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they must meet standards for cleanliness and timely, sanitary trash disposal.

Laboratories conducting studies to support research or product marketing applications also are required to meet certain standards. If they do not meet these criteria, the validity of the studies may be questioned and the studies may be disqualified. Thus, both the production facilities and laboratories must comply with animal waste and general refuse storage and disposal standards. (See 21 CFR 58.43 and §§ 211.50, 211.56, and 606.40).

For wastes shipped off-site that fall into one of today's regulated medical waste categories, today's regulations impose packaging, segregation, labeling, and tracking form requirements, and supplement the FDA rules.

2. Public Health Service (PHS)

Interstate shipments of etiologic agents are regulated by the Public Health Service. An "etiologic agent" is defined in PHS regulations (42 CFR 72.1) as a viable microorganism or its toxin which causes, or may cause, human disease. Shipments of certain etiologic agents must meet packaging requirements and must be labeled with a symbol for biological hazards. A sender also must receive notification that the shipment has arrived at its destination. If the notification is not received, the sender must notify the Centers for Disease Control (CDC).

Imports of etiological agents and human disease vectors are prohibited unless accompanied by a permit. Human remains from persons who died of certain communicable diseases also are prohibited from importation unless they have been cremated, or embalmed and placed in a sealed casket, or are accompanied by a permit.

EPA has determined that etiologic agents need not be regulated under the EPA medical waste tracking program if they are subject to PHS and Department of Transportation (DOT) rules for interstate shipments of etiologic agents. (See the discussion in section V.D. of this Preamble and paragraph E of this section.)

3. Health Care Financing Administration (HCFA)

To participate in the Medicare program, health care facilities are required to comply with specific conditions of participation or coverage that specify various patient health and safety requirements. Generally, with respect to waste disposal, these conditions require health care facilities to meet any State or local licensing requirements, to have procedures for proper, routine storage and prompt disposal of trash, and to have policies and procedures concerning infection control.

The specific conditions of participation or coverage for the various provider types may be found at 42 CFR 405 Subpart L, Home Health Agencies; Subpart M, Independent Laboratories; Subpart N, Portable X-ray Services; Subpart Q, Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and/or Speech Pathology Services, and Outpatient Physical Therapy Services Furnished by Physical Therapists in Independent Practice; Subpart U, End Stage Renal Disease Facilities; Subpart X, Rural Health Clinic Services; 42 CFR Part 416, Ambulatory Surgical Services; 42 CFR Part 418, Hospice Care; 42 CFR Part 482, Hospitals; 42 CFR Part 483, Subpart B (redesignated on February 2, 1989, 54 FR 5316), Long Term Care Facilities; and 42 CFR Part 485, Specialized Providers.

E. Department of Transportation (DOT)

1. Hazardous Materials Shipments

DOT regulates the transportation of hazardous materials in commerce (49 CFR Parts 171 to 179). The regulations address: (a) Interstate transportation of hazardous materials by motor vehicle, rail car, aircraft and vessel; and (b) intrastate transportation of certain hazardous materials (hazardous wastes, hazardous substances, and flammable cryogenic liquids in portable tanks and cargo tanks) by motor vehicle.

One class of hazardous materials is the "etiologic agents" hazard class. As currently defined in 49 CFR 173.386, an "etiologic agent" means a viable microorganism, or its toxin, which causes or may cause human disease, and is limited to those agents listed in 42 CFR 72.3 of the regulations of the Department of Health and Human Services. The list in 42 CFR 72.3 includes many bacterial, fungal, viral and rickettsial agents.

EPA has determined that etiologic agents that are wastes are not regulated medical wastes if they are shipped in accordance with DOT's regulations for etiologic agents. EPA made this determination because DOT's regulations for shipping etiologic agents, in combination with the Public Health Service regulations discussed previously, are generally more stringent than the regulations promulgated today.

DOT's regulations for etiologic agents specify that no person may ship a package containing over four liters gross volume of an etiologic agent. The packaging must meet requirements specified in 49 CFR 173.24 and 173.387, and must be labeled with the etiologic agents/biomedical material label as specified in 49 CFR 173.388. In the event of fire, breakage, spillage, or suspected contamination involving etiologic agents during the course of transportation (including loading, unloading and temporary storage), the carrier must notify DOT by telephone at (800) 424-8802 or (202) 267-2675, or the Centers for Disease Control at (404) 633-5513 (49 CFR 171.15). The telephone notice must be followed by a written report (49 CFR 171.16).

DOT has proposed to broaden its definition of "etiologic agent" and to eliminate an exception for cultures of etiologic agents of 50 milliliters or less total quantity in one outside package (53 FR 45525, November 10, 1988). DOT also plans to reconsider other aspects of its regulations for the transportation of etiologic agents.

