

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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MEMORANDUM

SUBJECT: Interpretations of the EPA Medical Waste Regulations (Numbers 50-63)

FROM: David Bussard, Director
Characterization and Assessment Division
Office of Solid Waste

Susan Bromm, Director
RCRA Enforcement Division
Office of Waste Programs Enforcement

TO: Regional, State and Territorial Medical Waste Contacts

Attached is the sixth set of interpretations for the 40 CFR Part 259 regulations for medical waste tracking and management. These questions and answers are EPA's interpretation of issues that have been raised. If you need clarifications, or if you have other questions you would like to see addressed in future documents, please call Mary Greene at (202) 475-8551.

Attachment

40 CFR - Questions and Answers

This document reflects the Environmental Protection Agency's interpretations of the Federal regulations at 40 CFR Part 259 - Standards for the Tracking and Management of Medical Waste. States or localities may have requirements that are more inclusive, or that pose additional restrictions on the management of medical wastes.

50. How can the regulated community and the general public know when and where to obtain information on the Federal medical waste program?

EPA is required to publish regulations and changes in regulations in the Federal Register. The Federal Register is available at most large libraries such as those found at universities. The notice of availability of the Reports to Congress will also be published in the Federal Register, but due to the length, the Reports to Congress will not be published in the Federal Register, but publicly available upon request from the RCRA docket. Additional information on medical waste documents can be obtained from the RCRA docket 202-475-7230 or the RCRA Hotline at 1-800-242-9346.

To obtain information on a state-specific issues, please contact the appropriate state regulatory authorities.

51. Several state and municipal governments located within the demonstration program have promulgated regulations for medical waste management. These regulations may differ from the requirements of the Part 259 regulations. Which regulations must a medical waste handler comply with, the Federal, State or local?

The states participating in the demonstration program have the authority to promulgate state specific regulations provided the state specific regulations are at least as stringent as the Part 259 requirements. All five states participating in the demonstration program have adopted the Part 259 regulations. However, regulatory agencies in Covered States do have the authority to implement medical waste regulations which are more stringent. Several covered states and municipalities have elected to promulgate more stringent medical waste regulations which the state and local officials felt enabled them to better address their state specific medical waste issues. When a Federal and state and local medical regulation differs, the more stringent regulation would take precedence, except for tracking forms, which under 11007(c), must be identical to the EPA form.

Consequently, the medical waste handlers located in the Covered States must comply with Federal, State and Local regulations which affect them. Destination facilities located outside the Covered States which are receiving RMW generated in the a Covered State must also comply with Part 259, Subpart I regulations.

52. A large clinic located in a Covered state contracts with a medical waste transporter. The transporter assists the generator by packaging the medical waste and completing the generator, initial

transporter, and destination facility portions of the appropriate tracking form. Upon completion, the generator signs the tracking form, as does the transporter, and the waste is transported. Who is ultimately responsible for the accuracy of the information entered on that tracking form and who is responsible for ensuring the pre-transport requirements (i.e., segregation, packaging, labeling, and marking) are met?

Generators of RMW are subject to the pre-transport requirements prior to shipping RMW off-site. Subpart E of Part 259 sets out the requirements for segregation, packaging, storage, decontamination of reusable containers, labeling and marking. While the transporter may assist the generator in completing these activities, the generator is ultimately responsible for ensuring that the requirements of Subpart E are complied with.

Section 259.52(a) states that “a generator who transports or offers for transportation 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.” While the transporter may assist the generator with the actual completion of that tracking form, the accuracy and completeness of the information is the responsibility of the generator. Therefore, the generator must verify that all information entered on the form in Boxes 1-14 is correct before signing the generator's certification statement in Box 15. The generator's certification in Box 15 states that “Under penalty of criminal and civil prosecution for the making or submission of false statements, representation or omissions, I declare,..... the contents of the consignment are fully and accurately described above and are classified, packaged, marked and labeled in accordance with all applicable State and Federal laws and regulations....” Upon signing the generator's certification the signee is indicating that not only is all the information on the tracking form correct, but the regulated medical waste is being handled in accordance with the requirements of Part 259 and applicable state requirements.

53. The Part 259 regulations require medical waste handlers to submit reports on their activities and requires transporters to notify.

A. Transporters are required to submit four semiannual reports on the medical waste they are transporting. Are generators and destination facilities required to submit a similar report?

