UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

July 14, 2023

OFFICE OF
LAND AND EMERGENCY
MANAGEMENT

COVERSHEET: THIS POLICY DOCUMENT HAS BEEN FULLY SUPERSEDED

This coversheet serves as a notification that the attached policy document, RCRA Online memorandum #11483, has been **fully superseded** and provides an explanation.

The entirety of this policy document is no longer in effect.

This December 26, 1989, memorandum discusses provisions of the regulations implementing the Medical Waste Tracking Act, which expired in 1991. See the June 29, 1995, Federal Register notice that removed the regulations implementing the Medical Waste Tracking Act from 40 CFR part 259 (60 FR 33912).

Jessica B. Young

JESSICA YOUNG Digitally signed by JESSICA YOUNG Date: 2023.07.14 16:26:53 -04'00'

Jessica Young
Chief of the Recycling and Generator Branch
Materials Recovery and Waste Management Division
Office of Resource Conservation and Recovery

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

DECEMBER 26, 1989

MEMORANDUM

SUBJECT: Interpretations of the EPA Medical Waste Regulations (Numbers 24-35)

FROM: Devereaux Barnes, 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 fourth 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) 475-7736, or Mary Jean Osborne on (202) 382-7948.

Attachment

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.

24. The sheath can be pulled down over a hypodermic needle after use to prevent the possibility of needle stick injuries. Certain manufacturers of hypodermic needles and syringes are now designing and fabricating these items with an integral resheathing capability. Generators of sharps are required to package sharps and sharps with residual fluids in packaging which is puncture resistant (40 CFR 259.41(b)(l)). Are such hypodermic needles and syringes considered to be puncture resistant once resheathed in such a manner?

    Yes, syringes which have been resheathed with an integral sheath generally would meet the puncture-resistant criteria set out in 40 CFR 259.41 (b)(l). However, generators of sharps and sharps with residual fluids must ensure that regulated medical waste, prior to transport or offering for transport off-site, is packaged in containers that meet the requirements of Section 259.41(a) and (b)(2), 259.44 and 259.45. Thus, additional packaging materials may be needed to satisfy the other packaging requirements (e.g., leak-resistance).

25. Compaction of regulated medical waste has been interpreted as being an acceptable practice according to a recent interpretation by USEPA (See Interpretation #7 on pages 4-5 of EPA's July, 1989 memorandum). Please comment on and clarify this interpretation.

    Transporters of regulated medical waste are required in Section 259.73(a)(2) to ensure that the waste is not subject to mechanical stress or compaction while being unloaded or off-loaded from the transport vehicle or during transit. “Transport” includes loading, unloading, and actual transit.

    In the July, 1989 Question and Answer document, interpretation #7 addresses a specific technology in which regulated medical waste is compacted while being loaded into a transport container. The regulations do not prohibit compaction of medical waste prior to or during packaging procedures for off-site transport. Compaction procedures may actually reduce the volume of medical waste to be transported. However, compaction of regulated medical waste during transport is prohibited (Section 259.73(a)(2)).

26. The description of Class 1 regulated medical waste found at 40 CFR 259.30(a) includes cultures from medical and pathological laboratories; and cultures and stocks of infectious agents from research and industrial laboratories.

A. Does this mean stocks of infectious agents from medical and pathological laboratories are not included in this waste class?

Class 1 regulated medical waste includes cultures and stocks of infectious agents and associated biologicals from all medical, pathological, research and industrial laboratories that are generated in the diagnosis, treatment and immunization of human beings or animals, in research pertaining thereto, or in the production or testing of biologicals. The description of Class 1 wastes in Section 259.30(a) provides examples of the items which would be considered regulated medical waste.

B. Are cultures from medical and pathological laboratories which are usually considered "non-pathogenic" included in this waste class?

An "infectious agent" as defined in Section 259.10(b) is 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. The ability of an organism to cause disease or adverse health impacts (i.e. to be "pathogenic") is, of course, dependent on many factors including the susceptibility of the host, specific characteristics of the organism and the route of transmission of the agent to the host. Those organisms found in Classes 2 through 4 of the CDC's Classification of Etiologic Agents as the Basis of Hazard (July 1974) would be included; however this does not mean that infectious agents not included on this list are not regulated.