EPA notes as a point of clarification that the rules promulgated today do not add any additional materials to the list of etiologic agents that are subject to DOT's Hazardous Materials Regulations, nor do the rules cause any additional materials to come under DOT regulation. Today's medical waste tracking rules are independent of the DOT Hazardous Materials Regulations.

2. MARPOL 73/78

The Protocol of 1978, relating to the International Convention for the Prevention of Pollution from Ships, 1973 (MARPOL 73/78), is an international treaty for preventing ship generated ocean pollution by oil, noxious liquid substances, harmful substances, sewage, and garbage. The section of the treaty that seeks to prevent garbage pollution is found in Annex V, recently in force and incorporated into U.S. law as the Act to Prevent Pollution from Ships (33 U.S.C. 1901-1911). The U.S. Coast Guard has initiated a rulemaking to address garbage disposal (53 FR 43622, October 27, 1988). The Coast Guard regulations will apply to all ship-generated garbage, including regulated medical waste. Ships that are owned or operated by the United States and that are in noncommercial service will be subject to compliance with Annex V on a delayed compliance schedule. EPA rules supplement these Coast Guard rules by regulating the medical waste brought ashore in a Covered State.

VIII. Federal Facilities

Under section 11006 of the MWTA, Federal facilities managing regulated medical waste generated in a Covered State are subject to all Federal, State,

interstate, and local requirements applicable to the management of such wastes and are thus subject to today's rule. This inclusion of Federal facilities in the demonstration tracking program is intended to ensure that Federal facilities generating or otherwise handling regulated medical waste are subject to the same level of regulation as non-Federal institutions. The participation of these facilities is important if the demonstration program is to capture all of the medical waste generated in the Covered States. In addition, Congress has indicated that Federal facilities should set an example in the proper management of medical waste (see 134 Cong. Rec. H 9539, Oct. 4, 1988).

Under today's rule, Federal facilities located in a Covered State must comply with all Federal, State, interstate, and local requirements applicable in that State, including regulations of the Federal demonstration program. If a State elects not to participate in the program and opts out, the medical waste generated by the Federal facilities located in the State will not be subject to the demonstration program.

In addition to expressly subjecting Federal facilities in demonstration States to medical waste regulations, the MWTA also waives all immunity for the United States and its agents, employees, or officers from suit, process, or sanction of any State or Federal court with respect to the enforcement of applicable medical waste regulations. This waiver ensures that Federal facilities are subject to the same legal deterrents with regard to violating medical waste regulations as non-Federal facilities.

However, the MWTA does provide for a potential limited exemption for Federal facilities from medical waste regulation. As noted in Section 11006 of RCRA Subtitle J, summarized in Section II.B. of this Preamble, the President may exempt Federal facilities under the Executive Branch from compliance with medical waste management requirements if he determines that such an exemption is in the paramount interest of the United States. Such an exemption can only be for one (1) year. Additional exemptions are allowed, but only if the President makes a new determination of need, and then only for a one (1) year period. The President must report to Congress each January on the exemptions to Federal facilities granted under this authority in the previous year, and state the reasons for granting such exemptions.

IX. Joint Federal and State Implementation

Several implementation issues have arisen because of interstate movement of medical waste. These are discussed below.

A. *Regulatory Authority*

Many States have begun regulating medical wastes under their own laws. Section 11007(b) of RCRA reserves for States and localities the ability to adopt and enforce their own laws. Any State or local requirement may be enforced only by that State or locality.

One specific limitation on the regulatory authority of States under RCRA section 11007(c) is the use of a uniform medical waste tracking form. This form must be identical in content and format to the Federal form when it is required from a person subject to the Subtitle J regulations. However, States may require supplemental information (e.g., additional reports or supplemental sheets to the tracking form).

EPA's experience with the hazardous waste manifest system has shown that uniformity in tracking form requirements is necessary to reduce conflicting and overlapping State requirements. (See 47 FR 9336, March 4, 1982, and 49 FR 10490, March 20, 1984, for further information on the need for uniformity in hazardous waste tracking forms.)

When non-Covered States require a tracking form for regulated medical waste generated in a Covered State, but transported into or through their jurisdictions, they also are bound by the section 11007(c) requirement that the tracking form be identical to the Federal form in content and format. Therefore, regulated medical waste generated in a Covered State and shipped to a non-Covered State may only be accompanied by a tracking form identical to the Federal form. If regulated medical waste is generated, transported, treated, or disposed only in non-Covered States, then those States may impose additional tracking requirements on the waste and are not limited by section 11007(c) of RCRA.

