landfills (53 FR 33314, August 30, 1988). These proposed revisions, if adopted, would establish specific requirements applicable to all municipal solid waste landfill facilities. These requirements include setting design goals for protecting groundwater, groundwater monitoring and corrective action, closure and post-closure care, and financial responsibility.

The responsibility for implementing the Subtitle D regulations traditionally has fallen upon the States, which are required to establish solid waste programs that meet the Federal criteria. Many States, however, have gone well beyond the Federal criteria in regulating solid waste management facilities. Additionally, the number of States that regulate medical waste is increasing; all of the States mentioned in Subtitle J either have such regulations in place or have indicated they will soon regulate medical waste. These regulations typically are comprehensive, including requirements for treatment of the waste (often specifying sterilization or incineration) prior to disposal, and for permitting the solid waste disposal facilities. Today's rule is intended to complement these State programs in providing for the effective management of medical waste.

Finally, in the MWTA Congress has expressed serious interest in the treatment and disposal of medical waste. The Act requires that the Agency report to Congress on current disposal methods and requirements, as well as on available treatment and disposal methods, and on the health impacts and costs of current and alternative methods. The requirements of this Subpart are intended to provide some of the information necessary to develop such reports. The Agency requests that commenters submit available information on alternative treatment and destruction technologies, as well as on disposal technologies. EPA will use any information provided to develop, a model State medical waste progran.

J. Subpart J—Rail Shipments of Regulated Medical Waste (Section 259.90)

Subpart J of today's rule establishes the procedures for handling the tracking form and recordkeeping requirements that rail carriers of regulated medical waste must follow. The requirements are identical to those established under Subtitle C of RCRA for rail carriers. The Agency believes that the unique operational characteristics of the rail industry necessitate that rail carriers be subject to somewhat different tracking and recordkeeping requirements than those that apply to other transporters of regulated medical waste.

Under today's rule, as under the hazardous waste regulations, rail transporters may, under certain conditions, move regulated medical waste without actually carrying the tracking form (i.e., it can be sent ahead by mail). Also, shipments may be transferred between two rail transporters without obtaining the accepting transporter's (rail carrier's) signature, if so directed on the manifest or tracking form. EPA explained the necessity and basis for these special provisions on February 26, 1980, for hazardous waste transporters (45 FR 12739), and the Agency believes similar provisions are appropriate for regulated medical waste when it is transported by rail.

VI. Relationship to Other EPA Programs

The regulations promulgated today for the medical waste tracking program are required by amendments to the Resource Conservation and Recovery Act (RCRA), one of several laws that EPA administers. Below is a discussion of other EPA programs that are related to the medical waste tracking program promulgated today.

A. Other Subtitles of RCRA

1. Subtitle C—Hazardous Waste Management

The definition of "medical waste" found in RCRA section 1004(40) specifically excludes hazardous waste identified or listed under Subtitle C of that act. The implementing regulations at 40 CFR Part 261 identify characteristics of hazardous waste and list specific hazardous wastes. A generator of a solid waste (which can be solid, semisolid, liquid, or contained gaseous waste) must determine if the waste is hazardous under the Part 261 regulations. If the waste is a listed or characteristic hazardous waste as generated, it is not subject to regulation under the Part 259 regulations. In making this determination, the generator must use the Federal regulations defining hazardous waste. If the waste is not hazardous under Federal regulations, the generator proceeds to determine whether the waste is regulated medical waste.

The hazardous waste programs in some States cover a broader universe of wastes than the Federal program. The wastes that are regulated as hazardous by certain States, but not by the Federal program, may also be regulated medical wastes, because the "hazardous waste" exclusion in section 1004(40) refers to Federally-regulated hazardous waste.

