³²⁸ Similarly, in *C.P. Holdings, Inc. v. Goldberg-Zoino & Associates, Inc.*,³²⁹ the court held that the sale of a building containing asbestos, with the knowledge that the purchaser would demolish the building, constituted arranging for disposal of hazardous substances under CERCLA.³³⁰

VI. PRACTICAL CONSIDERATIONS

The applicability of particular medical waste and worker safety regulations differs among the variety of health care facilities, which can include mobile clinics, industrial facilities with first aid facilities, veterinarians, research labs, hospitals, and office buildings with groups of health care providers. Each medical waste generator must assess its alternatives. For example, a generator could elect to collect, transport, and arrange for disposal or treatment of its own medical waste. A more cost effective approach, however, may be to use a medical waste collection station where permissible, or where several generators practice together, to use a transporter chosen by the group.³³¹ Regardless of the compliance method selected, each generator must assure itself that it employs the appropriate storage, packaging, and labeling practices regarding its waste. A facility audit of waste management practices would aid generators in verifying the types of waste present on-site and the effectiveness of the generator's waste management practices. Whether an audit is performed by an environmental consultant or in-house personnel, the facility should be aware of confidentiality issues. For example, an audit performed at the direction of counsel may be protected by the work product or attorney-client privilege. Before a waste management or environmental audit is performed, however, facility management should be committed to addressing concerns raised by the audit, because regulatory violations discovered in an audit can expose a facility and its management to civil and criminal liability.

In addition to assessing waste management needs and practices, genera-

327. 768 F. Supp. 1218 (W.D. Mich. 1991).

328. *Id.* at 1222.

329. 769 F. Supp. 432, 437 (D.N.H. 1991).

330. *Id.* at 438.

331. According to EPA, where a group of physicians work together, they may elect one person to transport the waste if it is less than 50 pounds a month or arrange with a transporter to have the waste removed. EPA states, however, that each physician is responsible for the segregation, labeling, storage conditions and recordkeeping requirements. See U.S. EPA, *MANAGING AND TRACKING MEDICAL WASTE: A GUIDE TO THE FEDERAL PROGRAM FOR GENERATORS* (Sept. 1989) (reproduced in *SECOND INTERIM REPORT*, *supra* note 20, at 67). TNRCC likely would follow this guidance.

tors must become knowledgeable of federal and state regulatory requirements. Often, EPA, OSHA, and state agencies will have materials available explaining their regulatory programs. Parties also can attend seminars or presentations on medical waste to become familiar with the issues. Training regarding medical waste segregation treatment and disposal requirements should be provided to all employees who have contact with medical waste. Having one employee who is familiar with all environmental matters for the facility is helpful, as is a central location for records and related documents. Health care facilities also should provide ample employee training on OSHA rules applicable at its workplace. The Occupational Safety and Health Administration will provide to facilities sample plans, such as the Bloodborne Pathogens Rule Exposure Plan and the Hazardous Chemicals in Laboratories Chemical Hygiene Plan. In addition, associations such as the National Safety Council and the American Hospital Association sponsor training programs regarding the Bloodborne Pathogens Rule.

The attention to detail in complying with regulatory requirements on-site must be carried over to the selection of transporters and disposal or treatment facilities. If a transporter improperly disposes of waste, each generator who has given waste to the transporter is subject to potential fines and remediation responsibility. The Texas Health & Safety Code imposes criminal penalties on persons who violate the medical waste regulations.³³² In addition, being associated with improper disposal, transport, or treatment of medical waste can have an adverse effect on public perception of the generator. Select only companies with expertise and a good reputation. Do not hesitate to check references and investigate the administrative history of the facility - for example, whether it has notices of violation in applicable agency files. Require all potential transporters and disposal facilities to provide a compliance history, applicable permits and registrations, proof of financial condition, insurance policies, and references. Counsel may assist in such inquiries, or the information may be available through various state open records acts and the federal Freedom of Information Act. It is also highly advisable to visit the location of the transporter or TDD facility.

If a facility decides to hire a consultant for waste management advice or to perform an environmental assessment, care also should be taken in selecting a consulting firm. Particularly when the market is new, the lack of competition may create unreasonable fees, or it may mean that few experienced firms are available to meet the needs of health care providers. Again, investigate carefully, and if possible, obtain proposals from more than one consulting firm before making the final decision. Determine initially your own medical waste disposal needs and clearly set forth the scope of the consultant's services before the consultant begins its activities.

Finally, when acquiring a new facility or expanding an existing facility, an environmental assessment of the property should be performed to identify contamination and land use restrictions. Status as an owner of contaminated

332. TEX. HEALTH & SAFETY CODE ANN. § 361.2215 (Vernon 1990).

property can carry significant liability for remediation, natural resource damages, and even consequential torts, regardless of fault. Therefore, environmental concerns related to a property should be identified before a sale closes so that warranties, indemnifications, and releases can be included in the property transfer instruments.

VII. CONCLUSION

Hospitals and other health care service providers must stay informed of the regulatory issues and take an active role in the initial development of laws and regulations pertaining to medical waste and worker safety. An opportunity is available today to get in on the ground floor of an area that will continue to affect the health care industry for years to come. Health care provider groups should offer constructive suggestions, whether challenging or proposing legislation and rules. By participating in the development of the new laws and sharing their experience with the process, health care providers have a unique advantage at the present time. Their participation in the debate may be the best means to assure that the government enacts effective and manageable laws that protect human health and the environment.

Comments