In some instances, medical waste will be generated in a non-Covered State and transported through or into a Covered State. While the waste is in the non-Covered State, that State can impose its own tracking requirements. Once the waste leaves the non-Covered State and enters a Covered State, it will be presumed to have been generated in that Covered State. (See the discussion in Section IV.A. of this Preamble.) This presumption may be rebutted by a preponderance of the evidence that the waste was generated outside the Covered State. Shipping papers or other documentation accompanying the shipment will thus be necessary to rebut this presumption; the burden is on the regulated party. In the absence of such documentation, the transporter is subject to, and must comply with, all applicable management and tracking requirements in today's rule.

B. *Enforcement Authority*

Section 11005 of the Medical Waste Tracking Act gives the Administrator authority to assess civil penalties, to seek injunctive relief in United States District Court for past or current violations, and to seek criminal penalties for knowing violations of the Act. Section 11004 gives the Administrator, or his representative, authority to conduct inspections and gather information on medical waste.

EPA will include a copy of its enforcement strategy in the docket for this rulemaking and will provide copies of its strategy for implementing the medical waste regulations to the Regions and States prior to the effective date of today's rule. Definition of the EPA and State roles in enforcement, information collection/management, and outreach are the major issues that will be addressed in the strategy.

As part of today's rule, EPA is broadening the scope of the applicability of the consolidated rules of practice governing the administrative assessment of civil penalties and the revocation and suspension of permits, 40 CFR part 22. The consolidated rules will govern enforcement actions taken pursuant to section 11005 of RCRA. The consolidated rules of practice are applicable only to enforcement actions initiated by the Administrator.

EPA is issuing the rule on an interim final basis pursuant to 5 U.S.C. 553(b)(A) and (B), which allows the issuance of rules without prior notice and comment where the rules concern agency practice or procedure or where the Agency finds for good cause that prior notice and comment is unnecessary. Both of these criteria are met by these rules. Use of the Consolidated Rules on an interim basis will allow EPA to begin prompt implementation of the administrative penalty authority provided in the Medical Waste Tracking Act. The Consolidated Rules, codified at 40 CFR Part 22, provide uniform procedures and were promulgated after notice and opportunity for comment. For these reasons, EPA believes that notice and comment on this rule is "unnecessary" under section 553 of the APA.

RCRA section 11005(a) also provides that civil penalties assessed by the United States for violations of Subtitle J shall be assessed in accordance with the Administrator's "RCRA Civil Penalty Policy," as such policy may be amended

from time to time. EPA issued its presently applicable "RCRA Civil Penalty Policy" on May 18, 1984, as an internal Agency Guidance. A copy of the policy is included in the docket for this rulemaking.

X. Regulatory Impacts

A. Executive Order 12291—Regulatory Impact

Executive Order 12291 requires that federal regulatory agencies determine whether a new regulation will be classified as a "major rule." EPA must conduct a Regulatory Impact Analysis for all major rules the Agency promulgates.

The Administrator has determined that today's final rule is not a major rule, because it has total estimated impact costs of less than $100 million per year. This conclusion is based on a cost analysis of today's rule. Therefore, EPA has not conducted a full Regulatory Impact Analysis. EPA has analyzed the costs and potential benefits of today's rule, but has not assessed the impact of the costs on affected businesses. This section provides the methodology and results of the Agency's cost analysis and the results of the benefit analysis.

The cost analysis involved developing cost estimates for management practices required by today's rule for the 10 states targeted for involvement in the demonstration program. Cost estimates will change if any of the Covered States opt out of the demonstration program, or if any other states opt in. State administrative costs as well as potential indirect costs associated with changes in waste management practices have not been analyzed; their combined effects on the costs of the rule are unclear.

1. Cost Methodology

In estimating the costs imposed on the regulated community by today's interim final rule, the Agency focused on estimating only the direct costs incurred through compliance with the rule (i.e., those costs incurred directly by complying with the explicit requirements of the rule) for the ten Covered States. The approach EPA developed involved the following steps: (1) Characterizing the regulated community in terms of the numbers and types of generators, and the numbers of transporters affected; (2) estimating the medical waste generation rates for each of the generator categories and their rate of waste shipments transported off site; (3) accounting for both current state regulations and existing waste management practices governing medical wastes that, for the purposes of this analysis, are similar to the requirements of today's rule; and (4) estimating direct compliance costs for packaging, tracking, generator recordkeeping for generators of less than 50 pounds of regulated medical waste per month, transporter recordkeeping and reporting, and incinerator recordkeeping and reporting.

