DEPARTMENT OF TRANSPORTATION

Research and Special Programs Administration

49 CFR Parts 171, 172, 173, and 178

[Docket No. HM-181G; Notice Number 94-11]

RIN 2137-AC36

Infectious Substances

AGENCY: Research and Special Programs Administration (RSPA), DOT

ACTION: Notice of proposed rulemaking and notice of public meeting.

SUMMARY: RSPA is proposing to revise the regulations pertaining to infectious substances, including regulated medical waste (RMW), based on petitions for reconsideration and comments received following issuance of a final rule in December 1991, comments received in response to an advance notice of proposed rulemaking issued in March 1993, and agency initiative. RSPA is proposing to clarify that RMW is a subcategory of infectious substances; allow RMW to be offered for transportation and transported if it conforms to certain requirements of the Occupational Safety and Health Administration; add provisions for transporting RMW by aircraft; and make other changes to clarify the regulatory provisions applicable to infectious substances. The proposed changes are intended to ensure the safe transportation of infectious substances, provide relief from certain requirements of the hazardous materials regulations in those instances where other Federal agency regulations achieve an acceptable level of safety for transportation of RMW and clarify provisions which were adopted in the December 1991 final rule.

RSPA also is announcing a public meeting to solicit comments on the proposals contained in this document.

DATES: *Comments.* Comments must be submitted on or before March 21, 1995.

Public Meeting. A public meeting will be held from 9:30 a.m. to 5 p.m. on January 17 1995, in Washington, DC.

ADDRESSES: *Comments:* Address comments to the Dockets Unit (DHM-30), Hazardous Materials Safety Room 8421, RSPA, U.S. Department of Transportation, 400 Seventh St., SW Washington, DC 20590-0001. Comments should identify the docket number (HM-181G) and Notice number (94-11) and be submitted, when possible, in five copies. Persons wishing to receive confirmation of receipt of their comments should include a self-addressed stamped postcard. The Dockets Unit is located in room 8421 of the Nassif Building, 400 Seventh Street SW., Washington, DC 20590-0001. Office hours are 8:30 a.m. to 5 p.m., Monday through Friday except on public holidays when the office is closed.

Public Meeting: The public meeting will be held at the Federal Aviation Administration Auditorium, 3rd Floor, Building FOB 10A, Washington, DC. Any person wishing to present an oral statement at the public meeting should notify Jennifer Antonelli, by telephone or in writing, by January 12, 1995. Each request must identify the speaker; organization represented, if any; daytime telephone number; and anticipated length of presentation, not to exceed 10 minutes. It is requested that written text of the oral presentation be presented to the presiding officer prior to the oral presentation. The meeting may conclude before 5:00 p.m. if all persons wishing to speak have been heard.

FOR FURTHER INFORMATION CONTACT: Eileen Martin or Jennifer Antonelli, Office of Hazardous Materials Standards, (202) 366-4488, Research and Special Programs Administration, U.S. Department of Transportation, 400 Seventh Street, SW Washington, DC 20590-0001.

SUPPLEMENTARY INFORMATION:

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I. Background

History of Department of Transportation Regulation of Etiologic Agents/ Infectious Substances

A. Regulation Prior to 1991

The Hazardous Materials Regulations Board (Board, a predecessor to the RSPA) adopted a final rule under Docket HM-142 on September 30, 1972 (37 FR 20554), that added "etiologic agents to the list of hazardous materials regulated by the Secretary The final rule at 49 CFR 173.386(a)(1) defined an etiologic agent as

> a viable microorganism, or its toxin, which causes or may cause human disease, and is limited to those agents listed in 42 CFR 72 25(c) of the regulations of the Department of Health, Education, and Welfare

(The Department of Health, Education, and Welfare (HEW) is now the Department of Health and Human Services (DHHS)). The final rule at 49 CFR 173.387 also specified packaging requirements for etiologic agents, and excepted, at 49 CFR 173.386(d), from DOT regulation "diagnostic specimens" and "biological products," which were subject to regulation by HEW The final rule was adopted after notice and opportunity to comment (36 FR 25163, December 29, 1971)

On November 29, 1972, after receiving two petitions for reconsideration and several comments, the Board proposed in the **Federal Register** (37 FR 25243) to except from DOT regulation cultures of etiologic agents of less than 50 milliliters (1.666 fluid ounces) in one package. The petitions stated that such an exception was necessary to allow physicians in rural areas to transport cultures to laboratories on passenger-carrying aircraft, rather than by slower surface transportation which, in turn, promotes health safety The petitions added that cultures of etiologic agents may perish if in transportation too long. The Board adopted the proposal as final on March 29, 1973 (38 FR 8161). One commenter objected to excepting such quantities of etiologic agents from all regulation. The Board noted, however, that quantities of etiologic agents excepted from DOT regulation would still be subject to HEW labeling and packaging regulations under 42 CFR 72.25(c). The March 29, 1973 rule also adopted incident notification requirements for etiologic agents, as proposed on July 22, 1972 (37 FR 14728).

B. The 1988 notice of proposed rulemaking (NPRM) under Docket HM-142A

On November 10, 1988, RSPA proposed (Docket HM-142A, 53 FR 45525) to revise the definition of etiologic agent, remove the 50 milliliter (ml) exception, and align the per package quantity limits of etiologic agents aboard aircraft with the International Civil Aviation Organization Technical Instructions for the Safe Transport of Dangerous Goods by Air (ICAO Technical Instructions). RSPA proposed broadening the definition of etiologic agent" to include, in addition to etiologic agents listed by DHHS (Centers for Disease Control and Prevention (CDC)) in 42 CFR 72.3, any agent that poses a similar degree of hazard, such as the human immunodeficiency virus (HIV). RSPA noted that the proposed definition was not as broad as the definition for infectious substances (Division 6.2) contained in the United Nations Recommendations on the Transport of Dangerous Goods (UN

Recommendations) and international regulations based on the UN Recommendations, such as the ICAO Technical Instructions. CDC has not updated the list in 42 CFR 72.3 since July 1, 1980 (45 FR 48627). On March 2, 1990 (55 FR 7678), CDC proposed to delete the list from its regulations and adopt criteria to define "etiologic agent, but a final rule has not been published.

C. January 3, 1991 final rule under Docket HM–142A

On January 3, 1991, RSPA published a final rule in the **Federal Register** (56 FR 197) under Docket HM–142A. The final rule (1) adopted a revised definition of "etiologic agent, (2) removed the 50 ml exception, and (3) clarified quantity limitations for etiologic agents transported aboard aircraft. "Etiologic agent" was defined to mean

a viable microorganism, or its toxin, which is listed in 42 CFR 72.3 of the regulations of the [CDC] or which causes or may cause severe, disabling or fatal human disease.