No; the Part 259 regulations require the following reports on medical waste activities: on-site incinerator reports for generators who are treating and destroying RMW on-site using an incinerator (See 40 CFR Part 259 Appendix II) and the transporter report which is submitted by the transporter and provides information on the generators and destination facilities that the transporter interacts with. (See Part 259, Appendix III).

B. Medical waste transporters are required to notify EPA and the Covered State in writing of their intent to transport medical waste and receive an EPA Identification Number. Does the EPA also require that generators and destination facilities register and obtain an identification number?

No; the Federal Part 259 regulations do not require generators of RMW, intermediate handlers, or destination facilities to notify or register with EPA. However, these facilities may be subject to other environmental programs which require notification (i.e., Subtitle C Hazardous Waste). In addition, Covered States may have state specific regulations which require generators, intermediate handlers, and owner/operators of destination facilities to notify of medial waste activities and/or obtain a registration number.

54. A generator is required to maintain copies of the uniform tracking form for a period of three years from the date the transporter first accepted the RMW. A generator has 45 days receive the signed tracking form back from the destination facility before filing an exception report. What procedure should be followed when a tracking form has not been returned?

Section 259.52(a) requires a generator of RMW to use a uniform tracking form when shipping RMW off-site. If the generator has not received a copy of the signed tracking form from the destination facility within 35 days of the acceptance of the waste by the initial transporter, the generator should contact the destination facility, the intermediate handler(s), and the transporter(s), as appropriate, to inquire as to the disposition of the waste.

If the generator has not received a signed copy back from the destination facility within 45 days of acceptance of the waste from the original transporter, he must submit an Exception Report to the State and the Regional EPA Administrator in which the generator is located. The Exception Report must be postmarked by or before the 46th day and must contain the following information as specified in Section 259.55(b):

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.

Section 259.55(c) also requires a copy of the exception reports be retained by the generator for 3 years.

55. The pre-transport requirements found in Subpart E of Part 259 require RMW to be segregated, packaged, stored, labeled and marked prior to transport or offering for transport offsite.

A. Generators may often load packages of RMW directly onto a trailer before shipment. This process may occur over several days before the trailer becomes full. Occasionally, the shipment may be delayed for various reasons (i.e., the destination facility may not be able to accept the waste and an alternate disposal site must be found.) Consequently, the shipping date which was placed on the boxes during the loading process is inaccurate. Is it necessary to unload the trailer of RMW and change the shipping date on each label prior to shipment off-site?

Section 259.45(a) requires generators to mark each package of RMW prior to transport off-site with a water resistant identification tag containing the following information:

- 1) Generator's or intermediate handler's name;
- 2) Generator's or intermediate handler's state permit or identification number;
- 3) Transporter's name;
- 4) Transporter's 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.

Therefore, the generator RMW is required to indicate the shipping date on the package prior to shipment off-site. If for some reason the RMW cannot be unloaded and remarked, the actual date of shipment must be noted on the tracking form in Box 14 along with an explanation of the delay.

B. A physician located in a Covered State packages RMW in a red plastic bag as an inner container. The plastic bags are then placed in boxes prior to transportation off-site for disposal. Is the use of red plastic bags a mandatory part of the packaging requirements for RMW?

No; Section 259.41(a) and (b) describe the performance based packaging requirements for RMW. The packaging requirements do not require the use of red bags. Section 259.44(a) requires each package of untreated RMW have a water-resistant label affixed onto the outside of the container. The label must include the words "medical waste" or "Infectious Waste," or display the uniform Universal biohazard symbol. Red plastic bag(s) used as an inner liner need not display a label.

C. A small clinic generates several types of RMW including cultures and stocks, human blood and blood products, and sharps. The sharps are packaged in rigid, puncture proof plastic containers which are then placed in a box with other RMW types before off-site transport. Are these plastic sharps containers required to be labeled and marked when they are placed in the same box with other RMW types?

Each container of Class 4 or Class 7 RMW must be labeled in accordance with the requirements of Section 259.44(a) if the RMW is untreated. Containers of sharps which are untreated 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. If the sharps have been treated the container is not required to be labeled. See Section 259.44(b).

In addition, inner containers of sharps and fluids are required to be marked in accordance with 259.45(b). Each inner container must be marked with indelible ink or imprinted with water-resistant tags. The markings must contain:

- 1) The generator's or intermediate handler's name; and
- 2) The generator's or intermediate handler's state permit or identification number. If the state does not issue permits or identification numbers then it should include the generator's or intermediate handler's address.

