Sanctions on each individual described above may apply to firms or other entities with which that individual is associated. Questions as to whether a particular transaction is affected by the sanctions should be referred to the contact listed above. The sanctions shall commence on November 19, 1994. They will remain in place for at least one year and until further notice. These measures shall be implemented by the responsible agencies as provided in Executive Order 12851 of June 11, 1993.

Dated: December 14, 1994.

Thomas E. McNamara,

Assistant Secretary of State for Political-Military Affairs.

[FR Doc. 94–31326 Filed 12–20–94; 8:45 am]

BILLING CODE 4710–25–M

DEPARTMENT OF TRANSPORTATION

Research and Special Programs Administration

Office of Hazardous Materials Safety; Notice of Applications for Exemptions

AGENCY: Research and Special Programs Administration, DOT.

ACTION: List of applications for exemptions.

SUMMARY: In accordance with the procedures governing the application for, and the processing of, exemptions from the Department of Transportation's Hazardous Materials Regulations (49 CFR part 107, subpart B), notice is hereby given that the Office of Hazardous Materials Safety has received the applications described herein. Each mode of transportation for which a particular exemption is requested is indicated by a number in the "Nature of Application" portion of the table below as follows: 1-Motor vehicle, 2-Rail freight, 3-Cargo vessel, 4-Cargo aircraft only, 5-Passenger-carrying aircraft.

DATES: Comments must be received on or before January 20, 1995.

ADDRESS COMMENTS TO: Dockets Unit, Research and Special Programs Administration, U.S. Department of Transportation, Washington, DC 20590.

Comments should refer to the application number and be submitted in triplicate. If confirmation of receipt of comments is desired, include a self-addressed stamped postcard showing the exemption application number.

FOR FURTHER INFORMATION: Copies of the applications are available for inspection in the Dockets Unit, Room 8426, Nassif, Building, 400 7th Street, SW. Washington, DC.

NEW EXEMPTIONS

Application No.	Applicant	Regulation(s) affected	Nature of exemption thereof
11352–N	Pepsico Puerto Rico, Inc., San Juan, PR.	49 CFR 172	To authorize interplant transportation, on public highway, of various hazardous materials, Class 3 and 8, without required labeling, placarding and shipping papers. (Mode 1)
11353–N	J.R. Simplot Co., et. al, Pocatello, ID.	49 CFR 172.101 (SPB14)	To authorize transportation in commerce of poisonous liquids, flammable, n.o.s., inhalation hazard, Packing Group 1, Zone B in uninsulated DOT specification 412 cargo tanks. (Mode 1)
11356–N	ACM, Inc., North Chicago, IL	49 CFR 173.202,173.203, 178.503.	To authorize coating solution, Class 3 material, with a specific gravity range of 1.75 to 2.3 which exceeds the gravity range authorized for shipment in 1A2 drums. (Mode 1)
11357–N	Laidlaw Environmental Services, Inc., Columbia, SC.	49 CFR 173.173, 173.202, 173.203.	To authorize transportation in commerce of paint and paint related material, Class 3, in glass and metal packaging not to exceed 5 gallons equipped with plastic liner and overpacked in strong outer packaging. (Mode 1)
11358–N	Vulcan Chemicals, Birmingham, AL.	49 CFR 173.28(b)(2)	To authorize transportation in commerce of tetrachloroethylene, Division 6.1 in reused specially designed packaging that have been exempt from leakproofness test with air. (Mode 1)
11359–N	Hach Co., Ames, IA	49 CFR 173.212, 173.4 Part 107, Part 172, Part 177.	To authorize transportation in commerce of small quantities of materials, Sodium dithionite, Division 4.2, to be transported without required marking, labeling and shipping papers. (Modes 1, 4, 5)
11360–N	Space Systems/Loral, Palo Alto, CA.	49 CFR 173.302(a)(1)	To authorize transportation in commerce of nickel-hydrogen batteries containing hydrogen gas, in their cells, not to exceed 250 psig to support the requirements of the international Space Station program managed by NASA. (Mode 1, 4)

This notice of receipt of applications for new exemptions is published in accordance with Part 107 of the Hazardous Materials Transportations Act (49 U.S.C. 1806; 49 CFR 1.53(e)).

Issued in Washington, DC, on December 16, 1994.

J. Suzanne Hedgepeth,

Chief, Exemption Programs, Office of Hazardous Materials Exemptions and Approvals.

[FR Doc. 94–31360 Filed 12–20–94; 8:45 am]

BILLING CODE 4910–60–M

Corrections

Federal Register
Vol. 59, No. 244
Wednesday, December 21, 1994

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 630

RIN 3206-AG45

Absence and Leave; Use of Restored Annual Leave

Correction

In rule document 94–30010 beginning on page 62971 in the issue of Wednesday, December 7, 1994 make following correction:

§630.308 [Corrected]

On page 62973, in the first column, in §630.308(a), in the eighth line, "rather" should read "prior".

BILLING CODE 1505–01–D

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-35009; File No. SR-MBS-94-02]

Self-Regulatory Organizations; MBS Clearing Corporation; Order Temporarily Approving Proposed Rule Change Establishing the Electronic Pool Notification Service

Correction

In notice document 94–29696 beginning on page 61913 in the issue of Friday, December 2, 1994 make the following correction:

On page 61915, in the first column, the signature and FR Doc. line were omitted and should read as set forth below.

Margaret H. McFarland,

Deputy Secretary

[FR Doc. 94-29696 Filed 12-01-94, 8:45 am]

BILLING CODE 8010-01-M

BILLING CODE 1505–01–D

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-35018; File No. SR-NASD 94-41]

Self-Regulatory Organizations; National Association of Securities Dealers, Inc.; Order Approving Proposed Rule Change Relating to Amendments to the Examination Question Bank, Specifications and Study Outline for the Direct Participation Programs Limited Representative (Series 22) Examination

Correction

In notice document 94–29790 appearing on page 62432 in the issue of Monday, December 5, 1994 make the following correction:

On page 62432, in the second column, above the FR Doc. line, the signature was omitted and should read as set forth below.

Margaret H. McFarland,

Deputy Secretary

BILLING CODE 1505–01–D

Federal Register

Wednesday
December 21, 1994

Part II

Department of Housing and Urban Development

Office of the Assistant Secretary for Housing-Federal Housing Commissioner

24 CFR Part 880 et al.

Preference for Elderly Families in Certain Section 8 Housing; and Reservation of Units for Disabled Families; Final Rule

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Housing-Federal Housing Commissioner

24 CFR Parts 880, 881, 883, 884, and 886

[Docket No. R-94-1719; FR-3465-F-02]

RIN 2502-AG05

Preference for Elderly Families in Certain Section 8 Housing; and Reservation of Units for Disabled Families

AGENCY: Office of the Assistant Secretary for Housing-Federal Housing Commissioner, HUD.

ACTION: Final rule.

SUMMARY: This rule makes final an interim rule published on May 3, 1994. The May 3, 1994 interim rule amended HUD's section 8 regulations for newly constructed and substantially rehabilitated housing projects to provide for the system of occupancy preferences in certain section 8 assisted housing authorized by subtitle D of title VI of the Housing and Community Development Act of 1992. Subtitle D allows owners of section 8 projects originally designed primarily for occupancy by elderly families to provide preferences to elderly families in selecting tenants for available units in those projects. Owners that elect to provide preferences to elderly families as authorized by subtitle D also must reserve no less than a statutorily determined number of units for disabled families who are not elderly or near-elderly families.

EFFECTIVE DATE: January 20, 1995

FOR FURTHER INFORMATION CONTACT: Barbara Hunter, Acting Director of the Planning and Procedures Division, Office of Multifamily Housing Management, Office of Housing, Department of Housing and Urban Development, Room 6184, 451 Seventh Street, SW, Washington, DC 20410. Telephone number (202) 708-3944 (voice) or (202) 708-4594 (TDD). (These telephone numbers are not toll-free.)

SUPPLEMENTARY INFORMATION:

I. Background

On May 3, 1994 (59 FR 22916), HUD published an interim rule that adopted the system of occupancy preferences authorized by Subtitle D (sections 651-661) of title VI of the Housing and Community Development Act of 1992 (Pub. L. 102-550, approved October 28, 1992) ("HCD Act of 1992"). Subtitle D, entitled "Authority to Provide Preferences for Elderly Residents and Units for Disabled Residents[1] in Certain Section 8 Assisted Housing" and codified at 42 U.S.C. 13611-13620, allows an owner of a covered section 8 housing project to elect to provide preferences to elderly families in selecting tenants for available units in the project, subject to certain statutory requirements. An owner who makes this election also must reserve a percentage of units, not to be less than the percentage determined according to a formula set out in the statute, for disabled families who are not elderly or near-elderly.[2]

The preamble to the May 3, 1994 interim rule provided a detailed summary of the provisions of subtitle D, and readers are referred to the May 3, 1994 interim rule for a more complete discussion of the provisions of subtitle D. The following, however, provides a review of which section 8 housing projects are covered by subtitle D, and therefore eligible for the election of occupancy preferences authorized by subtitle D.

[1] Definitions for "elderly families" and "disabled families" are codified in section 3(b) of the U.S. Housing Act of 1937 (1937 Act). Section 3(b) was amended by section 621 of the 1992 HCD Act. Where the definition for "elderly families" has, since 1974, encompassed disabled families, the amended section 3(b) now defines "elderly families" as families whose heads (or their spouses) or sole members are persons at least 62 years old. Thus, under the revised definition, a disabled person does not qualify as an elderly family solely because of the person's disability.

Section 3(b) defines "disabled families" to mean families whose heads (or their spouses) or sole members are persons with disabilities. "Person with disabilities" is defined to mean a person who: (1) Has a disability as defined in section 223 of the Social Security Act; (2) is determined pursuant to regulations issued by the Secretary of HUD, to have a physical, mental or emotional impairment which is expected to be of long-continued and indefinite duration, substantially impedes his or her ability to live independently, and is of such a nature that such ability could be improved by more suitable housing conditions; or (3) has a developmental disability as defined in section 102 of the Developmental Disabilities Assistance and Bill of Rights Act.

The Department's regulations for the terms defined in section 3(b) of the 1937 Act for the assisted housing programs are published at 24 CFR part 812. The 1992 HCD Act amendments to section 3(b) of the 1937 Act will be reflected in changes to 24 CFR part 812 that will be made by separate rulemaking. Accordingly, unless the context indicates otherwise, reference to the terms elderly families, disabled families, and near-elderly families in this preamble is reference to these terms as defined in section 3(b) of the 1937 Act, as amended by section 621 of the 1992 HCD Act.

[2] Under section 3(b) of the 1937 Act, as revised by section 621 of the 1992 HCD Act, the term "near elderly families" is defined as families whose heads (or their spouses) or sole members are persons who are 50-61 years old.

Eligibility to Provide Preferences for Elderly Residents

Section 651 of the HCD Act of 1992 provides in relevant part, "[n]otwithstanding any other provision of law, an owner of a *covered section 8 housing project designed primarily for occupancy by elderly families*, may in selecting tenants for units in the project that become available for occupancy, give preference to elderly families who have applied for occupancy in the housing * * *." (Emphasis added.)

With regard to the phrase "designed primarily for occupancy by elderly families," HUD believes that in using the term "primarily," the Congress intended to limit the applicability of subtitle D to either the section 8 units in those covered projects in which a majority of the section 8 units were designed for elderly families (i.e., seniors[3]), or to the section 8 units in covered projects where a distinct portion of the project (e.g., a tower or a wing of a project, but not just a floor) exists in which the majority of section 8 units were restricted to seniors only. Thus, section 651 may apply to the section 8 units in an entire project originally designed primarily for occupancy by elderly families ("covered section 8 housing project"), or section 651 may apply to the section 8 units in a portion of such project, but only where the section 8 units in this project or portion of the project were designed primarily for seniors. The preamble, at times, uses the term "covered section 8 units" to recognize that there are partially assisted projects whose section 8 units will be covered by this rule. Additionally, the term "non-elderly disabled families" is used to refer to disabled families who are not elderly or near-elderly families.

HUD points out that the statutory system of preferences authorized by subtitle D is only available to projects which qualify as "covered section 8 housing projects designed primarily for occupancy by elderly families." HUD emphasizes that many projects that have section 8 assistance are not "covered section 8 housing projects designed primarily for occupancy by elderly families" (as discussed in the following section), and may not elect the subtitle D statutory system of preferences.

