All records should be kept on-site so that they are easily accessible for inspection. If, however, recordkeeping operations are normally conducted at another corporate or business location, the generator may keep records there, if they will be readily accessible for inspection purposes.

As described in the next section of this Preamble (see Part 259, Subpart G), generators who incinerate wastes on-site must report the volume and type of waste incinerated. (Information about wastes accepted from off-site sources should also be included in the reports, where applicable.) Finally, generators who claim the § 259.30(c)(2)(iv) exemption for waste that has been treated and destroyed must keep records of the amounts treated in such a manner in order to qualify for the exemption.

7. Exception Reporting (Section 259.55)

For the tracking system to accomplish its purpose, officials must be alerted whenever the tracking "circle" is broken. If the generator who initiated a tracking form does not receive a signed copy of the form from the destination facility (and in the case of foreign shipments, from the last domestic transporter) within 35 days after the waste was accepted by the initial transporter, the generator must contact both the transporter and the destination facility to determine what happened to the waste and the tracking form. If a signed tracking form has not been received within 45 days from the initial date of transport, the generator must submit an exception report to the Regional Administrator and to his State that includes: (a) A legible copy of the tracking form for which the generator did not receive a signed copy; and (b) a letter signed by the generator, detailing his efforts to locate the waste.

A copy of the exception report must be kept in the generator's records for three (3) years.

8. Additional Reporting (Section 259.56)

Through broad authorities granted in Section 11004 of the Act, EPA can require generators to furnish additional reports concerning medical waste generated at their facilities. For example, during an enforcement proceeding, the Agency may require additional information concerning the disposition of certain quantities of waste, including medical wastes not sent off-site (e.g., wastes disposed of on-site in sewers or landfills). Section 259.56 codifies the information gathering authority provided in section 11004 with respect to generators of regulated medical waste. Generators are required to provide any information available upon request. EPA has codified similar provisions for transporters (§ 259.79) and for owners and operators of destination facilities (§ 259.84).

Also, EPA requests comment concerning the various sources of information and strategies available to gather the requisite information to develop the Reports to Congress, required under Section 11008. In particular, EPA requests comments on means to ascertain quantities of regulated medical wastes discharged to sewers or landfilled on-site. Currently, the regulations do not provide for recordkeeping of these practices.

Additionally, it has been requested that EPA require a one-time report from generators describing the quantities of medical waste in the section 11002(a)(6–10) waste types that are not regulated under the Part 259 requirements. EPA has determined that methods other than a generator report (e.g., a statistical sampling of the various generator types) could be used to obtain the same information, with significantly less burden on the generators. EPA requests comment on the necessity of such a generator report and on other means of obtaining similar information.

G. Subpart G—On-Site Incinerator Requirements

Section 11003(c) of RCRA requires EPA to promulgate recordkeeping and reporting requirements for medical waste generators in Covered States who incinerate regulated medical waste on-site and, thus, do not track such waste under the requirements of the demonstration program. The statute further directs EPA to require these generators to prepare and submit a report summarizing the volumes and types of medical waste incinerated on-site during the first 6-month period following the effective date of these regulatory provisions.

The on-site incinerator reporting requirements in today's regulation satisfy this statutory requirement. EPA has decided to use its broad authority under RCRA Section 11004(a) to require information on the incineration process and the incinerators themselves, in addition to the minimum information required by the Act. Also, EPA is requiring the submittal of two reports. The first report will cover the first six (6) months of the demonstration program, while the second will cover the thirteenth through the eighteenth month of the program. EPA believes the minimum information required by the statute will be more meaningful if it is supplemented by information on the incinerator operations, and if it is obtained both at the beginning of the demonstration program and after generators and regulators have acquired some experience with the specific requirements of the demonstration program. All of the information being requested will be necessary to satisfy the information requirements of RCRA Section 11008, including the present or potential threat to human health and the environment posed by medical waste incineration, and changes in incineration practices attributable to the demonstration program.

EPA chose not to require a breakdown of incinerator waste feed by waste classes as listed in today's rule for two reasons. First, it is not feasible (and in some cases it is impossible) for generators to segregate their wastes according to the seven waste classes. Furthermore, in some cases, the increased handling that would be necessary to segregate wastes could result in increased risks to health care workers and other handlers of the waste. Additionally, there is little benefit in knowing the composition by waste classes of the incinerator's waste feed. To determine health and environmental effects from incineration, knowledge of the BTU content of the wastes and the plastic and metal content is more useful.

