US EPA ARCHIVE DOCUMENT

Subpart A—General

§ 259.1 Purpose, scope, and applicability.

(a) The purpose of this part is to establish a demonstration program for tracking medical waste shipments pursuant to the Medical Waste Tracking Act of 1988.

(b) The regulations in this part apply to regulated medical waste as defined in Subpart D of this part that is generated in a Covered State as defined in Subpart C of this part.

(c) Generators, transporters, and owners or operators of intermediate handling facilities (e.g., treatment or destruction facilities) or destination facilities (e.g., disposal facilities) who transport, offer for transport, or otherwise manage regulated medical waste generated in a Covered State must comply with this part even if such transport or management occurs in a non-Covered State.

(d) *Regulatory presumptions.* The transportation and management of regulated medical waste, as defined in Subpart D of this part, in a Covered State is subject to regulations under this part, unless a person claiming a non-regulated status can demonstrate by a preponderance of the evidence, through shipping papers or other documentation, that the regulated medical waste was generated in a non-Covered State.

§ 259.2 Effective dates and duration of the demonstration program.

(a) Except for records and reports required to be maintained or submitted under this part, the demonstration program will be effective for the period June 22, 1989, to June 22, 1991.

(b) The length of time parties must keep records required under this part is automatically extended in the case where EPA or a State initiates an enforcement action, for which those records are relevant, until the conclusion of the enforcement action.

Subpart B—Definitions

§ 259.10 Definitions.

(a) For the purposes of this part, all of the terms defined in 40 CFR 260.10 are hereby incorporated by reference, except for the following terms, which have been redefined as appropriate to address the management of medical waste specifically:

"Facility" means all contiguous land and structures, other appurtenances, and improvements on the land, used for treating, destroying, storing, or disposing of regulated medical waste. A facility may consist of several treatment, destruction, storage, or disposal operational units.

"Generator" means any person, by site, whose act or process produces regulated medical waste as defined in Subpart D of this part, or whose act first causes a regulated medical waste to become subject to regulation. In the case where more than one person (e.g., doctors with separate medical practices) are located in the same building, each individual business entity is a separate generator for the purposes of this part.

"Landfill" means a disposal facility or part of a facility where regulated medical waste is placed in or on the land and which is not a land treatment facility, a surface impoundment, or an injection well.

"Person" means an 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.

"Solid waste" means a solid waste defined in Section 1004 (27) of RCRA.

"Storage" means the temporary holding of regulated medical wastes at a designated accumulation area before treatment, disposal, or transport to another location.

"Transfer facility" means any transportation-related facility including loading docks, parking areas, storage areas and other similar areas where shipments of regulated medical waste are held (come to rest or are managed) during the course of transportation. For example, a location at which regulated medical waste is transferred directly between two vehicles is considered a transfer facility. A transfer facility is a "transporter".

"Transportation" means the shipment or conveyance of regulated medical waste by air, rail, highway, or water.

"Transporter" means a person engaged in the off-site transportation of regulated medical waste by air, rail, highway, or water.

"Treatment" when used in the context of medical waste management means any method, technique, or process designed to change the biological character or composition of any regulated medical waste so as to reduce or eliminate its potential for causing disease. When used in the context of § 259.30(a) of this part, treatment means either the provision of medical services or the preparation of human or animal remains for interment or cremation.

(b) In addition, when used in this part, the following terms have the meanings given below:

"Biologicals" means preparations made from living organisms and their products, including vaccines, cultures, etc., intended for use in diagnosing, immunizing or treating humans or animals or in research pertaining thereto.

"Blood products" means any product derived from human blood, including but not limited to blood plasma, platelets, red or white blood corpuscles, and other derived licensed products, such as interferon, etc.

"Body fluids" means liquid emanating or derived from humans and limited to blood; cerebrospinal, synovial, pleural, peritoneal and pericardial fluids; and semen and vaginal secretions.

"Central collection point" means a location where a generator consolidates regulated medical waste brought together from original generation points prior to its transport off-site or its treatment on-site (e.g., incineration).

"Covered States" means those States that are participating in the demonstration medical waste tracking program. It includes States identified under Subtitle J of RCRA which have not petitioned out of the program pursuant to § 259.21 of this part and States which have petitioned into the program pursuant to § 259.22. Any other State is a "non-Covered State".

"Decontamination" means the process of reducing or eliminating the presence of harmful substances, such as infectious agents, so as to reduce the likelihood of disease transmission from those substances.

"Destination facility" means the disposal facility, the incineration facility, or the facility that both treats and destroys regulated medical waste, to which a consignment of such is intended to be shipped, specified in Box 8 of the Medical Waste Tracking Form.