D. A generator located in a covered state generates only sharps during the course of delivery of health care at his/her practice. This generator produces less than 50 pounds of RMW per month and wishes to utilize the exemption found in Section 259.51(c) for shipping sharps through the U.S. Postal Service. What are the outside label requirements for sharps shipped by registered mail?

Shipments of Class 4 and Class 7 RMW through the U.S. Postal Service must comply with all the requirements found in Subpart E. Generators must label each container of untreated RMW with a water resistant label which includes the words "Medical Waste," "Infectious Waste," or display the universal biohazard symbol.

Packages of sharps which are shipped via the U.S. Postal Service are subject to the marking requirements found at Section 259.45. The outside package must be labeled in accordance with Section 259.45(a). The inner containers must also be marked in accordance with Section 259.45(b) See Question 55C.

56. Regulated medical waste may be treated by the generator onsite to reduce the level of infectious agents and thereby lowering the risk of disease transmission.

A. A large clinical laboratory in a Covered State treats all of its regulated medical waste (e.g. cultures and stocks, free fluids, blood). Can the laboratory dispose of the treated RMW as regular solid waste at the local landfill?

The Part 259 regulations do not preclude the disposal of regulated medical waste (treated or untreated) in a sanitary landfill. However, the Part 259 regulations require that RMW be either treated and destroyed or tracked from the point of generation to disposal. Therefore, if the RMW was only treated, then the waste would still be subject to the tracking requirements of Part 259.

State and local regulatory agencies may have additional or more stringent medical waste regulations affecting landfilling of medical waste.

B. Disposal sites will sometimes not accept “treated” regulated medical waste or medical waste which is regulated unless it is ground up or made otherwise unrecognizable; is this a requirement of the regulation?

The Part 259 regulations require RMW to be “treated and destroyed” or tracked from the point of generation to the point of disposal. The Part 259 regulations do not prohibit the disposal of RMW (treated or untreated) in a landfill. Therefore, RMW which is treated can be landfilled provided that the waste is tracked in accordance with Part 259.

If the generator does not wish to track the RMW generated at his facility, he must treat and destroy the RMW. Section 259.10 (b) defines destroyed RMW as “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.”

Even though owners and operators of disposal facilities are not precluded from accepting RMW, treated or untreated, they may choose to limit the amount or not accept RMW for disposal at their facility.

57. The Part 259 regulations do not list acceptable methods a generator can utilize for disposal of RMW, and EPA has not provided a list of permitted destination facilities.

A. Is there an available “print out” of EPA registered or permitted disposal facilities?

No; the Part 259 regulations do not require the generator or the destination facility to register or obtain a permit specifically for RMW management and disposal. The Part 259 regulations do require transporters of RMW to notify prior to accepting RMW, but destination facilities are not required to register or obtain a permit through EPA.

However, state and local regulatory authorities may require generators, transporters, treatment and disposal facilities to notify, register and/or obtain a permit. They may be able to provide a print-out of such facilities.

B. A dentist utilizes suction equipment to remove saliva and blood during a tooth extraction process. The suction equipment drains directly to the sewer system. Are generators of RMW allowed to dispose of liquid body fluids (i.e., blood) through the domestic sewer? Can body fluids collected in suction canisters (plural, respiratory, peritoneal, etc.) be emptied into the sanitary sewer or must they be incinerated?

Generators of RMW containing body fluids are not prohibited under the Part 259 regulations from disposing of RMW through the sewer system. Rather, such disposal is regulated under the Clean Water Act.

58. A large university, located in a Covered State, houses several diabetic students in its dormitories. These students are insulin-dependent and must perform daily glucose testing and as needed, insulin injections. Each student uses lancets and glucose test strips, in addition to an insulin syringe and a vial of insulin, on a daily basis. Are these wastes generated by the diabetic students considered regulated medical wastes under the Federal program?

Section 259.30(b)(1)(ii) excludes household wastes as defined in 261.4(b)(1) from Part 259 regulation. A household is defined by 40 CFR 261.4 as “single, multiple residences, hotels and motels, bunkhouses, ranger stations, crew quarters, campgrounds and day-use recreation areas. As a multiple residence, a dormitory would be considered a “household.” Medical waste generated by a student in the dormitory, would be considered household waste, and therefore would not be regulated. If, however, a student should administer insulin in another area of the university campus, such as the health clinic or gymnasium, the household exemption may not apply, and those materials would be subject to the Federal regulations.

