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## I. Authority

These regulations are issued under the authority of sections 2002, 11001, 11002, 11003, 11004, 11005, 11010, and 11011 of the Solid Waste Disposal Act of 1970, as amended by the Medical Waste Tracking Act of 1988, 42 U.S.C. 6992 *et seq.*

## II. Background

### *A. The Medical Waste Tracking Act of 1988*

The Medical Waste Tracking Act (MWTA) of 1988 was signed into law on November 1, 1988. This Act amends the Solid Waste Disposal Act, commonly referred to as the Resource Conservation and Recovery Act (RCRA), to require the Administrator of the Environmental Protection Agency (EPA) to promulgate regulations that establish a demonstration tracking system for medical waste.

The MWTA was enacted as a response to public concern over the degradation of shoreline areas, particularly in Connecticut, New Jersey, and New York, from washups of sewage and other waste. The medical debris raising the most concern were wastes, such as needles, syringes, blood bags, bandages, and vials. See 134 Cong. Rec. S 10737 (August 3, 1988). There were also reports of other incidents of careless management of medical waste; for instance, by disposal into open dumpsters, creating additional concern for public safety. 134 Cong. Rec. H 9536 (October 4, 1988).

The result of the beach washups was the closure of beaches, economic losses in affected shore communities, and public concern over the health hazards associated with medical wastes and the general degradation of the shore environment. 134 Cong. Rec. S 19745 (August 4, 1988) and 134 Cong. Rec. H 9536 (October 4, 1988). Improper management of medical waste raised concerns over the health risks posed by the infectious character of the waste, the physical hazard posed by the wastes, particularly needles and other sharps, and the aesthetic degradation of the vulnerable shoreline environment. 134 Cong. Rec. S 10738 (August 3, 1988). Congress found the appearance of medical waste on the beaches to be repugnant, intolerable, and unacceptable. 134 Cong. Rec. S 10739–S 10745 (August 4, 1988).

The MWTA was enacted against this background of health and environmental concerns. The Act was intended to be a first step in addressing these problems. 134 Cong. Rec. S 15327 (October 7, 1988). The Act establishes a "cradle to grave" system to track medical waste generated in the regions most affected by medical waste mismanagement problems to its final destination. The Act thus is intended to address the medical waste mismanagement problem in several ways. First, the tracking system is designed to be implemented quickly so that, to the extent the program controls sources contributing to washups, washups of medical waste in the summer of 1989 will be avoided. *Id.* Second, the bill was designed to prevent careless management of the waste by establishing tracking and storage requirements and subjecting violators to administrative, civil, and criminal penalties. 134 Cong. Rec. S 15328 (October 7, 1988). Third, the Act was intended to provide, through the tracking system, assurance that the medical waste generated in the affected States in fact reaches its intended destination, and a mechanism for tracing incidents of improper disposal to responsible parties. 134 Cong. Rec. H 9537 (October 4, 1988) and 134 Cong. Rec. S 10745 (August 3, 1988). As noted by the sponsor of the bill, the tracking system is intended to work as a "burglar alarm," alerting EPA and State officials whenever waste has not reached its intended destination and leaving a paper trail that will lead to the violators. 134 Cong. Rec. H 9536 (October 4, 1988). Finally, the legislation is intended to provide information to Congress on the effectiveness of the program and whether and how a broader program should be developed. 134 Cong. Rec. S 10743 (August 3, 1988).

EPA has developed a regulatory program that should accomplish a number of objectives set forth in the Act. Under today's regulations, increased quantities of medical waste will be packaged securely. This will reduce the chances of waste handlers and the public being exposed to medical waste. Although currently available data suggest that medical waste does not generally pose a significant potential for disease transmission, proper packaging will reduce physical hazards (i.e., needle sticks, etc.), and it will help ensure that any health risks are minimized.

