US EPA ARCHIVE DOCUMENT

7. Delivery of Regulated Medical Waste Outside the United States (Section 259.74(e))

The Agency is aware that regulated medical waste generated in several of the Covered States is being transported to Canada for treatment and disposal. In addition, EPA understands that similar waste generated in Canada is being transported for treatment and disposal into some of the Covered States. Although the Agency believes that the documentation and tracking of all such regulated medical waste from its point of generation to its point of disposal may be advisable, the Medical Waste Tracking Act only provides the authority for tracking regulated medical waste generated in Covered States. Today's regulations do not apply to waste generated in a Covered State that is shipped internationally, once it leaves U.S. borders. In these cases, it is the responsibility of the last U.S. transporter (i.e., the transporter who delivers the waste to another transporter, a transfer facility, or a destination facility in a foreign country) to sign the tracking form verifying that the waste has been delivered to a foreign transporter or destination facility, retain one copy of the signed tracking form, and return all remaining copies by mail to the generator. As noted elsewhere in the Preamble, the Agency is requiring that the generator request written verification from the destination facility located in the foreign country that the waste was received by the facility.

The Agency requests comments on the need for other requirements to ensure that regulated medical wastes are properly managed when exported. For example, EPA could require that the generator have a contract with the foreign treatment and destruction facility and/or the foreign disposal facility stipulating that the facility return a signed copy of the tracking form to the generator.

I. Subpart I—Treatment, Destruction, and Disposal Facilities

Today's regulations establish a demonstration tracking program that includes requirements for intermediate handlers of regulated medical waste and for destination facilities to ensure that regulated medical waste is tracked from the point of generation to the point of final disposal. The MWTA does not authorize or require EPA to establish regulations that address the actual treatment, destruction, or disposal of regulated medical waste. The requirements of Part 259 cease when regulated medical waste is disposed of at a landfill or the waste has been "treated and destroyed" by incineration or other techniques. (See Preamble Section V.D. for a discussion of the criteria or conditions that must be satisfied for medical waste to be considered treated and destroyed.) Facilities meeting these latter conditions include incinerators and treatment facilities that, in addition to decontaminating, also destroy the regulated medical waste. Treatment, destruction, and disposal facilities may be subject to local, State, or other Federal requirements in addition to today's rules.

1. Applicability (Section 259.80)

The provisions described in § 259.80 of today's rule apply to destination facilities (treatment and destruction, and disposal facilities (including incinerators)) and to intermediate handlers that receive regulated medical waste generated in a Covered State that is required to be accompanied by a tracking form. As described above, the demonstration tracking program requires the tracking of regulated medical waste from the point of generation until such waste is delivered to the final disposal facility (or to incinerators or other facilities that both treat and destroy such waste). The rules do not require the tracking of regulated medical waste after it has been properly incinerated, treated and destroyed, or disposed of. Thus, waste that has been either treated or destroyed, but not both, must continue to be tracked until the waste reaches a destination facility. The requirements applicable to intermediate handlers and destination facilities, therefore, serve to ensure that facilities participating in the demonstration program properly complete the tracking document and maintain all necessary records for implementation of the program.

Interstate transport of regulated medical waste is now occurring, and many facilities receiving regulated medical waste are not located in States participating in the demonstration program. Today's rule requires that all intermediate handlers and destination facilities that accept regulated medical waste generated in a Covered State comply with Subpart I, whether they are located in a Covered State or a non-Covered State. This requirement is necessary to ensure that generators in Covered States receive a copy of the tracking form signed by the destination facility to which the waste is delivered.

In addition, the provisions of Subpart I are also applicable to on-site treatment and destruction and disposal facilities that accept regulated medical waste required to be accompanied by a tracking form from off-site sources. Such facilities include on-site incinerators that burn regulated medical waste and facilities that treat and destroy the waste.

2. Types of Treatment, Destruction, and Disposal Facilities

For purposes of today's rule, treatment, destruction, and disposal facilities can be differentiated into two distinct types: (a) Destination facilities—facilities that either dispose of the regulated medical waste or that meet the "treat and destroy" criteria so that the regulated medical waste no longer needs to be tracked; and (b) Intermediate handlers—facilities where regulated medical waste is treated but not destroyed and facilities where regulated medical waste is destroyed, but not treated, thereby requiring that the regulated medical waste must continue to be tracked to its final disposal site. Each type is discussed below. The reader should note that in addition to the Federal tracking requirements of today's rule, many States and localities have their own laws and regulations for treatment, destruction, and disposal facilities which are unaffected by today's rule.

a. *Destination facilities.* Included in this type are incinerators, treatment facilities that "treat and destroy" the waste, and disposal facilities.