In this cost analysis, EPA did not address any of the potential indirect cost effects of the tracking system. For example, medical waste disposal capacity in the demonstration States may be reduced if landfill facilities become more reluctant to accept medical wastes due to the associated increased labor load and heightened public awareness the rule will create (i.e., the combination of packaging, labeling, and tracking requirements may cause increasing numbers of landfill owner/operators to refuse handling medical wastes). As a result, medical waste disposal costs could increase. On the other hand, increased use of alternate treatment technologies would decrease the amount of waste regulated under today's rule and thus decrease compliance costs. For example, both on-site incineration and treatment and destruction exempt waste from today's rule. The combined effects of indirect changes in waste management practices on the costs of the rule are unclear. The Agency solicits comment on these other indirect costs, particularly in terms of cost and price data and how the tracking requirements will affect disposal practices. The comments received on the rule and the reporting requirements should provide the Agency information to assess the effects of th tracking rule on existing disposal practices. This assessment will be included in the subsequent Report to Congress.

2. Direct Compliance Costs

To estimate direct compliance costs, EPA first divided each of the major requirements of the rule into its component tasks and estimated the labor hours and material costs associated with completion of each task. The requirements of the rule fall into five categories: packaging, tracking, incineration recordkeeping and reporting, generator recordkeeping (for generators of less than 50 pounds per month), and transporter reporting and recordkeeping. Costs for the first four categories are estimated for generators; only costs for tracking are estimated for transporters and disposers.

3. Characterizing the Regulated Community

In order to estimate the direct compliance costs imposed on the regulated community by today's interim final rule, EPA first divided the regulated community into three groups: medical waste generators, transporters including transfer facilities, and treatment and disposal facilities. EPA subdivided the major generators of medical wastes potentially subject to regulation into 11 categories (ten categories of specific generator types and one "other generators" category) that are listed in Table 1. EPA obtained most of the data on the numbers in each generator category in each of the ten demonstration States from the Department of Health and Human Services and professional associations (e.g., the American Medical Association, the American Dental Association, etc.). Other medical waste generator groups, besides those included in this analysis, may likely exist; EPA requests comment and input on these additional generator categories.

TABLE 1.—GENERATOR CATEGORIES AND CHARACTERISTICS

Generator	Number [1]	Waste generated per week per gen. (lbs.)	Shipments per year per gen.
Hospitals	1,889	2,000	156
Physician' Offices	54,070	32	26
Dentists	51,592	8	12
Nursing Homes	5,232	10	12
Clinics	5,610	32	26
Medical Laboratories	1,279	250	52
Funeral Homes	9,560	10	12
Veterinarians	14,449	16	12
Blood Banks	419	200	52

TABLE 1.—GENERATOR CATEGORIES AND CHARACTERISTICS—Continued

Generator	Number [1]	Waste generated per week per gen. (lbs.)	Shipments per year per gen.
Infirmaries	1,000	16	26
Hospices	111	32	12
Other	759	32	26
Total	145,970		

[1] Data on the numbers of generators for the ten Covered states were obtained from the United States Department of Health and Human Services and from various professional associations (e.g., American Medical Association, American Dental Association, etc.).

The Agency did not have precise data on three of the generator categories: infirmaries, blood banks, and "other generators". The Agency used the total number of universities in each of the ten States as an estimate of the total number of "infirmaries". The Agency used the per capita number of freestanding blood banks in New Jersey to extrapolate an estimate of their numbers in the remaining nine states. To calculate the "other generators" category, the Agency used the per capita number of health maintenance organizations (HMOs) and home health agencies in New Jersey to estimate their numbers in the remaining nine States. The Agency has significant detailed information relative to the State of New Jersey's health care industry and thus has used this available data to estimate, through extrapolation, that information for other less well-characterized states. This analysis assumes that the per capita facility numbers of New Jersey are generally representative of the other nine States. The Agency is continuing to collect more detailed information to further refine these estimates.

The Agency had limited information concerning the number of transporters and treatment and disposal facilities that handle medical waste. For the purposes of this analysis, the number of treaters and disposers has no impact on costs, since their costs are a function of the number of shipments, not the number of disposers. Data on the number of transporters will affect cost estimates, because the total transporter reporting requirement costs are dependent on the number of transporters that must submit such reports. Information on transporter numbers is complicated by the fact that medical waste transporters often operate in multiple states and some states have no licensing requirements for transporters. In the absence of detailed information, EPA estimates the total number of transporters in the ten states to be 1,000, based on experience with current solid and hazardous waste transportation and disposal practices.