"Destroyed regulated medical waste" means regulated medical waste that has been ruined, torn apart, or mutilated through processes such as thermal treatment, melting, shredding, grinding, tearing or breaking, so that it is no longer generally recognizable as medical waste. It does not mean compaction.

"Destruction facility" means a facility that destroys regulated medical waste by ruining or mutilating it, or tearing it apart.

"Infectious agent" means any organism (such as a virus or a bacteria) that is capable of being communicated by invasion and multiplication in body tissues and capable of causing disease or adverse health impacts in humans.

"Intermediate handler" is a facility that either treats regulated medical waste or destroys regulated medical waste but does not do both. The term, as used in this Part, does not include transporters.

"Laboratory" means any research, analytical, or clinical facility that performs health care related analysis or service. This includes medical, pathological, pharmaceutical, and other research, commercial, or industrial laboratories.

"Medical waste" means any solid waste which is generated in the diagnosis, treatment (e.g., provision of medical services), or immunization of human beings or animals, in research pertaining thereto, or in the production or testing of biologicals. The term does not include any hazardous waste identified or listed under Part 261 of this chapter or any household waste as defined in § 261.4(b)(1) of this chapter.

Note to this definition: Mixtures of hazardous waste and medical waste are subject to this part except as provided in § 259.31.

"Original generation point" means the location where regulated medical waste is generated. Waste may be taken from original generation points to a central collection point prior to off-site transport or on-site treatment.

"Oversized regulated medical waste" means medical waste that is too large to be placed in a plastic bag or standard container.

"Regulated medical waste" means those medical wastes that have been listed in § 259.30(a) of this part and that must be managed in accordance with the requirements of this part.

"Tracking form" means the Federal Medical Waste Tracking Form that must accompany all applicable shipments of regulated medical wastes generated within one of the Covered States.

"Treated regulated medical waste" means regulated medical waste that has been treated to substantially reduce or eliminates its potential for causing disease, but has not yet been destroyed.

"Universal biohazard symbol" means the symbol design that conforms to the design shown in 29 CFR 1910.145(f)(8)(ii).

"Untreated regulated medical waste" means regulated medical waste that has not been treated to substantially reduce or eliminate its potential for causing disease.

"Waste category" means either untreated regulated medical waste or treated regulated medical waste.

Subpart C—Covered States

§ 259.20 States included in the demonstration program.

(a) The regulations of this part apply to all regulated medical waste that is generated in any Covered State. This Subpart further identifies the procedures for States electing to participate or not to participate in the demonstration program.

(b) For purposes of this part, Covered States are the States of Connecticut, Illinois, Indiana, Michigan, Minnesota, New Jersey, New York, Ohio, Pennsylvania, and Wisconsin. Any of these States may elect not to participate in the demonstration program using the procedures in § 259.21 of this subpart. States that the Administrator removes from the demonstration program pursuant to RCRA section 11001(b) are non-Covered States.

(c) Any States not listed in paragraph (b) of this section may petition to participate in the demonstration program pursuant to § 259.22 of this subpart. States that the Administrator has included in the demonstration program pursuant to a State petition are Covered States.

§ 259.21 States electing not to participate.

(a)(1) If Connecticut, New Jersey or New York elect not to participate in the demonstration program, the Governor of the State must notify the Administrator no later than April 24, 1989, of his decision that the State elects not to participate in the demonstration program. The notification must include:

(i) A statement that the State has implemented a medical waste tracking program that is no less stringent than the demonstration program of this part;

(ii) A copy of the State's regulations implementing that program; and

(iii) A copy of the State statutes authorizing that program, and a copy of the State statutes and regulations governing the State's administrative procedures.

(2) The Administrator will consider the information submitted under paragraph (a)(1) of this section and shall determine whether the State's program is no less stringent than the Federal program under this part. Upon a finding by the Administrator that the State's program is no less stringent than Part 259, the Administrator shall remove the State from the list of Covered States in this subpart.

(b) If Illinois, Indiana, Michigan, Minnesota, Ohio, Pennsylvania, or Wisconsin elect not to participate in the demonstration program, the Governor of the State must provide written notification to the Administrator no later than April 24, 1989.

§ 259.22 States electing to participate.

Any State not listed in § 259.20(b) of this subpart may elect to participate in the demonstration program. The Governor of such State must submit a petition to the Administrator no later than April 24, 1989, requesting inclusion in the demonstration program as a Covered State. Upon a determination to accept such a petition, the Administrator shall include the State on the list of Covered States.

§ 259.23 Notice of participating States.

The Administrator shall publish a notice in the **Federal Register** listing those States included in the demonstration program after April 24, 1989.

Subpart D—Regulated Medical Waste

§ 259.30 Definition of regulated medical waste.