Incinerators are subject to the demonstration program as medical waste treatment facilities when they accept regulated medical waste. The MWTA specifies that regulated medical waste must be tracked from its point of generation through either disposal or incineration. By designating incineration as an alternative end point, Congress intended that incinerators used to treat and destroy regulated medical waste must comply with the same basic requirements for signing and returning the tracking form as disposal facilities (i.e., each is the final destination of the waste).

Similarly regulated are those treatment facilities that subject the medical waste to a series of processes that both "treat" (e.g., steam autoclaving) and "destroy" (e.g., grinding or melting processes) the waste. These processes are similar to incinerators because they alleviate the potential to cause adverse human health effects, physical hazards, and aesthetic degradation of the environment. EPA has therefore exempted the residuals of these processes under § 259.30(c)(2)(iv). Regulated medical wastes that have been subjected to processes that both treat and destroy the waste, remove the

waste from the tracking requirements of today's rule.

The requirements applicable to the above-mentioned destination facilities are identical under today's rule, since each type of facility serves as an end point for the tracking forms accompanying regulated medical waste. These requirements generally include signing and returning (mailing) tracking forms, signing return receipts in the case of wastes shipped by mail, discrepancy reporting, and maintaining the necessary records (e.g., keeping copies of the tracking forms and discrepancy reports for three (3) years).

b. *Intermediate handlers.* Included in this type are facilities that treat regulated medical waste (disinfect or decontaminate) but do not destroy it or facilities that destroy the regulated medical waste but do not treat it. These intermediate handlers are required to initiate a new tracking form to accompany each shipment of treated or destroyed regulated medical waste from the intermediate handler's facility to the destination facility. They are, in effect, new generators of the regulated medical waste. Specific tracking form handling requirements have been established for intermediate handlers to ensure that the original generator of the waste obtains a copy of the tracking form with the signature of the destination facility. These requirements are explained below, under Use of the Tracking Form (see § 259.81(c)).

3. Use of the Tracking Form (§ 259.81)

a. *General.* All destination facilities and intermediate handlers that receive regulated medical waste generated in a Covered State accompanied by a tracking form must satisfy several requirements related to the form and the waste it covers. Upon receipt, the owner or operator must determine that the tracking form accurately reflects the waste received at the facility both in terms of the description of regulated medical waste specified on the form (i.e., whether it is labeled properly as "untreated" or "treated"), the number of containers, and the total quantity of the shipment. (The reader should note that under State regulations, the owner or operator also may have to account for State-regulated medical waste listed in Box 11(c) of the tracking form.) If the owner or operator discovers any discrepancies between the information contained on the tracking form and the waste contained in the shipment, he must note the discrepancy on the tracking form. When discrepancies are discovered (see discussion below), he must attempt to resolve these discrepancies by recounting or rechecking the tracking form(s), or, if the shipment was consolidated or remanifested, by checking the transporter's log and/or the tracking forms initiated by the generator. Once a discrepancy has been identified, the generator, transporter(s), and the owner or operator should take steps to resolve the discrepancy and/or locate the missing waste. If the discrepancy cannot be resolved, the owner or operator of the intermediate handling facility or the destination facility is required to file a discrepancy report as described below (see also § 259.82).

Discrepancies that must be noted on the tracking form are differences of either quantity or description of regulated medical waste. For purposes of today's rule, discrepancies exist (for containerized waste) if there is any variation in piece count (box, pail, or drum), or if containers are not labeled properly as untreated waste. Label discrepancies can be identified through a visual inspection of the label on the outer most surface of the package and the description of the waste on the tracking form (Box 11). If the material is untreated regulated medical waste, the label must contain the words "Infectious Waste," or "Medical Waste," or display the universal biohazard symbol. Packages containing treated regulated medical waste are not required to have a label. The Agency is not recommending that owners and operators open containers of waste to make further inspections, as this may increase occupational exposure to the waste.