4. Medical Waste Generation Rates

Based on EPA analyses and interviews of medical waste generators and transporters, EPA estimated the average quantity of medical waste generated by an average facility within each of the generator categories. The Agency recognizes that the size of the facility and the waste generation rates vary significantly within generator categories, particularly for hospitals. In estimating waste generation rates for hospitals and physician offices, EPA used data available on per bed and per patient waste generation rates, coupled with data on numbers of beds and numbers of patient visits, to determine waste generation estimates for these two generator categories. In determining the amount of medical waste generated by medical laboratories, the second largest per facility generator of medical waste by EPA estimates, EPA relied on a New York Department of Health (NYDH) study of 156 clinical laboratories which found that, on average, these facilities generate 51.7 pounds per day of "infectious" waste. EPA assumed the universe of waste for the NYDH study was equivalent to that regulated under today's rule. EPA used the NYDH survey result to estimate that medical laboratories generate 250 pounds per week (50 pounds/day x 5 days/week) of medical wastes.

EPA also estimated the total number of shipments for each generator category based on available waste generation rates and from interviews with both generators and transporters. Based on this information, EPA estimated that hospitals ship out waste 3 times per week, blood banks and medical laboratories once a week, and the remaining generator categories either once every other week or once a month. Table 1 provides a summary of the Agency's assumptions made in calculating waste generation and waste shipment rates. The Agency requests additional data on waste generation and shipment rates for all 11 generator categories.

5. Existing Management Practices

There are a number of current waste management practices that have been adopted voluntarily by medical waste generators that are substantively similar to the requirements set forth in today's interim final rule. In this cost analysis, EPA accounted for these baseline practices by reducing or eliminating either the incremental materials cost or the required task time associated with each component of the rule. For example, because the Agency assumes that sharps and fluids are already being segregated, EPA applied no additional compliance costs (for either materials or labor time) for this requirement of the rule.

6. Tracking System Requirements

EPA estimated the labor time required to process the tracking requirements of today's rule. A similar analysis of labor time had been performed for the Hazardous Waste Manifest's Information Collection Request document. EPA recognizes that some generators, transporters, and disposers already use manifests, shipping papers or other tracking mechanisms to document the movement of medical waste; however, this cost analysis does not attempt to adjust for these instances. To the extent that medical wastes are currently manifested in accordance with today's rule, compliance costs utilized in this analysis will tend to be overstated.

Each shipment of regulated medical waste requires use of a tracking form; therefore, the total number of shipments per generator per year determines the number of tracking forms that get processed. To estimate the costs of tracking, several different labor components are included to reflect the steps necessary to process waste through the tracking system. EPA estimates that completing and handling the tracking form takes 15 minutes for the generator and 5 minutes each for the transporter and disposer; recordkeeping takes 5 minutes for the generator; exception/discrepancy reporting takes 2 hours for the generator and one-half

hour for the disposer; and transporter reports require 80 hours of labor time. To the estimated labor time, EPA applied a fully loaded (benefits and overhead) salary rate of $47,000 to derive total labor costs. In addition to these components of tracking, EPA included estimates of the cost savings derived from the consolidation or remanifesting of multiple small shipments as allowed under today's rule. EPA realizes that consolidation or remanifesting of medical wastes is not commonly practiced and, therefore, estimated that only 10 percent of the medical waste shipments will be remanifested.

7. Generators of Less Than 50 Pounds

Today's interim final rule exempts generators of less than 50 pounds per month of medical waste from the tracking requirements. However, these generators are required to maintain log books for their waste shipments. For the generators of less than 50 pounds of medical waste per month, EPA estimated the incremental time required, per shipment, to complete the log book to be 5 minutes, which is one quarter of the per shipment time that EPA estimated it would take for all other medical waste generators to complete the tracking form and recordkeeping requirements. Within each generator category, EPA estimated the percentage of generators that would qualify for this exemption, and assigned either 0 percent, 10 percent, or 50 percent of each generator category to the subcategory of generators of less than 50 pounds. The Agency based its estimates of the proportion of generators of less than 50 pounds on the limited data available, assuming that 50 percent of the dentists, nursing homes, funeral homes, and hospices would qualify for the exemption. The Agency assumed that no hospitals, medical laboratories, or blood banks would qualify for the exemption. All other generator categories were assumed to have 10 percent of their facilities qualify as generators of less than 50 pounds per month. EPA believes these estimates are conservative, particularly for veterinarians, nursing homes, hospices, and funeral homes whose generated "medical waste" will consist principally of sharps.

