Title: Amendment of parts 2 and 90 of the Commission's rules to Provide for the Use of 200 Channels Outside the Designated Filing Areas in the 896–901 MHz and 935–940 MHz Bands Allocated to the Specialized Mobile Radio Service.
Action: New collection.
Respondents: State or local governments, business or other for profit entities, non-profit institutions, and small business or organizations.
Estimated Annual Burden: The item requires new reporting requirements which will impose 360 total burden hours for information to be filed as part of the original applications, 4.5 total hours for the three nationwide licensees to file system status reports at 4, 6, and 10 years after the initial license is granted and every 10 years after that, and 67.5 total hours for the 6 licensees in each of seven regions to file reports at 2, 5, and 10 years after the initial license is granted.
Estimated frequency of response. For nationwide licensees: At 4, 6, and 10 years after the initial license is granted and every 10 years after. For regional licensees: At 2, 5, and 10 years after the initial license is granted, and every 10 years after that.
Needs and uses. Periodic reports are required to ensure efficient use of the spectrum and to confirm that licensees have met the minimum construction requirements that their licenses are conditioned upon.

List of Subjects in 47 CFR Part 90

Business and industry, Communications equipment, Radio.

Federal Communications Commission.

Donna R. Searcy,

Secretary.

[FR Doc. 93–4736 Filed 3–2–93; 8:45 am]

BILLING CODE 6712–01–M

DEPARTMENT OF TRANSPORTATION

49 CFR Part 23

[Docket No. 48478; Notice 93–10]

RIN 2105–AB92

Participation by Disadvantaged Business Enterprise in Department of Transportation Programs

AGENCY: Department of Transportation, Office of the Secretary.

ACTION: Extension of comment period.

SUMMARY: The Department is extending the comment period on its notice of proposed rulemaking to amend its disadvantaged business enterprise (DBE) regulation. The NPRM proposed changes in a number of provisions of the DBE rule. The extension is in response to requests from interested parties for additional time to review the proposed rule and formulate comments.

DATES: Comments are requested by April 8, 1993. Late-filed comments will be considered to the extent practicable.

ADDRESSES: Comments should be sent, preferably in triplicate, to Docket Clerk, Docket No. 48478, Department of Transportation, 400 7th Street, SW., room 4107, Washington, DC 20590. Comments will be available for inspection at this address from 9 a.m. to 5:30 p.m., Monday through Friday. Commenters who wish the receipt of their comments to be acknowledged should include a stamped, self-addressed postcard with their comments. The Docket Clerk will date-stamp the postcard and mail it back to the commenter.

FOR FURTHER INFORMATION CONTACT: Robert C. Ashby, Deputy Assistant General Counsel for Regulation and Enforcement, Department of Transportation, 400 7th Street, SW., room 10424, Washington, DC 20590. (202) 366–9306 (voice); (202) 755–7687 (TDD).

SUPPLEMENTARY INFORMATION: The Department of Transportation published a notice of proposed rulemaking (NPRM) on December 9, 1992 (57 FR 58288) to amend its disadvantaged business enterprise (DBE) rule (49 CFR part 23). The proposed amendments would tighten the structure of the rule, improve administrative procedures, provide for better coordination of guidance from the Department, clarify certification standards, and add new DBE program elements. The original 90-day comment period for this NPRM would end March 9, 1993.

The Department has received a number of written requests from commenters, particularly transit authorities and DBE firms, for additional time to review the NPRM and to formulate comments on the proposal. Department staff have also received a number of informal comments and inquiries at meetings and in phone calls asking to extend the comment period. The Department believes that it would be beneficial to extend the comment period for a time, in order to ensure that it will have the benefit of thoughtful comments from the widest possible spectrum of interested parties. For these reasons, the Department has determined that a 30-day extension is appropriate. The comment period will now close on April 8, 1993. As is typically the case with DOT rulemakings, late-filed comments will be considered to the extent practicable.

Issued this 25th day of February, 1993 at Washington, DC.

Rosalind A. Knapp,

Acting General Counsel.