In addition to the discrepancies described above, arrival of improperly packaged regulated medical waste or arrival of regulated medical waste accompanied by unsigned or otherwise incomplete tracking forms are also discrepancies. The Agency believes it is important that the integrity of the packaging containing regulated medical waste be maintained from the point of generation to the point of treatment or disposal so that workers are not exposed to regulated medical waste. The Agency also believes that it is the responsibility of all regulated medical waste handlers—generators, transporters, treaters, and disposers—to ensure proper packaging and containment of the waste as it is transported and tracked through the management system.

The Agency believes that an unsigned or incomplete tracking form is a significant cause for concern. It is an indication that shipping papers may have been altered or that regulated medical waste has been mishandled inadvertently somewhere between the point of generation and the point at which the waste reaches an intermediate handler or destination facility. The owner or operator of a treatment or destruction facility, or a disposal facility is ideally placed to note such discrepancies.

EPA is also concerned that, when regulated medical waste arrives at an intermediate handler or a destination facility unaccompanied by a tracking form, it is impossible for the owner or operator to fulfill his requirement to determine that the tracking form accurately reflects the waste listed on the form. He will be unable to check the piece count or to determine that the waste is described appropriately as treated or untreated regulated medical waste. In these instances, if the owner or operator knows the waste should be accompanied by a tracking form and accepts it, he must file a discrepancy report as described later in this Preamble. EPA notes that it may be difficult for the owner or operator to identify regulated medical waste, except where the container bears a marking identifying the generator and transporter.

Finally, the owner or operator should follow any special instructions in Box 14 of the tracking form for oversized items, handling them accordingly.

b. *Destination facilities.* Once the information contained on the tracking form has been verified or any apparent discrepancies noted, the owner or operator of the destination facility must sign and date each copy of the tracking form. This signature certifies that the waste described by the tracking form has been received at the destination facility. The facility owner or operator must immediately give the transporter a signed copy. This copy is the transporter's confirmation that he delivered the waste as described on the tracking form or as otherwise noted in the discrepancy box.

The owner or operator of the destination facility must then return a signed copy of the tracking form within 15 days of acceptance of the waste either to the generator at the address indicated on the form or, in the case of consolidated or remanifested shipments or shipments remanifested by an intermediate handler, to the party that initiated the tracking form. (The transporter is then responsible for providing the original generator with a signed copy of the tracking document, as explained in Section V.H. of the Preamble.) If a transporter consolidated shipments or prepared the tracking form

because the waste originated from generators of less than 50 pounds per month, the tracking form must be returned to the transporter that reassigned or consolidated the shipment.

c. *Intermediate handlers.* Intermediate handlers, facilities that either treat or destroy the regulated medical waste but do not do both are required to continue to track the waste to a destination facility. These facilities are, in effect, new generators. Intermediate handlers who only treat the regulated medical waste must initiate a new tracking form to indicate that the waste category changed from untreated to treated, and to indicate any changes in the number of containers and/or weight of the wastes being shipped to the destination facility. Intermediate handlers who only destroy regulated medical waste must initiate a new tracking form to indicate the change in the number of containers and/or weight of regulated medical waste caused by the destruction process. These facilities also must meet all of the generator requirements under Subparts E and F of today's rule. In addition, intermediate handlers must maintain a log that correlates the waste accepted from each *original* generator to the waste shipments that he has initiated. The log must include the generator's name, State permit or identification number, or if none, the generator's address, the date of shipment or the generator's unique tracking form number assigned to that shipment, and the new tracking form number to which the waste was assigned.

Intermediate handlers that initiate a new tracking form must retain the original generator's tracking form until the new tracking form that he initiated is signed by the destination facility and returned. Once the intermediate handler has received the signed copy of the tracking form from the destination facility, he must send a copy of the signed form, together with the original generator's tracking form, to the original generator. This process provides the original generator of the waste with assurance that the waste was received by the destination facility (as required by section 11003(a)).

d. *Certification of disposal.* Discussions with members of the health care industry have indicated that many generators would prefer that the tracking form include a box for certification of disposal in addition to the certification of acceptance. Several reasons were cited for this preference, including concern for a generator's liability in the event of mishandling by the disposal facility and the fact that payment for disposal is often contingent upon a receipt of disposal certification. However, the Agency believes that this second certification is not necessary to meet the statutory requirement that the generator is assured that the disposal facility has received the waste. If the generator wants certification of disposal, he can stipulate the requirement through either a contract with the destination facility or by requesting such certification in the Special Handling and Additional Instruction box on the tracking form. The Agency requests comments on the need for inclusion of a separate or distinct box for certifying disposal on the tracking form.