Second, due to the presence of labels, marking tags, and a uniform tracking form, medical waste will be more easily identified. This should serve as a deterrent to careless or otherwise improper waste management, and it will help identify parties who do not manage their waste properly. Better identification of medical waste is also

likely to lead to the waste being managed separately from, and with greater care than, general refuse.

The principal intent of the Act was to prevent beach closings caused by the washup of medical waste. However, the available evidence suggests that the tracking program established today may have only a limited effect on reducing beach washups.

According to the report of the New York Department of Environmental Conservation (NYDEC), *Investigation: Sources of the Beach Washups of 1988*, November, 1988 (on file for public review in the docket), the debris that washed up on New Jersey and New York beaches consisted of "floatables," solid wastes such as household trash and garbage, wood and miscellaneous debris. NYDEC estimated that between 1% and 10% of these floatables consisted of insulin-type syringes, blood vials, and other "medical-related waste". The other "medical related waste" category encompasses several waste types *not* included within today's listing of regulated medical waste and hence not subject to regulation.

NYDEC's investigations of the 1988 washups and comparison with earlier beach washups have led to the following conclusions:

- With few exceptions, floatable debris cannot be traced to any specific source;
- Most of these wastes are likely to come from:
  - —The improper transport and handling of solid waste destined for disposal at the Fresh Kills landfill;
  - —Inadequate handling procedures, supervision, and maintenance at the marine transfer stations;
  - —Combined sewer overflows;
  - —Raw sewage discharges caused by occasional breakdowns at one or more of New York City's sewage treatment plants;
  - —Storm water outlets;
- Other activities that were judged less likely to contribute include:
  - —Litter deposited by beach users;
  - —Recreational boating;
  - —Commercial shipping;
- Floatables that become stranded on sandbars are sometimes refloated by the tides and washed ashore;
- Weather conditions contributed to the volume and persistence of washups; and
- Illegal disposal appears to account for some of the wastes (i.e., the blood vials).

The amount of medical waste washup was extremely small compared with both the total amount of garbage that washed ashore and the volume of such waste generated and disposed by New York City's hospitals. Moreover, had these wastes emanated from a hospital, a larger variety of waste types would have been present. Specifically, more noninsulin type syringes, bloody bandages and dressings, bed sheets, and surgical gowns and gloves would have appeared.

According to the NYDEC report, the extent and public health significance of medical waste washups were exaggerated by inaccurate news reports. For example, household trash was misidentified as medical waste, and what were erroneously reported to be discarded laboratory animals turned out to be common sewer rats that had drowned at sea.

Evidence indicates that some of the regulated medical waste is being placed into the solid waste stream of New York City. Hospitals are sometimes lax in sorting their wastes; doctors, laboratories, nursing homes, and clinics sometimes mix medical-related waste with trash; and intentional dumping of regulated medical waste is done to avoid the expense of disposal. Outpatients such as diabetics and other intravenous users also dispose of their waste in municipal trash.

In summary, today's regulations may not significantly reduce the amount of medical waste deposited on beaches. Sources of medical waste not addressed by the regulations (e.g., household medical care and intravenous drug use) are known to contribute significantly to beach waste wash-ups. However, the regulations should ensure that medical wastes from institutions and commercial sources are being managed properly. Furthermore, one of the intentions of the MWTA is to provide information to Congress about the sources and possible solutions to the medical waste problem. During the two-year demonstration program, EPA will collect information on the scope of the medical waste problem, the usefulness of the tracking system in solving that problem, and the availability of other effective solutions.

EPA will be assessing the effects of the program over the next two years. Generally we will look at factors such as:

(1) The extent of compliance with the requirements.

(2) The quantity and type of debris found on beaches in 1989 and 1990, and compare the results with those from last summer.

EPA will try to assess what sources are contributing to medical waste found on beaches, and therefore, to what extent the demonstration program, even when fully implemented, can reduce washups.