Covered Section 8 Housing Project Section 659

Subtitle D and this final rule (and the May 3, 1994 interim rule) define

[3] As used in this preamble, the term "seniors" refers to families whose heads of household, their spouses or sole members are 62 years or older.

"covered section 8 housing" to mean housing that:

(1) Was constructed or substantially rehabilitated pursuant to assistance provided under section 8(b)(2) of the United States Housing Act of 1937 (1937 Act), as in effect before October 1, 1983;

(2) Is assisted under a contract for assistance under such section; and

(3) Was originally designed primarily for occupancy by elderly families.

1. Projects that are Newly Constructed or Substantially Rehabilitated Pursuant to Assistance Provided Under Section 8(b)(2) of the 1937 Act, as in Effect Before October 1, 1983

HUD administers six section 8 programs that involve newly constructed or substantially rehabilitated housing. However, the system of preferences under subtitle D does not apply to all these programs.

The programs to which subtitle D applies are:

(1) The Section 8 New Construction Program, 24 CFR part 880;

(2) The Section 8 Substantial Rehabilitation Program, 24 CFR part 881;

(3) The State Housing Agencies program (insofar as it involves new construction and substantial rehabilitation), 24 CFR part 883;

(4) The New Construction Set-Aside for Section 515 Rural Rental Housing Projects Program, 24 CFR part 884; and

(5) The Section 8 Housing Assistance Program for the Disposition of HUD-Owned Projects (insofar as it involves substantial rehabilitation), 24 CFR part 886.[4]

Other programs which may involve section 8 new construction or substantial rehabilitation assistance, but which are *not* covered by the preferences in subtitle D are identified in section 658 of the HCD Act of 1992. Under section 658 of the HCD Act of 1992, an owner of a project (or portion of a project) that was originally designed for occupancy by elderly families, and assisted under the Section 221(d)(3) Below Market Interest Rate (BMIR) program, the Section 236 Mortgage Insurance and Interest Reduction Payment for Rental Projects program, or the Section 202 Loans for Housing for the Elderly or Handicapped Program, may continue to restrict occupancy in such projects (or portion of such projects) to elderly families in accordance with the rules, standards and agreements in effect when the housing project was developed. Accordingly, under this rule, the subtitle D statutory system of preferences does not apply to newly constructed or substantially rehabilitated section 8 projects with HUD insurance or assistance under any of these three programs.[5] HUD emphasizes that it is critical that a project owner understand the type of assistance a project receives to determine eligibility under subtitle D and these regulations.

Project owners should note that the following types of projects or assistance would *NOT* be covered by this rule:

—Section 202 housing projects,
—Section 221(d)(3) BMIR housing projects,
—Section 221(d)(4) retirement service centers (because such projects have FHA mortgage insurance but no section 8 assistance),
—Section 236 housing projects,
—Housing projects with contracts for section 8 loan management set aside (unless the projects also have contracts for section 8 assistance involving new construction or substantial rehabilitation, in which case only those units could be covered),
—Housing projects with project-based section 8 rental certificates, and
—Section 8 tenant-based assistance programs (rental vouchers and certificates).

2. Assisted Under a Contract for Assistance Under Section 8(b)(2)

Some newly constructed or substantially rehabilitated projects have unassisted units and assisted units. These projects are often referred to as "partially assisted projects." Because the statutory definition of "covered section 8 housing" only applies to housing that is under a contract for assistance, the subtitle D system of preferences would *not* apply to unassisted units in a partially assisted project. Additionally, nothing in this regulation establishes a cap on the number of unassisted units for disabled families in a partially assisted project.

While this regulation does not apply to the unassisted units in a partially assisted project, this regulation also does not relieve any owner of any project, including the owner of a partially assisted project, from complying with the Fair Housing Amendments Act of 1988, section 504 of the Rehabilitation Act of 1973, the implementing regulations for these statutes, or any other applicable statutory or regulatory requirement, including the requirements of the National Housing Act, with respect to the assisted or unassisted units. However, notwithstanding the foregoing, owners may provide the preferences in accordance with this rule, with respect to the assisted units.

3. Originally Designed Primarily for Occupancy by Elderly Families

The final statutory requirement for qualification as a "covered section 8 housing project" is that the project must have been *originally designed for occupancy by elderly families*. The statute does not define the term "originally" or define the phrase "originally designed for occupancy by elderly families." However, the House Report offers some insight on this subject. The House Report suggests that to qualify as housing originally designed for occupancy by elderly families, the owner of the project must have expressed an intent to create housing for elderly tenants when the developer negotiated with the Department for Federal financial assistance. (H.R. Rept No. 760, 102d Cong. 2d Sess. at 141 (1992).)

Because the various types of housing projects covered by this rule were developed under several different programs, and over a period of time which spans almost two decades, there is no uniform documentation at HUD which evidences the population group to be served by a project. In many instances, the application in response to a notice of funding availability (NOFA) shows that a project was designed as an elderly housing project. However, an indication of the population group to be served by the housing project does not always appear in any one document.

In addition, because one of the previous definitions of "elderly families" in section 3(b) of the 1937 Act included disabled families, it is not always clear from documents that indicate a project was developed for "elderly families" whether the project for elderly families was intended to mean housing for the broader eligible category of families (i.e., elderly families *and* disabled families) or for families who qualified by virtue of age alone

[4] The "Additional Assistance Program for Projects with HUD-Insured and HUD-Held Mortgages" (see 24 CFR part 886, subpart A) involves only existing housing. However, the "Section 8 Housing Assistance Program for the Disposition of HUD-owned Projects" (see 24 CFR part 886, subpart C) involves substantially rehabilitated housing, in addition to existing housing. Accordingly, this rule would amend subpart C of 24 CFR part 886, but only for projects involving substantially rehabilitated housing.

[5] Although in this regard, the Department is aware of no Section 221(d)(3) BMIR projects or Section 236 projects with Section 8 new construction or substantial rehabilitation assistance. As such, by its terms, "covered section 8 housing" does not seem to encompass the Section 236 Mortgage Insurance and Interest Reduction Payment for Rental Projects program or the Section 221(d)(3) BMIR program.

Further confusion may be added by the fact that for most of the period when this housing was being developed, HUD policy required all housing for the elderly (defined by age) to incorporate certain accessible features and to design a certain percentage of the units to be accessible for persons with physical disabilities. Typically, these units were made available to eligible families with physical disabilities, regardless of age.

Thus, in establishing whether a project was originally designed primarily for occupancy by elderly families within the meaning of subtitle D, two distinctions must be drawn: (1) the project was designed primarily for elderly families (as opposed to non-elderly families); and (2) the project was designed for elderly families (i.e., seniors), and not designed for elderly families under the broader meaning of this term, which formerly included elderly families and disabled families.

II. Final Rule—Adoption of Interim Rule With Only Clarifying Changes

As discussed in the May 3, 1994 interim rule, subtitle D is very prescriptive in establishing how the system of occupancy preferences is to operate (see 59 FR 22921–22922). Subtitle D establishes which section 8 housing projects are eligible for the election of preferences provided by subtitle D. Subtitle D establishes that the "elderly families" eligible to reside in covered section 8 housing projects for which the owner has made the election of preferences provided by subtitle D are those families who meet the definition of "elderly families" as set forth in section 3(b) of the 1937 Act, as amended by section 621 of the HCD Act of 1992. Subtitle D establishes the formula by which an owner will determine the number of units in the covered section 8 housing project that must be reserved for occupancy by disabled families who are not elderly or near-elderly. Subtitle D establishes the secondary system of preferences available to owners if there are insufficient numbers of elderly families and disabled families who are not elderly or near-elderly to occupy all the units reserved for such. Subtitle D also establishes the procedures to be followed if units remain vacant after the owner has elected to provide the secondary system of preferences, and the procedures to be followed concerning the order of selection within groups to whom a preference has been given. Given the statutory framework of the system of preferences for elderly families authorized by subtitle D, most of the provisions of the May 3, 1994 interim rule flow directly from the statute.

One provision in the May 3, 1994 interim rule that was not addressed by statute and added by regulation concerns the type of documentation that would support an owner's claim that the owner's project was originally designed primarily for occupancy by elderly families. In the May 3, 1994 interim rule, HUD noted that with the exception of possible further changes to this provision (to add additional types of documentation that should be included in the list) and possible clarifying changes, public comment would not alter the provisions of the interim rule because of the prescriptive nature of the subtitle D.

This final rule adopts the May 3, 1994 interim rule with eight clarifying changes, which are as follows:

1. The final rule clarifies that the election of elderly preference by an owner of a covered section 8 housing project can be made at any time. (See § 880.612a(a)(1)(i), and comparable sections in other parts covered by this rule.)

2. The final rule codifies the guidance provided in the preamble to the May 3, 1994 interim rule that states that where an election of an elderly preference would have an adverse effect on non-elderly families on the waiting list, the owner is required to notify those families of the new policy (i.e., the subtitle D system of preferences) and how this policy may affect them. (See new § 880.612a(a)(1)(iii), and comparable sections in other parts covered by this rule.)

3. The final rule also codifies the preamble guidance that otherwise qualified families for a section 8 housing project, such as disabled families, near-elderly disabled families and families with children, who are on the waiting list for the project, cannot be removed from the list because of the owner's election of an elderly preference. (See new § 880.612a(a)(1)(iv), and comparable sections in other parts covered by this rule.)

4. The final rule clarifies that an owner who makes the elderly preference election must be able to produce, if challenged, all relevant documentation in the owner's possession that pertains to the original design of the project, not only the evidence that was "supporting evidence" as the language read in the interim rule. (See § 880.612a(a)(2)(i) and comparable sections in other parts covered by this rule.)

5. The final rule clarifies that the primary source list in the rule is not limited to underwriting or financial documents. (See § 800.612(a)(b)(1)(i) and comparable sections in other parts covered by this rule.)

6. The final rule clarifies that in discussing project unit mix with a higher percentage of efficiency and one-bedroom units, higher percentage means more than fifty percent. (See § 880.612a(b)(1)(ii) and comparable sections in other parts covered by this rule.)

7. The final rule clarifies that the requirement to make vacant units available to otherwise eligible families if there are an insufficient number of families qualifying for the elderly preference or for the reserved units for non-elderly disabled families (or qualifying for the near-elderly disabled family secondary preference if adopted) applies to owners of covered projects who make the elderly preference election, and not solely to owners who elect the elderly preference and elect also the secondary preference as the May 3, 1994 interim rule indicated.

8. The final rule clarifies that projects under National Housing Act programs and receiving section 8 assistance may be subject to preferences in addition to those contained in the section 8 regulations. (See § 880.612a(g) and comparable sections in other parts covered by this rule.)

With the exception of these eight changes, the final rule remains the same as the May 3, 1994 interim rule.

The following section of the preamble provides a summary of the issues raised by the public commenters, and HUD's response to these issues. Although only six commenters commented upon the May 3, 1994 interim rule (also referred to as the subtitle D rule) by the end of the public comment period on July 5 1994, the six commenters raised a number of issues.

III. Discussion of Public Comments

Comment. One commenter stated that interim rulemaking was inappropriate for the subject matter addressed by subtitle D, and HUD should have solicited advance public comment before issuing the subtitle D rule for effect.

Response. As noted earlier in this preamble, and discussed in more detail in the preamble to the May 3, 1994 interim rule (59 FR 22921–22922), very little in HUD's subtitle D rule would be altered by public comment because the system of occupancy preferences established by subtitle D allows HUD little discretion to expand or depart from this system by regulation. Therefore advance public comment would not have been practicable or necessary

Additionally, as noted in the preamble to the May 3, 1994 interim rule, HUD, in issuing the subtitle D rule, had the benefit of public comment received on the rule that implemented subtitle B of title VI of the HCD Act of 1992 (59 FR 22921–22922). Subtitle B provides public housing agencies (PHAs) with the option, subject to certain requirements, to designate public housing projects, or portions of these projects, for occupancy by elderly families, disabled families or elderly families and disabled families. HUD's final rule implementing subtitle B was published on April 13, 1994 (59 FR 17652). To the extent that the subtitle D rule which concerns section 8 housing, and the subtitle B rule which concerns public housing, address similar issues, the public comments on the subtitle B rule were taken into consideration in development of the May 3, 1994 interim rule.