8. Incinerator Reporting

Waste incinerated on-site is not subject to the labeling, packaging, and tracking requirements of today's rule, but is subject to recordkeeping and periodic reporting requirements. EPA estimated that these requirements entail approximately 57 labor hours per facility per year. These reporting requirements impose much lower costs than if the incinerated waste is shipped off-site as medical waste.

For the purposes of this analysis, EPA assumed that only hospitals use on-site incineration, although a small portion of the other generator categories also utilize on-site incineration. An American Hospital Association survey (1983) estimates that 67 percent of United States hospitals use on-site incineration. Based on this estimate, EPA assumed that 67 percent of the hospitals, as characterized in this analysis, incinerate their waste. EPA believes using this estimate in its analysis is conservative, since the 67 percent of hospitals that have on-site incineration will tend to be larger facilities that generate a greater proportion of the total hospital waste and, therefore, more than 67 percent of total hospital waste is probably incinerated. Furthermore, hospital incineration use has likely increased since 1983. Therefore, since incineration of waste imposes lower costs to the generator than shipping the waste off-site, EPA's compliance cost estimate for hospitals tends to overstate the total cost to hospitals of tracking their waste.

9. Packaging

EPA recognizes that some form of packaging of medical waste is currently taking place, but the degree of labeling and packaging of medical waste varies widely. For the purposes of this analysis, EPA assumed that "leak-resistant" packaging requirements and the labeling requirements are voluntarily being met, but that the "rigid" packaging requirement is not. For the purpose of this analysis, EPA assumed that the rigid container performance standard would be met by a four cubic foot cardboard box with a cost of $0.80 per box. EPA recognizes that some medical waste is currently being packaged in rigid containers that would meet today's requirements. To the extent that these practices are currently being used, compliance costs will tend to be overstated. Similarly, to the extent that the performance standard can be met with alternative containers (either more or less expensive), compliance costs will vary from those estimated. In addition to the materials cost, EPA also has calculated the labor time for the generator to pack and seal each box of waste to be five minutes. The total number of boxes that are packed and labeled for each generator category is determined by dividing the weight of the generator's waste (that is to be shipped off-site) by the average weight capacity (assumed at 20 pounds per box) of a four (4) cubic foot cardboard box. For instance, EPA estimates that the average medical laboratory will generate 13,000 pounds or 650 boxes of medical waste per year (13,000/20=650).

10. Existing and Proposed Medical Waste Regulations

In establishing baseline waste management practices, EPA accounted for existing State regulations. EPA adjusted the cost estimates to reflect State requirements that, for the purposes of this cost analysis, were determined to be similar to today's rule. Where a current State requirement is determined to be similar to today's rule, EPA assigned no incremental cost in that State for that particular requirement. For purposes of this analysis, EPA assumed that none of the ten demonstration States have current requirements that are similar to all of the provisions in today's rule and thus all States will have facilities that incur compliance costs. Moreover, half of all affected States (Connecticut, Indiana, Michigan, Ohio, and Wisconsin) were assumed to have no existing requirements similar to the provisions that were analyzed in this cost analysis. In addition, EPA has estimated that Pennsylvania and Minnesota have similar provisions only for the packaging requirement; New York and New Jersey have similar provisions for all but the incinerator, generator of less than 50 pounds per month, and the transporter notification requirements; and Illinois has been estimated to have similar tracking requirements solely for hospitals.

11. Results

During the two year demonstration period, today's rule will impose average annual compliance costs of approximately $55.5 million, for a total estimated 2 year program cost of $111 million (undiscounted). Thus the annual costs of today's rule, according to EPA estimates, are well below the "major" rule threshold of $100 million. Estimated compliance costs by component and generator category are summarized in Table 2.

TABLE 2.—COST SUMMARY ANNUAL COSTS

[In thousands]

Regulated community	Packaging rqts.	Tracking rqts.	Reporting [1] rqts.	Total
Hospitals	$4,904	$519	$0	$[2]7,097
Physician' Offices	5,595	6,647	264	12,506
Dentists	1,407	1,686	582	3,675
Nursing Homes	332	217	59	608
Clinics	693	839	27	1,559
Medical Laboratories	1,196	410	0	1,606
Funeral Homes	331	345	112	788
Veterinarians	937	995	33	1,964
Blood Banks	344	128	0	442
Infirmaries	12	132	5	148
Hospices	35	4	1	40
Other	91	105	4	200
Transporters	0	[1] 13,865	0	[3]13,865
Disposal Facilities	0	10,983	0	10,983
Total	15,845	36,874	1,087	55,481

[1] For generators of less than 50 pounds per month.
[2] This estimate includes $1.67 million for the incinerator requirement.
[3] Average annual cost over the 2 years of the demonstration program.