(a) A regulated medical waste is any solid waste, defined in § 259.10(a) of this part, generated in the diagnosis, treatment, (e.g., provision of medical services), or immunization of human beings or animals, in research pertaining thereto, or in the production or testing of biologicals, that is not excluded or exempted under paragraph (b) of this section, and that is listed in the following table:

Note to paragraph (a): The term "solid waste" includes solid, semisolid, or liquid materials, but does not include domestic sewage materials identified in § 261.4(a)(1) of this subchapter.

TABLE—REGULATED MEDICAL WASTE

Waste class	Description
(1) Cultures and Stocks.	Cultures and stocks of infectious agents and associated biologicals, including: cultures from medical and pathological laboratories; cultures and stocks of infectious agents from research and industrial laboratories; wastes from the production of biologicals; discarded live and attenuated vaccines; and culture dishes and devices used to transfer, inoculate, and mix cultures.
(2) Pathological Wastes.	Human pathological wastes, including tissues, organs, and body parts and body fluids that are removed during surgery or autopsy, or other medical procedures, and specimens of body fluids and their containers.
(3) Human Blood and Blood Products.	(1) Liquid waste human blood; (2) products of blood; (3) items saturated and/or dripping with human blood; or (4) items that were saturated and/or dripping with human blood that are now caked with dried human blood; including serum, plasma, and other blood components, and their containers, which were used or intended for use in either patient care, testing and laboratory analysis or the development of pharmaceuticals. Intravenous bags are also included in this category.

TABLE—REGULATED MEDICAL WASTE—Continued

Waste class	Description
(4) Sharps	Sharps that have been used in animal or human patient care or treatment or in medical, research, or industrial laboratories, including hypodermic needles, syringes (with or without the attached needle), pasteur pipettes, scalpel blades, blood vials, needles with attached tubing, and culture dishes (regardless of presence of infectious agents). Also included are other types of broken or unbroken glassware that were in contact with infectious agents, such as used slides and cover slips.
(5) Animal Waste	Contaminated animal carcasses, body parts, and bedding of animals that were known to have been exposed to infectious agents during research (including research in veterinary hospitals), production of biologicals, or testing of pharmaceuticals.
(6) Isolation Wastes.	Biological waste and discarded materials contaminated with blood, excretion, exudates, or secretions from humans who are isolated to protect others from certain highly communicable diseases, or isolated animals known to be infected with highly communicable diseases.
(7) Unused Sharps.	The following unused, discarded sharps: hypodermic needles, suture needles, syringes, and scalpel blades.

(b)(1) *Exclusions.* (i) Hazardous waste identified or listed under the regulations in Part 261 of this chapter is not regulated medical waste.

Note to paragraph (b)(1)(i): Mixtures of regulated medical waste and hazardous waste are subject to Part 259, except as provided in § 259.31(b) of this subpart.

(ii) Household waste, as defined in § 261.4(b)(1) of this Chapter, is not regulated medical waste.

(iii) Ash from incineration of regulated medical waste is not regulated medical waste once the incineration process has been completed.

(iv) Residues from treatment and destruction processes are no longer regulated medical waste once the waste has been both treated and destroyed.

(v) Human corpses, remains, and anatomical parts that are intended for interment or cremation are not regulated medical waste.

(2) *Exemptions.* (i) Etiologic agents being transported interstate pursuant to the requirements of the U.S. Department of Transportation, U.S. Department of Health and Human Services, and all other applicable shipping requirements are exempt from the requirements of this part.

(ii) Samples of regulated medical waste transported off-site by EPA- or State-designated enforcement personnel for enforcement purposes are exempt from the requirements of this Part during the enforcement proceeding.

§ 259.31 Mixtures.

(a) Except as provided in paragraph (b) of this section, mixtures of solid waste and regulated medical waste listed in § 259.30(a) of this subpart are a regulated medical waste.

(b) Mixtures of hazardous waste identified or listed in Part 261 of this chapter and regulated medical waste listed in § 259.30(a) of this subpart are subject to the requirements in this part, unless the mixture is subject to the hazardous waste manifest requirements in Part 262 or Part 266 of this chapter.

Note to paragrah (b): Mixtures of regulated medical waste with hazardous waste that is exempt from the hazardous waste manifest requirements (e.g., under 40 CFR 261.5) remain subject to this Part.

Subpart E—Pre-Transport Requirements

§ 259.39 Applicability.

Generators must comply with the requirements of this subpart prior to shipping waste off-site, and generators must comply with § 259.42 of this Subpart for on-site storage. Transporters, intermediate handlers (e.g., treatment or destruction facilities), and destination facilities must comply with applicable requirements of this subpart, when specified in Subparts H or I of this part.

§ 259.40 Segregation requirements.

(a)(1) Generators must segregate regulated medical waste intended for transport off-site to the extent practicable prior to placement in containers according to paragraph (a)(2) of this section.