Finally, EPA is requesting the information in terms of weight of medical waste. Although the Act says "volume," EPA presumes Congress simply meant amount. Measurements of actual volume are not reliable in this instance. For example, compaction and other volume reduction processes could render a facility's volume estimate meaningless for estimating quantities of waste incinerated.

1. Recordkeeping (Section 259.61)

Today's rule requires medical waste generators who incinerate medical waste on site to compile an operating log containing information on the amounts of waste incinerated, the frequency of incineration, and the length of the incineration cycle.

EPA also is requiring generators with on-site incinerators to provide information on amounts of waste received from sources outside the facility, in order to assure compliance with the § 259.51(a) exemption and to determine how much regulated medical waste is brought from sources such as private physicians or small group practices. This information will provide a more complete picture of the quantities of regulated medical waste being incinerated.

EPA is requiring information on the number of days of operation during each reporting period, the load frequency, and load amount. Since the emissions vary throughout an incineration cycle, information on the number of start-ups from a cold unit will be used to estimate the health and environmental effects of incineration.

The required information must be kept in an operating log, and must be recorded for each load or operating cycle. The generator must retain the operating log for three (3) years from the effective date of today's rule.

2. Reporting (Section 259.62)

Today's rule requires generators of regulated medical waste who incinerate such waste on-site to prepare and submit two reports. These reports must summarize the information contained in the operating record. The legislation stipulates the first reporting period: the first six (6) months of the demonstration program. EPA added a second reporting period (months 13 to 18) in order to determine whether there have been changes in the management practices associated with regulated medical waste (e.g., changes in the volume of waste incinerated) as a result of today's rule. Reports must be submitted within 45 days of the last day of the reporting period. The Agency believes that this provides sufficient time to compile and summarize the information contained in the operating record and collect other necessary information to be included in the report.

EPA has developed a form for the reports, which is found in Appendix II to Part 259. Generators must use the form if they incinerate regulated medical waste on-site. EPA will make copies of the necessary reporting forms available, and generators also may use photocopies.

H. Subpart H—Transporter Requirements

This section of the Preamble describes specific requirements of today's rule as they pertain to the off-site transport of regulated medical wastes. It delineates the responsibilities of transporters and transfer facilities, and the Agency's rationale for establishing these responsibilities.

I. Transporter Notification (Section 259.72)

The central purpose of Subtitle J is to track the movement of medical waste from places of generation to the destination facility. In order to ensure that generators utilize transporters that are aware of and understand the new requirements of today's regulation, EPA is requiring a notification from transporters. This notification process will help EPA and State officials monitor implementation of the program and ensure that transporters complete their responsibilities under today's demonstration program and deliver the regulated medical waste to the destination facility. Accordingly, today's rule specifies that each transporter who handles regulated medical waste generated in a Covered State must notify EPA of its intention to perform this activity.

Transporters and transfer facilities must submit a separate notification for each Covered State in which the transporter intends to accept regulated medical waste directly from a generator. If they do not accept regulated medical waste directly from a generator, but from another transporter, they also must submit a notification for each Covered State where the waste originated. This notification may be by letter, or may be prepared using the form in Appendix IV of Part 259. The use of this form is not required, but is strongly recommended by EPA. Each notification must contain the following information: transporter's name, address (including all facilities intended for handling regulated medical waste which the transporter will operate within the Covered State), telephone number(s); State permit or identification number(s), if applicable; and a statement, signed by a corporate officer or the owner/operator, that he has read, understands, and will abide by today's regulations. An original and one copy of that notification letter must be sent to the Chief of the Waste Characterization Branch, EPA Office of Solid Waste, (OS-332), 401 M Street, SW, Washington, DC 20460. EPA recommends that transporters submit these notifications via certified mail return receipt requested. The return receipt can then serve as evidence that they have indeed submitted their notification.

A copy must also be sent to each Covered State for which the transporter is notifying. EPA will provide the mailing address of the agency within each State to whom the notification should be sent in a **Federal Register** notice to be published after the 30 day State petition-in/opt-out period has passed.

Transporters must provide separate notifications for each Covered State in which they will accept regulated medical waste directly from a generator, and for each Covered State whose generators' regulated medical waste they expect to transport. For example, if Transporter A expects to pick up waste in Covered States X and Y, he must provide two notifications to EPA (one for State X, one for Y), and he must also send separate notifications to Covered States X and Y. Also, if Transporter A plans to accept regulated medical waste generated in State Z, a Covered State, via an intermediate Transporter (e.g., transporter B), Transporter A must nonetheless notify for Covered State Z because he will be accepting Covered State Z's waste. (Notification for Covered State Z must be sent to EPA and to Covered State Z.) This is required even if Transporter A never enters Covered State Z. (In this example, Transporter B would also have to notify for Covered State Z.)