[FR Doc. 93–4879 Filed 3–2–93; 8:45 am]

BILLING CODE 4910–62–M

Research and Special Programs Administration

49 CFR Parts 171, 172, and 173

[Docket No. HM–181G; Notice No. 93–5]

RIN 2137–AC36

Infectious Substances; Notice of Public Hearing and Advance Notice of Proposed Rulemaking

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

ACTION: Notice of public hearing and advance notice of proposed rulemaking.

SUMMARY: On December 20, 1991, RSPA published a final rule in the **Federal Register** amending the Hazardous Materials Regulations (HMR), including those for infectious substances. RSPA received two petitions for reconsideration to revise the infectious substance provisions in the December 1991 final rule and a number of comments and exemption applications which raised issues for which RSPA needs additional public input. In this document, RSPA is announcing a public hearing to gain more detailed information on the need for additional regulatory action concerning infectious substances in light of petitions and comments received.

DATES: *Comments.* Written comments concerning this notice must be submitted on or before April 20, 1993.

Public Hearing. A public hearing will be held from 9:30 a.m. to 5 p.m. on March 17, 1993, in Washington, DC.

ADDRESSES: *Comments:* Address comments to Dockets Unit (DHM–30), Office of Hazardous Materials Safety, RSPA, U.S. Department of Transportation, Washington, DC 20590–0001. Comments should identify the docket (HM–181G) and notice number (Notice No. 93–5) 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 hearing. The March 17, 1993 public hearing will be held at the Regional Office Building Auditorium, room 1041, first floor, National Capital Region, General Services Administration, 7th and D Streets, SW., Washington, DC 20407.

Any person wishing to present an oral statement at the public hearing should notify Eileen Martin, by telephone or in writing, by March 15, 1993. Each request must identify the speaker; organization represented, if any; daytime telephone number; and the anticipated length of the presentation, not to exceed 10 minutes. Written text of the oral statement should be presented to the hearing officer prior to the oral presentation. The hearing may conclude before 5 p.m. if all persons wishing to testify have been heard.

FOR FURTHER INFORMATION CONTACT: Eileen Martin or Jennifer Posten, Office of Hazardous Materials Standards, (202) 366–4488, or George Cushmac, Office of Hazardous Materials Technology, (202) 366–4545, Research and Special Programs Administration, 400 Seventh St., SW., Washington, DC 20590–0001.

SUPPLEMENTARY INFORMATION:

I. History of Department of Transportation (DOT) 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 in 42 CFR 72.3, any agent that poses a similar degree of hazard, such as the acquired immune deficiency syndrome (AIDS) virus. The DHHS has not updated the list in 42 CFR 72.3 since July 1, 1980 (45 FR 48627). On March 2, 1990 (55 FR 7678), DHHS proposed to delete the list from its regulations but a final rule has not been published. 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.

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 [DHHS] 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 DHHS 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 171–80) 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—the Performance-Oriented Packaging Standards. In that 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 [DHHS]. 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 [DHHS] 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 latter document were primarily in response to petitions for reconsideration received on the December 21, 1990 final rule and also made editorial and technical corrections to the December 21, 1990 final rule, and to the January 3, 1991 final rule.

E. January 3, 1991 Final Rule and Partial Response to a Petition For Reconsideration

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's (EPA's) 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 do 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 transition 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 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 created a subcategory of infectious substances—infectious substances that are contained in or constitute medical waste. The threshold question to be addressed is whether an infectious substance is being offered for transportation or transported. If so, the infectious substance must be labeled, packaged, and offered for transportation in accordance with the HMR. If the infectious substance is also medical waste, or is contained in medical waste, then the shipper may use the less rigorous packaging requirements that are 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 two 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.

An issue of particular concern to petitioners and commenters was the HMR's potential overlap or inconsistency with other Federal regulations governing infectious substances. Federal agencies such as the Occupational Safety and Health Administration (OSHA) of the Department of Labor (DOL), the Centers for Disease Control (CDC) and the Food and Drug Administration (FDA) of the DHHS, the United States Postal Service (USPS), and the Animal and Plant Health Inspection Service (APHIS) of the Department of Agriculture (USDA) have regulations applying to infectious substances/etiologic agents.

