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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

generated in a Covered State. The tracking program applies to such waste, generated in a Covered State, from its point of generation to its final destination even if that destination is in a non-Covered State; however, these requirements do not apply to wastes shipped from a non-Covered State to a Covered State, as discussed below. (Shipments into a foreign country are discussed in Section V.H. of this Preamble.)

The Medical Waste Tracking Act of 1988 (MWTA) provides authority to establish a demonstration tracking program based on the type of waste being managed and the fact that the waste has been generated in a Covered State. In light of the common practice of interstate transport and disposal of medical waste, Congress provided this authority in order to ensure that such wastes can be tracked to their point of disposal or point of treatment and destruction (*e.g.*, incineration), regardless of whether that destination is within a Covered State. No limitation on this authority exists specifying that the waste must be generated and disposed of in a Covered State. In fact, Congress amended the original Senate medical waste tracking bill that did limit the program to waste generated and disposed of in a Covered State. Thus, the statutory basis for the scope of the demonstration program is tied to the waste at issue and is based on such waste meeting two conditions: (1) The waste must be listed by EPA under section 11002, and (2) such waste must be generated in a Covered State. Where these two conditions are satisfied, all persons or facilities handling such waste are subject to the demonstration program requirements. This includes transporters or facilities located in non-Covered States if they receive regulated medical waste generated in Covered States.

Accordingly, while the generator requirements for the tracking program are limited to persons located in Covered States, requirements for transporters and for owners or operators of treatment or disposal facilities apply to any person handling medical waste from a generator in those Covered States, even if the transportation, treatment, or disposal does not occur in a Covered State. Hence, owners and operators of treatment or disposal facilities operating in non-Covered States will still be responsible under today's rule for returning tracking forms to generators in Covered States, thus maintaining the integrity of the tracking program (see § 259.1(c)).

As discussed above, Congress clearly intended the program to apply to the management of medical wastes generated in Covered States wherever that activity occurs. It is also clear that medical waste which meets one of the EPA listing descriptions and was generated outside a Covered State, but transported into or through a Covered State, is not regulated under the demonstration program. Therefore, there is a need to identify the geographic origin of a particular shipment of medical waste in order to determine whether regulatory requirements apply. This raises enforcement and implementation problems with respect to waste found in a Covered State, but which is claimed to be generated in a non-Covered State and thus is not regulated. EPA has addressed this problem in § 259.1(d), which states that any regulated medical waste that is transported or otherwise managed within the boundaries of a Covered State will be presumed to have been generated in the Covered State and thus subject to all applicable tracking requirements. This presumption may be rebutted by proving by a preponderance of the evidence that the waste in question was generated outside the Covered State. The burden is on the regulated party to rebut the presumption.

EPA believes the presumption made in § 259.1(d) is necessary to allow effective implementation of the demonstration program. Precedent for such a presumption is found under other RCRA regulations (*e.g.*, 40 CFR 261.2 for recycled material). The presumption is based on the rationale that, since medical waste is generated in all of the Covered States, the physical presence of medical waste in a Covered State is a fairly reliable indication that the waste was generated in that State. EPA recognizes that there will be exceptions, but believes that the burden of demonstrating the origin of the waste should be placed on the persons managing the medical waste. *Id.*

Moreover, providing appropriate documentation should not be difficult. First, under current industry practices, medical wastes shipped out of State are accompanied by shipping papers. Second, many States not participating in the demonstration program are nonetheless implementing their own medical waste programs, which often include a requirement for manifesting or tracking the medical waste. In either case, easily accessible and sufficient documentation will be available to substantiate the claim of nonregulated status. The person claiming nonregulated status, however, bear the burden of proof in any enforcement action.

Comments are requested on this presumption and on alternative ways in which the Agency could implement the distinction between waste generated in a Covered State and waste generated in a non-Covered State.

2. Effective Dates and Duration of the Program (Section 259.2)

Congress specified that the demonstration program would be in place for 24 months, beginning on the effective date of the EPA regulations (see RCRA Section 11001(d)) and that EPA's regulations would generally take effect 90 days after promulgation. (See RCRA section 11011.) The regulations promulgated today will take effect and become enforceable on June 22, 1989. This is the full 90-day period authorized under RCRA Section 11011. Although New Jersey and New York currently are operating under programs quite similar to the rules promulgated today, the Agency believes the regulated communities in those States also will need the full 90 days to implement the medical tracking form and reach compliance. Therefore, the demonstration program will expire on June 22, 1991, for all waste generated in Covered States. Enforcement actions, however, may be initiated after the expiration date to address violations occurring during the demonstration program.

B. Subpart B—Definitions

Today's rule includes a list of terms that have been defined specifically to address the management of medical waste. These definitions are included in Subpart B of the rule (§ 259.10). Certain definitions from 40 CFR 260.10, applicable to hazardous waste management, have been incorporated by reference. Other terms used in the hazardous waste regulations, and defined in § 260.10, have been redefined in § 259.10(a) for use in the medical waste management regulations. Finally, terms that are unique to the medical waste management regulations are defined in § 259.10(b).

