

CHAPTER 2

MEDICAL WASTE REGULATIONS

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OVERVIEW

During the summer of 1988, syringes and other used medical materials washed up on beaches along the Atlantic seaboard. In response to public concern about this problem, Congress enacted the Medical Waste Tracking Act in November 1988, which added medical waste tracking provisions in RCRA Subtitle J. The Medical Waste Tracking Act directed EPA to establish a two-year demonstration program for the tracking and management of medical waste. Under this statutory authority, EPA codified regulations in 40 CFR Part 259 identifying the medical wastes to be tracked and creating management standards for handlers of medical waste. The States of Connecticut, New Jersey, New York, Rhode Island, and the Commonwealth of

Puerto Rico all participated in the two-year tracking program. For purposes of this program, they were known as **covered states**. This demonstration program began June 22, 1989, and ended June 22, 1991. Currently, the program is expired and no federal medical waste tracking and management regulations are in effect. As a result, the provisions in Part 259 have been removed from the CFR. States, however, have become active in managing medical waste and a majority have developed programs similar to the federal model. This chapter will discuss what was considered medical waste under the two-year demonstration program.

WHAT WAS MEDICAL WASTE?

Medical waste included:

- Cultures and stocks of infectious agents
- Human pathological wastes (e.g., tissues, body parts)
- Human blood and blood products
- Used sharps (e.g., hypodermic needles and syringes used in animal or human patient care)
- Certain animal wastes
- Certain isolation wastes (e.g., wastes from patients with highly communicable diseases)
- Unused sharps (e.g., suture needles, scalpel blades, hypodermic needles).

For purposes of the demonstration program, the definition of medical waste excluded household waste. In addition, residues from treatment and destruction processes, or from the incineration of regulated medical wastes, were not considered medical waste, nor were human remains intended to be buried or cremated. Etiologic agents (i.e., infectious substances) being shipped pursuant to other federal regulations, and samples of medical waste that were shipped for enforcement purposes were exempt from the 40 CFR Part 259 requirements.

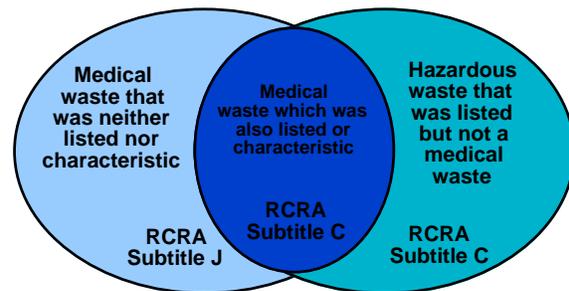
MEDICAL WASTE VS. HAZARDOUS WASTE

Because medical wastes met the RCRA regulatory definition of solid waste, these wastes were also subject to the Subtitle C hazardous waste characterization. In other words, once a facility identified a waste as a medical waste, it then had to determine if this waste was also listed or characteristic. (The hazardous waste identification process is fully discussed in Section III, Chapter 1.) If medical waste was a hazardous waste, it was subject to the Subtitle C hazardous waste requirements. When the Subtitle J medical waste tracking standards were in place, such hazardous medical wastes were excluded from the tracking requirements and were subject to those requirements in RCRA Subtitle C (see Figure V-3).

THE DEMONSTRATION PROGRAM

The medical waste tracking demonstration program set up provisions for tracking medical waste from the generator to the disposal site, similar to Subtitle C's hazardous waste manifest system. The program was designed to ensure proper handling, tracking, and disposal of medical waste. The system required that a tracking form accompany the waste and a signed copy be retained by the generator, each transporter, transfer station, and the treatment, destruction, and disposal facility that handled the waste. When the final disposal facility accepted the waste, a copy of the signed tracking form was returned to the generator. Through this process, the generator was assured that the waste

Figure V-3: Medical Waste vs. Hazardous Waste



If medical waste was neither listed nor characteristic, it was subject to regulation as medical waste under RCRA Subtitle J. If medical waste was also listed or characteristic, it was subject to regulation as hazardous waste under RCRA Subtitle C.

was actually received for disposal. The tracking program also included exception and discrepancy reporting to alert EPA and the states if wastes were not being handled properly.

To minimize contact with medical wastes by workers, handlers, and the public, the program also included specific requirements for segregation, packaging, labeling, marking, and storing of medical wastes before they were shipped to another site for treatment, destruction, or disposal.

The demonstration program focused on three groups of medical waste handlers:

- Generators
- Transporters
- Treatment, destruction, and disposal facilities.

■ Generators

A medical waste **generator** was any person whose act or processes produced medical waste or caused medical waste to become subject to regulation. These tracking provisions applied to persons or facilities that generated 50 pounds or more of medical waste in a month and shipped such waste off site. These generators were required to separate, package, label, mark, and track medical wastes according to the regulations. Generators

producing and shipping less than 50 pounds a month were required to prepare their wastes properly for shipment, but could use a log to account for wastes instead of a tracking form.

With the exception of medical waste burned in on-site incinerators, generators who disposed of medical wastes on site or in a sewer system were not covered by the requirements of this program. Similarly, wastes that were treated and destroyed or disposed of on site or in sewers were not counted as part of the 50-pound monthly total. Generators burning waste in on-site incinerators were required to report the volume of waste burned. All medical wastes, even those that were to be treated, destroyed, and disposed of on site, were required to be stored properly.