Finally, EPA will examine the comments received on today's rule. Many parts of the rule, such as the scope of the wastes that are covered and the packaging requirements, are based on EPA's best technical judgement. Comments may provide additional information and expert recommendations. Additional information may also be available from other sources, such as the study the Agency for Toxic Substances and Disease Registry (ATSDR) will be conducting under RCRA section 11009. This is discussed below.

*B. Subtitle J of RCRA*

The Medical Waste Tracking Act adds Subtitle J, discussed below, to RCRA.

*Section 11001* describes the scope of the demonstration program, which includes Connecticut, New Jersey, New York, and the States contiguous to the Great Lakes, which are Illinois, Indiana, Michigan, Minnesota, Ohio, Pennsylvania, and Wisconsin. Other States may petition the EPA Administrator for inclusion in the program. The States which have petitioned in, to date, include American Samoa. States in the program are referred to as "Covered States."

The States bordering the Great Lakes may opt out of the demonstration program by notifying EPA by April 24, 1989. In addition, Connecticut, New Jersey, and New York may remove themselves from participation if the Governor of the State notifies the Administrator by April 24, 1989, and EPA determines that the State has implemented a medical waste tracking program no less stringent than that promulgated by EPA under Subtitle J. Section 11001(d) provides that the program will expire two (2) years after the effective date of the regulations. Finally, States that wish to petition in must do so by April 24, 1989, in order to be considered for inclusion in the demonstration program.

*Section 11002* of the Act designates the following general types or classes of medical wastes that must be tracked under the demonstration program: (1) Cultures and stocks of infectious agents and associated biologicals; (2) pathological waste; (3) human blood and blood products; (4) used sharps (e.g., syringes, needles and surgical blades); (5) contaminated animal carcasses; (6) surgery or autopsy waste; (7) laboratory wastes; (8) dialysis wastes; (9) discarded medical equipment; and (10) isolation wastes. Section 11002 requires EPA to promulgate regulations within six (6) months following enactment of

MWTA (May 1, 1989) that list all of the wastes that are subject to tracking. EPA cannot exclude any wastes in the first five waste types (1-5), but is authorized to exclude wastes in the second five waste types (6-10) if the Administrator determines that such wastes do not pose a substantial present or potential hazard to human health or the environment when improperly managed. Further, EPA may regulate other waste associated with medical care that the Agency determines poses a substantial threat to human health or the environment. As required by this section, EPA has developed the list in today's rule, and refers to the wastes covered by the rule as "regulated medical wastes."

*Section 11003* discusses the requirements of the tracking program, for which EPA must promulgate regulations by May 1, 1989. Section 11003(a) specifies that the program must provide a system for tracking regulated medical wastes listed by EPA regulations under section 11002 (i.e., regulated medical waste), from a generator in a Covered State to the receiving, off-site incineration or disposal facility. (Under today's rule, medical waste that is incinerated, or otherwise treated and destroyed, must be tracked only to the point of such treatment and destruction, provided certain conditions are met.) The tracking program must use a uniform form for tracking and include a system for providing generators with assurance that the disposal or treatment facility has received the waste. In addition, the tracking program must provide that: (1) Wastes are segregated at the point of generation, where practicable; (2) wastes are placed in containers that will protect waste handlers and the public from exposure; and (3) appropriate labels are placed on containers of the waste. Section 11003(d) allows EPA to establish various regulations for different types of medical waste and for different types of generators.

Under section 11003(b), EPA may exempt from the tracking program generators of less than 50 pounds of medical waste in a calendar month. Section 11003(c) requires that EPA establish recordkeeping and reporting requirements for generators that incinerate medical wastes on-site and that would, on this basis, be exempt from tracking waste. Reporting must include, at a minimum, the volume and types of medical wastes incinerated during the six (6) months after the effective date of the tracking regulations.