OSHA's regulations under Docket H-370 (56 FR 64004), "Occupational Exposure to Bloodborne Pathogens," cover issues dealing with worker exposure to potentially infectious materials. CDC administers regulations under 42 CFR Part 72 concerning the interstate shipment of etiologic agents. USPS recently published a final rule (57 FR 29028) concerning the mailability of sharps. USPS requires DOT labels, packagings designed and constructed in accordance with 49 CFR, absorbent material, and a manifest for used sharps and other medical devices shipped in the mail. APHIS regulates biological products derived from animal blood and tissue by prescribing permits, packaging, and labeling under 9 CFR parts 102–104.

Both OSHA and CDC require packaging and labeling for infectious substances/etiologic agents which differ from those of the HMR. Neither OSHA nor CDC require testing or certification of packagings. However, OSHA's definition for infectious substances is broader than RSPA's in that it assumes all human blood and human body fluids are infectious unless proven otherwise. The HMR's definition for infectious substances includes materials known or suspected to contain infectious substances. OSHA uses the term "bloodborne pathogens and other potentially infectious substances" and CDC uses the term "etiologic agents." In HM–181, RSPA adopted "infectious substances" in place of "etiologic agents," in part for consistency with international standards. These materials are referred to herein generically as infectious substances. Perhaps the most obvious overlap of the various infectious substance regulations is the fact that each agency/organization involved requires one or more different labels on packages.

In addition to suggesting the need for a uniform Federal approach to regulating infectious substances, petitioners and commenters have indicated that there may be a need to revise certain definitions and packaging provisions adopted under Docket HM–181. RSPA is also faced with evaluating the merits of aligning the HMR with the United Nations Recommendations on the Transport of Dangerous Goods (UN Recommendations). The HMR embody performance-oriented packaging standards, hazard communication standards, and classification criteria generally consistent with the UN Recommendations. These and other issues are further addressed in the section of this notice entitled "Request for Comments."

H. Transitional Provisions

RSPA had not completed its evaluation of the petitions for reconsideration as of October 1, 1992, the date on which the new HM–181 provisions for infectious substances were to take effect. On October 1, 1992, RSPA published a final rule (57 FR 45442) extending this transition date, found at 49 CFR 171.14(b)(3), to April 1, 1993. Based on the issues raised in this document, it is apparent that even more time will be needed in order to provide for notice and opportunity to comment and, if warranted, to develop additional rulemaking documents. Therefore, elsewhere in today's **Federal Register**, RSPA is further extending the transition date to January 1, 1994.

During the transition period, a person may comply with either the applicable "old" requirements of the HMR, i.e., those in effect on September 30, 1991, or the current requirements adopted under HM–181. A person who was not subject to the old requirements, but is subject to the new requirements, has until expiration of the transition period to comply with the new requirements. For example, a material which meets the new "infectious substance" definition but not the old "etiologic agent" definition, or which qualifies for the old 50 milliliter exception, may be shipped in accordance with the new requirements, but compliance is not mandatory until January 1, 1994. A person who was subject to the old requirements and is subject to the new requirements must comply with either the old or the new requirements.

II. Request for Comments

RSPA is requesting comments in response to the following questions and recommendations on possible regulatory changes to the requirements adopted under HM–142A and HM–181. Further, RSPA is conducting the public hearing to discuss these issues. RSPA's aim is to ensure that its regulations (1) adequately protect the public, transport workers, and the environment from the hazards posed by infectious materials; (2) do not impose undue burdens on the regulated industry; and (3) do not unnecessarily overlap or conflict with the regulations of other Federal agencies. Commenters are requested to present as much quantitative information as is available concerning costs and benefits attributable to the recommendations.

In the following questions, the provisions adopted under HM–181 are referred to as the "current" regulations, even though they may not be in effect due to transitional provisions.

A. Consistency With Other Regulations

1. Agencies such as RSPA, OSHA, USPS, APHIS, FDA and CDC regulate infectious substances. To what extent do overlapping Federal regulations affect transportation costs and create other burdens? What regulatory changes are recommended to ease the movement of these materials in transportation while still providing an adequate level of safety?