EPA will maintain a master list of transporters who have notified EPA for their operations in Covered States. EPA will also provide a list to officials in each of the Covered States, to supplement their own information on transporters of waste that was generated in their State. This list also will facilitate any outreach, monitoring and enforcement activities. States also may use the information to develop transporter licensing and permitting programs, under State law, if they so choose.

The Agency will, upon receipt of the transporter's submittal of notification, transmit an acknowledgment signed by the Chief of the Waste Characterization Branch to the transporter. This will confirm that the transporter has provided all required information in his notification and will include an EPA assigned Medical Waste Identification Number.

2. Vehicle Requirements (Section 259.73)

a. *Vehicle configuration and condition.* Proper handling of regulated medical waste shipments will minimize the potential for accidental discharge of transported wastes and, thus, minimize the opportunity for personal injury and/or potential infection of waste handlers or others who could come in contact with it. Compaction and/or rough treatment of packaged regulated medical wastes may compromise the integrity of the packaging and, therefore, must be avoided. Based on these concerns and the statutory requirement that the regulations must provide for proper containerization of medical waste to protect waste handlers and the public from exposure to the waste, the Agency has required that all regulated medical waste be transported in a leak-resistant, fully enclosed, non-compactor, cargo-carrying body that is maintained in good operational and sanitary condition. Section V.E.4 of the Preamble discusses decontamination practices that have been described in various guidance documents or state regulations

for reusable containers. The Agency is also recommending that these practices be used to decontaminate vehicles. EPA solicits comments on the adequacy of these practices in protecting consumer products from contamination by residual regulated medical wastes. In addition, today's regulation allows the cargo carrying body to be used to transport properly packaged regulated medical waste simultaneously with other consumer products. EPA requests comment on whether vehicles should be dedicated to the transport of regulated medical waste.

The requirement that the vehicle not compact these wastes is based on evidence that compaction frequently will break the containers holding medical waste, resulting in the generation of loose waste, needles or sharps protruding from containers, or leaking blood and other fluids, all of which are potential sources of exposure to waste handlers or the public. Compaction also can destroy labels or container markings, thus making it difficult to track the waste accurately or to know whether a regulated medical waste has been properly treated. For the same reasons, medical waste must not be subjected to violent mechanical stress during loading and unloading.

b. *Protective clothing.* Although the Agency is not requiring specific protective clothing for persons transporting and handling regulated medical waste, EPA believes that in order to avoid potential contamination and/or injury while handling regulated medical waste, persons involved in the loading or unloading of packaged regulated medical wastes onto or off the transport vehicles should use appropriate protective apparel as required by the Occupational Safety and Health Administration (OSHA). In the event these protective garments become contaminated and are discarded, they should be disposed of properly (by inclusion in the waste load, for example).

c. *Vehicle identification and markings § 259.73(b).* The Agency believes that public awareness of the medical waste tracking system is essential and will help in monitoring compliance with the program. Public reporting of apparent illegitimate handling and disposal activities may help reduce the incidence of these occurrences. To facilitate identification of medical waste hauling vehicles, both for monitoring and reporting purposes, all vehicles involved in the transport of regulated medical waste must be marked appropriately with the hauler's name and any registration, license, or permit number required by the State. The marking must appear on both sides and the rear of the cargo carrying body of the vehicle. These markings must be at least three (3) inches in height, and should be in a color that contrasts with that of the vehicle. The lettering sizes specified above and in § 259.73 are based in part on existing State regulations in New York and New Jersey and should facilitate easy identification of such vehicles. Additionally, while carrying regulated medical waste, both sides and the back of the cargo carrying body shall display the words "Medical Waste" or "Infectious Waste." This may be in the form of a removable sign or markings. The Agency does not recommend that the vehicle display the universal biohazard symbol. Presently this symbol is being utilized internationally to identify vehicles carrying etiologic agents and, as such, provides a warning to emergency personnel in the event of an accident. The U.S. Department of Transportation is also considering adopting this symbol domestically as a label and placard for etiologic agents. The Agency requests comment on the appropriateness of these requirements.