59. Generators of RMW may choose to treat and destroy their medical waste on-site through incineration.

A. A large university hospital in a Covered State maintains and operates a large, on-site medical waste incinerator. The incinerator has capacity to treat and destroy all regulated medical waste generated

within the hospital. The facility currently maintains extensive records on the quantities and types of waste handled by its incinerator. What other types of information must the hospital record in order to fulfill Federal RCRA Subtitle J requirements?

Section 259.61(a) requires generators who incinerate their RMW on-site to maintain an operating log which includes the following information:

- 1) The date each incinerator cycle was begun;
- 2) The length of the incineration cycle;
- 3) The total quantity of medical waste incinerated, per incineration cycle; and
- 4) An estimate of the quantity of RMW incinerated, per incineration cycle.

The operating log must be retained through June 22, 1992. In addition to the operating log, Section 259.62 requires that all generators incinerating RMW on-site to submit two reports to the EPA describing the type of incinerator used, and the type and amount of waste treated. See Appendix II to Part 259.

B. The hospital noted in Question 60A has more incinerator capacity than is needed by the facility, the hospital plans to accept regulated medical waste from off-site generators, such as from other hospitals and private physicians not associated with the hospital. What additional record-keeping requirements would be necessary if the hospital accepts regulated medical waste from these outside sources?

Generators of RMW who incinerate their own RMW on-site and who accept regulated medical waste from other generators are required in Section 259.61(b) to maintain the following information on each shipment of RMW they accept:

- 1) The date the waste was accepted;
- 2) The name and state permit or identification number of the generator who originated the shipment; and if the state does not issue permits or identification numbers, the generators address;
- 3) The total weight of regulated medical waste accepted from the originating generator; and
- 4) The signature of the individual accepting the waste.

Under Section 259.60(b), generators of RMW who incinerate on-site and who accept RMW accompanied by a tracking form are also subject to the requirements of Subpart I. Under Section 259.61(c) generators accepting RMW 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.

C. Is the incinerator ash from the medical waste incinerator noted in Question 60A and B subject to the Part 259 regulations? If not, what other regulations might apply to the ash?

Section 259.30(b) (1) (iii) excludes ash from RMW incinerations from Part 259 regulation once the incineration process has been completed. Generators who treat and destroy their RMW on-site therefore are not subject to the tracking requirements for the ash generated from RMW incineration.

The generator must determine if the ash waste contains quantities of hazardous constituents which would make the ash subject to the Subtitle C regulations (See 55 FR 11798, March 29, 1990). If the waste does not contain hazardous constituents in concentrations which make it a hazardous waste, then the material could be disposed in a municipal landfill provided there are no state and local restrictions. Please contact the covered state to determine if any additional regulations apply.

60. Most generators in the Covered States produce less than 50 pounds of RMW per month. These generators often do not understand what Part 259 regulations apply to their health care activities.

A. A dentist located in a covered state generates less than 50 pounds of RMW per month. He wishes to utilize a local hospital's incinerator for treatment and destruction of the RMW.

What Part 259 regulations must the dentist comply with?

Generators of RMW are required to comply with Subpart E pre-transport requirements for RMW management which include waste segregation, packaging, storage, labeling, and marking. Generators of less than 50 pounds of RMW per month who transport or offer for transport, less than 50 pounds of RMW per month can qualify for specific exemptions found in Section 259.51. A generator of less than 50 pounds per month as noted in Section 259.51(a), is exempt from the requirement to use a transporter who has notified EPA, the tracking form, and exempt from the requirements of Subpart H (i.e., transporter) provided that he:

- 1) Transport the RMW to a health care facility, an intermediate handler or destination facility with which the generator has a written agreement to accept the RMW;
- 2) The RMW is transported by the generator in a vehicle owned by the generator or authorized employee; and

- 3) The generator compiles a shipment log and maintains records as required in Section 259.54 (b)(2).

The dentist must obtain a written agreement between himself and the hospital stating that the hospital is willing to accept and dispose of his RMW. The dentist need not secure transporter services for the waste, rather the dentist or one of his employees may transport properly-packaged, labeled and marked RMW in a vehicle owned either by himself or his employee.

B. A dentist in a covered state generates a small amount of RMW (i.e., less than 50 pounds) during a month. A company selling mail-in containers for shipment of RMW to treatment and/or disposal facilities calls on the dentist. Can the dentist utilize a “mail-in” disposal firm for treatment and destruction of these materials? What Part 259 regulations apply to the dentist and what should the dentist look out for?