The definition adopted differed from the proposed definition in response to commenters who suggested that the language of the definition be modified to better reflect agents that may pose an unreasonable risk to health and safety during transportation. Accordingly the wording was revised to include other agents that cause or may cause severe, disabling or fatal human diseases in humans in addition to the agents listed in 42 CFR 72.3 of the CDC regulations. In response to comments, RSPA indicated in the preamble that it believed most medical waste is composed of material that does not contain etiologic agents, either because it does not contain any infectious material or because the infectious material does not meet the regulatory definition of etiologic agent. RSPA also stated that, in many cases, if medical waste is known or suspected to contain an etiologic agent, it is treated on-site to destroy the agent by using a method such as incineration, autoclaving, or treatment with disinfectants. However RSPA clearly stated that "* if an infectious waste that contains an etiologic agent is offered for transportation, it must conform with the requirements in the Hazardous Materials Regulations (HMR; 49 CFR parts 171–180) for etiologic agents" (56 FR 198). As stated earlier, the final rule also removed the 50 ml exception, as proposed in 1988. The January 3 preamble responded to numerous comments received on the 50 ml proposal and comprehensively discussed the reasons for this action.

The January 3 preamble also discussed the relationship of Docket HM–142A to Docket HM–181. Docket HM–181, entitled "Performance-Oriented Packaging Standards; Miscellaneous Amendments, comprehensively revised the HMR by eliminating 350 pages of regulation and harmonizing HMR requirements for classification, hazard communication and packaging with standards in the UN Recommendations. In the preamble discussion, RSPA stated that HM–181 had proposed to replace the term "etiologic agent" with "infectious substance" for consistency with international regulations. However, RSPA noted that the scope of changes proposed under HM–181 was so extensive that RSPA was unsure when that proposal would be adopted as final. As a result, RSPA proceeded with a separate rulemaking under Docket HM–142A (an abbreviated version of the infectious substance provisions in HM–181) to ensure that the risks posed by etiologic agents were adequately regulated under the HMR. RSPA intended the provisions under HM–142A to serve as a transition until the provisions of HM–181 became effective. Both final rules were published at approximately the same time. However, the initial effective date for HM–142A was February 19, 1991, and the effective date for HM–181 was October 1, 1991. Although HM–142A was to become effective before HM–181, RSPA encouraged shippers to implement the HM–181 provisions as soon as practicable.

D. Performance-oriented packaging standards—HM–181

In 1987 RSPA proposed to align the classification, packaging, and hazard communications provisions in the HMR with the UN Recommendations and the ICAO Technical Instructions. The May 5, 1987 NPRM (Docket HM–181, 52 FR 16482) proposed to replace the term "etiologic agent with the term "infectious substance" and adopt the INFECTIOUS SUBSTANCE label (52 FR 16700). RSPA proposed to include "infectious substance in UN classification Class 6, Division 6.2. "Infectious substance was proposed to mean

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 [CDC]. The terms 'infectious substance and "etiologic agent" are synonymous

(52 FR 16700).

On December 21, 1990, RSPA issued a final rule under Docket HM–181 (55 FR 52402) which comprehensively revised the HMR with respect to hazard communication, classification, and packaging requirements. "Infectious substance was defined in 49 CFR 173.134(a)(1) to mean

a viable microorganism, or its toxin, which causes or may cause disease in humans or animals, and includes those agents listed in 42 CFR 72.3 of the regulations of the [CDC] or any other agent that has the potential to cause severe, disabling or fatal disease. The terms "infectious substance" and "etiologic agent" are synonymous.

RSPA had planned to issue a final rule under Docket HM–142A (etiologic agents) before issuing the final rule under Docket HM–181. However, the final rule under HM–181 was issued on December 21, 1990, and the final rule under HM–142A was not issued until January 3, 1991. As explained in the preamble to the January 3, 1991 rule, the comments on HM–142A were considered in the decisionmaking process for HM–181, and reflected in the December 21, 1990 rule. For example, not only did the December 1990 definition of "infectious substance adopt the broader definition of etiologic agent proposed in 1988, it also reflected RSPA s consideration of comments suggesting that the language be modified to better define agents that may pose an unreasonable risk to health and safety during transportation.

A document incorporating editorial and substantive revisions to the December 1990 final rule was published on December 20, 1991 [56 FR 66124]. (These final rules are referred to jointly herein as Docket HM–181.) The revisions contained in the December 1991 rule were primarily in response to petitions for reconsideration received on the December 1990 final rule. The December 1991 rule also made editorial and technical corrections to the December 21, 1990 final rule, and to the January 3, 1991 final rule.

E. Petition for reconsideration on the January 3, 1991 rule

A petition for reconsideration filed by the National Solid Wastes Management Association (NSWMA) recommended that RSPA revise the definition of infectious substances (etiologic agents) to exclude solid waste or medical waste as defined in 40 CFR 259.10 of the Environmental Protection Agency (EPA) regulations. To allow adequate time to evaluate the petition, RSPA delayed the effective date of the January 3 rule to September 30, 1991 (February 22, 1991. 56 FR 7312). In a meeting to obtain clarification of the petition, NSWMA

urged RSPA to reestablish the 50 ml exception for infectious substances. The NSWMA stated that RSPA s regulation was inconsistent with the approach taken by EPA, and would increase the costs of transporting medical waste for the regulated community. The NSWMA stated that, contrary to RSPA's preamble discussion that most medical waste did not contain etiologic agents or was treated on-site to destroy the agent before being transported for disposal, substantial quantities of untreated medical waste are transported off-site. This information was the first indication RSPA had received from any commenter that removal of the 50 ml exception would affect a larger segment of the industry than had previously been indicated.

On September 18, 1991 (56 FR 47158), RSPA incorporated HM–142A into HM–181 and, in partial response to NSWMA s request, extended the 50 ml exception from October 1, 1991, to October 1, 1992. (The September 1991 rule also required that packages exceeding the 50 ml exception comply on October 1, 1991, with the revised hazard communication (shipping paper, marking, and labeling) and classification requirements in Docket HM–181). RSPA anticipated that this extension would provide enough time to fully respond to NSWMA's comments in the final correction document to HM–181 that was being prepared. However, NSWMA submitted a September 26, 1991 letter asking that RSPA clarify that the January 3, 1991 and September 18, 1991 final rules "apply to only isolated cultures or stocks such as clinical laboratory specimens and not to 'medical waste' as defined in 40 CFR 259.30(a) and 'mixtures' as defined in 40 CFR 259.31." In essence, NSWMA was requesting clarification that the HMR did not apply to medical waste containing any amount of an infectious substance. In order to allow RSPA additional time to carefully review NSWMA s substantive concerns, RSPA again extended the compliance date for all new requirements for infectious substances until October 1, 1992 (October 1, 1991, 56 FR 49830).