*Section 11004* requires that any person who generates, stores, treats, transports, disposes, or otherwise handles medical waste must furnish, upon the request of any duly designated EPA official or representative, any information relating to such medical waste. The authority provided under this section is *not* limited to demonstration States or facilities covered by Subtitle J regulation nor is it limited to the types of medical waste regulated for purposes of the tracking program. The provisions of Section 11004 govern any "medical waste" as defined in section 1004(40) of RCRA. The Act provides EPA this authority for access to information needed to support the development of any regulation or report required under Subtitle J, or to assist in the enforcement of any provision of this Subtitle.

*Section 11005* contains enforcement provisions for the MWTA. Section 11005(a) specifies that, upon determining that a violation of Subtitle J has occurred, EPA may assess a civil penalty for any past or current violation and/or order of compliance, or commence a civil action in U.S. District Court. Penalties of up to $25,000 per day for each violation of a requirement or prohibition under the Act or for failure to comply after issuance of a compliance order may be assessed. An alleged violator may request a public hearing within 30 days after EPA's issuance of an order under this section.

Under section 11005(b), criminal penalties of up to $50,000 per day of violation or two (2) years of imprisonment may be assessed for those who knowingly omit material information or give false information in documents required under this Subtitle, or for those who knowingly handle listed medical wastes and destroy, alter, or conceal required documents. Persons who knowingly violate the requirements or the regulations under Subtitle J can be fined up to $50,000 per day of violation or imprisoned for up to five (5) years. Repeat offenders under this Subtitle are subject to double the maximum penalties.

Section 11005(c) specifies that any knowing violator who, at the time of the violations knowingly places another person in imminent danger of death or serious bodily injury by his or her violation, may be fined up to $250,000 or subject to imprisonment for 15 years, or both. Organizations may be fined up to $1,000,000 for knowingly endangering another person.

Section 11005(e) states that civil penalties assessed under this Act shall be in accordance with the Administrator's RCRA civil penalty policy.

*Section 11006* pertains to Federal activities and requires all Federal agencies in a demonstration State to comply with the provisions of this Act and with all Federal, State, interstate, and local medical waste requirements, both substantive and procedural, and including administrative orders and criminal, civil, and administrative penalties. Certain exemptions may be granted by the President if they are in the paramount interest of the United States. The President must report to Congress each January all exemptions granted during the previous year.

*Section 11007* concerns Subtitle J's relationship to State law. Subtitle J does not preempt State or local law, or otherwise affect State law, except that any State form for tracking medical waste from persons subject to regulation under Subtitle J must be identical to the one required by EPA in today's regulation. However, the State may require submission of additional information.

*Section 11008* requires EPA to submit to Congress two interim reports and a final report on medical waste and the demonstration tracking program. The final report is due within three (3) months following expiration of the demonstration program, and must include the following information:

- An analysis of medical waste generators in the U.S., the types and amounts of medical waste generated, and the methods currently used to manage medical waste;
- Evaluation of the threat posed by medical waste or its incineration to human health and the environment;
- Estimates of the costs associated with the improper management of medical waste;
- Estimates of the costs associated with the tracking and management requirements under the demonstration program;
- An evaluation of the success of the demonstration program, resulting changes in medical waste incineration and storage practices, and alternative tracking procedures;
- An examination of available and potentially available methods for managing and treating medical waste, including factors influencing the effectiveness of treatment methods;
- An analysis of the existing State and local controls on the management of medical waste and the appropriateness of using any existing State requirements or RCRA Subtitle C (hazardous waste) controls nationwide for medical waste;
- An evaluation of the appropriateness of the Act's provision for penalties for insuring compliance,

including a review of the penalty levels imposed;

- An evaluation of the effect of excluding households and small quantity generators from medical waste regulation and potential guidelines for these parties; and
- An examination of available and potentially available methods for the reuse or reduction in volume of medical waste generated.

The two interim reports submitted to Congress must detail any information available in these areas at the time of submission. These interim reports are due on August 1, 1989, and June 22, 1990, respectively. Because of the Congressional and public interest in the medical waste problem, the final Report to Congress will contain a comprehensive evaluation of the demonstration program. In the first interim report EPA will describe in detail the evaluation methodology to be used. The second interim report will provide preliminary results of this program evaluation.