(2) Generators must segregate regulated medical waste into sharps (Classes 4 and 7 of § 259.30(a) of this subpart including sharps containing residual fluid), fluids (quantities greater than 20 cubic centimeters), and other regulated medical waste.

(b) If other waste is placed in the same container(s) as regulated medical waste, then the generator must package, label, and mark the container(s) and its entire contents according to the requirements in §§ 259.41, 259.44, and 259.45 of this part.

§ 259.41 Packaging requirements.

Generators must ensure that all regulated medical wastes meet the following requirements before transporting or offering for transport such waste off-site. Generators may use one or more containers to meet these requirements.

(a) Generators must ensure that all regulated medical waste is placed in a container or containers that are:

(1) Rigid;

(2) Leak-resistant;

(3) Impervious to moisture;

(4) Has a strength sufficient to prevent tearing or bursting under normal conditions of use and handling; and

(5) Sealed to prevent leakage during transport.

(b)(1) In addition to the requirements of paragraph (a) of this section, generators must package sharps and sharps with residual fluids in packaging that is puncture-resistant.

(2) In addition to the requirements of paragraph (a) of this section, generators must package fluids (quantities greater than 20 cubic centimeters) in packaging that is break-resistant and tightly lidded or stoppered.

(c) Generators need not place oversized regulated medical waste in containers. Generators must note any special handling instructions for these items in Box 14 of the tracking form required under Subpart F and Appendix I of this part.

§ 259.42 Storage of regulated medical waste prior to transport, treatment, destruction, or disposal.

Any person who stores regulated medical waste prior to treatment or disposal on-site (e.g., landfill, interment, treatment and destruction, or incineration), or transport off-site, must comply with the following storage requirements:

(a) Store the regulated medical waste in a manner and location that maintains the integrity of the packaging and provides protection from water, rain and wind;

(b) Maintain the regulated medical waste in a nonputrescent state, using refrigeration when necessary;

(c) Lock the outdoor storage areas containing regulated medical waste (e.g., dumpsters, sheds, tractor trailers, or other storage areas) to prevent unauthorized access;

(d) Limit access to on-site storage areas to authorized employees; and

(e) Store the regulated medical waste in a manner that affords protection from animals and does not provide a breeding place or a food source for insects and rodents.

§ 259.43 Decontamination standards for reusable containers.

Generators, transporters, intermediate handlers, and destination facility owners and operators must comply with the following requirements with respect to reusing containers:

(a) All non-rigid packaging and inner liners must be managed as regulated medical waste under this part and must not be reused.

(b) Any container used for the storage and/or transport of regulated medical waste and designated for reuse once emptied, must be decontaminated if the container shows signs of visible contamination.

(c) If any container used for the storage and/or transport of regulated medical waste is for any reason not capable of being rendered free of any visible signs of contamination in accordance with paragraph (b) of this section, the container must be managed (labeled, marked and treated and/or disposed of) as regulated medical waste under this part.

§ 259.44 Labeling requirements.

Generators must label each package of regulated medical waste according to the following labeling requirements before transporting or offering for transport off-site:

(a) *Untreated regulated medical waste.* Each package of untreated regulated medical wastes must have a water-resistant label affixed to or printed on the outside of the container. The label must include the words "Medical Waste," or "Infectious Waste," or display the universal biohazard symbol. Red plastic bag(s) used as inner packaging need not display a label.

(b) *Treated regulated medical waste.* Packages containing treated regulated medical wastes are not required to be labeled under this section but are required to be marked according to § 259.45 of this subpart.

§ 259.45 Marking (identification) requirements.

Generators (including intermediate handlers) must mark each package of regulated medical waste according to the following marking requirements before the waste is transported or offered for transport off-site:

(a) The outermost surface of each package prepared for shipment must be marked with a water-resistant identification tag of sufficient dimension to contain the following information:

(1) Generator's or intermediate handler's name;

(2) Generator's or intermediate handler's State permit or identification number. If the generator's or intermediate handler's State does not issue permit or identification numbers, then the generator's or intermediate handler's address;

(3) Transporter name;

(4) Transporter State permit or identification number, or if not applicable, then the transporter's address;

(5) Date of shipment; and

(6) Identification of contents as medical waste.

(b) In addition to paragraph (a) of this section, if the generator has used inner containers, including sharps and fluid containers, each inner container must be marked with indelible ink or imprinted with water-resistant tags. The marking must contain the following information:

(1) Generator's or intermediate handler's name;

(2) Generator's or intermediate handler's State permit or identification number. If the generator's or intermediate handler's State does not issue permit or identification numbers, then the generator's or intermediate handlers' address.

Subpart F—Generator Standards

§ 259.50 Applicability and general requirements.