F December 20, 1991 final rule

In the December 20, 1991 final rule responding to petitions for reconsideration in Docket HM–181, RSPA agreed with NSWMA that medical waste containing an infectious substance should be treated differently than other infectious substances. RSPA had no basis, however, to except from regulation medical waste containing an infectious substance, and stated "* since the majority of these wastes are untreated and, thus, may potentially contain infectious substances, RSPA strongly believes that the public and transport personnel be protected from the hazards of these materials during transportation (56 FR 66142). Accordingly RSPA revised the regulations (49 CFR 173.197 (1991)) to specify "* less rigorous requirements for infectious substances that are 'regulated medical wastes'" (56 FR 66131). RSPA observed that EPA's regulations on medical waste in 40 CFR Part 259 had applied in only five States and had expired on June 22, 1991, with the end of a 2-year demonstration program that EPA had established under the Medical Waste Tracking Act of 1988 (MWTA, Pub.L. 100–582). To provide less rigorous requirements for medical waste containing infectious substances, RSPA turned to the expired EPA regulations as a model that could be adapted, with some modifications, to the HMR. RSPA wanted to take advantage of the technical expertise and knowledge of the medical waste industry that EPA had developed during its demonstration project under the MWTA. Accordingly RSPA adopted a definition of "regulated medical waste" (to distinguish between all medical waste and medical waste containing an infectious substance) and specified packaging requirements for regulated medical waste (RMW) that were consistent with those contained in the expired EPA regulations.

RSPA thus identified a subcategory of Division 6.2 (infectious substances) materials, i.e., RMW, which is an infectious substance that is contained in or constitutes medical waste, and provided packaging requirements for RMW that were less rigorous than those for other infectious substances.

Under the December 1991 rule, if an infectious substance is offered for transportation or transported, the infectious substance must be labeled, packaged, and offered for transportation in accordance with the HMR, unless it meets one of the exceptions from regulation. The 1991 rule provided that if the infectious substance was a medical waste, or was contained in medical waste, then a shipper could use the less rigorous packaging requirements that were provided for RMW

If RSPA had not provided this measure of regulatory relief in response to petitions, all infectious substances, regardless of how they are generated, would be classified and described as Division 6.2 materials, and would be subject to the full extent of regulation provided in the HMR.

G. Petitions for reconsideration and comments received in response to the December 20, 1991 rule

Following issuance of the December 1991 rule, RSPA received additional petitions for reconsideration and a number of requests for clarification and additional comments concerning the provisions for infectious substances and regulated medical waste. The petitioners requested a stay in the effectiveness of the final rule and the reopening of the rulemaking for additional public input.

Petitions were submitted by the American Hospital Association (AHA), the Association for Practitioners in Infection Control, Inc. (APIC), and the Conference on Safe Transportation of Hazardous Articles, Inc. (COSTHA). The petitioners asserted that RSPA violated the Administrative Procedure Act (5 U.S.C. 553; "APA") by adopting new requirements for medical waste in the December 20, 1991 rule without providing an opportunity for comment, did not adequately assess the risks associated with RMW in transportation and the costs and benefits of regulation, and did not coordinate with other Federal agencies to prevent imposition of conflicting regulations.

Petitioners also contended that the RMW requirements in the HMR conflict with information contained in the report entitled "The Public Health Implications on Medical Waste· A Report to Congress, prepared in 1990 by the Agency for Toxic Substances and Disease Registry (ATSDR) on the Medical Waste Tracking Act The ATSDR Report contains a compilation of information obtained from several State health and environmental departments on the amount and types of medical waste generated and health and environmental implications of medical waste in the United States. The report concludes that infection outside the health care setting is not likely and public health is not likely to be adversely affected by medical waste in transportation.

COSTHA also asserted that RSPA changed the definition of infectious substances to include substances "infectious to animals only" without providing an opportunity to comment

H. Advance notice of proposed rulemaking

On March 3, 1993, RSPA issued an advance notice of proposed rulemaking (ANPRM) and announced a public meeting under Docket HM–181G (58 FR 12207) concerning the issues raised by petitioners and commenters and the need for additional regulatory changes pertaining to infectious substances. In

order to provide time to evaluate the comments received in response to the ANPRM, RSPA also extended the compliance date (58 FR 12182) for provisions applicable to infectious substances from April 1, 1993, to January 1, 1994. The ANPRM addressed a number of complex issues pertaining to scope of regulation, consistency with regulations of other agencies, the need for revised standards for non-bulk and bulk packagings, and defining criteria for infectious substances and RMW Following issuance of the ANPRM, RSPA continued its efforts to gain information on other Federal agencies' regulatory requirements, and hosted and participated in a number of interagency meetings on these issues. On December 20, 1993 (58 FR 66302), RSPA again extended the compliance date for provisions applicable to infectious substances from January 1, 1994, to October 1, 1994 to provide additional time for resolving the issues of concern.

II. Final Rule Extending Compliance Dates

In a final rule published on September 22, 1994 (59 FR 48762), RSPA revised 49 CFR 171.14(b) to once again delay compliance dates. For regulatory requirements for RMW and for materials infectious only to animals, the compliance date was extended from October 1, 1994, to October 1, 1995. This time period should be adequate for RSPA to evaluate comments received in response to this Notice, and make any necessary changes to the HMR based on the merits of those comments.

For other infectious substances, e.g., for cultures and stocks of substances infectious to humans, the compliance date was extended from October 1, 1994, to January 1, 1995. The provisions for these materials generally were not at issue in comments or petitions to the December 1991 final rule. The principal effects of the January 1, 1995 compliance date will be a nomenclature change from the old "etiologic agent" hazard class to the new Division 6.2 (infectious substances) classification, broadening the definition of infectious substances to cover substances, such as the human immunodeficiency virus (HIV) and Lyme disease, which are not listed in the CDC regulations (42 CFR 72.3). The removal of the 50 ml exception and expansion of the definition of infectious substances originally were to have occurred on February 19, 1991 (Docket HM-142A; January 3, 1991, 56 FR 197). RSPA believes it is necessary to implement these requirements as quickly as possible to ensure public safety and end confusion as to the status of materials that were not regulated prior to 1990. The interested reader is directed to the final rule for further information concerning the extension of compliance dates.

III. Response to Petitions for Reconsideration

With respect to the issue of providing notice and comment, the December 20, 1991 final rule was issued to correct obvious errors and respond to over 250 petitions for reconsideration of the final rule published on December 21, 1990. The rulemaking proceeding under HM-181 spanned over 10 years, provided numerous opportunities for public comment (with over 2,500 comments received), and complied fully with the requirements of the APA. Similarly, the final rule issued under HM-142A was preceded by an NPRM and opportunity to comment.

The specific criteria and provisions for medical waste were contained in the December 20, 1991 final rule to provide relief from the more burdensome infectious substances packaging requirements adopted in the December 21, 1990 final rule. Relief was provided in response to petitions for reconsideration stating that packaging prescribed in § 173.196 would be both cost-prohibitive and impractical for medical waste and that, rather than being treated on-site, significant quantities of medical waste containing infectious substances were routinely transported off-site for treatment or disposal. The relief granted for medical waste was well within the scope of the NPRM and the final rule.