The generator of less than 50 pounds per month can send certain types of RMW through the U.S. Postal Service. Section 259.51(c) indicates that Class 4 and Class 7 (Sharps) wastes can be shipped through the U.S. Postal Service, provided that the generator generates and transports or offers for transport off-site less than 50 pounds of RMW in a calendar month. These generators, however, are subject to the requirements of Part 259, Subpart E (i.e., segregation, packaging, storage, labeling and marking) of this part and Sections 259.50, 259.51 and 259.54(b) of Subpart F.

Generators who generate RMW and transport the waste through 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 return registered mail receipt as required by 259.54(b)(3).

C. The dentist who individually generates less than 50 pounds of RMW per month joins a partnership. The practice collectively generates in excess of 50 pounds of regulated medical waste per month. All RMW is disposed of collectively. May the dentist maintain his small quantity generator's exemption?

No, if the practitioners in the partnership generate more than 50 pounds of RMW per month collectively, the partnership would be subject to all the requirements of subpart E and F of Part 259 for managing RMW.

61. Small quantity generators often send shipments of Class 4 and Class 7 RMW through the U.S. Postal Service to a destination facility for disposal. Sometimes these shipments are sent to collection points prior to actual shipment to a treatment or destination facility. What regulations apply to these collection facilities?

Facilities who accept RMW through the mail for storage and/or collection prior to shipment to an intermediate handler or destination facility act as a transfer facility. Section 259.10(a) defines a transfer facility as “any transportation-related facility including loading docks, parking areas, storage areas and other similar areas where shipments of RMW are held (come to rest or are managed) during the course of transportation. For example a location at which RMW is transferred directly between two vehicles is considered a transfer facility. A transfer facility is a ‘transporter.’ ” These facilities which collect and/or store RMW which has been shipped through the mail are subject to Part 259, Subpart H transporter requirements and must notify EPA and the State of their intent to transport RMW.

The transfer facility must also comply with Subpart E of Part 259 if it: stores the RMW in the course of transport; removes RMW from reusable container; or modifies the packaging of the RMW. Additionally, transfer facilities must complete the required transporter report forms found in Appendix III of Part 259.

Transfer facilities who subsequently transport or offers for transport RMW which has been received through the U.S. Postal Service, must initiate a tracking form as required by Section 259.52(a).

62. During the provision of medical treatment a dentist extracts several teeth from a young child. The child asks to take the extracted teeth home in order to place them under his pillow for a visit from the toothfairy. Is the dentist precluded by the Part 259 regulations from allowing the young child to take the extracted teeth home?

No; The Part 259 regulations apply to “solid wastes” generated during the provision of medical care as defined under Section 1004 of RCRA. Section 1004 generally defines a solid waste as any discarded material. Since the extracted tooth is not being discarded by the dentist in this situation it would not be a solid waste, and thus not RMW. However, in situations where

extracted teeth are discarded by the dentist as a waste they would be considered a Class 2 RMW.

In this scenario, the extracted tooth would not be discarded by the dentist as a “solid waste” and thus would not be a RMW. The child wishes to take the tooth home as a “prize,” to be placed under his/her pillow, therefore the tooth is not being discarded and has a further use.

63. Treated regulated medical waste is defined in Part 259 regulations as “RMW that has been treated to substantially reduce or eliminates its potential for causing disease, but has not yet been destroyed.” What treatment technologies can be used to meet this requirement?

The Part 259 regulation does not list or include accepted treatment technologies or methods for RMW. Section 259.10(a) defines treatment, when used in the context of medical waste management, as “any method, technique, or process designed to change the biological character or composition of any RMW so as to reduce or eliminate its potential for causing disease.” “Treated” RMW must have disease-causing potential substantially reduced. This performance standard was used to provide the health-care provider with the maximum flexibility to meet the Part 259 regulations.

Sections 11008(a)(6) and (7) of the Medical Waste Tracking Act (MWTa) requires the EPA to evaluate the effectiveness of the available and potentially available medical waste treatment technologies including autoclaving, chemical disinfection, incineration, irradiation and microwaving. These studies will help to identify the effectiveness, as well as the advantages and disadvantages of these treatment technologies. This information may assist EPA in providing additional guidance to health-care providers concerning the most appropriate treatment technology for their waste stream characteristics.

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