For three defined terms, "facility," "transporter," and "landfill," the only change from the definition in § 260.10 is the substitution of the words "medical waste" for the words "hazardous waste in the Subtitle C definition. This is necessary for the obvious reason that today's rule addresses medical waste and not hazardous waste. Three other terms listed in § 259.10(a); ("storage," "treatment," and "generator") also

replace the words "hazardous waste" with the words "medical waste;" however, the definitions of these terms in § 259.10 also include other changes from the existing § 260.10 definitions. These additional changes are indicated and explained below.

1. Storage

The definition of storage in § 259.10(a) differs slightly from the definition of storage in § 260.10. Today's rule specifies that storage is the temporary holding of medical waste at a central collection point, whereas the definition in § 260.10 defines storage as the temporary holding of waste prior to treatment, disposal, or transport elsewhere. This distinction is intended to clarify that medical waste storage is considered to be those instances where waste is held at a generator's facility where it is accumulated in the normal course of business prior to packaging, transport, treatment, or disposal (e.g., near a loading dock). It is also intended to clarify that the temporary holding of medical waste, for instance during brief periods for collection (e.g., at a nurses station in the pediatric ward), is not intended to constitute storage or subject the temporary accumulation area to applicable storage requirements.

2. Treatment

Treatment also is defined in today's rule in a different manner than it is defined in § 260.10. Under today's rule, treatment includes any method, technique, or process designed t. change the biological character or composition of any medical waste so as to reduce or eliminate its potential for causing disease. This definition differs from the Subtitle C definition in that changes to the physical or chemical character of medical waste which also affect the infectious nature of the waste are not considered treatment; rather, the focus of treatment is to reduce or eliminate the infectious biological character of the waste. Thus, the definition in today's rule emphasizes treatment of the biological hazard. (The definition is the same as that in the 1986 *EPA Guide for Infectious Waste Management.*)

Treatment as defined under today's rule is intended to encompass those processes, including thermal treatment (such as incineration), steam sterilization, and other treatment techniques (e.g., chemical treatment), that are generally effective in reducing or eliminating the infectious risk posed by these wastes. New technologies capable of rendering medical waste innocuous would also fall within this definition. Finally, the reader should note that the discussion above pertains to *waste* treatment. As discussed in a later section of the Preamble, the definition of medical waste also uses the term "treatment" but in that context the term refers to *patient* treatment (e.g., the provision of health care services). The regulatory definition of "treatment" also incorporates this distinction.

3. Generator

Generator, as used in today's rule, is intended to include any person. by site, whose act or process produces a regulated medical waste or whose act first causes a medical waste to be subject to this regulation. Two key aspects of this definition warrant emphasis. First, person, as defined under § 259.10, includes any individual, trust, firm, joint stock company, corporation (including a government corporation), partnership, association, State, municipality, commission, political subdivision of a State, any interstate body, or any department, agency or instrumentality of the United States. This definition is intended to include any form of business entity and to incorporate the Act's revision of the RCRA definition of "person" under section 11006(b) (Federal Facilities). Second, persons are evaluated by site to determine who satisfies the definition of a generator. Thus, each individual generation site, such as a hospital located on a contiguous piece of property, is an individual generator; however, a hospital which has four (4) noncontiguous pieces of property on which medical waste is generated, has four (4) generation sites, one on each piece of property, and each site is a generator. In contrast, several "persons" (for instance, independent, private practitioners) located in the same building are each separate generators, because the definition of generator is a "person, by site."

In addition to the terms defined in § 259.10(a) of Subpart B, several new terms have been defined in § 259.10(b). These terms are discussed below, as they are used in the regulations.

C. Subpart C—Covered States

When amending RCRA to establish the demonstration tracking progran for medical waste, Congress directed that the effort cover 10 specific States. However, the legislation also contains provisions for allowing these States to withdraw from participation in the program and for other States to join the effort. Congress provided that the Governors of the States be given 30 days from the promulgation date of these provisions to make decisions regarding their participation. This discussion elaborates on the process for petitioning in and opting out of the demonstration program. EPA has made special efforts, including working with the National Governors' Association, to provide Covered States and States interested in participating in the demonstration program with information concerning the program.

Once the 30-day opt-out/petition in period has expired, EPA will not add additional States or consider petitions to delete States from the demonstration program. Furthermore, persons who generate or manage medical waste in Covered States that do not opt out will be subject to the program for its 24-month duration as required by section 11001(d). The procedures for States to opt out or petition into the program are discussed below.