Infectious substances, including medical waste containing infectious substances, are regulated under the HMR and have been since 1973. For various reasons, many generators and transporters of medical waste may not have been fully aware of these requirements. The change in the definition of an etiologic agent/ infectious substance under Dockets HM-142A and HM-181, coupled with the elimination of the 50 ml exception, increased both the awareness of this issue and the likelihood that more medical waste would be subject to the HMR. Moreover, the petitions appeared to be based on a misconception that RSPA intended to regulate all medical waste, rather than only that medical waste containing an infectious substance. To the extent that there existed any confusion regarding the scope of RSPA s regulation of medical waste, the notice published today sets forth a proposed definition of RMW that clearly limits RMW to a waste containing an infectious substance. Accordingly in this notice, RSPA is giving those persons who may have been unaware of, or confused by the previous requirements an opportunity to comment on the proposals.

With regard to analysis of risk and economic impact, in the regulatory evaluation for HM-181, RSPA performed a macroscopic analysis of costs and benefits generically addressing all hazardous materials, their packagings, and impacts of changes to classification and hazard communication. The HMR address tens of thousands of hazardous materials and over 100 different types of packagings. Under HM-181, it was not feasible or necessary to specifically analyze each hazardous material or category of materials or each type of packaging and determine that the benefits of change to classification, hazard communication or packaging for each would outweigh associated costs. The benefits of the system put in place under HM-181, involving the assessment of levels of hazard for materials and assignment of packagings based on levels of hazard, were demonstrated to greatly exceed the costs of the system. RSPA did not receive any comments in response to the notices in Dockets HM-181 or HM-142A on any economic impacts the rule would have on the medical waste industry. Therefore, RSPA disagrees with the petitioners who claimed that RSPA did not adequately assess costs and benefits attributable to changes to regulatory requirements, particularly with regard to medical waste. For this notice, RSPA has prepared a regulatory evaluation and is providing an opportunity to comment on the proposals.

With respect to other Federal regulation of infectious substances, RSPA has participated in a number of interagency meetings to exchange information on the Federal regulations and identify any duplication, conflict, gaps, or discrepancies. As discussed in greater detail under Section VI of this notice, RSPA intends to continue to cooperate with other Federal agencies to harmonize requirements on infectious substances. With respect to State regulation, RSPA is aware that many States have regulations on the transportation of medical waste, although the States vary in the extent and scope of their regulation. As discussed in Section VII.B. below Federal law preempts State requirements applicable to the transportation of hazardous material that cover certain subjects and are not substantively the same as the Federal requirements. 49 U.S.C. 5125(b)(1). These subjects include the designation,

description, classification, packaging, handling, marking, and labeling of hazardous material.

With respect to the ATSDR Report, that report addressed all medical waste generated in the United States. RSPA is concerned only with regulating medical waste that contains an infectious substance, and is proposing to regulate only that medical waste.

With respect to COSTHA s petition concerning substances infectious only to animals, in the November 1987 NPRM under Docket HM–181, RSPA had proposed a shipping description for "Infectious substances, *affecting animals only*" applicable only to international transportation (i.e., identified with an "I" in Column 1 of the Hazardous Materials Table in § 172.101). In the December 1990 final rule, RSPA removed the "I" making the description applicable to both domestic and international transportation, and revised the definition for infectious substances to include those affecting animals only. This action was taken to harmonize with the UN Recommendations to the maximum extent practicable. In response to COSTHA s petition, RSPA is providing notice and opportunity to comment on the proposal in this NPRM.

Conclusion

By initiating rulemaking, including issuance of the ANPRM and this NPRM, RSPA has granted the petitioners requests to provide notice and an opportunity to comment on provisions concerning RMW and infectious substances that are infectious to animals only. RSPA agrees with the petitioners and commenters that the HMR should be carefully tailored to the hazards posed by these materials, so that they can be safely transported without imposing unreasonable requirements on industry To the maximum extent practicable, RSPA is proposing to accommodate RMW prepared in accordance with other Federal regulations, as discussed in Section V of this notice. Furthermore, RSPA is proposing to amend and clarify certain provisions that are frequently misconstrued.

IV General Summary of the ANPRM

The ANPRM was issued to invite interested persons to participate in the rulemaking process by submitting views and information on issues concerning Division 6.2 materials. RSPA asked 29 questions in the ANPRM. The questions addressed areas in the HMR that were identified as problem areas in comments and petitions received following issuance of the December 1991 final rule. RSPA requested information on a number of complex issues including the burdens of compliance with the HMR and other Federal regulations, the need for revised packaging standards, the need to expand or narrow the definitions for infectious substances and RMW and the costs incurred to manage these materials in transportation. RSPA requested commenters to provide as much quantitative information as was available concerning costs and benefits attributable to their recommendations.

RSPA received approximately 54 written comments in response to the ANPRM and 13 oral comments at the public meeting. Comments were submitted by a variety of organizations, including associations representing hospitals, blood centers and laboratories, disposal service companies, Federal and State agencies, packaging manufacturers, and private individuals. In responding to the ANPRM, some commenters submitted views on issues not specifically addressed in the ANPRM.

The commenters provided widely divergent views on the extent to which the regulations should be revised or amended. Some commenters believed that RSPA should adopt a "universal precautions approach, as utilized by the Occupational Safety and Health Administration (OSHA) of the Department of Labor in regulations applicable to bloodborne pathogens (29 CFR 1910.1030); that is, all materials that are potentially infectious are treated as if known to be infectious. Others suggested that RSPA should withdraw from regulation of infectious substances and RMW asserting that other agencies regulations provide an adequate level of safety in transportation. Several commenters claimed that the regulation of RMW was best left to the EPA, even though EPA regulation of RMW ended in 1991

Several commenters provided information on the overall quantities and costs of disposal for medical waste. However, there was not much useful information as to what portion of that waste stream was subject to RSPA requirements, either before or after the HM–181 final rules, incremental costs or savings resulting from the December 1991 final rule, or even what portion of the disposal costs were the result of regulatory requirements. Commenters estimated varying disposal costs from $0.10 to $2.00 per pound

V Proposed Rule

After considering the comments and petitions for reconsideration that were filed, and following an examination of the issues surrounding the transportation of infectious substances and RMW RSPA is limiting the proposals in this notice to those issues concerning infectious substances and RMW that must be addressed in the short term to ensure safe transportation of these materials without unduly impacting the regulated industry RSPA intends to address other pertinent issues, such as harmonizing the HMR with international regulations, adopting bulk packaging provisions for RMW and evaluating the adequacy of existing Federal regulations for biological products and diagnostic specimens, in future rulemaking action. Although these issues are important, they are complex and may result in additional requirements or substantial changes to the HMR. Thus, it is not appropriate to include them in this notice, except to discuss them in terms of future action. The "long-term issues are discussed further in Section VI of this notice.

In this NPRM, RSPA is proposing to amend the provisions of the HMR applicable to Division 6.2 materials to enhance the effectiveness of the HMR and minimize costs incurred by industry. Interested persons are invited to comment on these proposals. A public meeting will be held on January 17 1995, at which oral comments are invited.