Comment. One commenter stated that given the recent publication of the notice revising HUD's Occupancy Handbook for multifamily projects, and the May 3, 1994 interim rule, project owners are confused about their obligations and responsibilities to persons with disabilities, and further clarification is needed.

Response. The notice of the revision to Chapter 2 of HUD Handbook on Occupancy Requirements of Subsidized Multifamily Housing Programs, which was published on April 28, 1994 (59 FR 21992) advised that Chapter 2, as revised, would remain in effect pending issuance regulations for subtitle D, at which time further revisions to Chapter 2 would be issued. Those revisions are now in preparation. Chapter 2 remains in effect to the extent that it is not contradicted by the interim rule, and until such time as the next revision to this chapter is issued. The Department also intends to issue further guidance on subtitle D and the issue of mixed populations in the form of technical assistance materials.

Comment. One commenter expressed concern that HUD has not issued its rule that would revise the terms "families" and "elderly person," among others, in HUD's section 8 regulations to reflect the changes made to these terms by section 621 of the HCD Act of 1992.

Response. The definitions of these terms in section 621 of the HCD Act of 1992 are applicable without issuance of a HUD regulation. On April 10, 1992 (57 FR 12686), before enactment of the HCD Act of 1992, HUD published a proposed rule that would revise, among other things, the definition of "family" in parts 812 and 912 to reflect changes made to this definition by the National Affordable Housing Act (NAHA) (Pub.L. 101–625, approved November 28, 1990). Rather than issue separate rulemaking to revise the definitions in parts 812 and 912 to reflect the changes made to certain definitions (e.g., "elderly person," "person with disabilities") by the HCD Act of 1992, HUD determined to make these changes at the time of issuance of the final rule for the April 10, 1992 proposed rule. HUD anticipates publication of this final rule by December 1994. Again, however, the definition changes made by the HCD Act of 1992 are currently applicable despite the absence of a final rule that amends parts 812 and 912 to reflect these definition changes.

Comment. Two commenters requested that the final rule on subtitle D require approval by HUD before an owner may make the election of occupancy preferences authorized by subtitle D. The commenters stated that HUD approval of an owner's election is the only effective and available means to ensure that an owner is not improperly applying the provisions of subtitle D to discriminate against persons with disabilities under the age of 62. The commenters stated that if HUD declined to adopt this suggestion, then, at the least, the final rule should require owners to report to HUD the election of an elderly preference.

Response. HUD believes that to require an owner to seek approval by HUD before making the election of occupancy preferences authorized by subtitle D is without statutory support and is not consistent with Congressional intent.

As discussed earlier in this preamble, subtitle B of title VI of the 1992 HCD Act provides PHAs with the option to designate a public housing project or portion of a project for occupancy by elderly families, disabled families, or elderly families and disabled families. Subtitle B further provides that before one of these three designations can be made, a PHA must obtain the approval of HUD through the submission of an allocation plan. Accordingly, for subtitle B housing, Congress explicitly requires prior HUD approval. There is no comparable provision, however, in subtitle D. HUD does not believe that this was an oversight on the part of the Congress, but reflects clear Congressional intent that the election of occupancy preferences under subtitle B ("designation" as it is referred to in subtitle B) would require prior HUD approval, and the election of preferences under subtitle D would not.

With respect to reporting the election of preference by the owner, HUD has determined that this reporting requirement is not necessary. The applicable Section 8 regulations provide for periodic reviews of section 8 housing projects to determine contract compliance. The regulations in parts 880, 881 and 883 require annual reviews by the contract administrator (see §§ 880.612 and 881.612, 883.713), and the regulations in parts 884 and 886 require review by HUD at such intervals as deemed necessary to ensure that the owner is in full compliance with the terms and conditions of the contract. At the time of this review, the contract administrator or HUD, as the case may be, will identify those owners who have made an election of occupancy preference under subtitle D. HUD will revise its form that is used in management reviews to include identification of those projects which have elected the elderly preference authorized by subtitle D. Additionally, in reviewing occupancy procedures, the contract administrator will consider the operation of the title VI occupancy preferences along with other occupancy procedures. Finally, HUD's review of an owner's decision to provide preferences may also arise in connection with HUD civil rights complaint investigations under the Fair Housing Act, or compliance reviews and complaint investigations under section 504 of the Rehabilitation Act of 1973, as amended, or other applicable civil rights statutes.

Comment. One commenter requested that the final rule exempt accessible units from the covered section 8 units subject to the elderly preference. The commenter stated that at the very least these units should be rented only to those persons with disabilities who are near-elderly and elderly and who need the accessibility features of particular units.

Response. There is no basis in subtitle D for HUD to exempt accessible units from covered section 8 units subject to the elderly preference, nor is there a need for HUD to do so. In accordance with section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794) and HUD's implementing regulations in 24 CFR part 8, as well as the Fair Housing Act (42 U.S.C. 3601 *et seq.*) and HUD's implementing regulations in 24 CFR part 100, reasonable accommodations must be made for the needs of persons with disabilities who need an accessible unit. The housing provider is to accommodate the person either by (1) making an available inaccessible unit accessible (so long as doing so would not result in a fundamental alteration in the nature of the program or activity or undue financial and administrative burdens), or (2) by transferring a tenant who is living in an accessible unit but

does not need an accessible unit to the inaccessible unit, and offering the accessible unit to the disabled family (24 CFR 8.27). However, as discussed in the preamble to the May 3, 1994 interim rule, an owner who has made the election of occupancy preference authorized by subtitle D and who is selecting tenants from the waiting list, can (where it is an elderly family's turn for admission because the reserve requirement, if any, has been met) give an elderly family who needs an accessible unit a preference over a non-elderly disabled family who also needs the accessible unit. Once the reserve requirement, if any, for disabled families has been met, the owner can also give the accessible unit to an elderly family who does not need the accessibility features of the unit even if a non-elderly disabled family has also applied for the unit. HUD points out that once the reserve requirement, if any, for disabled families has been met, the owner can give the unit to an elderly family who does not need the accessibility features of the unit only if there is no elderly family who needs the accessibility features of the unit.

Comment. One commenter stated that the final rule should "grandfather-in" all non-elderly persons with disabilities on the project waiting lists as of June 2, 1994, the effective date of the interim rule, and prohibit a project owner from passing over these persons when selecting tenants from the waiting lists.

Response. The statute provides no authority for HUD to adopt this provision; to the contrary, by its plain language, the statute authorizes the immediate implementation of the preferences and the set aside. Existing residents are protected in the event that current occupancy of non-elderly families with disabilities exceeds the percentage of units under the set aside. As noted later in this preamble, however, owners of covered section 8 projects who make the election are prohibited from removing non-elderly persons with disabilities from the projects' waiting lists.

Comment. Two commenters objected to any reliance on secondary sources to support an owner's claim that the owner's project is a covered section 8 housing project. The commenters stated that secondary sources, which reflect actions taken by owners after they obtained HUD financial assistance, will do nothing to illuminate the project's original intent and should not be utilized. The commenters suggested that acceptable documents should include only legally binding documents submitted to HUD at the time of negotiations for Federal financial assistance. The commenters also strongly objected to the inclusion of "any other historical data" on the basis that this broad category of documentation would allow owners to circumvent the intended project eligibility requirements of subtitle D.

Response. HUD declines to drop secondary sources as acceptable sources of documentation. HUD carefully considered which documents may evidence project eligibility for the subtitle D system of preferences, and determined that it was important to include secondary sources as acceptable documentation. As discussed in the May 3, 1994 interim rule, because of the various types of housing projects covered by subtitle D and because these housing projects were developed under several different programs and over a period of time which spans almost two decades, there is no uniform documentation at HUD which identifies the population group to be served by the project. Further, difficulty in identifying the population group to be served is added by the fact that the previous definition of "elderly families" in the 1937 Act included disabled families, and HUD's policy required all housing for the elderly (defined by age) to incorporate certain accessible features and to design a certain percentage of units to be accessible for persons with physical disabilities. The difficulty in identifying the population group to be served is compounded by the fact that there often was no specific identification of projects as elderly (i.e., seniors) and standard program documents generally did not identify projects as elderly or, if they did so, did not distinguish between projects designed primarily for seniors, or for persons with disabilities, or for both. Given these difficulties, HUD determined that it was important not to limit the type of evidence that would lend support to an owner's claim that the owner's project was originally designed primarily for elderly families (seniors). Accordingly, the final rule provides, as did the interim rule, that if the primary sources do not provide clear evidence of the original design of the project, then original design may be established through secondary sources, of which there must be at least *two* secondary sources, establishing the identity of the project as elderly (seniors) housing. Additionally, secondary sources become important where primary sources conflict. Where primary sources conflict, then original design may be established through secondary sources.

Comment. One commenter stated that the use of project unit mix with a higher percentage of efficiency and one bedroom units as a secondary source makes no sense. The commenter stated that the size of the units is therefore wholly irrelevant to the original character of the property. Another commenter stated that if considered as a secondary source, project unit mix data must be applied uniformly, and HUD must develop and publish project configuration standards.

Response. HUD disagrees that project unit mix is totally irrelevant. As stated in the preamble to the May 3, 1994 interim rule ((59 FR 22918) and in the text of the regulation itself, a project unit mix with a higher percentage of efficiency and one-bedroom units may be particularly relevant in distinguishing elderly projects under the previous definition of elderly persons (in which disabled families were included in the definition of "elderly families") from non-elderly projects. Project unit mix, in combination with other factors such as the number of accessible units, may be useful in distinguishing projects for seniors from those serving the former broader definition of "elderly families" which included disabled families. (See 59 FR 22918 and § 880.612a(b)(1)(ii) and comparable sections in other parts covered by this rule.) HUD points out that, as a secondary source, project unit mix alone is not sufficient to establish the original character of the project. The project owner must be able to produce another secondary source to support that the project was originally designed primarily for occupancy by seniors.

With respect to establishing uniform project unit mix standards, HUD relies on the language of the statute itself. In describing projects covered by subtitle D, the statute uses the term "primarily designed for occupancy by elderly families" which HUD has defined as having at least a *majority* of the units designed for elderly families. In the preamble to the May 3, 1994 interim rule, HUD stated:

> The Department believes that in using the term 'primarily,' the Congress intended to limit the applicability of subtitle D to either the section 8 units in those covered projects in which a *majority* of the section 8 units were designed for elderly families (i.e., seniors), or to the section 8 units in covered projects where a distinct portion of the project (e.g., a tower or a wing of a project, but not just a floor) exists in which the *majority* of section 8 units were restricted to seniors only. Thus, section 651 may apply to the section 8 units in an entire project originally designed primarily for occupancy by elderly families ("covered section 8 housing project"), or section 651 may apply to the section 8 units in a portion of such project, but only where the section 8 units in

this project or portion of the project were designed primarily for seniors. (Emphasis added.) (59 FR 22916)

To be consistent with this interpretation that "primarily" means at least a majority of the units, the rule has been revised to state "project unit mix with more than fifty percent of the units which are efficiency or one-bedroom units."

Comment. One commenter stated that because there will be cases where neither the primary nor secondary sources establish original design and intent or where the project owner cannot produce original documentation, other evidence should be considered than that listed in the interim rule. The commenter suggested that the final rule provide that if a covered project is eligible for exemption from the familial status provisions of the Fair Housing Act because it constitutes housing for older persons it is also exempt under subtitle D. The commenter also suggested that if the project owner has had a fair housing complaint filed against the owner by a non-elderly disabled person on the basis of the person's eligibility to reside in the project that this indicate's management's belief that the project was built to serve seniors.

Response. HUD clearly rejects the latter suggestion. Coverage of a section 8 housing project under subtitle D must be based on evidence that the project was originally designed primarily for seniors, not solely on the owner's "belief" that it was designed primarily for seniors. HUD also declines to adopt the commenter's first suggestion. While some "housing for older persons," as this term is defined in 24 CFR part 100, subpart E, could also constitute section 8 housing that is covered by subtitle D, some would not.

HUD emphasizes that the list of primary and secondary documents are not intended to be all inclusive, but rather provide examples of the types of documents that would be acceptable. The language of the rule itself expresses that intent by referring in both cases to "sources *such as*" (emphasis added) before listing the examples. (See § 880.612a(b)(1) (i) and (ii) and comparable sections in other parts covered by this rule.)