2. OSHA's "BIOHAZARD" label, CDC's "BIOMEDICAL MATERIAL" label, and DOT's "INFECTIOUS SUBSTANCE" label may all appear on packages in transportation, sometimes with two or more different labels on the same package. Does the appearance of multiple labels on packages cause confusion to transport workers or emergency response personnel? Considering each agency's differing definitions for infectious substances, are there practicable alternatives to multiple labeling?

3. The infectious substance definition in the HMR is partially based on the sixth edition of the UN Recommendations for the Transport of Dangerous Goods. For consistency with the UN Recommendations, substances infectious to animals were included in the definition. Should the HMR address substances infectious to animals for transportation purposes? Are these substances adequately addressed in regulations of other agencies such as those of the USDA?

4. RSPA is considering development of a proposal to incorporate the seventh revised edition of the UN Recommendations into the HMR. The seventh edition of the UN Recommendations differs from the HMR in that it (1) modifies the definitions of biological products and diagnostic specimens by including those that may contain infectious substances; (2) excludes toxins from the definition of infectious substances; and (3) includes infectious genetically modified organisms and microorganisms. Should the infectious substance regulations of the HMR conform to the seventh revised edition of the UN Recommendations?

5. A CDC report defines the term "universal precautions" as an approach to infection control that treats all human blood and certain human body fluids as if known to be infectious. This approach is utilized internationally and domestically by agencies such as OSHA and USPS. What percent of medical waste transported off-site is known to be infectious? How much more waste would be covered under the universal precautions approach? Is there a practicable means of differentiating between waste which can reasonably be expected to be infectious versus waste which can be expected not to be infectious? Should RSPA adopt universal precautions to be consistent with other agencies' infectious substance regulations?

6. Under OSHA's bloodborne pathogens rule, contaminated laundry must be properly packaged and each package must be labeled or color-coded prior to shipment. Under the HMR, laundry and other reusable materials containing infectious substances are not specifically addressed. In the absence of specific provisions or exceptions, they are subject to the same hazard communication and packaging requirements as cultures and stocks of infectious substances. Should RSPA except certain reusable materials, such as laundry and surgical instruments, from the HMR, should these items be addressed in a manner similar to OSHA's regulations, or should the HMR remain unchanged?

7. The CDC has proposed to remove the list of agents in 42 CFR 72.3 and replace it with a general definition: "*Etiologic agent* means a microbiological agent or its toxin that causes, or may cause, human disease." The HMR currently references the CDC list in the definition of infectious substances in 49 CFR 173.134. If CDC adopts the new definition, it would apply to many more materials than does DOT's definition, which limits disease-causing agents to those which are "severe, disabling or fatal." Should RSPA consider adopting the broader definition proposed by CDC? Are estimates available as to the number of additional infectious substance and regulated medical waste shipments that would be subject to the HMR if this were done?

8. Biological products and diagnostic specimens are currently excepted from regulation (unless they become regulated medical waste) under the HMR even though many of them contain infectious substances. The CDC defines "biological products" and "clinical specimens" similar to the HMR definitions. However, CDC provides packaging and labeling requirements for these materials. FDA, APHIS, and OSHA also have regulatory requirements applicable to biological products. For example, OSHA requires packaging and labeling for potentially infectious biological products and clinical specimens. Should RSPA remove the exception for biological products and diagnostic specimens that contain infectious substances under the HMR? Should RSPA exclude waste biological products and diagnostic specimens from regulation? Should RSPA adopt the term "clinical specimens"? What hazard communication and packaging standards, if any, should apply to biological products and diagnostic/clinical specimens under the HMR?

9. Currently under the HMR, untreated cultures and stocks of infectious substances transported for disposal would meet the definition for regulated medical waste. As such, they are subject to less rigorous packaging and hazard communication requirements than those applicable to non-waste cultures and stocks of infectious substances. Commenters requested that RSPA remove this provision and subject all cultures and stocks, including waste, to the more stringent infectious substance requirements, particularly those for packaging in 49 CFR 173.196, because of their high level of hazard. To what extent are waste cultures and stocks transported off-site without being rendered harmless (i.e., treated so that they are no longer capable of causing severe, disabling, or fatal disease)? Should these cultures and stocks be transported in the same manner as non-waste, i.e., subject to the packaging provisions of § 173.196?