A. Definitions

Several commenters requested confirmation of their understanding that the provisions for RMW do not apply to sterilized medical wastes or wastes that do not contain an infectious substance. This understanding is correct. As stated in the preamble to the January 3, 1991 final rule, if a medical waste has been treated so as to eliminate its hazard as an infectious substance, then it is not subject to the HMR. No additional processing of the waste for aesthetics, such as that formerly required by the EPA under the MWTA, is required. To clarify this point, RSPA is proposing to revise § 173 134 by adding exceptions for any material that contained an infectious substance but has been treated to eliminate the hazard. In addition, consistent with EPA-provided exceptions under the MWTA regulations and based on RSPA s own initiative, RSPA is proposing to clarify that the following materials are not considered RMW: (1) EPA hazardous wastes; (2) household waste; (3) corpses remains, and anatomical parts intended for ceremonial interment or cremation, and (4) animal waste generated in animal husbandry or food production

Based on commenters requests and RSPA s initiative, RSPA is proposing to simplify the definition of RMW by

adopting a criteria-based definition, rather than a list-based definition. The definition in Appendix G to part 173 did not specify that a category of waste, such as "unused sharps," was only regulated if the waste contained an infectious substance. RSPA never intended to regulate medical waste that does not contain an infectious substance. Therefore, RSPA is proposing to revise the definition of RMW to remove the Appendix G categories and replace them with a generic definition. RMW would be defined as a waste or reusable material, other than a Class 7 (radioactive) material or a culture or stock of an infectious substance, which contains an infectious substance and is generated in the diagnosis, treatment or immunization of human beings or animals, research pertaining thereto, or the production or testing of biological products.

Another issue of concern to RSPA was whether waste cultures and stocks should be treated as RMW or as infectious substances for the purposes of packaging and hazard communication for transportation. Several commenters recommended that waste cultures and stocks should be treated as infectious substances rather than as RMW One commenter stated that the hazards posed by these materials are the same regardless of "whether the untreated cultures and stocks are to undergo further manipulation or are destined for disposal. Another commenter stated that cultures and stocks demand very careful packaging and handling. The commenter added that packagings required for most RMW are not adequate for untreated cultures and stocks. Some commenters stated that cultures and stocks should be handled as RMW because optimal conditions for growth are no longer present in the waste stream and most of these materials are sterilized before transportation. In the case of the generators that cannot sterilize on-site, the Texas Water Commission asserted that the quantity of these materials in the waste stream is probably insufficient to make the waste significantly more infectious than other forms of RMW

RSPA agrees with those commenters who suggested that discarded cultures and stocks, because of their concentration, pose a greater degree of risk than other medical waste and should be treated as infectious substances rather than RMW Therefore, RSPA is proposing to exclude untreated waste cultures and stocks from the definition of RMW and subject them to the more rigorous packaging provisions applicable to infectious substances other than RMW RSPA does not believe that this proposal will impose additional burdens on industry because, based on comments, these materials are largely treated on-site prior to disposal.

RSPA received comments stating that contaminated laundry and other recyclable/reusable materials, such as used surgical instruments that are cleaned and sterilized off-site, should be handled in accordance with OSHA regulations. The OSHA regulations in 29 CFR 1910.1030 provide that contaminated laundry shall be placed and transported in bags or containers labeled or color-coded in accordance with paragraph (g)(1)(i) of the OSHA regulations or, if utilizing universal precautions, alternative labeling is permitted if it is recognizable to all employees as requiring compliance with universal precautions. In addition, OSHA requires contaminated laundry that is wet and presents a reasonable likelihood of soak-through of or leakage from the bag or container to be placed in bags or containers which prevent soak-through and/or leakage of fluids to the exterior. One commenter stated that since these waste materials are not considered hazardous wastes under EPA regulations, they should not be RMW under DOT regulations. The American Type Culture Collection suggested that laundry and surgical instruments should only be regulated in transportation if they are known to be infectious. To relieve the burden of dual compliance with the HMR and OSHA regulations, RSPA is proposing to except contaminated laundry and other reusable materials from the HMR if they are handled in accordance with the OSHA requirements in 29 CFR 1910.1030.

In the ANPRM, RSPA reopened the issue of regulating infectious substances affecting animals only Several commenters objected to regulating substances "infectious to animals only Commenters suggested that RSPA include only those substances infectious to humans and those infectious to humans and animals (zoonotic), but not those infectious to animals only Some commenters stated that the regulations of the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture adequately covers substances infectious to animals. One commenter suggested that if RSPA defers to other regulations for these materials, the HMR should cross-reference those Federal regulations.

Under the Federal hazardous material transportation law RSPA must regulate the transportation of materials that may pose an unreasonable risk to health and safety or property Animal pathogens may pose an unreasonable risk to animals. Furthermore, RSPA has examined the APHIS regulations contained in 9 CFR parts 1–199 and determined that they do not address transportation concerns with regard to communication of hazard, provision of emergency response information, and adequacy of packaging. Therefore, in this notice, RSPA is proposing to regulate Division 6.2 materials affecting animals only Although the requirements that were scheduled to go into effect on October 1, 1994, included "animals" in the definition of "infectious substance, RSPA has delayed the compliance date for these materials until October 1, 1995. See Section II for more information concerning the extension of compliance dates. RSPA is requesting more comments on this issue.

RSPA received several requests to clarify that the terms "biological product" and "diagnostic specimen do not include materials that do not contain infectious substances. As previously stated, RSPA does not intend to regulate materials that do not pose a hazard in transportation. Therefore, for clarity RSPA is proposing to revise the definitions of "biological product" and "diagnostic specimen to include only those materials that contain an infectious substance. RSPA also would clarify that the terms "biological product, diagnostic specimen," and "regulated medical waste are all subcategories of Division 6.2 materials.

B. RMW Exception

RSPA received several comments on the ANPRM claiming that the regulations imposed by RSPA overlap, and sometimes conflict with, regulations/guidelines established by other agencies, which unnecessarily increases costs and confusion. One commenter suggested that inconsistencies should be eliminated between Federal and State regulations governing RMW Another commenter stated that overlapping regulations clearly increase non-compliance; however, the associated costs are difficult to assess. One commenter asserted that current Federal regulations do not appear to be financially burdensome but do complicate compliance. One commenter claimed that overlapping Federal regulations are not so much burdensome or costly as that they are largely ignored. Another commenter stated that varying medical waste regulations increase the volume of waste that must be specially handled. Many commenters requested consolidation of the regulations.

More specifically commenters stated that the appearance of multiple labels on a package of infectious substances causes unnecessary confusion to transport workers and emergency responders. One commenter claimed that multiple labels contribute to the mismanagement of medical waste by transport workers and emergency response personnel. Several commenters recommended that one label is sufficient to communicate the hazard. One commenter suggested that the CDC "BIOMEDICAL MATERIAL label and the OSHA "BIOHAZARD" marking should be allowed only on stationary materials and equipment. Some commenters recommended that RSPA adopt the UN Recommendations label for infectious substances because it is internationally recognized. One commenter stated that appropriate worker training would eliminate much of the confusion experienced by transport workers and emergency response personnel.