Comment. One commenter stated that documents that indicate approval of a project's final proposal frequently spell out the intended nature of a project, yet these documents may not qualify "as any other underwriting or financial document collected at or before loan closing."

Response. As noted in the response to the preceding comment, the list of sources does not exclude other sources such as a "final proposal" approved by HUD. To avoid any implication that the source list is limited to underwriting or financial documents, the word "other" has been removed from this section (e.g., see § 880.612a(b)(1)(i) and comparable sections in other parts covered by this rule).

Comment. One commenter stated that the language of the interim rule indicates that there could be five primary sources that demonstrate a project's eligibility and one which indicates otherwise in which case the owner would be required to turn to secondary sources to establish a project's eligibility. The commenter states that requiring an owner to look to secondary sources, which are inferior to primary sources, when a majority of sources indicate that the project was designed primarily for occupancy by elderly families does not make sense.

Response. HUD agrees with the commenter that requiring an owner to look at secondary sources when a majority of primary sources "demonstrate" the original design of the project does not make sense, but disagrees that the rule indicates that this is the course of action that an owner would have to follow. The critical language in the rule is "clear evidence" of original design. The rule states that "In any case where the primary sources do not provide *clear evidence* of original design of the project for occupancy primarily by elderly families, including those cases where primary documents conflict, secondary sources may be used to establish the use for which the project was originally designed." (Emphasis added.) (See 24 CFR 880.612a(b)(2) and comparable provisions in other parts covered by this rule.)

Establishing original design, therefore, is not simply a matter of where the numbers fall; that is, establishing original design is not a matter of counting how many documents favor a project originally designed for seniors and how many documents oppose such design. The focus is to be on the type of evidence located and how clearly the evidence may address the issue of original design. If one primary source clearly (unambiguously) establishes original design of a seniors project, and one or more other primary sources do not specifically address the original design of the project and are ambiguous, the owner need not look to secondary sources to establish a project's eligibility. In this case, the owner may rely on the single primary source that establishes clear evidence of a project originally designed for seniors. Conversely, the single primary source may clearly establish that the project was not originally designed for seniors. Again, however, where the primary sources conflict (i.e., are equally ambiguous or equally specific), the owner must go to secondary sources. An example of a document that clearly specifies the project's original design could be the market studies projecting occupancy by seniors on which underwriting decisions were made.

Comment. One commenter stated that the documentation concerning the project's identity must take into account the definitions of "elderly family" and "elderly person" as this term has been used over the past several years to include "persons with disabilities." The commenter stated that "documents using the words 'elderly person' or 'elderly family' must be viewed as evidence of an intent to serve people 62 years of age and older and people with disabilities."

Response. HUD disagrees with the commenter, and addressed this issue in the preamble to the May 3, 1994 interim rule. (59 FR 22917–22918) Because one of the previous definitions of "elderly families" in section 3(b) of the 1937 Act included disabled families, it is not clear from documents that indicate a project was developed for "elderly families" whether the project for elderly families was intended to mean housing for the broader eligible category of elderly families (i.e., elderly families and disabled families) or housing for families who qualified by virtue of age alone. Thus a document's statement that the project is a project for elderly families, in and of itself, would not constitute clear evidence which category of family was to be served, i.e., the broader category of elderly family or the family who qualified by age alone.

Comment. One commenter stated that the final rule must explicitly require owners to make available for inspection by applicants, tenants and their advocates, all relevant documents regarding elderly-only designation, including any conflicting documents.

Response. The interim rule provided that the owner, if challenged on the issue of eligibility of the project for the election, "must be able to support the project's eligibility through the production of supporting evidence." (See § 880.612a(a)(2)(i) and comparable sections in other parts covered by this rule.) HUD has revised this language in the final rule to provide that the owner, if challenged on the issue of eligibility of the project for the election, must be able to support the project's eligibility through the production of all relevant documentation in the owner's

possession that pertains to the original design of the project.

Comment. One commenter stated that the final rule must explicitly allow individual States to decide the question of how State law will regulate a permissive election of elderly selection preferences because subtitle D permits the election "notwithstanding any other provision of law." The commenter suggested that the following language be included in the rule: "Nothing in this rule is intended to limit any State or local law that affords disabled families greater access than the minimum required by this section to projects eligible for the preference provided by this section, nor is it intended to relieve an owner of fair housing obligations imposed by State or local law."

Response. The "notwithstanding any other provision of law" language of subtitle D (see first sentence of sections 651 and 652 of subtitle D; 42 U.S.C. 13611 and 13612) is not intended, as indicated by the commenter, to restrict or limit implementation of the elderly preference as authorized by subtitle D by requiring an owner to ensure that implementation of the subtitle D preferences is not inconsistent with other statutes and regulations that may address the issue of the degree of access to covered section 8 housing by non-elderly persons with disabilities. The "notwithstanding any other provision of law" is intended to do just the opposite, which is to allow an owner of a covered section 8 project to implement the subtitle D preferences and reservation of units in the manner authorized by subtitle D without concern whether other laws may provide for a different implementation of an elderly preference, or a greater percentage of units to be reserved for non-elderly disabled persons.

Comment. One commenter stated that the final rule must make clear that a zero reservation of units for disabled families is unacceptable. Two commenters objected to the statement in the preamble to the May 3, 1994 interim rule that if a covered project did not have any disabled families residing in the project on the two dates specified in the statute, the owner would not be required to reserve any units for disabled families.

Response. Subtitle D clearly allows for zero reservation of units. The statute does not impose a minimum percentage of units to be reserved for nonelderly disabled families, and the subtitle D rule reflects this statutory scheme. Subtitle D (section 652(b) of the HCD Act of 1992) provides as follows:

(b) *Number of Units*—Each owner required to reserve units in a project for occupancy under subsection (a) shall reserve a number of units in the project that is not less than the lesser of—

(1) the number of units equivalent to the higher of—

(A) the percentage of units in the project that were occupied by such disabled families upon the date of enactment of this Act; or

(B) the percentage of units in the project that were occupied by such families upon January 1, 1992; or

(2) 10 percent of the number of units in the project.

The Congress could have required the minimum number to be "not less than the *greater of*" as opposed to "not less than the *lesser of*," which would have ensured a minimum of 10 percent of the number of units in a covered project to be reserved for non-elderly disabled families. Alternatively, the Congress could have drafted the statute to provide that in the event the number of units occupied by disabled families on the two dates in paragraph (b)(1) [cited above] equaled zero, the minimum percentage of units to be reserved for non-elderly disabled families would be 10 percent or such other percentage as the Congress may have desired to impose. The Congress took neither of these courses of action, and without these or similar provisions, there is no question that the calculation in paragraph (b) could result in zero reservation of units. However, as stated in the preamble to the May 3, 1994 interim rule, HUD believes that few, if any, covered section 8 housing projects will fall into the category of having no disabled families occupying units in the project on the date of enactment of the HCD Act of 1992 or January 1, 1992.

Comment. One commenter stated that the replacement of the term "mobility impaired" with the term "tenants needing the accessibility features of the unit" represents a significant change. The commenter stated that this term departs from the language of section 504 of the Rehabilitation Act of 1973 and HUD's regulations in 24 CFR part 8 which use the term "individuals with physical handicaps." The commenter stated that this substitution of terms will make accessible units available to any disabled person who can establish a need for the accessible features of a unit regardless of whether or not the individual has a physical disability

Response As an initial matter, HUD points out that the term "tenants needing the accessibility features of the unit" is not used in the subtitle D rule, but was used in the preamble to the May 3, 1994 interim rule. (See 59 FR 22920). Secondly, HUD notes that while the term "mobility impaired" does appear in HUD's part 8 regulations (see 24 CFR 8.22(b)) issued in June 1988, it is now recognized that this term does not adequately reflect the broad range of disabilities which may cause an individual with a disability to need a unit with accessible features. The term "mobility impaired" was too often perceived as synonymous with the term "persons in wheelchairs" and did not appropriately reflect persons with other types of disabilities who may need accessible features of a unit. The term "tenants needing the accessibility features of the unit" used in the May 3, 1994 interim rule is not inconsistent with the language in HUD's section 504 regulations in 24 CFR part 8. The part 8 regulations also use the term "applicant or occupant having [disabilities] requiring the accessibility features of a unit." (See, e.g., 24 CFR 8.27). However, to have been more clear as to the types of tenants who may need the accessibility features of a unit, the preamble to the May 3, 1994 interim rule should have used the term "tenants with a disability that makes the accessibility features of the unit necessary."

With respect to the commenter's concern that a project owner may indiscriminately assign accessible units to tenants, HUD notes that its section 504 regulations require owners to take reasonable nondiscriminatory steps to maximize the utilization of such units by eligible individuals whose disability requires the accessibility features of the particular unit. Additionally, as stated earlier in this preamble, where an accessible unit is not available to a person with disabilities who needs an accessible unit, the housing provider is to accommodate the person either by (1) making the unit accessible (so long as doing so would not result in a fundamental alteration in the nature of the program or activity or undue financial and administrative burdens), or (2) by transferring a tenant who is living in an accessible unit but does not need an accessible unit to the inaccessible unit, and offering the accessible unit to the disabled family Given these requirements, it is unlikely that owners will not make every effort to maximize the utilization of accessible units by families who need the accessibility features of the unit.

Comment. One commenter stated that the interim rule failed to acknowledge that subtitle D requires owners who elect an elderly preference to open admissions to all section 8 eligible families without regard to age or disability when there are vacant units in the project and an insufficient number of elderly families to fill those vacant

units. Another commenter made a similar comment in stating that the final rule must clarify that an owner who does not elect to provide a secondary preference may admit any other eligible person if there is an insufficient number of applicants on the waiting list to fill either the elderly units or the units reserved for non-elderly disabled families.

Response. HUD acknowledges that although the May 3, 1994 interim rule touches upon this issue, the language of the rule is not as clear on this point as it could or should be. The May 3, 1994 interim rule provides: "If the owner of an elderly project who has elected to adopt the secondary preferences in paragraph (d) of this section determines, in accordance with paragraph (f) of this section, that there are an insufficient number of families for whom the preference, including secondary preference, in occupancy has been given, to fill all the vacant units in the elderly project, *the owner shall make the vacant units generally available to otherwise eligible families who apply for housing, without regard to the preferences and reservation of units provided in this section.*" (Emphasis added.) (See § 880.612a(e) and comparable sections in other parts covered by this rule.) HUD recognizes that this paragraph indicates that the open admission requirement when there are vacant units is only applicable to owners who elected to adopt the secondary preferences.

This section has been revised to clarify how an owner shall make vacant units in an elderly project if the owner has adopted the secondary preferences and there are an insufficient number of preferences, or if the owner has not adopted the secondary preferences and there are an insufficient number of preferences.

Comment. One commenter requested that the rule provide not only for HUD's right to review at any time the accuracy of the owner's identification of a project as an elderly project, but an owner's implementation of the system of preferences authorized by subtitle D.

Response. There is no need for the rule to include a provision addressing HUD's right to review an owner's implementation of the system of preferences authorized by subtitle D. An owner' implementation of the system of occupancy preferences is subject to HUD's ongoing monitoring activities of covered projects, as well as civil rights complaint investigations and compliance reviews.

Comment. One commenter stated that the final rule must address the issue of whether a tenant who was a non-elderly disabled person upon admission to a covered section 8 project may still be counted as non-elderly disabled when that person reaches the age of 50. The commenter stated that any tenant who is counted for the purpose of determining whether a project is meeting its required set-aside of units for non-elderly tenants who are disabled should continue to be counted for such purpose as long as the tenant continues to reside in the project notwithstanding the fact that the tenant reaches the age of 50.

Response. HUD disagrees with the commenter. As discussed in an earlier response, the statute allows for the possibility of zero reservation of units. However, where there is a required reservation of units (which HUD anticipates will be the case in the majority of covered section 8 projects), HUD believes that the Congress intended for project owners to maintain the required percentage of units for non-elderly disabled persons. When a non-elderly disabled person reaches the age of 50, this person's unit can no longer be counted as part of the required percentage of units reserved for non-elderly disabled families. The preamble to the May 3, 1994 interim rule addressed this issue in part when it stated: "In calculating actual utilization of units reserved for disabled families who are not elderly or near-elderly, units occupied by elderly families where a member of the family is disabled do not count as part of the required percentage" (59 FR 22920).