These provisions applied to medical wastes generated by federal facilities in covered states. These provisions also applied to ships and ocean vessels that brought medical wastes to shore by docking in a covered state.

■ Transporters

A medical waste **transporter** was any person engaged in the off-site transportation of medical waste by air, rail, highway, or water. Transporters were required to notify EPA of their intent to comply with the tracking program before they could accept medical waste for transport. Transporters were required to follow rules governing the transport, tracking, recordkeeping, and reporting of waste shipments. They were also required to make sure that the wastes they accepted for transport had been properly prepared for shipping and that the tracking form was accurate.

■ Treatment, Destruction, and Disposal Facilities

Treatment facilities were facilities that changed the biological character or composition of medical waste to substantially reduce or eliminate its potential for causing disease. Destruction facilities were facilities that destroyed medical waste by mutilating it, or tearing it apart to render it less infectious and unrecognizable as medical waste.

Once medical waste was properly treated and destroyed, it no longer needed to be tracked. These treatment and destruction facilities included incinerators and treatment operations that ground, steam-sterilized, or treated the waste with disinfectants, heat, or radiation. Disposal facilities were facilities where medical waste was placed in or on the land (e.g., landfills).

The demonstration program did not regulate the operation of these treatment, destruction, and disposal processes, but rather required tracking from generation to disposal and recordkeeping. When the wastes were accepted for disposal, these facilities had to send a signed copy of the tracking form back to the generator or initiator of the tracking form. The facility owners and operators were required to investigate any discrepancies between the accompanying papers and the shipments they received. If after investigation there was still a discrepancy, they were required to report to EPA and the generator's state agency. Once treated and destroyed, however, such wastes were no longer subject to the tracking requirements.

INTERSTATE SHIPMENTS

While only the States of Connecticut, New Jersey, New York, Rhode Island, and the Commonwealth of Puerto Rico participated in the tracking program, the medical waste tracking provisions also applied when shipments originating in these covered states were transported to states that did not participate in the program.

According to the provisions of the tracking program, if medical waste was generated in a covered state, any subsequent handling by a transporter or treatment, destruction, and disposal

SHIPMENTS TO STATES NOT PARTICIPATING IN THE DEMONSTRATION PROGRAM

While only the Commonwealth of Puerto Rico and the States of Connecticut, New Jersey, New York, and Rhode Island participated in the tracking program, the medical waste tracking provisions also applied when shipments originating in these covered states were transported to states that did not participate in the program.

facility in that state, another covered state, or a noncovered state was subject to the tracking provisions. For example, if a medical waste was generated in New Jersey (a covered state) and transported by truck to Pennsylvania (a noncovered state) for treatment and disposal, the waste would still be subject to the medical waste tracking provisions since the waste was originally generated in a covered state.

REPORTS TO CONGRESS

The Medical Waste Tracking Act also required EPA to submit two interim reports and a final report on medical waste management and the demonstration program to Congress. The information gathered during the demonstration program was used to determine whether such a program should be extended nationwide and what other options are available for medical waste management.

The first and second interim reports were released in 1990; the final report is still under development.



CURRENT REQUIREMENTS

While medical waste is not regulated under the current federal RCRA regulations, there are federal requirements for medical waste under CAA and FIFRA.

In 1997, under CAA, EPA established new source performance standards (NSPS) and emissions guidelines to reduce air emissions from new and existing hospital, infectious, and medical waste incinerators. These guidelines also established standards for incinerator operator training and qualification, equipment inspections, and siting. EPA estimates that there are approximately 2,400 such incinerators in operation in the United States that combust medical and infectious waste annually.

Under FIFRA, antimicrobial pesticides and disinfectants used in medical waste treatment technologies must be registered with EPA.

SUMMARY

Congress enacted the Medical Waste Tracking Act in November 1988, which added medical waste tracking provisions to RCRA Subtitle J. The Act directed EPA to establish a two-year demonstration program for the tracking of medical waste. The States of Connecticut, New Jersey, New York, Rhode Island, and the Commonwealth of Puerto Rico all participated in the tracking program. This demonstration program began June 22, 1989, and ended June 22, 1991. Currently, the program is expired and no federal tracking regulations are in effect. States, however, have become active in managing medical waste and many have developed programs similar to the federal model.

Medical wastes included:

- Cultures and stocks of infectious agents
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The medical waste demonstration program set up provisions for tracking the waste from the generator to the disposal site, similar to Subtitle C's hazardous waste manifest system.

The demonstration program focused on three groups of medical waste handlers:

- Generators
- Transporters
- Treatment, destruction, and disposal facilities.

The medical waste tracking provisions also applied when shipments originating in states covered by the program were transported to states that did not participate in the program.

The Medical Waste Tracking Act also required EPA to submit two interim reports and a final report on medical waste management and the demonstration program to Congress. The first and second interim reports were released in 1990, the final report is still under development.

While medical waste is not regulated under the current federal RCRA regulations, there are federal requirements for medical waste under CAA for medical waste incinerators and under FIFRA for

pesticides and disinfectants used in medical waste treatment technologies.

ADDITIONAL RESOURCES

Additional information about medical waste regulations can be found at www.epa.gov/epaoswer/other/medical/index.htm.