4. Tracking Form Discrepancies (Section 259.82)

Upon discovering a discrepancy, as described above, between the tracking form and the actual shipment, the owner or operator of a facility first must attempt to reconcile the discrepancy and should do so as soon as possible after discovering the problem. For example, the facility should first try to reconcile the discrepancy with the transporter by recounting the number of containers, or by contacting the transporter to see if the missing package(s) or tracking forms were placed on a different transport vehicle. The facility should make telephone inquiries to the other parties in the chain of custody, and keep a written record of these inquiries and the information obtained. If the discrepancy cannot be reconciled within 15 days, the owner or operator of the facility must notify the Regional Administrator for the Region in which the facility is located and the Regional Administrator and State where the generator of the regulated medical waste is located. The notification must be in the form of a letter describing the discrepancy and efforts to resolve it. The letter also must contain a legible copy of the tracking form and/or shipping paper at issue, if one exists.

In the case of acceptance of regulated medical waste unaccompanied by a tracking form where the owner or operator knows that a tracking form is required, the owner or operator must describe the quantity of waste that he received, the identity of the transporter who delivered the waste, and the identity of the generators of the waste. As a courtesy the facility also should mail a copy of the discrepancy report to the relevant generator(s) and transporter(s).

5. Recordkeeping Requirements (Section 259.83)

The owner or operator of a destination facility or an intermediate handler that receives regulated medical waste generated in a Covered State and accompanied by a tracking form must maintain records concerning the delivery of each shipment of regulated medical waste. These records must be maintained for a minimum of three (3) years from the date of receipt of the waste. Information that must be maintained includes: (a) copies of all tracking forms and/or shipping papers; (b) copies of all discrepancy reports submitted; and (c) for generators who deliver waste directly to destination facilities and intermediate handlers as allowed under the provisions of § 259.51(a), a log which includes the information required in § 259.83(b).

6. Treatment, Destruction, and Disposal of Medical Waste

The MWTA does not require or authorize EPA to establish standards for the treatment, destruction, or disposal of medical waste. Rather, the Act focuses on tracking these wastes. Accordingly, treatment, destruction, and disposal standards for regulated medical wastes are not included in today's rule. However, facilities are required to meet any specific local, State, or Federal requirements for the treatment, destruction, or disposal of regulated medical waste. Disposal facilities also must meet all applicable local, State, and Federal solid waste management requirements.

Under section 4004 of RCRA (Subtitle D), all solid waste must be disposed of in a manner that poses no reasonable probability of causing adverse effects to human health or the environment. Because solid waste classification encompasses nearly all waste, including medical waste, this restriction comprises the minimal standard that all disposal facilities for regulated medical waste must meet. Practices that do not meet this standard are considered by the Agency to constitute open dumping and thus are prohibited under 4005 of RCRA. The Agency has established criteria, detailed in 40 CFR Part 257, that specify general performance standards for solid waste disposal practices and facilities. Currently, these criteria address facility location, impact on surface and ground water and on air quality, land application of solid waste, and other concerns.

In addition, the Agency recently has proposed regulations revising the Subtitle D criteria for municipal waste

landfills (53 FR 33314, August 30, 1988). These proposed revisions, if adopted, would establish specific requirements applicable to all municipal solid waste landfill facilities. These requirements include setting design goals for protecting groundwater, groundwater monitoring and corrective action, closure and post-closure care, and financial responsibility.

The responsibility for implementing the Subtitle D regulations traditionally has fallen upon the States, which are required to establish solid waste programs that meet the Federal criteria. Many States, however, have gone well beyond the Federal criteria in regulating solid waste management facilities. Additionally, the number of States that regulate medical waste is increasing; all of the States mentioned in Subtitle J either have such regulations in place or have indicated they will soon regulate medical waste. These regulations typically are comprehensive, including requirements for treatment of the waste (often specifying sterilization or incineration) prior to disposal, and for permitting the solid waste disposal facilities. Today's rule is intended to complement these State programs in providing for the effective management of medical waste.

Finally, in the MWTA Congress has expressed serious interest in the treatment and disposal of medical waste. The Act requires that the Agency report to Congress on current disposal methods and requirements, as well as on available treatment and disposal methods, and on the health impacts and costs of current and alternative methods. The requirements of this Subpart are intended to provide some of the information necessary to develop such reports. The Agency requests that commenters submit available information on alternative treatment and destruction technologies, as well as on disposal technologies. EPA will use any information provided to develop, a model State medical waste progran.