In the case of mixtures of medical waste and hazardous waste identified or listed in Part 261, if the mixture is subject to the hazardous waste manifest requirements, it is exempt from the medical waste tracking requirements. Duplicative manifesting is unnecessary and inconsistent with Congressional intent, given the exclusion of hazardous waste from the definition of "medical waste." However, hazardous waste that is exempted from the RCRA Subtitle C manifest requirements does not present the problem of duplicative tracking when it is mixed with regulated medical waste. Therefore, if the mixture of regulated medical waste and hazardous waste is not required to be tracked under the Subtitle C rules, it must be managed and tracked as regulated medical waste. For example, if a hazardous waste is exempt from regulation because it is generated by a conditionally exempt small quantity generator (40 CFR 261.5) but is mixed with a regulated medical waste, then the entire quantity of waste must be handled as regulated medical waste.

Certain cytotoxic agents, including the following, are covered under RCRA Subtitle C hazardous waste regulations: Cyclophosphamide (also known as Cytoxin) (U058); Daunomycin (U059); Melphalan (U150); Mitomycin C (U010); Streptozotocin (U206); and Uracil Mustard (U237). The Agency will determine in further study and evaluation whether additional cytotoxins should be regulated under Subtitle C. The Agency requests comment from the regulated community regarding the proper management of cytotoxic and antineoplastic drugs.

Residues from the treatment of medical wastes may become hazardous wastes. For example, incineration reduces the volume of a waste, and the volume reduction may cause a concentration of metal constituents. Thus, it is possible that a medical waste regulated under Part 259 could become a hazardous waste if incinerated, and the resulting ash would be required to be managed as a hazardous waste under Subtitle C (40 CFR Parts 260 through 272).

Also, the reader may note several parallels between the Subtitle C (hazardous waste) and Subtitle J (medical waste) regulatory programs. However, differences in statutory language and Congressional intent have resulted in a program for medical waste that is different from the hazardous waste program. Section IV of this Preamble details the differences between the hazardous waste manifest and the medical waste tracking form.

Some examples of the differences identified in section V of this Preamble are the use of forms, and the various definitions for transportation and treatment.

Finally, under section 11010(c), EPA retains authority to list medical wastes under RCRA section 3001, if necessary. Available data do not suggest that such a listing is warranted. The Agency will reconsider this decision after collection of additional information over the next 2 years during the development of the interim and final reports on medical waste required for submission to Congress.

2. Subtitle D—State or Regional Solid Waste Plans

Subtitle D of RCRA contains objectives for environmentally sound nonhazardous solid waste resource recovery and disposal methods. To satisfy one of these objectives, EPA has promulgated criteria for determining which land disposal facilities are sanitary landfills (40 CFR Part 257). Thus, solid waste disposal at a facility meeting the sanitary landfill criteria poses no reasonable probability of adverse effects on human health or the environment.

Medical wastes regulated under Part 259 may be disposed in facilities that meet the sanitary landfill criteria, subject to State or local restrictions on such disposal. EPA has not promulgated requirements for any form of treatment (such as autoclaving or incineration) prior to land disposal; however, a State or locality may enact such treatment requirements.

Finally, medical wastes not listed under Part 259, Subpart D, of today's rule remain subject to the requirements of Subtitle D.

3. Subtitle G—Miscellaneous Provisions

Since medical waste is a solid waste, EPA retains authority under RCRA section 7003 to respond to situations in which past or present solid waste handling, storage, treatment, transportation, or disposal may present imminent and substantial endangerment to human health or the environment. EPA may either issue an administrative order or file suit in the United States District Court to obtain any necessary relief. The Agency must provide notice to the affected State of any suit under this section. This authority supplements section 11005 medical waste enforcement authority.

B. CERCLA

The Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended (CERCLA), also known as Superfund, provides for emergency and long-term cleanup of hazardous substances, pollutants, or contaminants. Section 104(14) of this act defines "hazardous substances," and 40 CFR 302.4 specifically lists or references all CERCLA hazardous substances. "Pollutant or contaminant," as defined in section 101(33) of CERCLA, includes disease-causing agents. There is no tabulation of substances that fits the definition of "pollutant or contaminant." The broad language in the definition could include pathogens, bacteria, and viruses.