EPA estimates that physicians' offices, due to their large number, and hospitals, due to their high medical waste generation rate, together account for over one-third of all costs. EPA estimates that all generators combined bear approximately half (55 percent) of the total costs of today's rule, with the remaining costs divided between transporters and disposers.

EPA estimates that the overall average compliance costs of today's rule on a per generator facility basis range from $3,757 per year for hospitals to $71 per year for dentists. EPA estimates that the average incremental cost per pound of generated medical waste for these same two generator categories is $0.04 for hospitals and $0.17 for dentists. The lower per pound cost for hospitals is due to the fact that hospitals frequently incinerate their waste; also, hospitals dispose of more waste per shipment, and therefore their per-pound tracking costs are lower than dentists. EPA estimates the average incremental cost to generators in all the generator categories is $0.08 per pound of medical waste.

EPA estimates that the highest per facility compliance cost is for hospitals that do not incinerate their waste and that do not currently meet the requirements of today's rule. EPA estimated the highest cost for a "typical" hospital (one that generates an average of one ton of medical waste per week) to be $15,638 per year. In contrast, a facility that generates more than 50 pounds of medical waste per month and already meets the requirements of today's rule will have no additional compliance costs.

EPA estimates the packaging requirements will impose costs of approximately $16 million per year. The amount of waste generated per year for all generators in a category is the driving force behind the costs for this component; thus physicians' offices and hospitals together account for two-thirds of the total packaging costs. The remaining nine generator categories incur estimated aggregate annual packaging costs that range from $12,000 for infirmaries to $1.4 million for dentists.

EPA estimates that the costs of compliance with the tracking requirements ($36.8 million per year) account for approximately two-thirds of the total compliance costs. EPA estimates that the generators will incur approximately $12 million of these tracking costs. Physician offices will account for $6.6 million of this estimate, dentists will account for $1.7 million, and the remaining nine generator categories account for less than $1 million each. The additional tracking costs are distributed between transporters and disposal facilities. EPA estimates that transporters will incur average annual tracking system costs of approximately $14 million and disposers approximately $11 million. The transporters also must notify the Agency of their intent to transport medical waste; EPA estimates this onetime cost will total approximately $8,000.

EPA estimates that incinerator recordkeeping and reporting requirements will total approximately $1.7 million for the estimated 1,266 hospitals in the demonstration States that currently use on-site incinerators.

Generators of less than 50 pounds per month of medical waste, although exempt from the tracking requirements, are required to maintain a log of their generated wastes. This requirement will impose relatively small costs on these generators ($1.1 million per year in aggregate). For example, the estimated 5,400 physician offices that EPA estimated are generators of less than 50 pounds of medical waste per month will have recordkeeping costs of approximately $264,000 (or $49 per office) per year.

12. Sensitivity Analysis

These estimates may understate actual costs. For example, transport vehicle and disposal costs are assumed to be unchanged. For various reasons, landfills are apparently less willing (and in some cases unwilling) to accept infectious waste, a phenomenon which suggests that the rule will increase disposal costs two additional ways. First, landfills willing to accept regulated medical waste will be able to charge more for the service. Second, the increased cost of land disposal will stimulate the demand for incineration.

Limited information available to EPA suggest that the current price for medical waste incineration is about $0.30 per pound. Based on Table 1, EPA estimates about 230 million pounds of medical waste (that is not currently incinerated on site) are generated per year in the 10 States expected to participate. Assuming constant returns to scale in incineration, every 1 percent of this waste shift from land disposal to off-site incineration will increase total costs by less than $1 million per year. Thus, if just 10 percent of the medical waste tallied in Table 2 is shifted to off-site incineration, the annual cost of the rule will be about 12 percent higher than estimated. Savings from avoiding landfill disposal fees, increased on-site management, and alternative treatment technologies, will offset this amount,

while limited incineration capacity combined with increased demand will tend to increase it.

In addition, EPA has not estimated the effects of the transporter vehicle components of today's rule that requires all regulated medical waste be transported in a leak resistant, fully enclosed, non-compactor, cargo-carrying body that is maintained in good operational and sanitary condition. However, today's rule does not prohibit the transport of regulated medical waste simultaneously with other waste. The Agency does not have data to rigorously analyze how these transporter vehicle requirements will affect current practices and costs. However, limited information supplied by transporters and generators indicates that in many instances medical wastes are already transported in vehicles meeting the requirements of today's rule. To the extent that current practices do not reflect these requirements, transporter costs will be incurred. The Agency solicits comments on existing transport practices and the effects of today's rule (including transport costs).