d. *Accident response preparedness.* The Agency believes that proper preparation for accidental releases involving medical wastes can limit the potential damage and/or contamination associated with such incidents. Although the Agency has insufficient information to establish specific standards for dealing with accidental releases of regulated medical waste during transport, EPA believes the following guidance should be observed to protect workers and the public. Vehicles engaged in the transport of medical waste should be equipped with spill containment and cleanup materials, have properly documented procedures for responding to accidental releases, and carry protective clothing (including gloves and coveralls). Additionally, the Agency believes all vehicles involved in medical waste spills should be decontaminated following any accidental release. The Agency requests further comment on the need for specific requirements regarding accidental releases, necessary spill containment equipment for vehicles, protective clothing for transport personnel, and vehicle decontamination standards.

e. *Storage restrictions and requirements.* (Section 259.73(a)(5)): Regulated medical waste, as discussed in Section V.E. of the Preamble, is to be kept from reaching a putrescent state. In addition, pathological wastes, body fluids, anatomical parts, etc. must be maintained in a nonputrescent state during transport and storage or must be refrigerated. Additionally, to prevent unauthorized access to these wastes, all vehicle cargo compartments containing regulated medical waste must be secured (locked) if at anytime the vehicle is unattended. For example, the vehicle should be secured if unattended during a lunch break, during rest stops, or when the driver or other responsible persons will not be in visual sight of the vehicle.

3. Transporter Tracking Form Requirements (Section 259.74)

As explained in the introduction to Section IV of the Preamble, the Agency has determined that a tracking system, designed along the lines of the UHWM system, will be an effective method for documenting the transport of regulated medical waste from its point of generation to its final destination. Exception and discrepancy reports will further aid in validating the system and ensure that the proper management and disposal of regulated medical waste occurs. The tracking form documents the movement of waste from the site of generation to the site of disposal, through each transaction phase in the process. The tracking procedure for transporters is specified in § 259.74. [As explained previously, transporters who intend to transport regulated medical generated in a covered State to a destination facility in a different covered State that supplies and requires the use of its medical waste tracking form must provide the generator with the tracking form of the destination covered State.] Compliance with the tracking form amounts to a chain-of-custody procedure. The form must accompany the shipment and each person who signs the form is taking responsibility ("custody") for the shipment while it is in his possession.

4. Acceptance of Medical Waste

Before accepting any regulated medical waste for transport, the transporter must make certain through visual inspection that the waste is packaged, labeled, and marked in accordance with all applicable requirements (Subpart E of today's rule).

5. Consolidation or Remanifesting of Regulated Medical Waste

Today's rule also specifies conditions under which transporters must initiate tracking forms. This need arises when transporters receive shipments of less than 50 pounds that are not accompanied by a tracking form. Given that today's rule requires that all

shipments of regulated medical waste generated in a Covered State be accompanied by a tracking form when delivered to a subsequent transporter, intermediate handling or to a destination facility, transporters will be required to document such shipments with tracking forms prior to transfer of custody. The Agency believes that transporters will have accumulated more than 50 pounds of regulated medical waste from numerous generators of less than 50 pounds; therefore, the tracking form is required. The Agency is also allowing transporters and owners or operators of transfer facilities to consolidate and remanifest individual shipments of regulated medical waste that weigh less than 220 pounds onto a single tracking form. This provision will avoid the significant burden that would otherwise exist if transporters and treatment and disposal facilities were required to sign and account for individual tracking forms for each and every shipment of regulated medical waste. Specific conditions and requirements for each follow.

a. *Generators of less than 50 pounds per month.* Shipments from generators of less than 50 pounds per month may be documented in one of two ways. First, upon mutual agreement between the generator and transporter, the parties may simply use the tracking form as required for generators of 50 pounds or more per month. As an alternative, however, the parties may take advantage of the special provisions of §§ 259.50(e)(2) and 259.74(g).

Under the second approach, shipments of less than 50 pounds from generators of less than 50 pounds per month do not require a tracking form. Rather, the transporter is required to sign the generator's log and maintain his own log recording each shipment of less than 50 pounds. The transporter's log must contain the following information for each shipment: (1) Generator's name; (2) generator's State permit or identification number or address; (3) quantity of waste by category (untreated, treated); and (4) date of shipment. (It is not the obligation of the transporter to ensure that generators who log shipments of less than 50 pounds of regulated medical waste actually generate less than 50 pounds of regulated medical waste per month; this is the responsibility of the generator. However, any individual shipments of 50 pounds or more must be accompanied by a tracking form originated by the generator.)