Comment. One commenter stated that the preamble to the May 3, 1994 interim rule imposes an important responsibility on owners, that did not appear in the text of the regulation. That responsibility is to give notice to families on the waiting list adversely affected by the elderly preference. (See 59 FR 22921.) The commenter urged that this preamble language be included in the text of the regulation.

Response. The commenter is correct. In the preamble to the May 3, 1994 interim rule, HUD stated as follows:

> [W]hen an owner's decision to provide preferences to elderly families under subtitle D would have an adverse effect on non-elderly families on the waiting list, the owner would be required to notify those families of the new policy and how this policy may affect them. The notification requirement would be triggered if the current percentage of disabled families who are neither elderly nor near-elderly exceeds the minimum required percentage, and non-elderly families on the waiting list (including those with disabilities) may be passed over for covered section 8 units for the elderly, or if the project is one of the few which will have no units set aside for such disabled families under subtitle D.

HUD had intended to include this notification requirement in the May 3, 1994 interim rule, and its omission was inadvertent. This requirement appears in this final rule with one change. (See new § 880.612a(a)(1)(iii) and comparable sections in other parts covered by this rule.) The final rule provides that notification is triggered if the percentage of disabled families who are neither elderly nor near-elderly "equals or exceeds" the minimum required percentage.

The purpose of requiring this notice is to alert non-elderly families on the waiting list where the owner's election of the preference scheme would possibly have an "adverse effect" on them. Once the percentage of non-elderly disabled families in occupancy "is equal to" the required percentage determined under subtitle D, non-elderly families may be passed over for covered section 8 units, unless, of course, the next unit to become vacant is a unit occupied by a non-elderly family.

Comment. One commenter stated that the preamble to the May 3, 1994 interim rule makes the point that owners are not allowed to use the interim rule to remove applicants from the waiting list, and that this point should be included in the text of the regulations.

Response. HUD agrees with the commenter, and as noted earlier in this preamble has added a new paragraph (a)(1)(iii) to the rule which makes this point. (See new § 880.612a(a)(1)(iv) and comparable sections in other parts covered by this rule.)

Other Comments for Clarifying Changes or Editorial Corrections. Several other comments requested adoption of preamble language in the rule for clarity purposes or recommended editorial changes to certain of the regulatory provisions.

Response. The significant clarifying changes have been individually addressed in this section of the preamble. With respect to other comments requesting clarifying changes, HUD determined that these requests for changes did not address significant issues that needed to be addressed individually in this preamble. In many cases, HUD determined that the clarification was not needed because the May 3, 1994 interim rule clearly and adequately addressed the issue or other HUD regulations addressed the issue of concern expressed by the commenter. An example of the former situation is one commenter's request that the subtitle D rule state that the subtitle D

preferences do not apply to unassisted units. Since the rule clearly states that the subtitle D preference system applies to assisted, vacant units, HUD determined that there was no need to adopt the language suggested by the commenter. A few comments concerning clarification involved commenters requests to provide examples of application of subtitle D to certain circumstances. This, however, is the type of guidance best addressed by a handbook or other technical assistance materials, which HUD is now preparing.

IV. Other Matters

Executive Order 12866

This final rule was reviewed by the Office of Management and Budget (OMB) under Executive Order 12866 on Regulatory Planning and Review. Any changes made in this final rule as a result of that review are clearly identified in the docket file, which is available for public inspection in the Office of the Department's Rule's Docket Clerk, Room 10276, 451 Seventh St. SW, Washington, DC.

Environmental Impact

A Finding of No Significant Impact with respect to the environment was made in accordance with HUD regulations at 24 CFR part 50, which implement section 102(2)(C) of the National Environmental Policy Act of 1969, at the time of development of the interim rule. This finding remains applicable to this final rule and is available for public inspection during regular business hours in the Office of General Counsel, the Rules Docket Clerk room 10276, 451 Seventh Street, SW, Washington, DC 20410.

Executive Order 12612, Federalism

The General Counsel, as the Designated Official under section 6(a) of Executive order 12612, Federalism, has determined that the policies contained in this final rule will not have substantial direct effects on States or their political subdivisions, or the relationship between the Federal government and the states, or on the distribution of power and responsibilities among the various levels of government. Specifically, the final rule is directed to owners of multifamily housing projects, and will not impinge upon the relationship between the Federal Government and State and local governments. As a result, the rule is not subject to review under the order.

Executive Order 12606, The Family

The General Counsel, as the Designated Official under Executive Order 12606, The Family, has determined that this final rule does not have potential for significant impact on family formation, maintenance, and general well-being within the meaning of the order. This final rule implements the system of preferences authorized by subtitle D of title VI of the 1992 HCD Act, which provides that owners of certain section 8 covered projects that were originally designed primarily for occupancy by elderly families (i.e., families whose heads, spouses or sole members are 62 years or older) may elect to give preference in occupancy to vacant units in the project to elderly families. Although subtitle D provides for preferences for elderly families in projects meeting the conditions established by subtitle D, subtitle D also requires that owners of such projects must reserve no less then a minimum number of units in these projects for disabled families who are not elderly or near-elderly. The minimum number is determined in accordance with the formula established by statute.

Since the subtitle D preference system provides a primary preference for elderly families, and a secondary preference for disabled families who are near-elderly, there is the possibility that this statutory system of preferences would limit the availability of certain section 8 housing for (1) disabled families who are not elderly or near-elderly (if an owner gives preference to elderly families for units), and (2) such families with children, and thus adversely impact the maintenance and well-being of these families. (Although owners can apply the same preferences and reservation of units to families with children as to families without children, owners cannot restrict admission to any units because of familial status as long as the family qualifies for the unit on the basis of the relevant age or disability criterion for admission.) The Department believes that the number of projects that would be eligible for the preferences provided by subtitle D is limited, and thus, the impact on family maintenance and well being would not be significant within the meaning of the order

Regulatory Flexibility Act

The Secretary, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)) has reviewed and approved this final rule, and in so doing certifies that this final rule would not have a significant economic impact on a substantial number of small entities. This final rule reflects a system of occupancy preferences authorized by statute which applies to section 8 newly constructed or substantially rehabilitated housing without regard to the size of entities involved.

Regulatory Agenda

This rule was listed as sequence number 1803 in the Department's Semiannual Agenda of Regulations published on November 14, 1994 (59 FR 57632, 57657) in accordance with Executive Order 12866 and the Regulatory Flexibility Act.

Catalog of Federal Domestic Assistance Programs

The Catalog of Federal Domestic Assistance program number is 14.156

List of Subjects

24 CFR Part 880

Grant programs—housing and community development, Rent subsidies, Reporting and recordkeeping requirements.

24 CFR Part 881

Grant programs—housing and community development, Rent subsidies, Reporting and recordkeeping requirements.

24 CFR Part 883

Grant programs—housing and community development, Rent subsidies, Reporting and recordkeeping requirements.

24 CFR Part 884

Grant programs—housing and community development, Rent subsidies, Reporting and recordkeeping requirements, Rural areas

24 CFR Part 886

Grant programs—housing and community development, Lead poisoning, Rent subsidies, Reporting and recordkeeping requirements.

Accordingly, 24 CFR parts 880, 881 883, 884, and 886 are amended as follows:

PART 880—SECTION 8 HOUSING ASSISTANCE PAYMENTS PROGRAM FOR NEW CONSTRUCTION

1 The authority citation for 24 CFR part 880 continues to read as follows:

Authority: 42 U.S.C. 1437a, 1437c, 1437f, 3535(d), and 13611–13619.

2 Section 880.612a is revised to read as follows:

§ 880.612a Preference for occupancy by elderly families.

(a) *Election of preference for occupancy by elderly families.*

(1) *Election by owners of eligible projects.* (i) An owner of a project assisted under this part (including a

partially assisted project) that was originally designed primarily for occupancy by elderly families (an "eligible project") may, at any time, elect to give preference to elderly families in selecting tenants for assisted, vacant units in the project, subject to the requirements of this section.

(ii) For purposes of this section, a project eligible for the preference provided by this section, and for which the owner makes an election to give preference in occupancy to elderly families is referred to as an "elderly project." "Elderly families" refers to families whose heads of household, their spouses or sole members are 62 years or older.

(iii) An owner who elects to provide a preference to elderly families in accordance with this section is required to notify families on the waiting list who are not elderly that the election has been made and how the election may affect them if:

(A) The percentage of disabled families currently residing in the project who are neither elderly nor near-elderly (hereafter, collectively referred to as "non-elderly disabled families") is equal to or exceeds the minimum required percentage of units established for the elderly project in accordance with paragraph (c)(1) of this section, and therefore non-elderly families on the waiting list (including non-elderly disabled families) may be passed over for covered section 8 units; or

(B) The project, after making the calculation set forth in paragraph (c)(1) of this section, will have no units set aside for non-elderly disabled families.

(iv) An owner who elects to give a preference for elderly families in accordance with this section shall not remove an applicant from the project's waiting list on the basis of having made the election.

(2) *HUD approval of election not required* (i) An owner is not required to solicit or obtain the approval of HUD before exercising the election of preference for occupancy provided in paragraph (a)(1) of this section. The owner, however, if challenged on the issue of eligibility of the project for the election provided in paragraph (a)(1) of this section must be able to support the project's eligibility through the production of all relevant documentation in the possession of the owner that pertains to the original design of the project.

(ii) The Department reserves the right at any time to review and make determinations regarding the accuracy of the identification of the project as an elderly project. The Department can make such determinations as a result of ongoing monitoring activities, or the conduct of complaint investigations under the Fair Housing Act (42 U.S.C. 3601 through 3619), or compliance reviews and complaint investigations under section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794) and other applicable statutes.

(b) *Determining projects eligible for preference for occupancy by elderly families.* (1) *Evidence supporting project eligibility* Evidence that a project assisted under this part (or portion of a project) was originally designed primarily for occupancy by elderly families, and is therefore eligible for the election of occupancy preference provided by this section, shall consist of at least one item from the sources ("primary" sources) listed in paragraph (b)(1)(i) of this section, or at least two items from the sources ("secondary" sources) listed in paragraph (b)(1)(ii) of this section.

(i) *Primary sources.* Identification of the project (or portion of a project) as serving elderly (seniors) families in at least one primary source such as: The application in response to the notice of funding availability; the terms of the notice of funding availability under which the application was solicited; the regulatory agreement; the loan commitment; the bid invitation; the owner's management plan, or any underwriting or financial document collected at or before loan closing; *or*

(ii) *Secondary sources.* Two or more sources of evidence such as: lease records from the earliest two years of occupancy for which records are available showing that occupancy has been restricted primarily to households where the head, spouse or sole member is 62 years of age or older; evidence that services for elderly persons have been provided, such as services funded by the Older Americans Act, transportation to senior citizen centers, or programs coordinated with the Area Agency on Aging, project unit mix with more than fifty percent of efficiency and one-bedroom units [a secondary source particularly relevant to distinguishing elderly projects under the previous section 3(b) definition (in which disabled families were included in the definition of "elderly families") from non-elderly projects and which in combination with other factors (such as the number of accessible units) may be useful in distinguishing projects for seniors from those serving the broader definition of "elderly families" which includes disabled families]; or any other relevant type of historical data, unless clearly contradicted by other comparable evidence.

(2) *Sources in conflict.* If a primary source establishes a design contrary to that established by the primary source upon which the owner would base support that the project is an eligible project (as defined in this section), the owner cannot make the election of preferences for elderly families as provided by this section based upon primary sources alone. In any case where primary sources do not provide *clear evidence* of original design of the project for occupancy primarily by elderly families, including those cases where primary sources conflict, secondary sources may be used to establish the use for which the project was originally designed.

(c) *Reservation of units in elderly projects for non-elderly disabled families.* The owner of an elderly project is required to reserve, at a minimum, the number of units specified in paragraph (c)(1) of this section for occupancy by non-elderly disabled families.

(1) *Minimum number of units to be reserved for non-elderly disabled families.* The number of units in an elderly project required to be reserved for occupancy by non-elderly disabled families, shall be, at a minimum, the lesser of:

(i) The number of units equivalent to the higher of—

(A) The percentage of units assisted under this part in the elderly project that were occupied by non-elderly disabled families on October 28, 1992; and

(B) The percentage of units assisted under this part in the elderly project that were occupied by non-elderly disabled families upon January 1, 1992; *or*

(ii) 10 percent of the number of units assisted under this part in the eligible project.