B. Non-bulk packagings

10. RSPA is aware that packages of medical waste may undergo rough handling in transportation. However, commenters have stated that some of the performance tests in subpart M of part 178 of 49 CFR are irrelevant to the transportation of regulated medical waste in non-bulk packagings. Which tests are irrelevant and why?

11. The HMR require use of UN performance-based packagings which meet a Packing Group II performance level for regulated medical waste. UN packagings are required for other hazardous materials which pose an equivalent or lesser degree of potential hazard than regulated medical waste. What justification, if any, exists for relaxing packaging requirements for these materials?

12. For the purposes of packaging, medical waste may be differentiated as liquids, solids, or sharps. (Sharps are described in 49 CFR part 173, appendix G.) Are there different levels of risk associated with these forms? If so, should different packing group levels or different packaging standards apply?

13. Medical waste may often include both liquids and solids, with the liquids either absorbed in the solids or remaining as residues in bottles, bags, needles, or other containers. Under the provisions of the HMR, if there are any

liquid contents to be packaged, then only a UN packaging tested and certified for liquids may be used. This can necessitate the testing of many combinations of inner and outer packagings. Under what conditions, if any, should RSPA permit a packaging tested for solids to be used for regulated medical waste containing liquids? For example, should RSPA permit small amounts of liquid residues to be packaged as a solid, provided the inner packaging also contains absorbent waste materials in sufficient quantity to absorb the total volume of waste liquid residue?

14. Under the HMR, a plastic film bag (generally known as a "red bag") is authorized for regulated medical waste only as an inner packaging inside a rigid outer packaging, such as a fiberboard box. The completed package must be capable of withstanding Packing Group II performance levels. The thickness of the red bag is not specified. Is there a need to specify thicknesses for red bags of various capacities and, if so, what should they be?

15. What is the average or typical weight of a plastic film red bag containing medical waste? What is the maximum weight that might be found in transportation?

16. Presently under the HMR, the size of a sharps container may be as great as 400 kilograms maximum net mass for solids or 450 liters maximum capacity for liquids. As a practical matter, much smaller containers (e.g., 17 kilograms; 19 liters) are in use. In the interest of safety, should RSPA further restrict container size for sharps and, if so, to what degree? Is it practical to drain sharps containers of their liquid contents prior to transportation? Do any state or local laws require sharps to be disinfected (e.g., soaking needles in liquid bleach)? Should all sharps containers meet the requirements of the HMR applicable to packagings for liquids?

C. Bulk Packagings

17. The HMR prohibit the bulk transportation of regulated medical waste. However, RSPA is aware that medical waste has been transported in bulk packagings and currently has several applications for exemptions pending to permit the use of bulk packagings under the HMR. Generally, these bulk packagings are covered bins, constructed of polyethylene and ranging from about 450 to 850 liters (119 to 225 gallons) in capacity, into which red-bagged material and sharps receptacles are placed with no other intermediate containment. There are also roll-on-roll-off containers and van-type transport vehicles which have been used for the bulk transport of medical waste. Should RSPA revise the HMR to provide for the transport of regulated medical waste in bulk packagings?

18. For sizes where it might be practicable, such as for packagings in the 450 to 800 liter range, should RSPA authorize the use of bins which meet performance requirements applicable to non-bulk packagings?

19. Most of the covered bins which have been used for medical waste are seamless on their bottoms and sides, making them leakproof when in an upright position. Should RSPA require that bins be seamless or have fully sealed bottom and side seams? Most bins have top closures which are not leakproof, but are held closed by positive means (i.e., are held in place by other than gravity or friction). Is it necessary and practicable to require that top closures be leakproof and have positive means of closure or would operating controls such as "must be transported in a manner that will ensure they remain in an upright position" suffice in place of such a requirement?

20. Most bins used for wastes would not withstand the hydrostatic pressure test currently required for non-bulk packagings used for liquids. Under what circumstances, if any, should RSPA relax the hydrostatic test requirement for bulk packagings intended to contain liquid, infectious medical waste?