Under CERCLA section 104, EPA may clean up releases or threatened releases of either hazardous substances or pollutants/contaminants that may present an imminent and substantial danger to the public health or welfare. (This authority and CERCLA section 106, which authorizes injunctive relief against responsible parties for releases of hazardous substances, is similar to the RCRA section 7003 authority described above.) Medical waste could contain hazardous substances, or it could contain pollutants or contaminants. Thus, certain releases of medical waste may be subject to Superfund authority.

The Part 259, Subpart D, listing of medical wastes promulgated today, however, does not trigger the addition of wastes to the 40 CFR 302.4 list of hazardous substances (in contrast to Subtitle C listings). Today's rule does not alter CERCLA authority or the CERCLA liabilities of any persons handling medical waste. In addition, the hazardous material regulations of the U.S. Department of Transportation (which are tied to CERCLA listings) are not affected by today's rules.

C. Clean Air Act

Currently, the Clean Air Act regulations include a New Source Performance Standard for incinerators of solid waste, of which 50 percent or more is municipal waste, charging more than 50 tons per day, if those incinerators were constructed or modified after August 17, 1971. The regulations, found at 40 CFR 60.50, specify a particulate matter emission limit. Many health care facility incinerators have a lower charging rate and would not be regulated under this performance standard. However, they may be subject to other State or local air pollution control regulations, including State Implementation Plans which are Federally enforceable under section 110 of the Clean Air Act.

The regulations promulgated today for the medical waste demonstration program do not require a particular treatment technology for medical waste. Certain States, however, have taken steps to limit land disposal of untreated medical waste. The actions of these States could result in increased use of incineration or other treatment techniques. In addition, Congress directed that incineration residues do not require tracking under the medical waste demonstration program. This exemption may encourage generators to incinerate their medical waste.

EPA's Office of Air Quality Planning and Standards has begun investigating the risks associated with hospital waste incineration and is developing a training course for hospital waste incinerator operators. The Agency may decide to develop standards for these sources under the Clean Air Act.

D. Water Pollution Control

1. Clean Water Act

This law establishes the requirement that discharges of pollutants, except in compliance with the Act, are unlawful, and further establishes programs to control the discharges of pollutants to navigable waters. The pretreatment program establishes standards for the introduction of pollutants into publicly owned treatment works (section 307). Direct discharges of pollutants to navigable waters require a permit incorporating technology-based limitations and any more stringent limitations necessary to comply with State water quality standards.

Recent amendments to the Clean Water Act prohibit the discharge of medical waste to navigable waters (United States Public Vessel Medical Waste Anti-Dumping Act of 1988, Public Law 100-688, Title III, Subtitle B, section 3202). The Agency will be addressing these amendments in a rulemaking amending its National Pollution Discharge Elimination System (NPDES) regulations.

2. Marine Plastic Pollution Research and Control Act of 1987 (Pub. L. 100-220)

Title II of this Act requires several activities to be conducted and is divided into three subtitles.

Subtitle A requires the U.S. Coast Guard to prepare regulations to implement the 1978 Protocol Relating to The International Convention for the Prevention of Pollution from Ships (MARPOL), relating to disposal of wastes from vessels. These regulations were proposed in 1988.

Subtitle B requires the Environmental Protection Agency and the Commerce Department's National Oceanic and Atmospheric Administration to study

the sources and effects of plastic materials on the environment, including the marine environment, and on waste disposal. A public education program which encourages citizen pollution patrols is also required to be developed under this Subtitle. The objective of the citizen pollution patrols is to assist State and local officials in monitoring and cleaning up ocean and shoreline pollution. These activities are underway.

Subtitle C includes the development of a plan specific to the restoration of water quality in the New York Bight.

All three subtitles include plastics-related activities which will aid efforts to reduce the pollution of the marine environment with medical waste.

3. Marine Protection, Research and Sanctuaries Act of 1972

This Act prohibits the transportation of materials from the United States for the purpose of ocean dumping unless authorized by a permit. Recent amendments to this law prohibit the issuance of a permit for the transportation of medical wastes for the purpose of dumping.