RSPA recognizes that overlapping Federal regulations for infectious substances and RMW cause confusion and result in frustrated shipments. Therefore, RSPA is proposing to provide an exception from the HMR labeling and packaging requirements for RMW transported by private and contract carriers, that is packaged in a packaging that complies with OSHA requirements, is rigid, conforms to the general packaging requirements of 49 CFR 173.24 and 173.24a, and is marked with the OSHA "BIOHAZARD" marking. This exception would be limited to transport by private or contract carrier because these carriers generally transport RMW exclusively and have the demonstrated ability to implement appropriate handling procedures which offset potentially lesser packaging integrity RMW that is offered for transportation and transported by common carrier would be subject to the packaging requirements of § 173.197 RSPA invites comments on this matter.

Other than this exception for RMW RSPA is not proposing in this NPRM to accept other agencies' labels or markings in place of the label or marking requirements for infectious substances packagings. The "INFECTIOUS SUBSTANCE" label is internationally recognized, is required under the ICAO Technical Instructions for transport by aircraft, and is consistent in size and appearance with DOT's other hazard warning labels. Unlike OSHA s "BIOHAZARD" marking, the DOT label conveys the class number of the material, emergency information in the event of a spill or incident, and has minimum size requirements to ensure its visibility

C. Miscellaneous

RSPA is proposing to relocate the exceptions for biological products and diagnostic specimens in § 173.196 and the definition and exceptions for RMW in Appendix G to part 173 to § 173.134 to ease compliance. Also, in response to a question concerning use of the term "diagnostic specimen versus "clinical specimen," many commenters recommended that RSPA continue using diagnostic specimen instead of "clinical specimen because the term "diagnostic specimen is commonly used in industry RSPA agrees and would retain the terminology. RSPA is proposing to amend the terminology used in the incident reporting requirements in § 171.15 from "etiologic agents to "infectious substances (etiologic agents)"

RSPA has received several requests for clarification as to whether infectious substance packagings that successfully pass the tests in § 178.609 must be certified and marked. According to § 173.196, packagings for infectious substances are required to be capable of passing the tests in § 178.609. These packagings are not required to be marked and certified. RSPA is proposing to add a provision in § 178.609 that clarifies that packagings conforming to this section are not subject to the marking requirements of § 173.503. However, the eighth revised edition of the UN Recommendations prescribes packaging certification marking requirements for infectious substances packagings. Therefore, RSPA may propose similar requirements in the interest of international harmonization, in future rulemaking action. (See Section VI of this notice.)

RSPA would clarify in § 173.134 that Division 6.2 materials other than RMW are not assigned a packing group. RMW would be assigned to a Packing Group II performance level.

D. Air Transportation

In response to a question in the ANPRM, RSPA received comments concerning shipments of RMW by modes other than highway Commenters stated that RMW is transported predominantly by highway however other modes of transportation also are used. Some commenters reported that used sharps are transported by air through the U.S. Postal Service (USPS) "mail-in" sharps program. RSPA received a petition requesting an amendment to the HMR to permit the transportation of similar quantities and packages of RMW by aircraft other than in mail. RSPA also received comments from a number of health care facilities located in rural areas, e.g., Alaska, requesting that the regulations facilitate transportation of medical wastes by aircraft. The commenters stated that health clinics in remote areas are only accessible by air or water. Commenters reported that it is not practical for the air carriers to provide cargo-only flights.

RSPA is proposing to add two special provisions that would permit the transportation of RMW by aircraft. A new Special Provision A13" would be added to allow the transportation of sharps aboard passenger and cargo-carrying aircraft in quantities of not more than 16 kilograms (35 pounds) per package and maximum liquid content of 50 milliliters for each inner packaging. This provision is consistent with USPS regulations for the mailability of used sharps under 39 CFR Part 111 and would serve to eliminate confusion as to whether sharps mailers are acceptable for air transportation. RSPA also is proposing to add Special Provision A14" to allow shipments of RMW to be transported by aircraft in quantities not exceeding 16 kilograms (35 pounds) for solid waste and 12 liters (3 gallons) for liquid waste, when means of transportation other than air are impracticable or unavailable. Even though these provisions would not have any effect on the movement of RMW until adopted, proposal of these provisions is intended to clarify that sharps and RMW from Alaska and other remote areas are permitted aboard aircraft. See Section VI of this preamble for possible future rulemaking concerning quantity limitations aboard aircraft.

RSPA also is proposing to revise the I.D. number for RMW from a domestic only recognized I.D. number (NA 9275) to an internationally recognized I.D. number (UN 3291). This proposed amendment is consistent with the UN Recommendations and the ICAO Technical Instructions.

E. Proposed Extension of Compliance Date

RSPA intended to issue this notice of proposed rulemaking simultaneously with the final rule which was published on September 22, 1994 (see Section II of this notice). Due to a delay in publication of this notice, RSPA is proposing to extend the compliance date once again for requirements applicable to regulated medical waste and infectious substances affecting only animals from October 1, 1995, to January 1, 1996. This is intended to allow sufficient time for the public to comment on the proposals contained in

this notice, for RSPA to evaluate the comments received, and, based on the merits of the comments, publish a final rule. RSPA invites comments on the need for this proposed extension.

VI. Scope of Future Work

RSPA believes that uniform standards, applicable to both domestic and international transportation, are essential to ensuring the safe and efficient movement of infectious substances. To this end, RSPA continues to work with other Federal agencies and the United Nations Subcommittee of Experts on the Transport of Dangerous Goods to improve standards for classification, hazard communication, packaging and operational control of infectious substances. The HMR are generally consistent with the United Nations Recommendations on the Transport of Dangerous Goods (UN Recommendations), although there are some differences. RSPA anticipates proposing changes to the HMR in future rulemaking concerning defining criteria, particularly the adoption of risk groups and regulation of genetically-modified organisms and microorganisms, and new shipping descriptions and marking requirements for non-bulk packagings based on the UN Recommendations.

The ICAO Technical Instructions prescribe no air quantity limits for RMW RSPA may propose to align its air quantity limits for RMW with the ICAO in future rulemaking action.

Transportation safety for all categories of infectious substances (i.e., cultures and stocks, diagnostic specimens, biological products containing infectious substances, and RMW) could be enhanced through imposition of uniform classification, hazard communication and packaging requirements. Both through rulemaking action and in working with other Federal agencies, RSPA anticipates advocating standards based on UN Recommendations, such as for the internationally-recognized "INFECTIOUS SUBSTANCE" label and for performance-oriented packaging.

RSPA intends to continue its review of the HMR and the regulations of other Federal agencies and to work with these agencies to identify and eliminate inconsistencies, overlaps, gaps and inadequacies in regulatory coverage. Although RSPA is aware of allegations of inconsistent regulations, RSPA has not identified any regulatory impediment to compliance with the HMR and the regulations of other agencies.

