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• 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

York programs into the Federal medical waste tracking program. In particular, the Agency felt that the emergency manifest format used by New Jersey and New York could be adapted readily to achieve the objectives of the Federal program; therefore, the New Jersey and New York form have been a basis for the tracking form promulgated today.

In summary, the Agency determined that the medical waste tracking system outlined in today's regulation should establish a system separate and distinct from the hazardous waste program, yet should incorporate several essential elements of the UHWM system as well as significant portions of the New Jersey and New York State programs. This combination best meets the objectives of the Medical Waste Tracking Act. The essential elements of the system are discussed next.

A. Uniform Tracking Form

Section 11003 of the Medical Waste Tracking Act requires the Agency to develop a uniform form for tracking to be used in each of the Covered States. The use of such a form will facilitate inspection and enforcement activities and the adoption of standard operating procedures for waste handlers. Section 11007 stipulates that States or localities that require a tracking form for waste subject to the Federal program must use a form identical to EPA's. States, however, may require additional information to be provided on a separate attachment. Although the Agency initially considered adopting the Uniform Hazardous Waste Manifest tracking form as the standard form, the Agency has determined that a unique tracking form would be more useful for the medical waste tracking program. Several factors contributed to this decision:

(1) The legislative history indicates that the Agency, to the extent possible, should avoid disrupting either New Jersey's or New York's emergency medical waste tracking programs. These programs do not utilize the UHWM tracking form. While the Agency recognizes that the form promulgated in today's rule also varies slightly from the State forms, EPA engaged in extensive consultations with the two States and, ultimately, the States and EPA agreed that the form issued today is appropriate for the Federal program;

(2) The health care industry generally believes that the information requirements (e.g., DOT shipping description) of the existing hazardous waste manifest are not appropriate;

(3) Most generators of regulated medical waste subject to the medical waste tracking form requirements do not have an EPA Hazardous Waste identification (ID) number, which is required for the UHWM, and it would be very difficult to establish an ID system for the estimated 150,000 medical waste generators subject to this rule;

(4) Because of the special information needs for medical waste tracking, the Agency would need to develop a new set of instructions for completing the UHWM when it is utilized for tracking regulated medical waste. A new set of instructions for completing this manifest for regulated medical waste is likely to create confusion for those persons transporting and disposing of RCRA hazardous wastes. The potential for confusion may also be exacerbated by the short duration and limited scope (i.e., waste generated in Covered States only) of this program;

(5) In most States and under RCRA, medical waste need not be disposed of in RCRA Subtitle C facilities. However, because transporters and disposal facility owners and operators have been trained that waste shipments accompanied by a UHWM may be disposed of only in a RCRA Subtitle C facility, use of the UHWM may create confusion over where medical waste may be disposed or treated. As a result, disposal or treatment facilities might reject medical waste accompanied by the Subtitle C manifest. At the same time, because waste accompanied by the UHWM would no longer be restricted to Subtitle C facilities, some hazardous waste may be diverted to general solid waste facilities.

Ultimately, the medical waste tracking system must provide the necessary paper trail to meet the objectives of the demonstration tracking program while, at the same time, being easy to implement by the regulated community. The Agency requests comments as to whether another tracking system or tracking form is more appropriate than the distinct Medical Waste Tracking Form that has been developed for the Federal demonstration program. For example, the Agency requests comments on whether advance notice of tracking should be required of generators so that a treatment or disposal facility would be notified to expect delivery of regulated medical waste in advance of the waste's arrival.

B. How the Tracking System Operates

Under the medical waste tracking system, the tracking form serves as a shipping document and as a record that will verify the movement and disposition of regulated medical waste following its generation. Each party (i.e., generator, transporter, and treatment and disposal facility) who handles regulated medical waste has responsibilities to make certain that the waste is properly managed. The following paragraphs identify the general responsibilities of each party.

1. Generator Responsibilities

a. *Generators of 50 pounds or more per month.* Today's rule requires generators in the Covered States who generate 50 pounds or more of regulated medical waste in a calendar month to complete a tracking form for each shipment of regulated medical waste intended for off-site treatment or disposal.

The tracking form must be prepared by the generator when regulated medical waste is transported or offered for transport off-site (i.e., when the generator turns waste over to a transporter for delivery to an off-site treatment and destruction or disposal facility). The generator must obtain a copy of the medical waste tracking form (see the acquisition of manifest discussion in the section-by-section analysis that follows), complete the form according to the instructions provided in Appendix I to Part 259, and sign and date the tracking form certification by hand. The generator also must make certain that the regulated medical waste is properly segregated, packaged, labeled, and marked. Before releasing custody of the waste to the transporter, he must obtain the signature of the transporter and the date of acceptance on all copies of the tracking form. The generator must retain a copy of the tracking form for his records and give the remaining copies of the tracking form to the initial transporter. The generator also should receive a copy of the form back from the disposal facility within 35 days. The generator must file an exception report with the Regional Administrator and the State if he does not receive the copy within 45 days from the initial date of acceptance by the transporter.

b. *Generators of less than 50 pounds per month.* In many cases, very small volumes of medical waste have been responsible for extensive public concern. Due to the potential adverse effects that could be caused by mismanagement, the Agency decided not to exempt generators of small amounts of regulated medical waste from all aspects of the program. However, as provided by the statute, today's rule exempts generators of less than 50 pounds of regulated medical waste per calendar month from preparing a tracking form, unless they ship an individual shipment of 50 pounds or more. Such generators,

however, still are required to maintain logs recording each of their shipments of less than 50 pounds. In addition, EPA has determined that proper packaging of regulated medical waste is necessary to ensure proper containment of the waste and to protect waste handlers and the public from exposure to these materials. Labeling and marking are directly related to the tracking requirements because the transporters are initiating forms for these wastes, and other waste handlers must be able to identify the contents as regulated medical waste. The Agency, therefore, has not exempted these generators from the requirements to properly package, label, mark and transport their waste in accordance with today's regulations.