1. Connecticut, New Jersey, and New York

Because improper medical waste disposal incidents on the East Coast have arisen most visibly, Congress conditioned the opting out by three specified States—Connecticut, New Jersey, and New York—on a showing that their respective State medical waste tracking programs are no less stringent than the Federal demonstration program. Therefore, if any of these three States request not to participate, EPA will evaluate that State's program elements to determine whether or not they are at least as stringent as the Federal program. In the absence of specific Congressional direction regarding the requirement that these States' programs be "no less stringent" than the Federal program, EPA intends to use the existing RCRA Subtitle C State authorization criteria as guidance (see 40 CFR Part 271). Under the Subtitle C process, the State's program requirements are generally compared to the Federal requirements item-by-item. If EPA determines that the State's program is no less stringent as the program promulgated today, the Agency will revise today's interim final rule by amending Part 259 to remove that State from the Covered States list. If the State's program is not found to meet the no less stringent standard, the State will remain in the Federal program.

2. Great Lakes States

Congress also directed that seven States contiguous to the Great Lakes (Illinois, Indiana, Michigan, Minnesota, Ohio, Pennsylvania, and Wisconsin) be subject to the demonstration program, unless the Governors of such States notify EPA in writing within 30 days of promulgation that they have chosen not

to participate. Congress did not establish a "no less stringent" standard for these States. EPA will identify those States that elect to opt out in a later **Federal Register** notice.

3. Other States

States not mentioned above may elect to participate in the demonstration program. The Governor of a State electing to participate must petition EPA by April 24, 1989 to be included on the list of Covered States. The definition of "State" in RCRA section 1004(31) includes the several States, the District of Columbia, Puerto Rico, the Virgin Islands, American Samoa, Guam, and the Commonwealth of the Northern Mariana Islands. EPA interprets the term "Governor" to include the Governor in any of the several States, or the equivalent head of the executive branch of the government for those other governmental entities. The Act specifies that EPA must determine whether to include a petitioning State in the program within 30 days of receipt of the petition (RCRA section 11001(c)). American Samoa has already petitioned to be included in the program, and EPA will make a determination regarding American Samoa and any other petition-in States after the 30 day period.

The Agency is planning to publish the final list of Covered States in the **Federal Register** shortly after the April 24, 1989, opt-out/petition-in deadline.

D. Subpart D—Regulated Medical Waste

Section 11002 of RCRA requires EPA to develop and promulgate a list of medical wastes to be tracked under the demonstration program. The statute provides the basic components of the list by identifying five waste types that must be included: (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); and (5) contaminated animal carcasses. The statute also identifies five additional waste types that EPA is authorized to exclude from the demonstration program if the Agency determines that mismanagement of such wastes would not pose a substantial threat to human health or the environment; (6) surgery or autopsy waste; (7) laboratory wastes; (8) dialysis wastes; (9) discarded medical equipment; and (10) isolation wastes. The Act also gives EPA authority to add other medical wastes to the list if the Agency determines that such wastes may pose a substantial threat to human health or the environment.

The Act's designation of two different "universes" of medical waste originates, in part, from EPA's *Guide for Infectious Waste Management* (1986). In that document, the Agency identified two universes of medical waste: "infectious" medical waste and "miscellaneous contaminated wastes." The first universe, "infectious" medical wastes, included those wastes listed in the Act as waste types 1, 2, 3, 4, 5, and 10. The Agency, at the time, believed that all of these wastes should be specially managed. The second universe included those wastes listed in the Act as waste types 6, 7, 8, and 9. EPA recognized that, depending on the specific characteristics of the "miscellaneous contaminated wastes," they could be handled appropriately as "infectious" medical wastes or noninfectious medical wastes based on the determination of a responsible infection control practitioner.

Clearly, one of the most controversial aspects of EPA's guidance document has been its inclusion of isolation wastes (waste type 10 in the Act) in the first universe of "infectious" medical wastes. The health care community, medical professionals, and public health officials have strongly criticized this aspect of the guidance document stating that, except under special circumstances, isolation wastes are unlikely to pose a significant hazard to human health or the environment. Thus, EPA believes that Congress, in formulating the statutory list of medical wastes subject to the demonstration program, relied on the basic format of the original waste listing as set forth in the 1986 guidance document (i.e., separating the universe of medical waste into "infectious" and "miscellaneous contaminated waste" categories). However, EPA also believes that Congress concurred with prevailing scientific opinion concerning the relative threat posed by isolation patient waste (listed in the EPA guidance document as an infectious waste category) and designated this as a category that the Administrator may exclude from the demonstration program based on the authority of section 11002(b).

In today's rule, medical wastes to be tracked under the demonstration program are referred to as "regulated medical waste." Regulated medical waste is a subset of medical waste which, in turn, is a subset of "solid waste" as defined in RCRA section 1004. This relationship is illustrated in Figure 1. The term "regulated medical waste" includes the list of medical wastes, as determined by EPA, and certain mixtures of these wastes with other types of wastes. This section of the Preamble discusses the criteria used to define or designate medical waste as "regulated medical waste," explains the content and rationale behind the regulatory listing of regulated medical waste, and describes the conditions under which waste classes may be exempted from regulation.

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