21. If RSPA were to authorize bulk size packagings (i.e., bins over 800 liters capacity and van-type vehicles or dump-body vehicles), what standards should apply? Should side and bottom seams be fully sealed? Should plastic film red bags be required as an intermediate packaging when infectious medical waste is transported? Should standards address ease of cleaning and provision of sumps to retain leakage from intermediate packaging?

D. Scope

22. Is infectious medical waste imported to or exported from the U.S.? If so, what are the circumstances of these shipments (e.g., why, where, what types of materials, mode of transport)?

23. To what extent is infectious medical waste transported by modes other than highway?

24. Some commenters suggested that of an estimated 158 million tons of U.S. municipal solid waste produced annually, between 0.3 percent to 1.0 percent is medical waste. Some sources suggest that approximately 15% of all medical waste actually contains infectious substances. Are these estimates accurate? Are they consistent with known operating experience?

25. Some commenters have stated that the risk of infection from medical waste comes almost entirely from sharps and is negligible for other wastes. Is this an accurate assessment? Are there objective criteria or statistics to support this assessment?

26. It has been suggested that 5% of the infectious medical waste in transportation contains sharps. Is this a reasonable estimate? If not, what is a better percentage?

27. What percentage of infectious substances offered for transportation off-site by hospitals, clinics and similar entities is intended for reuse or treatment rather than for disposal?

28. To what extent is infectious medical waste treated on-site to eliminate the risks posed by infectious substances? What percent of the U.S. hospital population treats its medical waste on-site using methods such as chemical decontamination, autoclaving, incineration, or irradiation? How do smaller generators of medical waste, e.g., medical offices and clinics, typically treat or dispose of their waste?

29. It has been stated that costs are between $0.04 to $0.06 per pound for disposal of non-infectious medical waste and that prices of up to 10 times this amount are charged for infectious medical waste. How accurate are these estimates?

III. Rulemaking Analyses and Notices

A. Executive Order 12291

The effect of this advance notice of proposed rulemaking does not meet the criteria specified in section 1(b) of Executive Order 12291 and is determined not to be a major rule. It is a significant rule under the regulatory procedures of the Department of Transportation (44 FR 11034) because of potential impacts on medical facilities. This advance notice of proposed rulemaking does not require a Regulatory Impact Analysis, or an environmental assessment or impact statement under the National Environmental Policy Act (42 FR 4321 et seq.) A preliminary regulatory evaluation will be prepared if further rulemaking action is warranted.

B. Executive Order 12612

This advance notice of proposed rulemaking has been analyzed in accordance with the principles and criteria in Executive Order 12612 ("Federalism").

The Hazardous Materials Transportation Act (49 App. U.S.C. 1801–1819) contains express preemption provisions (49 App. U.S.C. 1811) that preempt a non-Federal

requirement if (1) compliance with both the non-Federal and the Federal requirement is not possible; (2) the non-Federal requirement creates an obstacle to accomplishment of the Federal law or regulations; or (3) it is preempted under section 105(a)(4), concerning certain covered subjects, or section 105(b), concerning highway routing. Covered subjects include:

(i) The designation, description, and classification of hazardous materials;

(ii) The packing, repacking, handling, labeling, marking, and placarding of hazardous materials;

(iii) The preparation, execution, and use of shipping documents pertaining to hazardous materials and requirements respecting the number, content, and placement of such documents;

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

(v) 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 materials. (49 App. U.S.C. 1804(a)(4)(A) and (B)).

This advance notice of proposed rulemaking addresses certain covered subjects. If rulemaking action leads to promulgation of a final rule, this rule would preempt any State, local, or Indian tribe requirements concerning covered subjects unless the non-Federal requirements are "substantively the same" (56 FR 20424, May 13, 1992) as the Federal requirement. Thus, RSPA lacks discretion in this area, and preparation of a federalism assessment is not warranted.

C. Regulatory Flexibility Act

Based on limited information concerning size and nature of entities likely affected, I certify that this advance notice of proposed rulemaking will not, if promulgated, have a significant impact on a substantial number of small entities under criteria of the Regulatory Flexibility Act. This certification is subject to modification based on the merits of comments received.