(2) *Option to reserve greater number of units for non-elderly disabled families.* The owner, at the owner's option, and at any time, may reserve a greater number of units for non-elderly disabled families than that provided for in paragraph (c)(1) of this section. The option to provide a greater number of units to non-elderly disabled families will not obligate the owner to always provide that greater number to non-elderly disabled families. The number of units required to be provided to non-elderly disabled families at any time in an elderly project is that number determined under paragraph (c)(1) of this section.

(d) *Secondary preferences* An owner of an elderly project also may elect to establish secondary preferences in accordance with the provisions of paragraph (d) of this section.

(1) *Preference for near-elderly disabled families in units reserved for elderly families.* If the owner of an elderly project determines, in accordance with paragraph (f) of this section, that there are an insufficient number of elderly families who have applied for occupancy to fill all the vacant units in the elderly project reserved for elderly families (that is, all units except those reserved for the non-elderly disabled families as provided in paragraph (c) of this section), the owner may give preference for occupancy of such units to disabled families who are near-elderly families.

(2) *Preference for near-elderly disabled families in units reserved for non-elderly disabled families.* If the owner of an elderly project determines, in accordance with paragraph (f) of this section, that there are an insufficient number of non-elderly disabled families to fill all the vacant units in the elderly project reserved for non-elderly disabled families as provided in paragraph (c) of this section, the owner may give preference for occupancy of these units to disabled families who are near-elderly families.

(e) *Availability of units to families without regard to preference.* An owner shall make vacant units in an elderly project generally available to otherwise eligible families who apply for housing, without regard to the preferences and reservation of units provided in this section if either:

(1) The owner has adopted the secondary preferences and there are an insufficient number of families for whom elderly preference, reserve preference, and secondary preference has been given, to fill all the vacant units; or

(2) The owner has *not* adopted the secondary preferences and there are an insufficient number of families for whom elderly preference, and reserve preference has been given to fill all the vacant units.

(f) *Determination of insufficient number of applicants qualifying for preference.* To make a determination that there are an insufficient number of applicants who qualify for the preferences, including secondary preferences, provided by this section, the owner must:

(1) Conduct marketing in accordance with § 880.601(a) to attract applicants qualifying for the preferences and reservation of units set forth in this section; and

(2) Make a good faith effort to lease to applicants who qualify for the preferences provided in this section, including taking all feasible actions to fill vacancies by renting to such families.

(g) *Federal preferences.* An owner that gives preferences to elderly families and reserves units for non-elderly disabled families in accordance with this section also shall select applicants among each respective group in accordance with the Federal preferences contained in § 880.613. Projects under National Housing Act programs and receiving section 8 assistance may be subject to preferences in addition to those contained in § 880.613 which also must be applied in selecting applicants among each respective group.

(h) *Prohibition of evictions.* An owner may not evict a tenant without good cause, or require that a tenant vacate a unit, in whole or in part because of any reservation or preference provided in this section, or because of any action taken by the Secretary pursuant to subtitle D (sections 651 through 661) of title VI of the Housing and Community Development Act of 1992 (42 U.S.C. 13611 through 13620).

PART 881—SECTION 8 HOUSING ASSISTANCE PAYMENTS PROGRAM FOR SUBSTANTIAL REHABILITATION

3. The authority citation for 24 CFR part 881 continues to read as follows:

Authority: 42 U.S.C. 1437a, 1437c, 1437f, 3535(d), 12701, and 13611–13619.

4. Section 881.612a is revised to read as follows:

§ 881.612a Preference for occupancy by elderly families.

(a) *Election of preference for occupancy by elderly families.*

(1) *Election by owners of eligible projects.* (i) An owner of a project assisted under this part (including a partially assisted project) that was originally designed primarily for occupancy by elderly families (an "eligible project") may, at any time, elect to give preference to elderly families in selecting tenants for assisted, vacant units in the project, subject to the requirements of this section.

(ii) For purposes of this section, a project eligible for the preference provided by this section, and for which the owner makes an election to give preference in occupancy to elderly families is referred to as an "elderly project." "Elderly families" refers to families whose heads of household, their spouses or sole members are 62 years or older.

(iii) An owner who elects to provide a preference to elderly families in accordance with this section is required to notify families on the waiting list who are not elderly that the election has been made and how the election may affect them if:

(A) The percentage of disabled families currently residing in the project who are neither elderly nor near-elderly (hereafter, collectively referred to as "non-elderly disabled families") is equal to or exceeds the minimum required percentage of units established for the elderly project in accordance with paragraph (c)(1) of this section, and therefore non-elderly families on the waiting list (including non-elderly disabled families) may be passed over for covered section 8 units; or

(B) The project, after making the calculation set forth in paragraph (c)(1) of this section, will have no units set aside for non-elderly disabled families.

(iv) An owner who elects to give a preference for elderly families in accordance with this section shall not remove an applicant from the project's waiting list solely on the basis of having made the election.

(2) *HUD approval of election not required.* (i) An owner is not required to solicit or obtain the approval of HUD before exercising the election of preference for occupancy provided in paragraph (a)(1) of this section. The owner, however, if challenged on the issue of eligibility of the project for the election provided in paragraph (a)(1) of this section must be able to support the project's eligibility through the production of all relevant documentation in the possession of the owner that pertains to the original design of the project.

(ii) The Department reserves the right at any time to review and make determinations regarding the accuracy of the identification of the project as an elderly project. The Department can make such determinations as a result of ongoing monitoring activities, or the conduct of complaint investigations under the Fair Housing Act (42 U.S.C. 3601 through 3619), or compliance reviews and complaint investigations under section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794) and other applicable statutes.

(b) *Determining projects eligible for preference for occupancy by elderly families.* (1) *Evidence supporting project eligibility.* Evidence that a project assisted under this part (or portion of a project) was originally designed primarily for occupancy by elderly families, and is therefore eligible for the election of occupancy preference provided by this section, shall consist of at least one item from the sources ("primary" sources) listed in paragraph (b)(1)(i) of this section, or at least two items from the sources ("secondary"

sources) listed in paragraph (b)(1)(ii) of this section:

(i) *Primary sources.* Identification of the project (or portion of a project) as serving elderly (seniors) families in at least one primary source such as: the application in response to the notice of funding availability; the terms of the notice of funding availability under which the application was solicited; the regulatory agreement; the loan commitment; the bid invitation; the owner's management plan, or any underwriting or financial document collected at or before loan closing; *or*

(ii) *Secondary sources.* Two or more sources of evidence such as: lease records from the earliest two years of occupancy for which records are available showing that occupancy has been restricted primarily to households where the head, spouse or sole member is 62 years of age or older; evidence that services for elderly persons have been provided, such as services funded by the Older Americans Act, transportation to senior citizen centers, or programs coordinated with the Area Agency on Aging; project unit mix with more than fifty percent of efficiency and one-bedroom units [a secondary source particularly relevant to distinguishing elderly projects under the previous section 3(b) definition (in which disabled families were included in the definition of "elderly families") from non-elderly projects and which in combination with other factors (such as the number of accessible units) may be useful in distinguishing projects for seniors from those serving the broader definition of "elderly families" which includes disabled families]; or any other relevant type of historical data, unless clearly contradicted by other comparable evidence.

(2) *Sources in conflict.* If a primary source establishes a design contrary to that established by the primary source upon which the owner would base support that the project is an eligible project (as defined in this section), the owner cannot make the election of preferences for elderly families as provided by this section based upon primary sources alone. In any case where primary sources do not provide *clear evidence* of original design of the project for occupancy primarily by elderly families, including those cases where primary sources conflict, secondary sources may be used to establish the use for which the project was originally designed.

(c) *Reservation of units in elderly projects for non-elderly disabled families.* The owner of an elderly project is required to reserve, at a minimum, the number of units specified in paragraph (c)(1) of this section for occupancy by non-elderly disabled families.

(1) *Minimum number of units to be reserved for non-elderly disabled families.* The number of units in an elderly project required to be reserved for occupancy by non-elderly disabled families, shall be, at a minimum, the lesser of:

(i) The number of units equivalent to the higher of—

(A) The percentage of units assisted under this part in the elderly project that were occupied by non-elderly disabled families on October 28, 1992; and

(B) The percentage of units assisted under this part in the elderly project that were occupied by non-elderly disabled families upon January 1, 1992; *or*

(ii) 10 percent of the number of units assisted under this part in the eligible project.

(2) *Option to reserve greater number of units for non-elderly disabled families.* The owner, at the owner's option, and at any time, may reserve a greater number of units for non-elderly disabled families than that provided for in paragraph (c)(1) of this section. The option to provide a greater number of units to non-elderly disabled families will not obligate the owner to always provide that greater number to non-elderly disabled families. The number of units required to be provided to non-elderly disabled families at any time in an elderly project is that number determined under paragraph (c)(1) of this section.

(d) *Secondary preferences.* An owner of an elderly project also may elect to establish secondary preferences in accordance with the provisions of this paragraph (d) of this section.

(1) *Preference for near-elderly disabled families in units reserved for elderly families.* If the owner of an elderly project determines, in accordance with paragraph (f) of this section, that there are an insufficient number of elderly families who have applied for occupancy to fill all the vacant units in the elderly project reserved for elderly families (that is, all units except those reserved for the non-elderly disabled families as provided in paragraph (c) of this section), the owner may give preference for occupancy of such units to disabled families who are near-elderly families.

(2) *Preference for near-elderly disabled families in units reserved for non-elderly disabled families.* If the owner of an elderly project determines, in accordance with paragraph (f) of this section, that there are an insufficient number of non-elderly disabled families to fill all the vacant units in the elderly project reserved for non-elderly disabled families as provided in paragraph (c) of this section, the owner may give preference for occupancy of these units to disabled families who are near-elderly families.

(e) *Availability of units to families without regard to preference.* An owner shall make vacant units in an elderly project generally available to otherwise eligible families who apply for housing, without regard to the preferences and reservation of units provided in this section if either:

(1) The owner has adopted the secondary preferences and there are an insufficient number of families for whom elderly preference, reserve preference, and secondary preference has been given, to fill all the vacant units; or

(2) The owner has *not* adopted the secondary preferences and there are an insufficient number of families for whom elderly preference, and reserve preference has been given to fill all the vacant units.

(f) *Determination of insufficient number of applicants qualifying for preference.* To make a determination that there are an insufficient number of applicants who qualify for the preferences, including secondary preferences, provided by this section, the owner must:

(1) Conduct marketing in accordance with § 881.601(a) to attract applicants qualifying for the preferences and reservation of units set forth in this section; and

(2) Make a good faith effort to lease to applicants who qualify for the preferences provided in this section, including taking all feasible actions to fill vacancies by renting to such families.

(g) *Federal preferences.* An owner that gives preferences to elderly families and reserves units for non-elderly disabled families in accordance with this section also shall select applicants among each respective group in accordance with the Federal preferences contained in § 881.613. Projects under National Housing Act programs and receiving section 8 assistance may be subject to preferences in addition to those contained in § 881.613 which also must be applied in selecting applicants among each respective group.

(h) *Prohibition of evictions.* An owner may not evict a tenant without good cause, or require that a tenant vacate a unit, in whole or in part because of any reservation or preference provided in this section, or because of any action taken by the Secretary pursuant to subtitle D (sections 651 through 661) of

title VI of the Housing and Community Development Act of 1992 (42 U.S.C. 13611 through 13620).

PART 883—SECTION 8 HOUSING ASSISTANCE PAYMENTS PROGRAM—STATE HOUSING AGENCIES

5. The authority citation for 24 CFR part 883 continues to read as follows:

Authority: 42 U.S.C. 1437a, 1437c, 1437f, 3535(d), and 13611–13619.

6. Section 883.704a is revised to read as follows:

§ 883.704a Preference for occupancy by elderly families.

(a) *Election of preference for occupancy by elderly families.*

(1) *Election by owners of eligible projects.* (i) An owner of a project assisted under this part (including a partially assisted project) that was originally designed primarily for occupancy by elderly families (an "eligible project") may, at any time, elect to give preference to elderly families in selecting tenants for assisted, vacant units in the project, subject to the requirements of this section.