Before delivery to the disposal facility, the transporter must initiate a tracking form, completing the generator section, to account for all consignments of less than 50 pounds of regulated medical waste in that load. Thus, in effect, the transporter becomes a surrogate generator for these materials. The transporter also must attach to the tracking form a list containing the names of all generators and the number of containers from each generator that have been consolidated onto the tracking form (e.g., this could be a copy of the transporter's log sheet). This will provide the transporter and the treatment or disposal facility with information necessary to handle any discrepancies that may occur.

b. *Shipments of less than 220 pounds.* All shipments of 50 pounds or more of regulated medical waste or from a generator of 50 pounds or more per month must be accompanied by a tracking form which has been filled out by the generator and signed by both generator and transporter. This form must be completed before the waste is transported off-site. Transporters may consolidate and remanifest shipments of less than 220 pounds onto a single tracking form for transport to a destination facility or at the time those materials are transferred to a second transporter (see § 259.76 (b)-(d)). This "remanifesting" also may include shipments of less than 50 pounds that are accompanied by tracking forms. However, to facilitate recordkeeping by transporters, EPA strongly recommends that shipments of less than 220 pounds accompanied by a tracking form *not* be consolidated or remanifested onto the same tracking form as shipments of less than 50 pounds that were not accompanied by a tracking form. Instead, transporters should consolidate onto separate tracking forms: (1) Shipments accompanied by tracking forms; and (2) shipments of less than 50 pounds that are not accompanied by a tracking form. Keeping the two types of shipments separate will facilitate recordkeeping for returning the tracking forms to the original generators who originated those tracking forms.

Remanifesting is done to condense information from the tracking forms of many small shipments onto a new tracking form so that owners or operators of destination facilities need not sign an overwhelmingly large number of individual tracking forms. EPA believes the approach described here will reduce a potentially overwhelming paperwork burden on destination facilities while still meeting the RCRA section 11003(a)(2) statutory objective of "* * * providing the generator of the waste with assurance that the waste is received by the destination facility."

EPA has decided to allow remanifesting of only relatively small quantities of regulated medical waste because the remanifesting provision is somewhat less stringent than requiring each original tracking form to accompany the shipment all the way to its destination. This approach has not been implemented by any of the individual States, and has not previously been allowed for hazardous waste shipments. The remanifesting provision increases the possibility of clerical errors that could lead to discrepancies in the quantities of regulated medical waste being shipped to their intended destinations. Thus, prior to allowing such a provision for all quantities of regulated medical waste, EPA believes that the Agency must monitor the effectiveness of this more flexible procedure. Therefore, EPA is restricting its use to shipments of less than 220 pounds during the duration of the demonstration program. EPA will determine whether there is a significant increase in the number of tracking system violations for remanifested regulated medical waste relative to that which requires that individual tracking forms accompany the waste. Comments are requested on the 220 pound limit in today's rule.

At the time the transporter initiates the new tracking form, he also must attach a copy of the transporter's log indicating the following for each consolidated load: (1) Generator's name; (2) generator's identification number or address; (3) quantity of waste by category (untreated, treated); and (4) date of shipment or original tracking form number. Again, the purpose of carrying and providing such information to the destination facility is to facilitate the resolution of any discrepancies that may occur. Here, as with consolidation of logged material from generators of less than 50 pounds per month, the transporter becomes a surrogate generator of the redocumented waste, filling out the tracking form accordingly. In these instances, the new tracking form number must be indicated on the original (the generator's) tracking form(s), as specified in the instructions for completing the tracking form (see Appendix I to Part 259). The transporter must not return a copy of the original tracking form (the tracking form from the original generator) to the generator until he receives a signed, completed copy of the new transporter-initiated tracking form from the disposal facility. A copy of that tracking form, signed by the destination facility, must be

attached to the original form, and copies of both forms returned to the generator. The transporter also must enter on the generator's original tracking form the name of the destination facility if it is different from the one already listed on the form.

c. *Shipments of more than 220 pounds.* Shipments greater than 220 pounds must always be accompanied by the generator-initiated tracking form which must remain with that shipment until it is accepted by the final destination facility. Individual shipments over 220 pounds may not be consolidated onto another tracking form by the transporter. For each such shipment over 220 pounds, the transporter shall sign the form when accepting the waste, leaving the designated copy with the generator. The remaining copies of the form must be maintained in the same vehicle as the waste it covers at all times (except as provided for in Subpart J for rail carriers) until it is accepted by the destination facility. The waste is officially accepted by that facility when the form is signed by a representative of the destination facility and a signed copy given to the transporter.