4. United States Public Vessel Medical Waste Anti-Dumping Act of 1988

Vessels that are owned, chartered or operated by the U.S. Government, and that are not engaged in commercial service, are prohibited, except in limited specific circumstances, from disposing into ocean waters potentially infectious medical waste generated on board the vessel. EPA, the Department of Defense, and affected agencies must publish guidance to implement this law.

5. Shore Protection Act of 1988

This law requires vessels (other than public vessels) to obtain permits for transporting municipal or commercial solid wastes in coastal waters. The law specifies loading, securing, unloading, and clean-up procedures for waste sources, vessels, and receiving facilities. It also requires EPA, in consultation with the Department of Transportation, to promulgate regulations implementing these requirements.

E. EPA Research Activities

The Agency's research facilities are conducting studies to assess current medical waste incineration practices for improving combustion and to assess risks from incineration of medical waste. In addition, EPA is collecting and evaluating information to meet the requirements under the MWTA for the Reports to Congress.

F. EPA's Office of International Activities

Subtitle J has no specific provisions for imports and exports of medical waste, except a requirement that EPA consult with the International Joint Commission (IJC) to determine how to monitor disposal of medical waste emanating from Canada. Furthermore, the Act implicitly requires the Agency to track medical wastes generated in a State subject to the demonstration program and disposed of in a foreign country. It is the Office of International Activities' (OIA) responsibility to make certain that the concerns regarding the import and export of medical wastes are addressed.

EPA is currently consulting with the Canadian government through the OIA to identify and discuss issues related to the transboundary movement of regulated medical wastes between the United States and Canada. The Agency intends to use this information from Canada in assessing the need for a program which controls the export and import of regulated medical wastes. This information will be summarized in the Reports to Congress. EPA, through the Department of State, is providing a copy of this interim final rule to the IJC to meet the requirements of the MWTA.

VII. Relationship to Other Federal Regulatory Programs

This section discusses the relationship between the rule EPA is promulgating today for medical waste tracking and the regulatory programs of other Federal agencies that in one way or another, may apply to the same wastes. In general, the fact that another set of Federal regulations applies to wastes does not mean that the Resource Conservation and Recovery Act (RCRA) does not apply. In some cases, RCRA regulations apply independently of, and in addition to, other Federal rules. However, the RCRA definition of solid waste, given in section 1004(27), excludes certain materials regulated under other laws from RCRA coverage. Further, section 11002(b) of RCRA allows EPA to exclude medical waste that does not pose a substantial hazard to human health or the environment if improperly managed. In exercising this authority, EPA considered whether existing Federal regulatory programs may provide adequate protection for some wastes, making RCRA Subtitle J regulation unnecessary.

A. Nuclear Regulatory Commission (NRC)

Certain waste streams may contain materials that are source, special nuclear, or by-product material, as defined in the Atomic Energy Act, and also may contain materials that meet the definition of medical waste in section 1004(40) of RCRA. These wastes are subject to regulation under both laws; if one law's requirements are more stringent, those requirements supersede and supplement the less stringent ones. As explained previously, generators may treat and destroy their regulated medical wastes, if they so choose, thus making their mixed radioactive and medical waste subject only to Nuclear Regulatory Commission requirements. Otherwise, such wastes are subject to both sets of rules.

EPA has reviewed the NRC regulations and finds that, while there are similarities between EPA and NRC requirements, there are also several significant differences, particularly with respect to labeling, manifesting, and packaging. Because today's rule does not exempt radioactive medical waste, EPA is requiring generators of mixed radioactive and medical waste to meet both EPA and NRC labeling, manifesting, and packaging requirements. For a complete description of the applicable NRC regulations, refer to 10 CFR Part 20 and 10 CFR Part 61. Some important areas where NRC regulations are clearly distinct and more stringent than EPA regulations are discussed below.

1. Labeling

The low-level radioactive waste category (that which is suitable for near-surface landfill) is broken down by the NRC into three classes—A, B, and C—according to its level of radioactivity. As specified in 10 CFR 20.311(d), it is the responsibility of the generator to classify the waste properly. Radioactive medical waste is most often Class A (the least radioactive) waste. In any case, as specified in 10 CFR 61.55 and § 61.57, it must be labeled appropriately, in addition to the labeling requirements of Part 259, Subpart E, promulgated today.