*Section 11009* requires the Agency for Toxic Substances and Disease Registry (ATSDR) to report to Congress, by November 1, 1990, the potential for infection or injury to workers and the public from handling medical waste, estimates concerning the number and seriousness of cases of infection or injury resulting from handling sharps or from other medical waste management activities, and estimates concerning the number of cases of diseases traceable to medical wastes (particularly the Human Immunodeficiency Virus (HIV) and Hepatitis-B). EPA is coordinating its activities with ATSDR in the health assessment area.

*Section 11010* identifies general provisions for the Subtitle including a requirement that EPA consult with the affected States (i.e., the 10 States named in the Act) on the regulations and with the International Joint Commission with respect to medical waste originating in Canada. In addition, this section exempts EPA from otherwise applicable requirements for public comment under the Administrative Procedure Act (APA) and for paperwork burden analysis under the Paperwork Reduction Act (PRA) concerning the listing and tracking regulations.

*Section 11011* establishes the effective date for regulations under Subtitle J. The regulations must become effective 90 days after promulgation, unless EPA finds that 90 days is unnecessary for compliance.

Section III of the MWTA amended RCRA, adding a new definition of "medical waste" to Section 1004 of RCRA related to the new program established by the MWTA.

*C. Previous Agency Action Concerning Infectious Waste*

On December 18, 1978, the Agency proposed comprehensive regulations under the Solid Waste Disposal Act, as amended by RCRA, for hazardous waste management. In this proposal, EPA proposed to classify certain infectious wastes as hazardous waste (43 FR 58946). (Wastes listed or designated by EPA as "hazardous" under Section 3001 of RCRA are subject to stringent "cradle-to-grave" regulations under Subtitle C of RCRA, which include, among other provisions, tracking of such wastes via a national uniform manifest, restrictions on land disposal, and permits for all treatment, storage, and disposal facilities.) The wastes proposed for listing in 1978 included infectious materials generated by certain departments in health care facilities and veterinary hospitals, laboratories handling infectious agents, and sewage treatment facilities. These wastes would have been exempt if they were sterilized or incinerated in accordance with specified methods.

EPA proposed to list these wastes as hazardous because the Agency believed at the time that if they were improperly managed, they could pose a substantial hazard to human health and the environment. Thus, such wastes would meet the RCRA Section 1004 definition of "hazardous waste." A number of comments received in response to the proposed regulation claimed, however, that there was no evidence that infectious wastes pose serious hazards to human health or the environment. As a result of these comments and EPA's reconsideration of the hazards posed by these wastes, EPA did not list infectious waste as a hazardous waste in the final rule (45 FR 33087; May 19, 1980). EPA explained that it was not listing infectious waste at this time because "* * * the Agency has not been able to complete the work necessary to identify the treatment methods it would allow to be used to exempt these wastes from regulation". *Id.* Instead, the Agency initiated several data collection activities to assess the problems posed by infectious waste management and disposal. EPA used the resulting information to develop a guidance document which was distributed to the public in draft form in 1982 outlining a practical approach for infectious waste management (47 FR 43162, September 30, 1982). The Agency then solicited comments on the draft guidance document, specifically seeking advice from professionals in the health care industry. The text was revised based on these comments and published in 1986 as a final guidance document, entitled *EPA Guide for Infectious Waste Management.*

In addition to publishing the guidance document, the Agency has taken an active role in training health care professionals in the responsible management of infectious medical waste. Agency staff have participated as faculty or professional experts at symposia sponsored by the American Hospital Association and the American Society for Hospital Engineering.

However, in 1987, several isolated incidents of improper management and disposal of infectious wastes led to increased public concern about the potential threat of these wastes to human health and the environment. In response, the Agency convened a panel of experts in November 1987 to discuss the definition, proper management of, and risks posed by infectious wastes.