(a) This subpart establishes standards for generators of regulated medical waste.

(b) A person who generates a medical waste, as defined in § 259.10(b) of this part, and who is located in a Covered State, must determine if that waste is a regulated medical waste.

(c) A generator who either treats and destroys or disposes of regulated medical waste on-site (e.g., incineration, burial or sewer disposal covered by section 307(b)–(d), of the Clean Water Act) is not subject to tracking requirements for that waste.

Note to the section: Generators of regulated medical waste with on-site incinerators are subject to the on-site incinerator requirements in Subpart G of this Part. In addition, generators who treat and destroy regulated medical waste are subject to § 259.54(c). Generators who treat or dispose of medical waste on-site may be subject to additional Federal, State or local laws and regulations.

(d) Vessels at port in a Covered State are subject to the requirements of this Part for those regulated medical wastes that are transported ashore in the Covered State. The owner or operator of the vessel and the person(s) removing or accepting waste from the vessel are considered co-generators of the waste.

(e) A generator of regulated medical waste must determine the quantity of regulated medical waste that he generates in a calendar month, and that is transported or offered for transport off-site for treatment, destruction, or disposal.

(1) *Generators of 50 pounds or more per month.* Generators who generate and transport or offer for transport off-site 50 pounds or more of regulated medical waste in a calendar month are subject to the requirements of Subpart E and all of the requirements of this Subpart for each shipment of regulated medical waste.

(2) *Generators of less than 50 pounds per month.* (i) Generators who generate and transport or offer for transport off-site less than 50 pounds of regulated medical waste in a calendar month are subject to the requirements of Subpart E of this Part and §§ 259.50, 259.51 and 259.54(b) of this subpart.

(ii) Generators of regulated medical waste who generate less than 50 pounds in a calendar month but who transport or offer for transport off-site more than 50 pounds in any one shipment, are also subject to Subpart E of this part and all of the requirements of this subpart for each shipment of 50 pounds or more.

(f) Generators or regulated medical waste must use transporters who have notified EPA under § 259.72 of this part to transport their regulated medical waste, except as provided in § 259.51 of this subpart.

§ 259.51 Exemptions.

(a) *Generators of less than 50 pounds per month.* Generators who meet the conditions of § 259.50(e)(2) of this subpart are exempt from the requirement to use a transporter who has notified EPA, exempt from the requirement to use the tracking form, and exempt from the requirements of Subpart H of this part provided that the following conditions are met:

(1)(i) The regulated medical waste is transported to a health care facility, an intermediate handler, or a destination facility with which the generator has a written agreement to accept the regulated medical waste; or

(ii) The generator is transporting the regulated medical waste from the original generation point to the generator's place of business; and

(2) The regulated medical waste is transported by the generator (or an authorized employee) in a vehicle owned by the generator or authorized employee; and

Note to the section: Owned vehicle means a vehicle which is owned by or registered to the generator or employee or is under lease by the generator or authorized employee for a minimum of 30 days.

(3) The generator must compile a shipment log and maintain records as required by § 259.54(b)(2).

(b) *Shipments between generator's facilities.* Generators are exempt from the requirement to use a transporter who has notified EPA, exempt from the use of the tracking form, and exempt from the requirements of Subpart H of this part when transporting regulated medical waste from the original generation point to a central collection point, provided they meet all of the following conditions:

(1) The regulated medical waste is transported by the generator (or the generator's authorized employee) in a vehicle owned by the generator or the employee;

(2) The regulated medical waste is brought to a central collection point or treatment facility owned or operated by the generator;

(3) The original generation point and the central collection point or treatment facility are located in the same Covered State; and

(4) The generator compiles and maintains a shipment log at each original generation point and each central collection point as required by § 259.54(a)(2) of this part.

(c) *Shipments of regulated medical waste (Classes 4 and 7) through the U.S. Postal Service.* Generators who meet the conditions of § 259.50(e)(2)(i) of this subpart who transport regulated medical waste (Classes 4 and 7 of § 259.30(a) of this part) by the U.S. Postal Service, are exempt from the requirement to use a transporter who has notified EPA and from the requirement to use the tracking form, provided they meet the following conditions:

(1) The package is sent registered mail, return receipt requested (indicating to whom, signature, date, and address where delivered); and

(2) The generator compiles a shipment log and maintains the original receipt and the returned registered mail receipt as required by § 259.54(b)(3) of this part.

§ 259.52 Use of the tracking form.

(a) Except as provided in §§ 259.50(e)(2)(i) and 259.51 of this Subpart, a generator who transports or offers for transport regulated medical waste for off-site treatment or disposal, must prepare a tracking form according to this section and the instructions included in Appendix I to this part.