Considering all the variables that must be evaluated, the classification of an organism as "pathogenic" or "non-pathogenic" is difficult. Generally all cultures from medical and pathological laboratories are considered regulated medical waste because they are covered in the Class 1 or Class 4 waste class descriptions in Section 259.30(a). Therefore, virtually any culture or stock is subject to requirements for regulated medical waste.

27. Most transporters supply their clients (the generator) with tracking forms that are pre-printed with the transporter name, address, EPA ID no., State ID No., phone number and destination facility information. Is that transporter "initiating" the tracking form?"

No, in this case the generator is still the initiator of the tracking form as required in 40 CFR 259.52(a); in all cases, the generator ultimately is responsible for the accuracy of the information that is required to be completed on the form before the generator signs in Box 15. However, a transfer facility or transporter may also initiate tracking forms when waste shipments are consolidated or remanifested as noted in Section 259.76.

28. What regulations apply to transporters of regulated medical waste who are based in a non-covered state and are there any special requirements for transporters of regulated medical waste to a foreign country?

Transporters of regulated medical waste generated in a covered state must meet all the requirement of 40 CFR Part 259 Subpart H. These requirements apply regardless of the location of the transporter's base of operation.

Regulations for delivery of regulated medical waste outside the United States are found in Section 259.74(e). Transporters of regulated medical waste who cross any international border, or who deliver regulated medical waste to a transporter, destruction or destination facility located in a foreign country, must sign the tracking form and verify the waste has been delivered to the next transporter, treatment, destruction or destination facility, retain a copy of the signed tracking form for his records, and return all remaining copies of the tracking form by mail to the generator.

29. When regulated medical waste is transported between facilities owned by the same generator, who is responsible for marking and labeling the regulated medical waste: the personnel at the satellite facility (original generation point) prior to transportation to the central collection point or the central collection point personnel who will be offering the waste for transport to a destination facility?

In Part 259 a generator is defined as any person, by site, whose act or process produces regulated medical waste, or whose first act causes a regulated medical waste to become subject to regulation. In accordance with Section 259.51(b), generators are exempt from: the requirements to use a transporter who has notified EPA, the use of the tracking form, and the requirements of Subpart H when transporting regulated medical waste from the original generation point to a central collection point provided that the generator meets the requirements specified in Section 259.51 (b)(l-4). However, Section 259.51(b) does not exempt the generator at the original generation point from compliance with all the pre-transport requirements in Subpart E, including Sections 259.44 and 259.45, which require proper labeling and marking of regulated medical waste prior to transport (or offer for transport) off-site.

Section 259.39 specifies the applicability of the Subpart E pre-transport requirements, and states that "generators must comply with the requirements of this subpart prior to shipping waste off-site..." Generators would only use the Section 259.51(b) exemption for off-site transportation; therefore, before moving the waste from the original generation point, off-site to the central collection point, the regulated medical waste must be properly packaged, labeled and marked at the original generation point. Once the waste is at the central collection point,

the generator does not need to provide additional labeling and marking before shipping the waste off-site again to another location.

Note, however, that if the generator treats the regulated medical waste at the central collection point, the labeling must be altered to reflect the fact that waste has been treated.

30. What is an acceptable length of time for storage of regulated medical waste and is storage of regulated medical waste allowed at transfer facilities?

The length of time allowed for storage of regulated medical waste prior to transport or disposal of the waste is not specifically stipulated within the 40 CFR Part 259 regulations. However, storage time may be affected by the ability of the waste handler to meet the regulations in Section 259.42. The storage requirements found in Section 259.42 require the generator (or any RMW handler) to store regulated medical waste in a manner and location which maintains the integrity of the packaging and provides protection from water, rain and wind, maintains the waste in a non-putrescent state (using refrigeration when necessary), limits access to the waste, affords protection from animals and does not provide a breeding place for insects and rodents.

Storage time may also be constrained, as a practical matter, for generators wishing to take advantage of the reduced requirements for generators of less than 50 pounds per month. Generators of less than 50 pounds of regulated medical waste per month, who transport or offer for transport off-site more than 50 pounds in any one shipment are subject to the regulations found in Subparts E and F for each shipment of 50 pounds or more (Section 259.50(e)(ii)). Therefore, the exemption found at Section 259.51(a) would only apply to those generators who generate and transport off-site less than 50 pounds of regulated medical waste per month. This criteria could affect the length of time a generator would accumulate regulated medical waste prior to shipment.

There is no prohibition of RMW storage at transfer facilities. However, owners and operators of transfer facilities and transporters of regulated medical waste must comply with the requirements of Subpart E if they store regulated medical waste in the course of transport.