6. Transporter Recordkeeping and Reporting Requirements

a. *Recordkeeping.* Today's rule also specifies that all transporters who transport regulated medical waste originated in a Covered State must maintain records of all transactions involving these materials. Copies of all tracking forms that the transporter has signed must be kept for at least three (3) years from the date of signature; this includes all generator-initiated forms as well as any that the transporter has initiated himself. Additionally, copies of all logs pertaining to consolidation activities (whether for shipments of less than 50 pounds that are not accompanied by tracking forms or for those of up to 220 pounds that are accompanied by forms) must be maintained for a minimum of three (3) years from the date of their initiation. Finally, the transporter must keep copies on file of all reports that he is required to submit to EPA or any of the Covered States during the demonstration program; these will include all copies of the transporter periodic reports as well as any other reports, as required by today's rule that relate to the medical waste tracking program (e.g., Exception Reports, Discrepancy Reports).

b. *Transporter periodic reports.* The transporter must prepare and submit periodic reports to EPA and the appropriate State agency responsible for medical waste monitoring and enforcement concerning the management of regulated medical waste. Transporters must prepare a separate report for each Covered State in which the transporter accepted regulated medical waste directly from a generator, and for each Covered State that the transporter has accepted regulated medical waste from another transporter who accepted waste directly from a generator. (The transporter who accepted waste directly from the generator may be the first of three or more transporters that are involved in the transport of such waste. Each transporter involved in the transport of the waste must report.) These reports, which will provide EPA and the State with information regarding implementation of the program, must contain the information required on the form in Appendix III to Part 259. Use of this form is required. Reports must be submitted for the first, second, third, and fourth 180-day periods of the demonstration program and must be submitted 45 days after the last day of the reporting period.

The report must be submitted to EPA, addressed to: Chief, Waste Characterization Branch, Office of Solid Waste, US EPA (OS-332), 401 M Street SW., Washington, DC 20460. Transporters must include their EPA Medical Waste Identification Number on the report. One copy of the report also must be sent to the Director of the State agency responsible for implementing the medical waste tracking regulations. EPA will publish a list of State agency addresses after the 30 day petition-in/opt-out period.

The information required includes the quantities of regulated medical waste (broken down into the "untreated" and "treated" categories) accepted from each generator, by name and site, during the reporting period. These reports will provide EPA not only with a list of all generators entering waste into the tracking system, but also the quantity of regulated medical waste entering the system. EPA will use this information to help prepare the Reports to Congress required under Section 11008, and by the States or EPA to target inspection and compliance monitoring efforts.

Transporters also must report on the disposition of regulated medical waste (i.e., whether the waste has been delivered to a treatment or disposal facility, or to another transporter), again broken down into the "untreated" or "treated categories." This information, which will include both the names and addresses of receiving facilities as well as waste quantity information, also will be used for the Reports to Congress and to target EPA or State inspection and enforcement efforts.

The reports are intended to provide a picture of the regulated medical waste transportation system for such wastes generated in Covered States. The distinction between "untreated" and "treated" medical waste will allow EPA to assess changes in treatment practices over the life of the program. All of the information can be taken from the required tracking forms or logs; transporters should not need to generate new information.

The reports must be submitted according to the schedule outlined above. The first report will provide EPA and the States with information on generators and treatment and disposal facilities so that the Agency can immediately target public outreach efforts and make modifications to the system to improve its efficiency. EPA believes there is a strong likelihood that, upon analysis of the first report, EPA will have identified all generators, treaters, and disposers of regulated medical waste. After this initial period, the reporting will meet enforcement needs and provide information for the Reports to Congress. These periodic reports will enable EPA and the States to assess trends during the life of the program.

EPA initially considered requiring that all generators, transporters and treatment and disposal facilities submit detailed reports concerning their handling of regulated medical waste. However, the Agency was concerned about the ability to assimilate the information from the estimated 150,000 generators, transporters, and destination facilities within the Covered States. Since transportation is the essential link between generators and off-site treatment and disposal, EPA believes that the most efficient means of compiling information will be from the transporters. EPA anticipates that the total number of regulated medical waste transporters will number less than a thousand.

In summary, the Agency has attempted to minimize reporting requirements in today's rule. However, EPA believes monitoring of waste movement is essential, and the transporter, as the central actor, is in the best position to collect, compile, and report this information. Accordingly, EPA is using its Section 11004(a) authority to require submission of these reports.

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