In short, the cost figures provided here are meant to be rough estimates of the actual costs of implementing the management standards and tracking requirements promulgated today. As part of the program evaluation that will be conducted pursuant to section 11008 and discussed earlier in this Preamble, EPA will update these cost estimates as new data is obtained. The Agency encourages generators, transporters, and disposers to submit cost information that they consider relevant to assessing the actual costs of the demonstration program.

13. Benefits

EPA has identified several benefits of today's rule that are discussed below. Although the Agency has not quantified all of these benefits, they may be significant.

For instance, medical and solid waste is often released into the environment due to improper waste handling practices. Today's rule, which includes tracking requirements and transporter vehicle requirements (i.e., leak-resistant, fully enclosed, non-compacting vehicles) will likely induce waste transporters to haul medical waste separately from general refuse, most likely in separate trucks. These requirements will ensure that greater care is taken when transporting medical wastes so that it is not mishandled during transport and released into the environment.

EPA has not quantified benefits to waste handlers and the general public fron the packaging and labeling requirements contained in today's rule. Waste handlers will be able to recognize contained medical waste so they can manage it safely; furthermore, medical waste will be more safely packaged than general refuse so that handlers will be less likely to be exposed to its hazards. Likewise, if the general public inadvertently comes into contact with packaged medical waste, they will be able to distinguish it from other solid waste.

Today's rule will increase awareness of the potential hazards and adverse environmental and aesthetic consequences of improper management of medical waste. As a result of this heightened awareness, EPA believes that the proper handling of wastes in the health care industry will extend beyond the scope of today's rule.

In addition, EPA believes that the tracking system may increase the incentives for on-site treatment of medical waste. Specifically, generators may incinerate or treat and destroy their wastes in order to exempt these wastes from today's requirements. As a result, there will be less untreated medical waste transported off-site, thereby reducing the chance that it will be aesthetically or biologically harmful.

Finally, there are inadequate data on medical waste generation rates, treatment practices, fate and transport characteristics, and disposal practices currently available. Implementing the medical waste tracking system will enable EPA to collect the detailed information needed for the Reports to Congress that the Agency is required to complete (see Section 11008 of RCRA). In fact, information gathering is one of the principal purposes of the Act. By collecting this information, the Agency will be better able to identify the problems associated with the management of medical waste, quantify the amounts and types of medical waste generated, and thereby improve the technical basis for evaluating the need for further regulation.

In addition to the benefits discussed qualitatively above, EPA has quantified one additional potential social benefit of today's interim final rule. For the purposes of this particular benefits analysis, EPA assumed the tracking system to be effective in eliminating the problem of medical wastes appearing on the beaches of the demonstration States. The data sources on which to base this analysis are sparse, and the Agency has estimated benefits based on limited data. The Agency further recognizes that the sources of beach wash-ups are not certain. Moreover, a recent study (NYDEC, 1988) suggests that combined sewer overflows and transfer operations at municipal solid waste landfills located near water bodies contribute to the problem. Also, household waste generators, a known source of medical waste found on beaches, are not subject to today's rule. Therefore, it is likely that today's tracking rule may not directly or significantly affect these potential sources for wash-ups. However, since reducing the wash-up of medical wastes caused by sources subject to today's rule is one of the goals of the tracking system, EPA has performed the benefits analysis to illustrate the potential gains from doing so.

For purposes of assessing this potential benefit of the tracking system, the Agency developed two approaches. The two methodological approaches are simplistic, but do provide some quantitative estimation of the effects of medical waste. The first approach is based on benefits that accrue specifically to beach users (e.g., sunbathers, swimmers, strollers). It uses an estimate of the economic value of a beach-day visit and the number of lost beach-day visits a successful tracking system would prevent. The second approach is based on a broader range of benefits that accrue not only to beach users, but also to other groups such as those who value the option to visit the beach and those among the general population who are not completely indifferent to the fact that medical waste is washing up on the nation's beaches. In the first approach, analyzed benefits are limited to Connecticut, New Jersey, and New York; in the second approach, benefits are accrued from all 10 demonstration States. Both methodologies involve simple extrapolations based on rough approximations of the relevant parameters. They are therefore extremely sensitive to the assumptions used and are, at best, accurate by perhaps an order of magnitude.

The first method estimates the value of medical-waste related beach closing in Connecticut, New York, and New Jersey, at approximately $30 million. This figure is obtained by extrapolation based on very limited data concerning New Jersey beach visitation. The second approach uses a different method of extrapolation to obtain an estimate of $100 million for all 10 States expected to participate in the demonstration program.

In both cases, the management standards and tracking program established today are assumed to eliminate all beach closings due to medical waste. As indicated in the background section of this Preamble, however, the program is not expected to