2. Manifesting

The NRC requires a shipping manifest for all radioactive waste destined for a licensed land disposal facility. An EPA medical waste tracking form is sufficient for this requirement, provided that certain additional information as described below is recorded in Box 14 (Special Handling Instructions and Additional Information) of the medical waste tracking form. The tracking form must indicate, as completely as practicable, a physical description of the waste, the volume of the waste, the radionuclide identity and quantity, the

total radioactivity, and the principal chemical form. Generators may attach a separate sheet with this information to the Medical Waste Tracking Form.

NRC requires that the solidification agent for liquid wastes must be specified. Waste containing more than 0.1 percent chelating agents by weight must be identified and the percentage weight of the chelating agent estimated. Again, all of this information can be included in Box 14 or on a separate sheet. These and other NRC tracking requirements are specified in 10 CFR 20.311.

NRC's exception reporting requirement described in 10 CFR 20.311(h) is particularly noteworthy and is more stringent than the EPA medical waste exception reporting requirement. Any shipment for which acknowledgment of receipt by the disposal facility is not received by the generator within 20 days must be investigated by the generator, traced, and reported. In today's rule, EPA sets forth a requirement that the exception reporting process begins after 35 days. Therefore, NRC's 20-day investigation requirement is more stringent and takes precedence, but if the exception is not resolved within 45 days, then EPA's exception reporting requirements also would have to be met, in addition to NRC's reporting requirements.

3. Packaging

NRC requires that all classes of radioactive waste be handled and packaged according to specific requirements. These requirements are intended to provide stability to the waste, to facilitate handling at the disposal site, and to ensure the health and safety of personnel at the disposal site. EPA's and NRC's objectives in providing requirements for proper waste packaging are consistent with each other. However, to protect personnel handling and disposing of the waste, NRC requires waste which contains hazardous, biological, pathogenic, or infectious material to be treated to reduce, to the maximum extent practicable, the potential hazard from the nonradiological materials. This requirement is more stringent than EPA's and is in addition to the requirements promulgated today.

Other important handling and packaging requirements that are more stringent than EPA's and must be followed for radioactive medical waste include the following: waste must not be packaged for disposal in cardboard or fiberboard boxes; liquid waste must be solidified or packaged in sufficient absorbent material to absorb twice the volume of the liquid; solid waste containing liquid shall contain as little freestanding and noncorrosive liquid as is reasonably achievable, but in no case shall the liquid exceed one (1) percent of the volume; waste must have structural stability, which can be provided by the waste form itself, by processing the waste to a stable form, or by placing the waste in a disposal container or structure that provides stability after disposal. These and other waste handling and packaging requirements are specified in 10 CFR 61.56.

4. Limitation of Generator's Disposal Options

Today's medical waste tracking regulations do not restrict the treatment or disposal options the generator may choose, although generators may be limited by State regulations. However, the NRC regulations, in some cases, limit the generator's disposal options. These requirements are more stringent and are in addition to the requirements promulgated today.

B. United States Department of Agriculture (USDA)

1. Animals With Communicable Diseases

Certain animal wastes are regulated by USDA under 9 CFR Parts 50 through 56. According to the rules, contaminated materials must be cleaned and disinfected, or in some cases destroyed. A USDA or State veterinary official determines which materials must be disinfected. Carcasses of animals killed because of exposure to certain diseases are sometimes sent for incineration or burial. The USDA regulations require Federal or State employees to supervise the incineration or burial and to prepare reports identifying the animal and its disposition. However, USDA regulations do not require tracking of the carcasses. The area of overlap between the USDA rules and today's rule is minimal because the waste regulated by EPA under Class 5 are contaminated animal carcasses, body parts, and bedding of animals exposed to infectious agents during research, production of biological, or testing of pharmaceuticals. Although no exemption was included in today's rule, EPA requests comment on whether animal carcasses that are both regulated medical waste under §259.30(a) and regulated by USDA should be exempted from part 259 requirements.