(ii) For purposes of this section, a project eligible for the preference provided by this section, and for which the owner makes an election to give preference in occupancy to elderly families is referred to as an "elderly project." "Elderly families" refers to families whose heads of household, their spouses or sole members are 62 years or older.

(iii) An owner who elects to provide a preference to elderly families in accordance with this section is required to notify families on the waiting list who are not elderly that the election has been made and how the election may affect them if:

(A) The percentage of disabled families currently residing in the project who are neither elderly nor near-elderly (hereafter, collectively referred to as "non-elderly disabled families") is equal to or exceeds the minimum required percentage of units established for the elderly project in accordance with paragraph (c)(1) of this section, and therefore non-elderly families on the waiting list (including non-elderly disabled families) may be passed over for covered section 8 units; or

(B) The project, after making the calculation set forth in paragraph (c)(1) of this section, will have no units set aside for non-elderly disabled families.

(iv) An owner who elects to give a preference for elderly families in accordance with this section shall not remove an applicant from the project's waiting list solely on the basis of having made the election.

(2) *HUD approval of election not required.* (i) An owner is not required to solicit or obtain the approval of HUD before exercising the election of preference for occupancy provided in paragraph (a)(1) of this section. The owner, however, if challenged on the issue of eligibility of the project for the election provided in paragraph (a)(1) of this section must be able to support the project's eligibility through the production of all relevant documentation in the possession of the owner that pertains to the original design of the project.

(ii) The Department reserves the right at any time to review and make determinations regarding the accuracy of the identification of the project as an elderly project. The Department can make such determinations as a result of ongoing monitoring activities, or the conduct of complaint investigations under the Fair Housing Act (42 U.S.C. 3601 through 3619), or compliance reviews and complaint investigations under section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794) and other applicable statutes.

(b) Determining projects eligible for preference for occupancy by elderly families. (1) *Evidence supporting project eligibility.* Evidence that a project assisted under this part (or portion of a project) was originally designed primarily for occupancy by elderly families, and is therefore eligible for the election of occupancy preference provided by this section, shall consist of at least one item from the sources ("primary" sources) listed in paragraph (b)(1)(i) of this section, or at least two items from the sources ("secondary" sources) listed in paragraph (b)(1)(ii) of this section:

(i) *Primary sources.* Identification of the project (or portion of a project) as serving elderly (seniors) families in at least one primary source such as: the application in response to the notice of funding availability; the terms of the notice of funding availability under which the application was solicited; the regulatory agreement; the loan commitment; the bid invitation; the owner's management plan, or any underwriting or financial document collected at or before loan closing; *or*

(ii) *Secondary sources.* Two or more sources of evidence such as: lease records from the earliest two years of occupancy for which records are available showing that occupancy has been restricted primarily to households where the head, spouse or sole member is 62 years of age or older; evidence that services for elderly persons have been provided, such as services funded by the Older Americans Act, transportation to senior citizen centers, or programs coordinated with the Area Agency on Aging; project unit mix with more than fifty percent of efficiency and one-bedroom units [a secondary source particularly relevant to distinguishing elderly projects under the previous section 3(b) definition (in which disabled families were included in the definition of "elderly families") from non-elderly projects and which in combination with other factors (such as the number of accessible units) may be useful in distinguishing projects for seniors from those serving the broader definition of "elderly families" which includes disabled families]; or any other relevant type of historical data, unless clearly contradicted by other comparable evidence.

(2) *Sources in conflict.* If a primary source establishes a design contrary to that established by the primary source upon which the owner would base support that the project is an eligible project (as defined in this section), the owner cannot make the election of preferences for elderly families as provided by this section based upon primary sources alone. In any case where primary sources do not provide *clear evidence* of original design of the project for occupancy primarily by elderly families, including those cases where primary sources conflict, secondary sources may be used to establish the use for which the project was originally designed.

(c) *Reservation of units in elderly projects for non-elderly disabled families.* The owner of an elderly project is required to reserve, at a minimum, the number of units specified in paragraph (c)(1) of this section for occupancy by non-elderly disabled families.

(1) *Minimum number of units to be reserved for non-elderly disabled families.* The number of units in an elderly project required to be reserved for occupancy by non-elderly disabled families, shall be, at a minimum, the lesser of:

(i) The number of units equivalent to the higher of—

(A) The percentage of units assisted under this part in the elderly project that were occupied by non-elderly disabled families on October 28, 1992, and

(B) The percentage of units assisted under this part in the elderly project that were occupied by non-elderly disabled families upon January 1, 1992; *or*

(ii) 10 percent of the number of units assisted under this part in the eligible project

(2) *Option to reserve greater number of units for non-elderly disabled families.* The owner, at the owner's option, and at any time, may reserve a greater number of units for non-elderly disabled families than that provided for in paragraph (c)(1) of this section. The option to provide a greater number of units to non-elderly disabled families will not obligate the owner to always provide that greater number to non-elderly disabled families. The number of units required to be provided to non-elderly disabled families at any time in an elderly project is that number determined under paragraph (c)(1) of this section.

(d) *Secondary preferences.* An owner of an elderly project also may elect to establish secondary preferences in accordance with the provisions of this paragraph (d) of this section.

(1) *Preference for near-elderly disabled families in units reserved for elderly families.* If the owner of an elderly project determines, in accordance with paragraph (f) of this section, that there are an insufficient number of elderly families who have applied for occupancy to fill all the vacant units in the elderly project reserved for elderly families (that is, all units except those reserved for the non-elderly disabled families as provided in paragraph (c) of this section), the owner may give preference for occupancy of such units to disabled families who are near-elderly families.

(2) *Preference for near-elderly disabled families in units reserved for non-elderly disabled families.* If the owner of an elderly project determines, in accordance with paragraph (f) of this section, that there are an insufficient number of non-elderly disabled families to fill all the vacant units in the elderly project reserved for non-elderly disabled families as provided in paragraph (c) of this section, the owner may give preference for occupancy of these units to disabled families who are near-elderly families.

(e) *Availability of units to families without regard to preference.* An owner shall make vacant units in an elderly project generally available to otherwise eligible families who apply for housing, without regard to the preferences and reservation of units provided in this section if either:

(1) The owner has adopted the secondary preferences and there are an insufficient number of families for whom elderly preference, reserve preference, and secondary preference has been given, to fill all the vacant units; or

(2) The owner has *not* adopted the secondary preferences and there are an insufficient number of families for whom elderly preference, and reserve preference has been given to fill all the vacant units.

(f) *Determination of insufficient number of applicants qualifying for preference.* To make a determination that there are an insufficient number of applicants who qualify for the preferences, including secondary preferences, provided by this section, the owner must:

(1) Conduct marketing in accordance with § 883.702(a) to attract applicants qualifying for the preferences and reservation of units set forth in this section; and

(2) Make a good faith effort to lease to applicants who qualify for the preferences provided in this section, including taking all feasible actions to fill vacancies by renting to such families.

(g) *Federal preferences.* An owner that gives preferences to elderly families and reserves units for non-elderly disabled families in accordance with this section also shall select applicants among each respective group in accordance with the Federal preferences contained in § 883.714. Projects under National Housing Act programs and receiving section 8 assistance may be subject to preferences in addition to those contained in § 883.714 which also must be applied in selecting applicants among each respective group.

(h) *Prohibition of evictions.* An owner may not evict a tenant without good cause, or require that a tenant vacate a unit, in whole or in part because of any reservation or preference provided in this section, or because of any action taken by the Secretary pursuant to subtitle D (sections 651 through 661) of title VI of the Housing and Community Development Act of 1992 (42 U.S.C. 13611 through 13620).

PART 884—SECTION 8 HOUSING ASSISTANCE PAYMENTS PROGRAM, NEW CONSTRUCTION SET-ASIDE FOR SECTION 515 RURAL RENTAL HOUSING PROJECTS

7. The authority citation for 24 CFR part 884 continues to read as follows:

Authority: 42 U.S.C. 1437a, 1437c, 1437f, 3535(d), and 13611–13619.

8. Section 884.223a is revised to read as follows:

§ 884.223a Preference for occupancy by elderly families.

(a) *Election of preference for occupancy by elderly families.*

(1) *Election by owners of eligible projects.* (i) An owner of a project assisted under this part (including a partially assisted project) that was originally designed primarily for occupancy by elderly families (an "eligible project") may, at any time, elect to give preference to elderly families in selecting tenants for assisted, vacant units in the project, subject to the requirements of this section.

(ii) For purposes of this section, a project eligible for the preference provided by this section, and for which the owner makes an election to give preference in occupancy to elderly families is referred to as an "elderly project." "Elderly families" refers to families whose heads of household, their spouses or sole members are 62 years or older.

(iii) An owner who elects to provide a preference to elderly families in accordance with this section is required to notify families on the waiting list who are not elderly that the election has been made and how the election may affect them if:

(A) The percentage of disabled families currently residing in the project who are neither elderly nor near-elderly (hereafter, collectively referred to as "non-elderly disabled families") is equal to or exceeds the minimum required percentage of units established for the elderly project in accordance with paragraph (c)(1) of this section, and therefore non-elderly families on the waiting list (including non-elderly disabled families) may be passed over for covered section 8 units; or

(B) The project, after making the calculation set forth in paragraph (c)(1) of this section, will have no units set aside for non-elderly disabled families.

(iv) An owner who elects to give a preference for elderly families in accordance with this section shall not remove an applicant from the project's waiting list solely on the basis of having made the election.

(2) *HUD approval of election not required.* (i) An owner is not required to solicit or obtain the approval of HUD before exercising the election of preference for occupancy provided in paragraph (a)(1) of this section. The owner, however, if challenged on the issue of eligibility of the project for the election provided in paragraph (a)(1) of this section must be able to support the project's eligibility through the production of all relevant documentation in the possession of the owner that pertains to the original design of the project.

(ii) The Department reserves the right at any time to review and make determinations regarding the accuracy of the identification of the project as an elderly project. The Department can make such determinations as a result of

ongoing monitoring activities, or the conduct of complaint investigations under the Fair Housing Act (42 U.S.C. 3601 through 3619), or compliance reviews and complaint investigations under section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794) and other applicable statutes.

(b) *Determining projects eligible for preference for occupancy by elderly families.* (1) *Evidence supporting project eligibility.* Evidence that a project assisted under this part (or portion of a project) was originally designed primarily for occupancy by elderly families, and is therefore eligible for the election of occupancy preference provided by this section, shall consist of at least one item from the sources ("primary" sources) listed in paragraph (b)(1)(i) of this section, or at least two items from the sources ("secondary" sources) listed in paragraph (b)(1)(ii) of this section:

(i) *Primary sources.* Identification of the project (or portion of a project) as serving elderly (seniors) families in at least one primary source such as: the application in response to the notice of funding availability; the terms of the notice of funding availability under which the application was solicited; the regulatory agreement; the loan commitment; the bid invitation; the owner's management plan, or any underwriting or financial document collected at or before loan closing; *or*

(ii) *Secondary sources.* Two or more sources of evidence such as: lease records from the earliest two years of occupancy for which records are available showing that occupancy has been restricted primarily to households where the head, spouse or sole member is 62 years of age or older; evidence that services for elderly persons have been provided, such as services funded by the Older Americans Act, transportation to senior citizen centers, or programs coordinated with the Area Agency on Aging; project unit mix with more than fifty percent of efficiency and one-bedroom units [a secondary source particularly relevant to distinguishing elderly projects under the previous section 3(b) definition (in which disabled families were included in the definition of "elderly families") from non-elderly projects and which in combination with other factors (such as the number of accessible units) may be useful in distinguishing projects for seniors from those serving the broader definition of "elderly families" which includes disabled families]; or any other relevant type of historical data, unless clearly contradicted by other comparable evidence.

(2) *Sources in conflict.* If a primary source establishes a design contrary to that established by the primary source upon which the owner would base support that the project is an eligible project (as defined in this section), the owner cannot make the election of preferences for elderly families as provided by this section based upon primary sources alone. In any case where primary sources do not provide *clear evidence* of original design of the project for occupancy primarily by elderly families, including those cases where sources documents conflict, secondary sources may be used to establish the use for which the project was originally designed.

(c) *Reservation of units in elderly projects for non-elderly disabled families.* The owner of an elderly project is required to reserve, at a minimum, the number of units specified in paragraph (c)(1) of this section for occupancy by non-elderly disabled families.