On June 2, 1988, the Agency published a notice in the **Federal Register** (53 FR 20140), announcing the availability of various documents and requesting public comments on five issues affecting infectious waste management: the definition of infectious waste; the nature of infectious waste (risks and problems; the extent of mismanagement; pretreatment and packaging, and disposal requirements); the role of EPA in infectious waste management; tracking of infectious waste; and exemptions from medical waste management controls. Although the passage of MWTA superceded many aspects of the June 2 notice, EPA considered relevant comments received on the June 2 notice in developing today's rule.

*D. Consultation and Public Comment*

Because publication of a proposal for today's rule was not possible given Congressional requirement that this program be expeditiously implemented, the Agency has made special efforts to coordinate the development and implementation of today's rule with interested parties. The Act specifically requires EPA to consult with the affected States, and allows for consultation with other interested parties at EPA's discretion, in promulgating today's rule. Also, EPA was directed to consult with the International Joint Commission (IJC) to determine how to monitor the disposal of medical waste emanating from Canada.

1. Consultation with States and Other Parties

EPA began the consultation process by contacting virtually every State to obtain information on medical waste regulatory programs. EPA then concentrated on the ten States named in the Act, and developed a detailed summary of these States' medical waste regulations, both existing and proposed. (See the report entitled, "State Medical Waste Regulatory Summary Report for Medical Waste Tracking Act States" available in the docket.) EPA considered these regulations in developing the program promulgated today.

EPA sponsored two meetings with the affected States to obtain input on the interim final rule. EPA sponsored a meeting in New York City on December 14, 1988, with the States of Connecticut, New Jersey, and New York to solicit their input in drafting the regulation. Then, on December 19 and 20, EPA, in conjunction with the National Governors' Association (NGA), sponsored a two-day workshop in which representatives from the 10 affected States, plus the States of Alabama, Delaware, Florida, Massachusetts, North Carolina, and South Carolina, and from the Great Lakes Commission discussed regulatory and implementation issues associated with today's Part 259 regulations. (*See EPA/State Meeting to Consider Medical Waste Tracking Regulation Issues*, available in the docket.)

The Agency also sponsored a meeting on medical waste on November 14–16, 1988, in Annapolis, Maryland. Over 50 individuals representing trade and professional associations, government agencies, several States, and other organizations attended the meeting. Comments and suggestions were solicited from the participants concerning three major topic areas relevant to the Medical Waste Tracking Act of 1988: medical waste definitions; segregation, packaging, labeling, and tracking requirements; and information needs to develop the Reports to Congress. The Agency compiled the comments and suggestions from the meeting. (See "Proceedings of the Meeting on Medical Waste" available in the docket for this rule.) All of these meetings provided information upon which this rule is based.

In addition to these activities, the Agency met individually with appropriate staff of several Federal agencies including the Department of Defense (DOD), the Veterans Administration (VA), the National Institutes of Health (NIH), the Centers for Disease Control (CDC), and the Department of Transportation (DOT) to obtain information on medical waste management practices.

2. Consultation with International Joint Commission

In compliance with the requirements of the Medical Waste Tracking Act, EPA has initiated discussions with the International Joint Commission regarding the development of the Agency's medical waste tracking program. EPA also is working with the Canadian Government on the tracking of these wastes.

## III. Future A ency Action

### *A. Actions Under Other Agency Programs*

EPA's efforts on this rule represent only one phase of a multiphase program to investigate and address the medical waste problem. Other aspects of this program are described in Section VI.

Another continuing effort with particular bearing on this rule is a study of medical waste generation, treatment, transportation, and disposal in the States of New Jersey and New York, which have been particularly affected by medical waste mismanagement. Through a combination of site visits and surveys, EPA is developing a baseline of information that will be used later in evaluating the effectiveness of the demonstration program.