(b) Generators must obtain the tracking form from the following sources:

(1) For generators who transport or offer for transport off-site regulated medical waste to an intermediate handler or a destination facility in a Covered State which prints the tracking form and requires its use, the form from that State; and

Note to paragraph (b)(1): For generators who transport or offer for transport regulated medical waste to another Covered State which prints the tracking form and requires its use, the transporter is required to provide the generator with the receiving State's form.

(2) For all other generators, the tracking form from the State in which the waste was generated.

(3) If the generator's State does not print the tracking form, the generator must use the tracking form in Appendix I of this part.

(c) The generator must prepare at least the number of tracking form copies that will provide the generator, each transporter(s), and each intermediate handler with one copy, and the owner or operator of the destination facility with two copies.

Note to paragraph (c): The destination facility keeps one copy for their records and returns the second copy to the generator.

(d) The generator must also:

(1) Sign the certification statement on the tracking form by hand;

(2) Obtain the handwritten signature of the initial transporter and date of acceptance on the tracking form; and

(3) Retain one copy, in accordance with § 259.54.

(e) For rail shipments of regulated medical waste within the United States that originate at the site of generation, the generator must send at least three (3) copies of the tracking form dated and signed in accordance with this section to:

(1) The next non-rail transporter, if any; or

(2) The intermediate handler or destination facility if transported solely by rail; or;

(3) The last rail transporter to handle the waste in the United States if exported by rail.

§ 259.53 Generators exporting regulated medical waste.

Generators (including transporters and intermediate handlers that initiate tracking forms) who export regulated medical waste to a foreign country (e.g., Canada) for treatment and destruction, or disposal, must request that the destination facility provide written confirmation that the waste was received. If the generator has not received that confirmation from the destination facility within 45 days from the date of acceptance of the waste by the first transporter, the generator must submit an exception report as required under § 259.55 of this subpart.

§ 259.54 Recordkeeping.

(a) Except as provided in paragraph (b) of this section, each generator must:

(1)(i) Keep a copy of each tracking form signed in accordance with § 259.52 of this part, for at least three (3) years from the date the waste was accepted by the initial transporter; and

(ii) Retain a copy of all exception reports required to be submitted under § 259.55(c) of this subpart.

(2) Generators who meet the conditions of § 259.51(b) of this subpart must meet the following requirements:

(i) A shipment log must be maintained at the original generation point for a period of three (3) years from the date the waste was shipped. The log must contain the following information:

(A) Date of shipment;

(B) Quantity (by weight) of regulated medical waste transported, by waste category (i.e., untreated and treated);

(C) Address or location of central collection point; and

(D) Signature of generator's employee who will transport the waste, indicating acceptance.

(ii) A shipment log must be maintained at each central collection point for a period of three (3) years from the date that regulated medical waste was accepted from each original generation point and must contain the following information:

(A) Date of receipt;

(B) Quantity (by weight) of regulated medical waste accepted, by waste category (i.e., untreated and treated);

(C) Address or location of original generation point; and

(D) Signature of generator or generator's representative who operates the central collection point, indicating acceptance of the waste.

(b) Generators who meet the conditions of § 259.50(e)(2)(i) of this subpart, who do not transport or offer for transport off-site more than 50 pounds of regulated medical waste in a single shipment, and who do not voluntarily comply with the use of the tracking form are subject to the following recordkeeping requirements:

(1) Generators who use a transporter who has notified EPA must maintain a log for a period of three (3) years from the date of shipment that contains the following information for each shipment or pickup:

(i) Transporter's name and address;

(ii) Transporter's State permit or identification number, if one is required by the State;

(iii) Quantity of regulated medical waste transported, by waste category (i.e., untreated and treated);

(iv) Date of shipment; and

(v) The signature of the transporter's representative accepting the regulated medical waste for transport.

(2) Generators who transport regulated medical waste to a health care facility or to a treatment, destruction, or disposal facility as specified in § 259.51(a) of this subpart must compile and maintain a log for a period of three (3) years from the date of the last shipment entered into the log. The log must contain the following information:

(i) Name and address of the intermediate handler, destination facility, or health care facility to which the generator has transported that shipment of regulated medical waste;

(ii) Quantity (by weight) of regulated medical waste transported, by waste category (i.e., untreated and treated);

(iii) Date of shipment; and

(iv) Signature of the generator or his authorized representative who transported the waste.

(3) Generators who transport regulated medical waste by the U.S. Postal Service under § 259.51(c) of this subpart must retain the original U.S. Postal Service receipt and the return mail receipt and maintain a shipment log for a period of three (3) years from the date of shipment. The log must contain the following information:

(i) Quantity (by weight) of regulated medical waste transported, by waste category (i.e., untreated and treated);

(ii) Date of shipment; and

(iii) Name and address of each intermediate handler or destination facility to which the generator has transported the regulated medical waste by the U.S. Postal Service.