There are obvious overlaps between agency regulations, such as differing labeling and packaging requirements of RSPA and the CDC for cultures and stocks of infectious substances. CDC has expressed a willingness to work with RSPA in resolving these differences through changes to one or both agencies' regulations. There also are differing labeling and packaging requirements of RSPA and OSHA for medical waste as discussed in the proposed rule change elsewhere in this notice. Although compliance with two or more differing agencies' regulations may be burdensome, RSPA has not identified any situation where compliance with one agency's regulations is a barrier to compliance with another agency's regulations. However, RSPA agrees with commenters' contentions that differing requirements cause confusion and increase compliance costs and the likelihood of non-compliance based on misunderstanding. RSPA intends to work with other Federal agencies to eliminate overlaps, where feasible.

Of more concern to RSPA than overlapping requirements are gaps or inadequacies of regulation which may impact transportation safety. RSPA is particularly concerned that diagnostic specimens and biological products known or suspected to contain infectious substances may be transported with inadequate or no hazard communication (e.g., shipping paper descriptions identifying them as hazardous, package markings and labels to identify the hazard class and name of the hazardous material, emergency response information specifying steps to be taken in the event of an incident in transportation) and may be transported in packagings which are inadequate for the conditions of transport and the risks posed by the materials contained therein.

RSPA recognizes that the regulations under the Food and Drug Administration (FDA) of the Department of Health and Human Services (21 CFR parts 312 and 600–680) and APHIS of the United States Department of Agriculture (9 CFR parts 102–104) are designed to protect the safety, potency, and purity of the biological product and are not specifically intended to protect transport workers or the public against exposure to biological products. RSPA also understands that CDC regulations in 42 CFR 72.3 govern packaging and labeling for diagnostic specimens that are equivalent to the HMR for infectious substances. However, regulatory gaps may exist in CDC's regulations because the list of agents is outdated. For example, the list does not include HIV or Lyme disease.

Because of the need for expeditious delivery, many biological products and diagnostic specimens are transported by aircraft. Although not subject to incident reporting requirements of the HMR, RSPA understands that packages of these materials often are damaged in transit aboard aircraft, causing costly delays and posing risks to cargo handlers, emergency responders, others who may be exposed to the materials and property. Although many commenters to the ANPRM on this issue supported regulation of these materials under the HMR, RSPA is not proposing to impose requirements on biological products and diagnostic specimens at this time. RSPA would continue to except biological products and diagnostic specimens from the HMR. RSPA anticipates proposing deletion of exceptions for these materials, if justified in terms of benefits versus costs, in future rulemaking action. Other exceptions, such as those for hazardous wastes, may be reconsidered at a future date if safety concerns warrant.

RSPA would authorize, by today's proposed rule, non-bulk, non-specification packagings for RMW under specified conditions. RSPA intends to monitor closely incident reports for these shipments to ensure that the packaging and handling requirements achieve an acceptable level of safety and, if not, will propose adjustments in future rulemaking action.

Several other issues may be considered in future rulemaking action. Although no bulk packagings for RMW are specified in the HMR, their use is authorized under the provisions of a number of exemptions. RSPA anticipates proposing to convert the provisions of some or all of these exemptions into regulations of general applicability RSPA currently requires the segregation of poisons from foodstuffs. There may be sufficient justification, in terms of safety, to impose similar restrictions on all infectious substances or RMW only RSPA is aware that a number of States have differing vehicle marking requirements for vehicles containing RMW Although RSPA has not required a vehicle marking to date, there may be a need to propose one. Finally in the interest of minimizing cost impacts on the regulated industry RSPA did not adopt vehicle placarding requirements for Division 6.2 materials. For purposes of emergency response and international harmonization, it may be beneficial to adopt an "INFECTIOUS SUBSTANCE" placard in future rulemaking action.

VII. Regulatory Analyses and Notices

A. Executive Order 12866 and DOT Regulatory Policies and Procedures

This proposed rule is considered a significant regulatory action under section 3(f) of Executive Order 12866 and, therefore, was reviewed by the Office of Management and Budget. This rule is significant under the Regulatory Policies and Procedures of the Department of Transportation (44 FR 11034), because of substantial public interest. A regulatory evaluation is available for review in the docket.

B. Executive Order 12612

This proposed rule has been analyzed in accordance with the principles and criteria contained in Executive Order 12612 ("Federalism"). Federal law expressly preempts State, local, and Indian tribe requirements applicable to the transportation of hazardous material that cover certain subjects and are not substantively the same as the Federal requirements. 49 U.S.C. 5125(b)(1). These subjects are:

(A) The designation, description, and classification of hazardous material;

(B) The packing, repacking, handling, labeling, marking, and placarding of hazardous material;

(C) The preparation, execution, and use of shipping documents pertaining to hazardous material and requirements respecting the number, content, and placement of those documents;

(D) The written notification, recording, and reporting of the unintentional release in transportation of hazardous material; or

(E) The design, manufacturing, fabrication, marking, maintenance, reconditioning, repairing, or testing of a package or container which is represented, marked, certified, or sold as qualified for use in the transportation of hazardous material.

This proposed rule concerns the classification, packaging, labeling, and handling of hazardous material, among other covered subjects.

If adopted as final, this rule would preempt any State, local, or Indian tribe requirements concerning these subjects unless the non-Federal requirements are "substantively the same" (see 49 CFR 107.202(d)) as the Federal requirements.

Federal law (49 U.S.C. 5125(b)(2)) provides that if DOT issues a regulation concerning any of the covered subjects after November 16, 1990, DOT must determine and publish in the **Federal Register** the effective date of Federal preemption. That effective date may not be earlier than the 90th day following the date of issuance of the final rule and not later than two years after the date of issuance. RSPA requests comments on what the effective date of Federal preemption should be for the requirements in this proposed rule that concern covered subjects.

C. Regulatory Flexibility Act

This proposed rule would revise the requirements for infectious substances and regulated medical waste contained in the HMR by narrowing the scope of these provisions. The proposed changes in this rule would provide relief to shippers, carriers of infectious substances and regulated medical waste, and some packaging manufacturers, some of whom are small entities (e.g., medical clinics, governmental jurisdictions, and not-for-profit organizations). Therefore, I certify that this proposal will not, if promulgated, have a significant economic impact on a substantial number of small entities. This certification is subject to modification as a result of a review of comments received in response to this proposal.

D. Paperwork Reduction Act

There are no new information collection requirements in this proposed rule.

E. Regulation Identifier Number (RIN)

A regulation identifier number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN numbers contained in the heading of this document can be used to cross-reference this action with the Unified Agenda.

List of Subjects

49 CFR part 171

Exports, Hazardous materials transportation, Hazardous waste, Imports, Incorporation by reference, Reporting and recordkeeping requirements.

49 CFR part 172

Hazardous materials transportation, Hazardous waste, Labeling, Marking, Packaging and containers, Reporting and recordkeeping requirements.