### *B. Reports to Congress*

In response to section 11008 of RCRA Subtitle J, and as discussed in section II.B. of this Preamble, EPA will develop three reports—two interim and one final—describing the extent of the medical waste management problem. These reports will provide Congress with an account of medical waste generation, management, potential for causing adverse health or environmental effects, costs, and the results of the demonstration program. This information is intended to aid Congress in determining the most appropriate course of future action in this area. The interim reports are to be based on the best information available to the Agency at the time of submission. The final report will provide a thorough evaluation of the identified subjects.

### *C. Regulatory Assessment*

Following the evaluation of the demonstration program and the completion of research for the reports to Congress, the Agency also will reassess the need for regulation of medical waste on a national scale and identify alternatives to national regulations. Currently, EPA is considering developing guidance for State legislative and regulatory programs for medical waste as an alternative to national regulations. These programs could be adopted in whole or in part by individual States, depending on the needs and resources of the States. These issues will be addressed in the context of the EPA reports to Congress.

### *D. Educational Activities*

EPA has undertaken efforts that will enable the Agency and affected States to communicate the new requirements promulgated today to the regulated communities within those States. EPA plans to sustain its educational efforts in these States throughout the duration of the demonstration program. As part of this endeavor, the Agency continues to recommend its 1986 *EPA Guide for Infectious Waste Management* both to health care facilities outside the scope of the demonstration program, and as a supplement to today's regulations for health care facilities in the Covered States.

Informational materials may be obtained by contacting the implementing State agency, or by calling the EPA RCRA Hotline at (800) 424–9346 or (202) 382–3000. The *EPA Guide for Infectious Waste Management* is available for purchase only from the National Technical Information Service (telephone (703) 487–4650) as publication PB–86–199130.

### *E. Program Evaluation*

Congress directed EPA to establish this system as a demonstration project to determine whether such an approach would be an effective means of reducing beach closings due to medical waste wash-ups. A critical element of the program consists of the evaluation necessary to determine if the approach mandated by the MWTA achieves the policy goals identified by Congress. In consultation with ATSDR, EPA will establish a baseline of existing disposal practices; the incidences and causes of past beach closings; and the incidences of recreational and occupational injuries caused by medical waste. Using this baseline, EPA will evaluate the program under the following criteria:

- The effect on treatment and disposal practices, including the volume of elicit disposal;
- The effect on the number of beach closings;
- Changes in aggregate health and environmental effects;
- Changes in risks faced by health care providers, patients, and medical waste handlers;

• The effect on the cost of medical waste disposal; and

• Covered States effectiveness in utilizing tracking system data to discover improper medical waste disposal.

EPA requests comments on these criteria.

## IV. Overview of the Demonstration Program Tracking System

As indicated above, the principal Congressional concern with medical waste was the lack of any tracking mechanism. Thus the MWTA requires EPA to institute a tracking program that would provide assurance that medical wastes reach their proper destinations for disposal.

EPA, for the purpose of these regulations, is using the term destination facility to signify the facility to which the medical waste is transported for proper disposal. Section 259.10(b) of today's rule defines a destination facility as a disposal facility including facilities that both treat and destroy medical waste (e.g., off-site incinerators) which complete the medical waste tracking form by signing the form and sending a copy to the party that initiated it, thus closing the chain-of-custody requirements.

The framework Congress established does not provide for regulation of household-generated medical waste, but otherwise grants EPA authority to regulate medical waste generated in the Covered States, even when this waste is transported into non-Covered States. Therefore, the regulations apply to generators in Covered States, and to transporters and owners and operators of transfer, treatment, and disposal facilities who accept or handle regulated medical waste generated in one of the Covered States.