2. Transporter and Transfer Facility Responsibilities

a. *General.* Transporters, including transporters who operate transfer facilities, must be authorized through a notification process to transport and/or operate in a Covered State. (The notification procedures are explained in Subsection V.) After submitting notification, the transporter may accept regulated medical waste for transport. Before accepting any shipment of regulated medical waste, however, the transporter must verify that all the information required on the tracking form is complete and that the regulated medical waste is properly packaged, labeled, and marked. The transporter then must sign and date the medical waste tracking form certifying his acceptance of the shipment from the generator, and return a copy of the form to the generator.

The transporter then must carry the tracking document and the associated medical waste to the destination facility or to the next transporter of the waste. If delivery to the next transporter or destination facility is not possible, the transporter must contact the generator for further instructions, note such instructions in the space provided on the form for additional information, and carry out those instructions consistent with applicable law. Until the signature of the destination facility or subsequent transporter is obtained, the waste is considered to be in the custody of the transporter who last signed the tracking form.

b. *Consolidation or remanifesting of regulated medical waste.* Under today's rule, certain transporters and owners or operators of transfer facilities must initiate tracking forms. A transporter who receives one or more individual shipments from generators of less than 50 pounds per month of regulated medical waste that are not accompanied by a tracking form must initiate the form. The transporter is also required to consolidate all such shipments onto a single tracking form. As noted in the section-by-section analysis, transporters and owners or operators of transfer facilities will be required to attach a separate sheet of paper or log to the tracking form that identifies each generator and the amount of corresponding waste that has been consolidated onto the tracking form.

The Agency also is allowing transporters and owners or operators of transfer facilities to consolidate or remanifest individual shipments of regulated medical waste weighing less than 220 pounds onto a single tracking form. The Agency believes that the tracking program would become unimplementable if treatment and disposal facility operators were required to sign and account for a tracking form for each and every generator, including generators of less than 50 pounds, of regulated medical waste (e.g., a single truck could contain as many as 500 individual shipments of regulated medical waste, each weighing 100 pounds or less). However, to facilitate recordkeeping by transporters, EPA recommends that shipments between 50 and 220 pounds accompanied by a tracking form *not* be consolidated with shipments of less than 50 pounds from generators exempt from use of the tracking form. To simplify recordkeeping procedures, EPA believes that shipments between 50 and 220 pounds should be consolidated onto a single tracking form while shipments of less than 50 pounds from generators exempt from use of the tracking form should be consolidated onto a second, separate tracking form.

Today's rule also requires that transporters (including owners or operators of transfer facilities) maintain copies of all tracking forms for a period of three (3) years. Transporters must submit periodic reports to the State and to EPA summarizing waste quantity information (generation and destination).

3. Treatment and Disposal Facility Responsibilities

a. *General.* When regulated medical waste is delivered to the destination facility, the owner or operator of the facility must sign and date the tracking form to certify that the regulated medical waste was received. The owner or operator also must note discrepancies such as differences in the quantity or type of waste identified on the tracking form and the quantity or type of waste actually received at the facility. When such discrepancies cannot be resolved with the generator and transporters, the owner or operator must notify appropriate State and EPA officials.

After acceptance, the owner or operator must send a copy of the signed tracking form to the generator within 15 days of delivery. This represents the final segment of the tracking loop. It signifies to the generator that his waste has been received by the destination facility.

b. *Treatment or destruction facilities initiating tracking forms.* An owner or operator of a treatment facility must initiate a tracking form when the waste has been treated, but has not been destroyed through such processes as grinding or shredding. Similarly when waste has been either shredded or ground but not treated the facility must initiate a tracking form. The waste thus still requires transport to a final disposal site. Specific instructions for dealing with this situation are included next in the detailed section-by-section analysis.

V. Analysis of the Rule—Part 259 Standard for the Tracking and Management of Medical Waste

The previous section explained the general operation of the demonstration tracking program, as well as the basic responsibilities of each individual involved in the generation, transport, and treatment and disposal of regulated medical waste. The paragraphs that follow provide a detailed section-by-section analysis of the rule, discussing the rationale behind the requirements, and providing guidance for interpreting various sections of the rule. Those sections of the rule that are self-explanatory are not addressed in the Preamble.

A. Subpart A—General

Subpart A of today's rule provides general information on the new Part 259. This section of the Preamble deals with three issues concerning the program's scope and applicability: the limitation of the program to medical waste generated within the Covered States; effective dates and duration of the program; and notification to EPA by the State when taking enforcement actions.

1. Waste Generated in a Covered State (Section 259.10)

Section V.C. of this Preamble discusses how States may petition in or opt out of the demonstration program. States that are in the program are referred to as "Covered States" (see RCRA section 11001). Other States are referred to as "non-Covered States." RCRA section 11003(a) requires EPA to establish a demonstration tracking program for listed medical wastes