49 CFR part 173

Hazardous materials transportation, Packaging and containers, Radioactive materials, Reporting and recordkeeping requirements, Uranium.

49 CFR part 178

Hazardous materials transportation, Motor vehicle safety Packaging and containers, Reporting and recordkeeping requirements.

In consideration of the foregoing, 49 CFR parts 171, 172, 173, and 178 would be amended as follows:

PART 171—GENERAL INFORMATION, REGULATIONS, AND DEFINITIONS

1. The authority citation for part 171 would continue to read as follows:

Authority: 49 U.S.C. 5101–5127 49 CFR 1.53

2. In § 171.8, the following definition would be added in appropriate alphabetical order:

§ 171.8 Definitions and abbreviations.

Regulated medical waste See § 173.134 of this subchapter

§ 171.15 [Amended]

3. In § 171.15, the wording "etiologic agents" in paragraphs (a)(3) and (b) introductory text would be revised to read "infectious substances (etiologic agents)"

PART 172—HAZARDOUS MATERIALS TABLE, SPECIAL PROVISIONS, HAZARDOUS MATERIALS COMMUNICATIONS, EMERGENCY RESPONSE INFORMATION, AND TRAINING REQUIREMENTS

4. The authority citation for part 172 would continue to read as follows:

Authority: 49 U.S.C. 5101–5127 49 CFR 1.53

§ 172.101 [Amended]

5. In § 172.101, in the Hazardous Materials Table, the following changes would be made:

a. For the entry "Infectious substances, affecting animals *only*" in Column (8A), "196" would be removed and replaced with "134"

b. For the entry "Infectious substances, affecting humans" in Column (8A), "196" would be removed and replaced with "134"

c. For the entry "Regulated medical waste" in Column (4), the identification number "NA9275" would be removed and replaced with "UN3291" in Column (7), A13, A14 would be added; and in Column (8A), "197" would be removed and replaced with "134"

6. In § 172.102, in paragraph (c)(2), Special Provisions A13 and A14 would be added in alphanumeric sequence, to read as follows:

§ 172.102 Special provisions.

(c)

(2)

Code/Special Provisions

*

A13 Non-bulk packagings conforming to § 173.197 of this subchapter not exceeding 16 kilograms (35 pounds) gross mass containing used sharps are permitted for transportation by aircraft. Maximum liquid content in each inner packaging may not exceed 50 milliliters (1.7 ounces).

A14 Non-bulk packagings of regulated medical waste conforming to § 173.197 of this subchapter not exceeding 16 kilograms (35 pounds) gross mass for solid waste or 12 liters (3 gallons) total volume for liquid waste may be transported by passenger and cargo aircraft when means of transportation other than air are impracticable or not available.

PART 173—SHIPPERS—GENERAL REQUIREMENTS FOR SHIPMENTS AND PACKAGINGS

7 The authority citation for part 173 would continue to read as follows:

Authority: 49 U.S.C. 5101–5127; 49 CFR 1.53.

8. Section 173.134 would be revised to read as follows:

§ 173.134 Class 6, Division 6.2—Definitions, exceptions and packing group assignments.

(a) *Definitions.* For the purposes of this subchapter, the categories of materials that comprise Division 6.2 are defined as follows:

(1) An *infectious substance* means a viable microorganism, or its toxin, which causes or may cause disease in humans or animals, and includes those agents listed in 42 CFR 72.3 of the regulations of the Department of Health and Human Services and any other agent that causes or may cause severe, disabling or fatal disease. The terms *infectious substance* and *etiologic agent* are synonymous.

(2) A *diagnostic specimen* means any human or animal material being shipped for purposes of diagnosis which contains an infectious substance including, but not limited to, excreta, secreta, blood, blood components, tissue, and tissue fluids.

(3) A *biological product* means a material which contains an infectious substance and is prepared and manufactured in accordance with the provisions of 9 CFR part 102 (Licenses for biological products), 9 CFR part 103 (Experimental products, distribution, and evaluation of biological products prior to licensing), 9 CFR part 104 (Permits for biological products), 21 CFR part 312 (Investigational new drug application), or 21 CFR parts 600 to 680 (Biologics).

(4) A *regulated medical waste* means a waste or reusable material, other than a Class 7 (radioactive) material or a culture or stock of an infectious substance, which contains an infectious substance and is generated in—

(i) The diagnosis, treatment or immunization of human beings or animals;

(ii) Research pertaining to the diagnosis, treatment or immunization of human beings or animals; or

(iii) The production or testing of biological products.

(b) *Exceptions.* (1) The following are not subject to any requirements of this subchapter if the items as packaged do not contain any material otherwise subject to the requirements of this subchapter:

(i) Biological products;

(ii) Diagnostic specimens;

(iii) Laundry or medical equipment which conforms to 29 CFR 1910.1030 of the regulations of the Occupational Safety and Health Administration of the Department of Labor;

(iv) A material, including waste, which previously contained an infectious substance, that has been treated by steam sterilization, chemical disinfection, or other appropriate methods, so that it no longer poses the hazard of an infectious substance;

(v) Household waste, i.e., any waste material, including garbage, trash and sanitary waste in septic tanks, derived from households, including single and multiple residences, hotels and motels;

(vi) Corpses, remains and anatomical parts that are intended for ceremonial interment or cremation; and

(vii) Animal waste generated in animal husbandry or food production.

(2) A hazardous waste is not subject to regulation as a regulated medical waste.

(3) A regulated medical waste that is transported by a private or contract carrier is excepted from—

(i) The requirement for an "INFECTIOUS SUBSTANCE" label if the outer packaging is marked with a "BIOHAZARD" marking in accordance with 29 CFR 1910.1030; and

(ii) The specific packaging requirements of § 173.197 if packaged in a rigid non-bulk packaging conforming to—

(A) The general packaging requirements of §§ 173.24 and 173.24a and

(B) Packaging requirements specified in 29 CFR 1910.1030.

(c) *Assignment of packing groups/applicable packaging sections.* (1) Division 6.2 materials, other than regulated medical waste, are not assigned a packing group. Packaging requirements for these materials are prescribed in § 173.196.

(2) Except as otherwise provided, regulated medical waste is assigned to Packing Group II and must be packaged as specified in § 173.197

Appendix G [Removed]

9. Appendix G to part 173 would be removed.

PART 178—SPECIFICATIONS FOR PACKAGINGS

10. The authority citation for part 178 would continue to read as follows:

Authority: 49 U.S.C. 5101–5127; 49 CFR 1.53

11. In § 178.609, paragraph (i) would be added to read as follows:

§ 178.609 Test requirements for packagings for infectious substances (etiologic agents).

(i) Packagings subject to this section are not subject to § 178.503 or any other requirements of this subpart, except § 178.608.

Issued in Washington, DC on December 14 1994, under authority delegated in 49 CFR part 106, appendix A

Alan I. Roberts,

Associate Administrator for Hazardous Materials Safety

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