(c) Each generator who treats and destroys regulated medical waste on-site by a method or process other than incineration, must maintain the following records:

(1) The approximate quantity by weight, of regulated medical waste that is subject to the treatment and destruction processes;

(2) Approximate percent, by weight, of total waste treated and destroyed that is regulated medical waste;

(3) For regulated medical waste accepted from generators meeting the exemption conditions in § 259.51 (a) or (c), information identifying the generator, the date the waste was accepted, the weight of waste accepted, and the date the waste was treated and destroyed; and

(4) Records must be maintained by the generator for a period of at least three (3) years from the date the waste was treated and destroyed.

§ 259.55 Exception Reporting.

(a) A generator who meets the conditions of § 259.50 (e)(1) or (e)(2)(ii) of this subpart must contact the owner or operator of the destination facility, transporter(s), and intermediate handler(s), as appropriate, to determine the status of any tracked waste if he does not receive a copy of the completed tracking form with the handwritten signature of the owner or operator of the destination facility within 35 days of the date the waste was accepted by the initial transporter.

(b) A generator must submit an Exception Report, as described below, to the State and the EPA Regional Administrator for the Region in which the generator is located if he has not received a completed copy of the tracking form signed by the owner or operator of the destination facility within 45 days of the date the waste was accepted by the initial transporter. The Exception Report must be postmarked on or before the 46th day and must include:

(1) A legible copy of the original tracking form for which the generator does not have confirmation of delivery; and

(2) A cover letter signed by the generator or his authorized representative explaining the efforts taken to locate the regulated medical waste and the results of those efforts.

(c) A copy of the exception report must be kept by the generator for a period of at least three (3) years from the due date of the report.

§ 259.56 Additional Reporting.

The Administrator may require generators to furnish additional information concerning the quantities and management methods of medical waste as he deems necessary under RCRA section 11004.

Subpart G—On-Site Incinerators

§ 259.60 Applicability.

(a) The regulations in this subpart apply to generators of regulated medical waste who incinerate regulated medical waste on-site.

(b) Generators of regulated medical waste who incinerate such waste on-site and who accept regulated medical waste accompanied by a tracking form are also subject to the requirements of Subpart I of this part.

§ 259.61 Recordkeeping.

(a) Generators must keep an operating log at their incineration facility that includes the following information:

(1)(i) The date each incineration cycle was begun;

(ii) The length of the incineration cycle;

(iii) The total quantity of medical waste incinerated, per incineration cycle; and

(iv) An estimate of the quantity of regulated medical waste incinerated, per incineration cycle.

(2) Generators with on-site incinerators that accept regulated medical waste from generator(s) subject to § 259.51(a) of this Part must maintain the following information for each shipment of regulated medical waste accepted:

(i) The date the waste was accepted;

(ii) The name and State permit or identification number of the generator who originated the shipment. If the State does not issue permit or identification numbers, then the generator's address;

(iii) The total weight of the regulated medical waste accepted from the originating generator; and

(iv) The signature of the individual accepting the waste.

(b)(1) Generators must compile the operating log required by paragraph (a)(1) of this section during the following period: June 22, 1989, to June 22, 1991.

(2) Generators must retain the operating log until at least June 22, 1992.

(c) Generators with on-site incinerators that accept regulated medical waste from generators subject to the tracking form requirements must keep copies of all tracking forms for a period of three years from the date they accepted the waste.

(d) Generators must retain a copy of the on-site incinerator report form required under § 259.62 of this subpart for three (3) years from the date of submission.

§ 259.62 Reporting.

(a) *General.* The owner or operator of an on-site incinerator must prepare and submit two copies of the on-site incinerator report on the form provided in Appendix II of this part to: Chief, Waste Characterization Branch, Office of Solid Waste (OS-332), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460. The reports must summarize information collected in the operating log during the first and third six-month period after the effective date of the demonstration program, and must contain the following information in the format provided in Appendix II of this part:

(1) Facility name, mailing address, and location;

(2) Facility type (e.g., hospital, laboratory);

(3) Contact person;

(4) Waste feed information;

(5) The total number of incinerators at the facility that incinerate regulated medical waste and information concerning each incinerator.

(b) Each report must contain the following certification, signed by the facility owner or his authorized representative: I certify that I have personally examined and am familiar with the information submitted in this and all attached documents, and that based on my inquiry of those individuals immediately responsible for obtaining the information, I believe that the submitted information is true, accurate, and complete.

(c)(1) *Dates.* The first report is due February 6, 1990, and must contain information from the first six months of the demonstration program.

(2) The second report is due February 6, 1991, and must contain information from the thirteenth through the eighteenth month of the demonstration program.