The tracking system promulgated in today's rule will provide assurances that regulated medical waste is properly handled and managed from its point of generation until it reaches the disposal facility. The tracking system requires each person in the chain-of-custody of medical waste management to take responsibility for assuring that the waste reaches the proper treatment or disposal facility. A tracking form must accompany the waste from generation to disposal or to treatment and destruction, thus leaving a paper trail which may identify sources of mismanagement. Exception and discrepancy reporting requirements are specified so that appropriate State and Federal officials are notified if regulated medical wastes do not reach their designated destination.

Generators, transporters, treaters, and disposers are also required to keep certain records that will aid in determining whether mismanagement of regulated medical waste has occurred. Additionally, today's rule establishes segregation and packaging standards to limit the possibility of exposure of waste handlers and the general public to regulated medical waste. This rule also requires that transporters submit periodic reports that EPA will use to identify the generators of regulated medical waste, types and amounts of medical waste generated, current methods of medical waste management, and to obtain information on the number and identity of generators of less than 50 pounds per month of regulated medical waste. The Agency has determined that requiring transporters to submit such reports is the most effective means of obtaining this information during a short demonstration program because of their central position within the medical waste management system, the fewer numbers of transporters relative to generators under this rule, and because transporters are more likely to already maintain such types of information.

The Agency has accelerated this rulemaking to ensure that the rule, consistent with Congressional intent, is in place by this summer's beach season. The rule is issued in interim final form without prior notice and comment, as specifically authorized by Congress, because there is insufficient time available to propose the regulation, accept comments, and promulgate it so that it becomes effective prior to the summer of 1989. In addition, EPA did not shorten the 90 day period between promulgation and the effective date of the program (as provided in section 11011) because EPA believes that the regulated community will generally need the full 90-day period in order to come into compliance with today's rule. For the same reasons, the Agency is extending the applicability of the consolidated rules of practice to administrative hearings for violations of the Act and regulations.

The remainder of this section generally outlines the responsibilities of each person (i.e., the generator, transporter, and treatment or disposal facility) in the management of regulated medical waste. As discussed in Section I of the Preamble, the general structure for the system is explained in section 11003 of the Medical Waste Tracking Act of 1988. The Act establishes three performance standards for the tracking system. The program must:

(1) Provide for tracking of the transportation of the waste from the generator to the disposal facility with the exception of wastes that are incinerated (which need not be tracked after incineration);

(2) Include a system for assuring the generator of the waste that the waste is received by the disposal facility; and

(3) Use a uniform form for tracking in each of the Covered States.

Given this mandate, EPA looked to two primary sources for developing a Federal medical waste tracking program. First, the Agency examined the existing Uniform Hazardous Waste Manifest (UHWM) system under RCRA Subtitle C. In the UHWM system, a "manifest" functions as a shipping document that accompanies the waste from its point of generation to its ultimate destination. The manifest provides a record for waste handlers (generators, transporters, and treatment and disposal facilities), documenting when the waste changes hands and if it has ultimately been delivered to a disposal facility.

Second, the legislative history indicates Congressional intent that EPA consider New Jersey and New York tracking regulations as a model for the Federal program. Therefore, EPA also reviewed the emergency medical waste tracking programs currently being implemented in New Jersey and New York. Both States have instituted medical waste tracking programs similar to the UHWM.

Based on its analysis of these systems, the Agency concluded that a system utilizing a tracking form would provide the most feasible means for monitoring the movement of medical waste from its point of generation to ultimate treatment and destruction or disposal and that, given the relatively short time frame available, the system should be based in large part on the UHWM. Additionally, a tracking form system would be largely self-implementing; under this system, the generator would bear the responsibility for reporting any waste he ships off-site that does not actually arrive at the destination treatment and destruction facility or the disposal facility. The paper trail established through the use of a multiple-copy tracking form would confirm the physical delivery of the waste to transporters and designated disposers, thereby providing checks on the activities of all parties involved. Furthermore, reporting requirements associated with manifesting, such as exception and discrepancy reports, have been incorporated into the tracking system to alert the Agency to any anomalies that develop. Finally, the Agency incorporated many of the elements of the New Jersey and New