J. Subpart J—Rail Shipments of Regulated Medical Waste (Section 259.90)

Subpart J of today's rule establishes the procedures for handling the tracking form and recordkeeping requirements that rail carriers of regulated medical waste must follow. The requirements are identical to those established under Subtitle C of RCRA for rail carriers. The Agency believes that the unique operational characteristics of the rail industry necessitate that rail carriers be subject to somewhat different tracking and recordkeeping requirements than those that apply to other transporters of regulated medical waste.

Under today's rule, as under the hazardous waste regulations, rail transporters may, under certain conditions, move regulated medical waste without actually carrying the tracking form (i.e., it can be sent ahead by mail). Also, shipments may be transferred between two rail transporters without obtaining the accepting transporter's (rail carrier's) signature, if so directed on the manifest or tracking form. EPA explained the necessity and basis for these special provisions on February 26, 1980, for hazardous waste transporters (45 FR 12739), and the Agency believes similar provisions are appropriate for regulated medical waste when it is transported by rail.

VI. Relationship to Other EPA Programs

The regulations promulgated today for the medical waste tracking program are required by amendments to the Resource Conservation and Recovery Act (RCRA), one of several laws that EPA administers. Below is a discussion of other EPA programs that are related to the medical waste tracking program promulgated today.

A. Other Subtitles of RCRA

1. Subtitle C—Hazardous Waste Management

The definition of "medical waste" found in RCRA section 1004(40) specifically excludes hazardous waste identified or listed under Subtitle C of that act. The implementing regulations at 40 CFR Part 261 identify characteristics of hazardous waste and list specific hazardous wastes. A generator of a solid waste (which can be solid, semisolid, liquid, or contained gaseous waste) must determine if the waste is hazardous under the Part 261 regulations. If the waste is a listed or characteristic hazardous waste as generated, it is not subject to regulation under the Part 259 regulations. In making this determination, the generator must use the Federal regulations defining hazardous waste. If the waste is not hazardous under Federal regulations, the generator proceeds to determine whether the waste is regulated medical waste.

The hazardous waste programs in some States cover a broader universe of wastes than the Federal program. The wastes that are regulated as hazardous by certain States, but not by the Federal program, may also be regulated medical wastes, because the "hazardous waste" exclusion in section 1004(40) refers to Federally-regulated hazardous waste.

In the case of mixtures of medical waste and hazardous waste identified or listed in Part 261, if the mixture is subject to the hazardous waste manifest requirements, it is exempt from the medical waste tracking requirements. Duplicative manifesting is unnecessary and inconsistent with Congressional intent, given the exclusion of hazardous waste from the definition of "medical waste." However, hazardous waste that is exempted from the RCRA Subtitle C manifest requirements does not present the problem of duplicative tracking when it is mixed with regulated medical waste. Therefore, if the mixture of regulated medical waste and hazardous waste is not required to be tracked under the Subtitle C rules, it must be managed and tracked as regulated medical waste. For example, if a hazardous waste is exempt from regulation because it is generated by a conditionally exempt small quantity generator (40 CFR 261.5) but is mixed with a regulated medical waste, then the entire quantity of waste must be handled as regulated medical waste.

Certain cytotoxic agents, including the following, are covered under RCRA Subtitle C hazardous waste regulations: Cyclophosphamide (also known as Cytoxin) (U058); Daunomycin (U059); Melphalan (U150); Mitomycin C (U010); Streptozotocin (U206); and Uracil Mustard (U237). The Agency will determine in further study and evaluation whether additional cytotoxins should be regulated under Subtitle C. The Agency requests comment from the regulated community regarding the proper management of cytotoxic and antineoplastic drugs.

Residues from the treatment of medical wastes may become hazardous wastes. For example, incineration reduces the volume of a waste, and the volume reduction may cause a concentration of metal constituents. Thus, it is possible that a medical waste regulated under Part 259 could become a hazardous waste if incinerated, and the resulting ash would be required to be managed as a hazardous waste under Subtitle C (40 CFR Parts 260 through 272).

Also, the reader may note several parallels between the Subtitle C (hazardous waste) and Subtitle J (medical waste) regulatory programs. However, differences in statutory language and Congressional intent have resulted in a program for medical waste that is different from the hazardous waste program. Section IV of this Preamble details the differences between the hazardous waste manifest and the medical waste tracking form.