Subpart H—Transporter Requirements

§ 259.70 Applicability.

(a) These requirements apply to transporters, including generators who transport their own waste, and owners and operators of transfer facilities engaged in transporting regulated medical waste generated in a Covered State.

(b) These regulations do not apply to on-site transportation of regulated medical waste, nor to shipments exempted under § 259.51 (a), (b), or (c) of this part.

(c) A transporter of regulated medical waste must also comply with Subpart F of this part when he consolidates two or more shipments of regulated medical waste onto a single tracking form.

(d) Transporters must also comply with Subpart E of this part if they:

(1) Store regulated medical waste in the course of transport; or

(2) Remove regulated medical waste from a reusable container; or

(3) Modify packaging of regulated medical waste.

§ 259.71 Transporter acceptance of regulated medical waste.

(a) Transporters must not accept for transport any regulated medical waste generated in a Covered State unless the outer surface of the container is labeled and marked in accordance with Subpart E of this part.

(b) Transporters must not accept a shipment of regulated medical waste from a generator unless accompanied by a properly completed tracking form as required under Subpart F of this part, unless the generator is exempt from the use of the tracking form under either § 259.50(e)(2)(i) or § 259.51 of this part.

(c) *Marking (identification).* When regulated medical waste is handled by more than one transporter, each subsequent transporter must attach a water resistant identification tag below the generator's marking on the outer surface of the packaging, that does not obscure the generator's or previous transporter's markings. The transporter taking possession of the shipment must ensure that the tag contains the following information:

(1) Name of transporter taking possession (receiving) of the regulated medical waste;

(2) Transporter State permit or identification number. If the State does not issue permit or identification numbers, then the transporter's address; and

(3) Date of receipt.

§ 259.72 Transporter notification.

(a)(1) Transporters (including owners or operators of transfer facilities) are prohibited from transporting regulated medical waste generated in a Covered State unless they have notified EPA and the Covered State in writing as provided in this Section.

(2) Transporters who accept regulated medical waste that was generated in a Covered State, or who transport regulated medical waste that was generated in a Covered State, must submit a separate notification form for each Covered State in which the regulated medical waste was generated.

(3)(i) The original and one copy of the transporter notification must be sent to: Chief, Waste Characterization Branch (OS-332), EPA Office of Solid Waste, 401 M Street, SW., Washington, DC 20460.

(ii) An additional copy must be sent to the Director of the waste management agency in the Covered State for which the transporter is notifying.

(b) Each transporter notification must contain the following information:

(1) Transporter's name, mailing address, and EPA hazardous waste identification number (if any);

(2) Name, address and telephone number for each transportation or transfer facility (by site) that the transporter will operate from for each Covered State for which the transporter is notifying;

(3) Identifications (State permit or license numbers) required to handle medical or infectious waste; and

(4) The following statement signed by a corporate official or the owner or operator: I certify, under penalty of criminal or civil prosecution for making or submission of false statements, representations, or omissions, that I have read, understand, and will comply with the regulations at 40 CFR Part 259, issued under authority of Subtitle J of the Resource Conservation and Recovery Act.

Note paragraph (b): The Agency has published a suggested form for transporter notification in Appendix IV of this part which may be utilized by transporters notifying EPA.

(c) EPA will issue transporters, who notify under this section, a unique EPA Medical Waste Identification Number for each Covered State for which they have notified. This identification number will apply to all transporter sites identified in paragraph (b)(2) of this section, that relate to each Covered State. Transporters may accept regulated medical waste after notifying under this section. Upon receipt of an EPA Medical Waste Identification Number the transporter must include it on Box 5 of the Medical Waste Tracking Form found in Appendix I of this part.

Note to the section: States may impose or may presently have in place additional licensing, permitting or other requirements that apply to transporters of regulated medical waste.

§ 259.73 Vehicle requirements.

(a) Transporters must use vehicles to transport regulated medical waste that meet the following requirements:

(1) The vehicle must have a fully enclosed, leak-resistant cargo-carrying body;

(2) The transporter must ensure that the waste is not subject to mechanical stress or compaction during loading and unloading or during transit;

(3) The transporter must maintain the cargo-carrying body in good sanitary condition; and

(4) The cargo-carrying body must be secured if left unattended.

(b) The transporter must use vehicles to transport regulated medical waste that have the following identification on the two sides and back of the cargo-carrying body in letters a minimum of 3 inches in height:

(1) The name of the transporter;

(2) The transporter's State permit or license number, if any; and

(3) A sign or the following words imprinted:

(i) MEDICAL WASTE; or

(ii) REGULATED MEDICAL WASTE.

(c) A transporter must not transport regulated medical waste in the same container with other solid waste unless the transporter manages both as regulated medical waste in compliance with this subpart.