(1) *Minimum number of units to be reserved for non-elderly disabled families.* The number of units in an elderly project required to be reserved for occupancy by non-elderly disabled families, shall be, at a minimum, the lesser of:

(i) The number of units equivalent to the higher of—

(A) The percentage of units assisted under this part in the elderly project that were occupied by non-elderly disabled families on October 28, 1992; and

(B) The percentage of units assisted under this part in the elderly project that were occupied by non-elderly disabled families upon January 1, 1992; *or*

(ii) 10 percent of the number of units assisted under this part in the eligible project.

(2) *Option to reserve greater number of units for non-elderly disabled families.* The owner, at the owner's option, and at any time, may reserve a greater number of units for non-elderly disabled families than that provided for in paragraph (c)(1) of this section. The option to provide a greater number of units to non-elderly disabled families will not obligate the owner to always provide that greater number to non-elderly disabled families. The number of units required to be provided to non-elderly disabled families at any time in an elderly project is that number determined under paragraph (c)(1) of this section.

(d) *Secondary preferences.* An owner of an elderly project also may elect to establish secondary preferences in accordance with the provisions of this paragraph (d) of this section.

(1) *Preference for near-elderly disabled families in units reserved for elderly families.* If the owner of an elderly project determines, in accordance with paragraph (f) of this section, that there are an insufficient number of elderly families who have applied for occupancy to fill all the vacant units in the elderly project reserved for elderly families (that is, all units except those reserved for the non-elderly disabled families as provided in paragraph (c) of this section), the owner may give preference for occupancy of such units to disabled families who are near-elderly families.

(2) *Preference for near-elderly disabled families in units reserved for non-elderly disabled families.* If the owner of an elderly project determines, in accordance with paragraph (f) of this section, that there are an insufficient number of non-elderly disabled families to fill all the vacant units in the elderly project reserved for non-elderly disabled families as provided in paragraph (c) of this section, the owner may give preference for occupancy of these units to disabled families who are near-elderly families.

(e) *Availability of units to families without regard to preference.* An owner shall make vacant units in an elderly project generally available to otherwise eligible families who apply for housing, without regard to the preferences and reservation of units provided in this section if either:

(1) The owner has adopted the secondary preferences and there are an insufficient number of families for whom elderly preference, reserve preference, and secondary preference has been given, to fill all the vacant units; or

(2) The owner has *not* adopted the secondary preferences and there are an insufficient number of families for whom elderly preference, and reserve preference has been given to fill all the vacant units.

(f) *Determination of insufficient number of applicants qualifying for preference.* To make a determination that there are an insufficient number of applicants who qualify for the preferences, including secondary preferences, provided by this section, the owner must:

(1) Conduct marketing in accordance with § 884.214(a) to attract applicants qualifying for the preferences and reservation of units set forth in this section; and

(2) Make a good faith effort to lease to applicants who qualify for the preferences provided in this section including taking all feasible actions to

fill vacancies by renting to such families.

(g) *Federal preferences.* An owner that gives preferences to elderly families and reserves units for non-elderly disabled families in accordance with this section also shall select applicants among each respective group in accordance with the Federal preferences contained in § 884.226. Projects under National Housing Act programs and receiving section 8 assistance may be subject to preferences in addition to those contained in § 884.226 which also must be applied in selecting applicants among each respective group.

(h) *Prohibition of evictions.* An owner may not evict a tenant without good cause, or require that a tenant vacate a unit, in whole or in part because of any reservation or preference provided in this section, or because of any action taken by the Secretary pursuant to subtitle D (sections 651 through 661) of title VI of the Housing and Community Development Act of 1992 (42 U.S.C. 13611 through 13620).

PART 886—SECTION 8 HOUSING ASSISTANCE PAYMENTS PROGRAM—SPECIAL ALLOCATIONS

11. The authority citation for 24 CFR part 886 continues to read as follows:

Authority: 42 U.S.C. 1437a, 1437c, 1437f, 3535(d), and 13611–13619.

12. Section 886.329a is revised to read as follows:

§ 886.329a Preferences for occupancy by elderly families.

(a) *Election of preference for occupancy by elderly families.*

(1) *Election by owners of eligible projects.* (i) An owner of a project involving substantial rehabilitation and assisted under this part (including a partially assisted project) that was originally designed primarily for occupancy by elderly families (an "eligible project") may, at any time, elect to give preference to elderly families in selecting tenants for assisted, vacant units in the project, subject to the requirements of this section.

(ii) For purposes of this section, a project eligible for the preference provided by this section, and for which the owner makes an election to give preference in occupancy to elderly families is referred to as an "elderly project." "Elderly families" refers to families whose heads of household, their spouses or sole members are 62 years or older.

(iii) An owner who elects to provide a preference to elderly families in accordance with this section is required to notify families on the waiting list who are not elderly that the election has been made and how the election may affect them if:

(A) The percentage of disabled families currently residing in the project who are neither elderly nor near-elderly (hereafter, collectively referred to as "non-elderly disabled families") is equal to or exceeds the minimum required percentage of units established for the elderly project in accordance with paragraph (c)(1) of this section, and therefore non-elderly families on the waiting list (including non-elderly disabled families) may be passed over for covered section 8 units; or

(B) The project, after making the calculation set forth in paragraph (c)(1) of this section, will have no units set aside for non-elderly disabled families.

(iv) An owner who elects to give a preference for elderly families in accordance with this section shall not remove an applicant from the project's waiting list solely on the basis of having made the election.

(2) *HUD approval of election not required.* (i) An owner is not required to solicit or obtain the approval of HUD before exercising the election of preference for occupancy provided in paragraph (a)(1) of this section. The owner, however, if challenged on the issue of eligibility of the project for the election provided in paragraph (a)(1) of this section must be able to support the project's eligibility through the production of all relevant documentation in the possession of the owner that pertains to the original design of the project.

(ii) The Department reserves the right at any time to review and make determinations regarding the accuracy of the identification of the project as an elderly project. The Department can make such determinations as a result of ongoing monitoring activities, or the conduct of complaint investigations under the Fair Housing Act (42 U.S.C. 3601 through 3619), or compliance reviews and complaint investigations under section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794) and other applicable statutes.

(b) *Determining projects eligible for preference for occupancy by elderly families.* (1) *Evidence supporting project eligibility.* Evidence that a project assisted under this part (or portion of a project) was originally designed primarily for occupancy by elderly families, and is therefore eligible for the election of occupancy preference provided by this section, shall consist of at least one item from the sources ("primary" sources) listed in paragraph (b)(1)(i), or at least two items from the sources ("secondary" sources) listed in paragraph (b)(1)(ii) of this section:

(i) *Primary sources.* Identification of the project (or portion of a project) as serving elderly (seniors) families in at least one primary source such as: the application in response to the notice of funding availability; the terms of the notice of funding availability under which the application was solicited; the regulatory agreement; the loan commitment; the bid invitation; the owner's management plan, or any underwriting or financial document collected at or before loan closing; *or*

(ii) *Secondary sources.* Two or more sources of evidence such as: lease records from the earliest two years of occupancy for which records are available showing that occupancy has been restricted primarily to households where the head, spouse or sole member is 62 years of age or older; evidence that services for elderly persons have been provided, such as services funded by the Older Americans Act, transportation to senior citizen centers, or programs coordinated with the Area Agency on Aging; project unit mix with more than fifty percent of efficiency and one-bedroom units [a secondary source particularly relevant to distinguishing elderly projects under the previous section 3(b) definition (in which disabled families were included in the definition of "elderly families") from non-elderly projects and which in combination with other factors (such as the number of accessible units) may be useful in distinguishing projects for seniors from those serving the broader definition of "elderly families" which includes disabled families]; or any other relevant type of historical data, unless clearly contradicted by other comparable evidence.

(2) *Sources in conflict.* If a primary source establishes a design contrary to that established by the primary source upon which the owner would base support that the project is an eligible project (as defined in this section), the owner cannot make the election of preferences for elderly families as provided by this section based upon primary sources alone. In any case where primary sources do not provide *clear evidence* of original design of the project for occupancy primarily by elderly families, including those cases where primary sources conflict, secondary sources may be used to establish the use for which the project was originally designed.

(c) *Reservation of units in elderly projects for non-elderly disabled families.* The owner of an elderly project is required to reserve, at a minimum, the number of units specified in paragraph

(c)(1) of this section for occupancy by non-elderly disabled families.

(1) *Minimum number of units to be reserved for non-elderly disabled families.* The number of units in an elderly project required to be reserved for occupancy by non-elderly disabled families, shall be, at a minimum, the lesser of:

(i) The number of units equivalent to the higher of—

(A) The percentage of units assisted under this part in the elderly project that were occupied by non-elderly disabled families on October 28, 1992; and

(B) The percentage of units assisted under this part in the elderly project that were occupied by non-elderly disabled families upon January 1, 1992; *or*

(ii) 10 percent of the number of units assisted under this part in the eligible project.

(2) *Option to reserve greater number of units for non-elderly disabled families.* The owner, at the owner's option, and at any time, may reserve a greater number of units for non-elderly disabled families than that provided for in paragraph (c)(1) of this section. The option to provide a greater number of units to non-elderly disabled families will not obligate the owner to always provide that greater number to non-elderly disabled families. The number of units required to be provided to non-elderly disabled families at any time in an elderly project is that number determined under paragraph (c)(1) of this section.

(d) *Secondary preferences.* An owner of an elderly project also may elect to establish secondary preferences in accordance with the provisions of this paragraph (d) of this section.

(1) *Preference for near-elderly disabled families in units reserved for elderly families.* If the owner of an elderly project determines, in accordance with paragraph (f) of this section, that there are an insufficient number of elderly families who have applied for occupancy to fill all the vacant units in the elderly project reserved for elderly families (that is, all units except those reserved for the non-elderly disabled families as provided in paragraph (c) of this section), the owner may give preference for occupancy of such units to disabled families who are near-elderly families.

(2) *Preference for near-elderly disabled families in units reserved for non-elderly disabled families.* If the owner of an elderly project determines, in accordance with paragraph (f) of this section, that there are an insufficient number of non-elderly disabled families to fill all the vacant units in the elderly project reserved for non-elderly disabled families as provided in paragraph (c) of this section, the owner may give preference for occupancy of these units to disabled families who are near-elderly families.

(e) *Availability of units to families without regard to preference.* An owner shall make vacant units in an elderly project generally available to otherwise eligible families who apply for housing, without regard to the preferences and reservation of units provided in this section if either:

(1) The owner has adopted the secondary preferences and there are an insufficient number of families for whom elderly preference, reserve preference, and secondary preference has been given, to fill all the vacant units; or

(2) The owner has *not* adopted the secondary preferences and there are an insufficient number of families for whom elderly preference, and reserve preference has been given to fill all the vacant units.

(f) *Determination of insufficient number of applicants qualifying for preference* To make a determination that there are an insufficient number of applicants who qualify for the preferences, including secondary preferences, provided by this section, the owner must:

(1) Conduct marketing in accordance with § 886.321(a) to attract applicants qualifying for the preferences and reservation of units set forth in this section; and

(2) Make a good faith effort to lease to applicants who qualify for the preferences provided in this section, including taking all feasible actions to fill vacancies by renting to such families.

(g) *Federal preferences.* An owner that gives preferences to elderly families and reserves units for non-elderly disabled families in accordance with this section also shall select applicants among each respective group in accordance with the Federal preferences contained in § 886.337. Projects under National Housing Act programs and receiving section 8 assistance may be subject to preferences in addition to those contained in § 886.337 which also must be applied in selecting applicants among each respective group.

(h) *Prohibition of evictions.* An owner may not evict a tenant without good cause, or require that a tenant vacate a unit, in whole or in part because of any reservation or preference provided in this section, or because of any action taken by the Secretary pursuant to subtitle D (sections 651 through 661) of title VI of the Housing and Community Development Act of 1992 (42 U.S.C. 13611 through 13620).

Dated: November 30, 1994.

Nicolas P. Retsinas,

Assistant Secretary for Housing-Federal Housing Commissioner

[FR Doc. 94-31212 Filed 12-20-94; 8:45 am]

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December 21, 1994

Part III

Department of Transportation

Research and Special Programs Administration

49 CFR Part 171, et al.
Infectious Substances; Proposed Rule

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 Antonielli, 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 Antonielli, 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

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§ 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.

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Alan I. Roberts,

Associate Administrator for Hazardous Materials Safety

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