31. Hazardous waste as defined in 40 CFR Part 261 is mixed with regulated medical waste generated at a facility within a covered state. The mixture of wastes is then sent to an on-site incinerator for treatment. Is the waste mixture regulated under Subtitle C of RCRA and/or the medical waste regulations prior to incineration?

The mixture of medical waste and hazardous waste listed in Part 261 is regulated under the RCRA Subtitle C (hazardous waste) rules, but it is also subject to Part 259 if the waste is not subject to the manifesting rules under Subtitle C. For example, if the hazardous waste generated by the facility which is exempt from the hazardous waste manifest regulations because the generator is classified as a conditionally exempt small quantity generator, then the mixture of

regulated medical waste and hazardous waste would be regulated under Part 259 (as well as any applicable Subtitle C regulations). If the generator is not exempt from tracking hazardous waste shipments and mixes hazardous waste with regulated medical waste, then the mixture would be subject to regulations under RCRA Subtitle C (See Section 259.31), and not Part 259.

32. What regulations apply to regulated medical waste which contains radioactive wastes?

Specific waste streams may contain materials which are source, special nuclear, or by-product materials as defined in the Atomic Energy Act and that also contain material which meet the definition of regulated medical waste as defined in 40 CFR Part 259. These wastes are subject to regulation under both laws. However, if one law has similar requirements which are more stringent, these requirements supersede the less stringent. Additionally, Part 259 has requirements which supplement those required by NRC. See the discussion of applicability of U.S. Nuclear Regulatory Commission requirements and the Part 259 regulations in the preamble to the rule (54 FR 12362-63, March 24, 1989).

33. Residues from treatment and destruction processes are no longer subject to the tracking requirements in 40 CFR Part 259 once the waste has been both treated and destroyed (Section 259.30(b)(1)(iv)). What procedures are used to meet this criteria?

Treated regulated medical waste means regulated medical waste that has been treated to substantially reduce or eliminate its potential for causing disease, but has not been destroyed as noted in 40 CFR 259.10. There are a number of treatment methods which can be utilized to treat medical waste including autoclaving, chemical disinfection and incineration. It is important to note that EPA has not promulgated requirements or standards for any form of treatment prior to disposal.

Destroyed regulated medical waste is 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 compaction does not meet the criteria set out for destruction of regulated medical waste.

Note: Incineration will meet both the treatment and destruction criteria and ash from incineration of regulated medical waste is not regulated medical waste once the incineration process has been completed (See Section 259.30(b)(1)(iii)).

34. Animals suspected of being infected with a zoonotic disease such as rabies are usually isolated to protect humans and other animals. Veterinarians are often called upon to sacrifice the animal and obtain specimens of brain and spinal cord tissues for diagnosis of this disease. Are the animal carcass and tissues regulated medical waste?

A regulated medical waste includes any solid waste generated in the diagnosis, treatment or immunization of human beings or animals listed in Section 259.30(a). While the transportation of a specimen, i.e., animal carcass of body part, to a laboratory for diagnosis would not be regulated under the medical waste demonstration program, upon disposal, the animal carcass and tissues would be considered Class 6 regulated medical waste. In addition, other types of regulated medical waste may be generated during the course of treatment and diagnosis of this disease which may fall into other waste classes listed in Part 259.30(a).

35. The transporter vehicle requirements at 40 CFR Part 259.73 require the use of a "fully enclosed, leak-resistant cargo-carrying body." Would vehicles such as a van, in which the driver's compartment is accessible from the cargo area, meet this requirement?

The intent of the requirement for a transporter to provide a "fully enclosed cargo carrying body" for transportation of RMW was to prevent the waste from being exposed to the elements which could result in the deterioration of the packaging, to provide adequate security, and to lower the likelihood the waste would become dispersed if the vehicle was involved in an accident.

The regulations do not specify whether the driver's compartment must be separated from the cargo-carrying body. However, the regulations at Section 259.73 do require the transporter: to ensure the waste is not subject to mechanical stress or compaction during loading and unloading, or during transit; to maintain the vehicle in good sanitary condition; to secure the vehicle when unattended; to provide proper identification on the outside of the vehicle; and to avoid transporting regulated medical waste in the same container with other solid waste unless the transporter manages both as regulated medical waste. Thus, if the van met the requirements outlined in Section 259.73, it could be used to transport regulated medical waste.