Issued in Washington, DC, on February 26, 1993, under authority delegated in 49 CFR part 106, appendix A.

Robert A. McGuire,

Deputy Associate Administrator for Hazardous Materials Safety.

[FR Doc. 93-4882 Filed 3-2-93; 8:45 am]

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49 CFR Part 195

[Docket No. PS-117; Notice 3]

RIN 2137-AB86

Transportation of a Hazardous Liquid in Pipelines Operating at 20 Percent or Less of Specified Minimum Yield Strength

AGENCY: Research and Special Programs Administration, DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: By regulatory exception, the Federal pipeline safety standards governing hazardous liquid pipelines do not apply to pipelines operated at a stress level of 20 percent or less of the specified minimum yield strength (SMYS) of the pipe. In this Notice of Proposed Rulemaking (NPRM), the Research and Special Programs Administration (RSPA) proposes to revise the current exception and to apply the pipeline safety standards to certain pipelines operating at a stress level of 20 percent or less of SMYS. RSPA expects that this rulemaking will improve public safety and environmental protection by minimizing the possibility of accidents.

DATES: Comments must be received by May 3, 1993. Late-filed comments will be considered to the extent practicable.

ADDRESSES: Send comments in duplicate to the Dockets Unit, room 8421, Research and Special Programs Administration, U.S. Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590. Identify the docket and notice number stated in the heading of this notice. All comments and docketed material will be available for inspection and copying in Room 8421 between 8:30 a.m. and 5 p.m. each business day.

FOR FURTHER INFORMATION CONTACT: G. Joseph Wolf, (202) 366-4560, regarding the subject matter of this NPRM. Contact the Dockets Unit, (202) 366-4453, for copies of the NPRM or other docket material. Contact the Transportation Safety Institute, Pipeline Safety Division, 6500 South MacArthur Boulevard, Oklahoma City, OK 73125, (405) 680-4643, for a copy of 49 CFR part 195.

SUPPLEMENTARY INFORMATION:

Background

When the Federal pipeline safety regulations applicable to transportation of hazardous liquids by pipeline (49 CFR part 195) were issued in 1969, pipelines operated at a stress level of 20 percent or less of SMYS, hereafter referred to as low stress pipelines, were excepted from the regulations because they were thought to pose little risk to public safety. Since then, however, accidents that have occurred on low stress pipelines provide reasons to reconsider the exception. Recent failures of such pipelines and recommendations to revise their exception from regulation were described in the Advance Notice of Proposed Rulemaking (ANPRM) published on October 31, 1990 (Notice 1; 55 FR 45822). The ANPRM noted that RSPA would determine whether and to what extent to remove the exception. Based on data in the responses to the ANPRM, which indicate a favorable benefit to cost ratio, RSPA is proposing to regulate certain low stress pipelines.

Current Requirements

Section 195.1(b)(3) provides that Part 195 does not apply to "Transportation of a hazardous liquid through pipelines that operate at a stress level of 20 percent or less of the specified minimum yield strength of the line pipe." The pipelines excepted are those steel pipelines in which the internal operating pressure results in a stress level of the pipe that does not exceed 20 percent of SMYS at any point along the length of the pipeline.

Information Acquisition

Because low stress pipelines have been excepted under § 195.1(b)(3), owners and operators are excepted from filing accident reports with RSPA pursuant to subpart B of part 195.

Consequently, RSPA lacked accident data about such pipelines. However, the ANPRM contained a questionnaire for the purpose of gathering information to make a decision regarding rulemaking. The owners or operators of hazardous liquid pipelines operated at 20 percent or less of SMYS and not otherwise excepted under § 195.1(b) were requested to complete the questionnaire for each such pipeline and return it. RSPA requested the information in the questionnaire to estimate the number and mileage of low stress pipelines, to perform a regulatory impact analysis (including a cost-benefit analysis), and to develop and consider alternatives that would ensure the safe operation of low stress pipelines.

In addition, state and local governments and other interested parties were invited to provide comments and available information about low stress pipelines located within their jurisdictions. Comments received provided the data to develop the proposals in this NPRM.