2. Veterinary Biological Products

Products such as vaccines and serums, intended for use in the diagnosis, treatment, or prevention of animal diseases, are regulated by USDA. A warning label, required on substances containing viable or dangerous organisms (9 CFR Part 112), instructs the user to burn the container and all unused contents. USDA also regulates imports of some veterinary biological products which are classified as wastes if they are imported without appropriate permits and are then sent for destruction. Today's medical waste tracking regulations supplement these existing USDA waste management requirements.

C. Department of Labor (DOL)—Occupational Safety and Health Administration (OSHA)

OSHA regulations, specifically 29 CFR Part 1910, Subparts I and J, include a variety of general requirements for worker protection. Personal protective equipment, such as eye protection and respirators, is required when necessary. For all places of employment, waste removal must be conducted to keep the work environment sanitary. Special tags and signs are required to identify equipment, rooms, materials, and experimental animals that contain, or are contaminated with, biological hazards.

OSHA is developing regulations to protect health care workers from the transmission of blood-borne infectious diseases (52 FR 45438, November 27, 1987). A draft of the proposed regulation was released to the public and is available from the OSHA Docket Office ((202) 532-7894; Docket H-370). Additionally, the Departments of Labor and Health and Human Services (HHS) have initiated efforts to educate health care workers concerning blood-borne disease (see 52 FR 41888, October 30, 1987).

To the extent that workers are protected by OSHA's regulations, some regulations for hazard identification and protective clothing already exist. The packaging requirements for sharps and fluids in today's rule also should serve to protect waste handlers. Finally, OSHA is considering the use of the universal biohazard symbol in certain workplace situations. This is compatible with today's EPA rule, which specifies that symbol as one means of identifying packages of medical waste.

D. Department of Health and Human Services

1. Food and Drug Administration (FDA)

The FDA regulates the production of biological substances for preventing, treating, or curing human diseases or injuries. Facilities developing biological products are licensed by the FDA, and

they must meet standards for cleanliness and timely, sanitary trash disposal.

Laboratories conducting studies to support research or product marketing applications also are required to meet certain standards. If they do not meet these criteria, the validity of the studies may be questioned and the studies may be disqualified. Thus, both the production facilities and laboratories must comply with animal waste and general refuse storage and disposal standards. (See 21 CFR 58.43 and §§ 211.50, 211.56, and 606.40).

For wastes shipped off-site that fall into one of today's regulated medical waste categories, today's regulations impose packaging, segregation, labeling, and tracking form requirements, and supplement the FDA rules.

2. Public Health Service (PHS)

Interstate shipments of etiologic agents are regulated by the Public Health Service. An "etiologic agent" is defined in PHS regulations (42 CFR 72.1) as a viable microorganism or its toxin which causes, or may cause, human disease. Shipments of certain etiologic agents must meet packaging requirements and must be labeled with a symbol for biological hazards. A sender also must receive notification that the shipment has arrived at its destination. If the notification is not received, the sender must notify the Centers for Disease Control (CDC).

Imports of etiological agents and human disease vectors are prohibited unless accompanied by a permit. Human remains from persons who died of certain communicable diseases also are prohibited from importation unless they have been cremated, or embalmed and placed in a sealed casket, or are accompanied by a permit.

EPA has determined that etiologic agents need not be regulated under the EPA medical waste tracking program if they are subject to PHS and Department of Transportation (DOT) rules for interstate shipments of etiologic agents. (See the discussion in section V.D. of this Preamble and paragraph E of this section.)

3. Health Care Financing Administration (HCFA)

To participate in the Medicare program, health care facilities are required to comply with specific conditions of participation or coverage that specify various patient health and safety requirements. Generally, with respect to waste disposal, these conditions require health care facilities to meet any State or local licensing requirements, to have procedures for proper, routine storage and prompt disposal of trash, and to have policies and procedures concerning infection control.

