

US EPA ARCHIVE DOCUMENT

significantly reduce medical waste wash-ups.

### *B. Regulatory Flexibility Act*

In sections 11002 and 11003 of RCRA, Congress set a six-month deadline for EPA to promulgate regulations listing the types of medical waste to be tracked and establishing segregation, packaging, labeling, and tracking requirements. Section 11010 gives EPA specific authority to promulgate today's regulations without prior opportunity for public comment. EPA has determined that the time constraints established by the statute make it impracticable to propose the regulations and accept public comments before promulgation of the rule.

Because the Agency is not required to publish a proposal for public comment in connection with today's rule, this rulemaking is not subject to the Regulatory Flexibility Act (see 5 U.S.C. 603 and 604). Accordingly, no Regulatory Flexibility Analysis has been prepared for this rule, although future rulemakings under RCRA Subtitle J may require such an analysis. Also, section 11008(a)(3)(B) requires EPA to report to the Congress on the costs to businesses to comply with the tracking program. To the extent practical, EPA plans to assess, in particular, costs to small businesses affected by the rules in the reports required by section 11008.

### *C. Paperwork Reduction Act*

Section 11010 of RCRA states that the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.*, does not apply to regulations required to be promulgated within nine months of Subtitle J's enactment. Thus, the recordkeeping and reporting requirements contained in today's rule are not subject to approval by the Office of Management and Budget. However, EPA has adhered to a policy of minimizing the reporting requirements in today's rule to the extent possible consistent with statutory requirements. For instance, where EPA is requiring information to help develop the section 11008 reports to Congress (i.e., the transporter periodic reports and the expanded incinerator report), EPA is requiring these reports from transporters because that is the most efficient way to obtain the information Congress requires. EPA also has developed special exemptions for generators of less than 50 pounds per month under which they need not initiate tracking forms for each shipment; instead they must maintain a log (see Part 259, Subpart F, and Section V of today's Preamble).

## List of Subjects

### 40 CFR Part 22

Administrative practice and procedure, Penalties.

### 40 CFR Part 259

Medical waste, Labeling, Packaging and containers, Reporting and recordkeeping requirements, Tracking, Incinerators.

Dated: March 13, 1989.

William K. Reilly,  
Administrator.

For the reasons set out in the preamble, Title 40 of the Code of Federal Regulations is amended as follows:

## **PART 22—CONSOLIDATED RULES OF PRACTICE GOVERNING THE ADMINISTRATIVE ASSESSMENT OF CIVIL PENALTIES AND THE REVOCATION OR SUSPENSION OF PERMITS.**

1. The authority citation for Part 22 is revised to read as follows:

Authority: 15 U.S.C. sec. 2615; 42 U.S.C. secs. 7545 and 7601; 7 U.S.C. secs. 136(l) and (m); 33 U.S.C. secs. 1415 and 1418; 42 U.S.C. secs. 6912, 6928, 6991(e), and 6992(d);

2. Section 22.01 is amended by revising paragraph (a)(4) to read as follows:

### **§ 22.01 Scope of these rules.**

(a) \* \* \*

(4) The issuance of a compliance order or the issuance of a corrective action order, the suspension or revocation of authority to operate pursuant to section 3005(e) of the Solid Waste Disposal Act, or the assessment of any civil penalty under sections 3008, 9008 and 11005 of the Solid Waste Disposal Act, as amended (42 U.S.C. 6928, 6991(e) and 6992(d)), except as provided in 40 CFR Parts 24 and 124.

3. A new Part 259 is added to read as follows:

## **PART 259—STANDARDS FOR THE TRACKING AND MANAGEMENT OF MEDICAL WASTE**

### **Subpart A—General**

Sec.

259.1 Purpose, scope, and applicability.

259.2 Effective dates and duration of the demonstration program.

### **Subpart B—Definitions**

259.10 Definitions.

### **Subpart C—Covered States**

259.20 States included in the demonstration program.

259.21 States electing not to participate.

259.22 States electing to participate.

Sec.

259.23 Notice of participating States.

### **Subpart D—Regulated Medical Waste**

259.30 Definition of regulated medical waste.

259.31 Mixtures.

### **Subpart E—Pre-Transport Requirements**

259.39 Applicability.

259.40 Segregation requirements.

259.41 Packaging requirements.

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

259.43 Decontamination standards for reusable containers.

259.44 Labeling requirements.

259.45 Marking (identification) requirements.

### **Subpart F—Generator Standards**

259.50 Applicability and general requirements.

259.51 Exemptions.

259.52 Use of the tracking form.

259.53 Generators exporting regulated medical waste.

259.54 Recordkeeping.

259.55 Exception reporting.

259.56—Additional reporting.

### **Subpart G—On-Site Incinerators**

259.60 Applicability.

259.61 Recordkeeping.

259.62 Reporting.

### **Subpart H—Transporter Requirements**

259.70 Applicability.

259.71 Transporter acceptance of regulated medical waste.

259.72 Transporter notification.

259.73 Vehicle requirements.

259.74 Tracking form requirements.

259.75 Compliance with the tracking form.

259.76 Consolidating or remanifesting waste to a new tracking form.

259.77 Recordkeeping.

259.78 Reporting.

259.79 Additional reporting.

### **Subpart I—Treatment, Destruction, and Disposal Facilities**

259.80 Applicability.

259.81 Use of the tracking form.

259.82 Tracking form discrepancies.

259.83 Recordkeeping.

259.84 Additional reporting.

### **Subpart J—Rail Shipments of Regulated Medical Waste**

259.90 Applicability.

259.91 Rail shipment tracking form requirements.

Appendix I to 40 CFR Part 259 Medical Waste Tracking Form and Instructions

Appendix II to 40 CFR Part 259 On-site Incinerator Report Form and Instructions

Appendix III to 40 CFR Part 259 Transporter Report and Instructions

Appendix IV to 40 CFR Part 259

Recommended Medical Waste Transporter Notification Form and Instructions

Authority: 42 U.S.C. 6912, 6992 *et seq.*