The specific conditions of participation or coverage for the various provider types may be found at 42 CFR 405 Subpart L, Home Health Agencies; Subpart M, Independent Laboratories; Subpart N, Portable X-ray Services; Subpart Q, Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and/or Speech Pathology Services, and Outpatient Physical Therapy Services Furnished by Physical Therapists in Independent Practice; Subpart U, End Stage Renal Disease Facilities; Subpart X, Rural Health Clinic Services; 42 CFR Part 416, Ambulatory Surgical Services; 42 CFR Part 418, Hospice Care; 42 CFR Part 482, Hospitals; 42 CFR Part 483, Subpart B (redesignated on February 2, 1989, 54 FR 5316), Long Term Care Facilities; and 42 CFR Part 485, Specialized Providers.

E. Department of Transportation (DOT)

1. Hazardous Materials Shipments

DOT regulates the transportation of hazardous materials in commerce (49 CFR Parts 171 to 179). The regulations address: (a) Interstate transportation of hazardous materials by motor vehicle, rail car, aircraft and vessel; and (b) intrastate transportation of certain hazardous materials (hazardous wastes, hazardous substances, and flammable cryogenic liquids in portable tanks and cargo tanks) by motor vehicle.

One class of hazardous materials is the "etiologic agents" hazard class. As currently defined in 49 CFR 173.386, an "etiologic agent" means a viable microorganism, or its toxin, which causes or may cause human disease, and is limited to those agents listed in 42 CFR 72.3 of the regulations of the Department of Health and Human Services. The list in 42 CFR 72.3 includes many bacterial, fungal, viral and rickettsial agents.

EPA has determined that etiologic agents that are wastes are not regulated medical wastes if they are shipped in accordance with DOT's regulations for etiologic agents. EPA made this determination because DOT's regulations for shipping etiologic agents, in combination with the Public Health Service regulations discussed previously, are generally more stringent than the regulations promulgated today.

DOT's regulations for etiologic agents specify that no person may ship a package containing over four liters gross volume of an etiologic agent. The packaging must meet requirements specified in 49 CFR 173.24 and 173.387, and must be labeled with the etiologic agents/biomedical material label as specified in 49 CFR 173.388. In the event of fire, breakage, spillage, or suspected contamination involving etiologic agents during the course of transportation (including loading, unloading and temporary storage), the carrier must notify DOT by telephone at (800) 424-8802 or (202) 267-2675, or the Centers for Disease Control at (404) 633-5513 (49 CFR 171.15). The telephone notice must be followed by a written report (49 CFR 171.16).

DOT has proposed to broaden its definition of "etiologic agent" and to eliminate an exception for cultures of etiologic agents of 50 milliliters or less total quantity in one outside package (53 FR 45525, November 10, 1988). DOT also plans to reconsider other aspects of its regulations for the transportation of etiologic agents.

EPA notes as a point of clarification that the rules promulgated today do not add any additional materials to the list of etiologic agents that are subject to DOT's Hazardous Materials Regulations, nor do the rules cause any additional materials to come under DOT regulation. Today's medical waste tracking rules are independent of the DOT Hazardous Materials Regulations.

2. MARPOL 73/78

The Protocol of 1978, relating to the International Convention for the Prevention of Pollution from Ships, 1973 (MARPOL 73/78), is an international treaty for preventing ship generated ocean pollution by oil, noxious liquid substances, harmful substances, sewage, and garbage. The section of the treaty that seeks to prevent garbage pollution is found in Annex V, recently in force and incorporated into U.S. law as the Act to Prevent Pollution from Ships (33 U.S.C. 1901-1911). The U.S. Coast Guard has initiated a rulemaking to address garbage disposal (53 FR 43622, October 27, 1988). The Coast Guard regulations will apply to all ship-generated garbage, including regulated medical waste. Ships that are owned or operated by the United States and that are in noncommercial service will be subject to compliance with Annex V on a delayed compliance schedule. EPA rules supplement these Coast Guard rules by regulating the medical waste brought ashore in a Covered State.

VIII. Federal Facilities

Under section 11006 of the MWTA, Federal facilities managing regulated medical waste generated in a Covered State are subject to all Federal, State,