shall be kept at least 150 feet from pillar recovery workings.

§ 57.21078 Permissible equipment.

Only permissible equipment maintained in permissible condition shall be used beyond the last open crosscut or in places where dangerous quantities of flammable gases are present or may enter the air current.

§ 57.21079 Distribution boxes.

Only permissible distribution boxes shall be used in working places and other places where 1 percent or more of methane may be present or may enter the air current.

§ 57.21080 Methane monitors.

A methane monitoring device (methane monitor), approved by the Secretary of Labor, shall be installed and properly maintained on all continuous miners and longwall face equipment. The sensing unit of the methane monitor shall be positioned as close to the working face as practicable. When the concentration of methane is 1.0 percent or more, the monitor shall give a warning and deenergize the equipment automatically when the concentration reaches 1.5 percent. The methane monitor also shall de-energize such equipment automatically when the monitor is not functioning properly.

Illumination

§ 57.21090 Permissible electric lamps.

Only permissible electric lamps shall be used for portable illumination underground.

Explosives

§ 57.21095 Approval of explosives.

Explosives not designated as permissible by the Bureau of Mines or the Mine Safety and Health Administration shall not be used in any underground gassy mine until the Bureau of Mines and State Inspector of Mines have given written approval for each such specific explosive to be used.

§ 57.21096 Conditions of use.

The Mine Safety and Health Administration and the State Inspector of Mines, in granting approval referred to in standard 57.21095, shall provide the operator with a written list of conditions for using the specific explosives covered by the approval and adapted to the mining operation.

§ 57.21097 General requirements for blasting.

Blasts in gassy mines shall be initiated electrically, and multiple-shot blasts shall be initiated only with millisecond-delay detonators. Permissible blasting units of capacity suitable for the number of holes in a round to be blasted shall be used unless the round is fired from the surface when all persons are out of the mine.

§ 57.21098 Stemming boreholes.

Boreholes shall be stemmed as prescribed for the explosives used.

§ 57.21099 Examination for methane when blasting on shift.

When blasting on shift, examinations for methane shall be made immediately before firing each shot or round, and again before other work is performed. Examinations shall be made by competent persons with devices approved by the Secretary for detecting methane.

§ 57.21100 Methane limits for blasting.

Shots or rounds shall not be fired in places where 1.0 percent or more of methane is present at a point no less than 12 inches from the back, face, or rib. Tests to determine the presence of methane shall be made by a competent person with devices approved by the Secretary for detecting methane.

§ 57.21101 Firing shots and rounds.

Shots and rounds shall be fired by competent persons.

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Tuesday
January 29, 1985

Part IV

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 600, 606, 610, 620, 630, 640, and 660

Changes in Proper Names of Certain Biological Products; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 600, 606, 610, 620, 630, 640, and 660

[Docket No. 80N-0053]

Changes in Proper Names of Certain Biological Products

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the biologics regulations by changing the proper names of certain biological products; updating all applicable regulations to reflect these new names; and updating, clarifying, and reorganizing certain regulations. The "proper name" of a product is the name that FDA requires that manufacturers use on the label of the product. FDA is taking these actions to reduce the length of a name, more accurately identify a product, or make the name more consistent with the name of the same product in the United States Pharmacopeia (U.S.P.) or in the United States Adopted Names (USAN).

EFFECTIVE DATE: January 29, 1986 for all affected products initially introduced or initially delivered for introduction into interstate commerce. See Supplementary Information for full discussion of proposed effective date.

FOR FURTHER INFORMATION CONTACT: Joseph Wilczek, Center for Drugs and Biologics (HFN-368), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1306.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 31, 1980 (45 FR 72404), FDA proposed to change the proper names of more than 50 biological products, including various blood, viral, and bacterial products, antivenins, and one category of allergenic extracts, and update applicable regulations in 21 CFR Parts 600 through 660 to reflect these new proposed proper names. (The term "proper name" is defined in 21 CFR 600.3(k).) Further, FDA proposed to reorganize and clarify 21 CFR 610.53(a) concerning the prescribed dating periods for licensed biological products. FDA also proposed to delete the names of 30 biological products in 21 CFR 610.53(a) that are no longer licensed and add the names of 11 biological products that are licensed now but are not listed in the regulations. FDA developed and issued these regulations in collaboration with the United States Adopted Names Council (USAN) to designate meaningful and distinctive nonproprietary names for these biological products. USAN is sponsored by the American Medical Association, the United States Pharmacopeial Convention, and the American Pharmaceutical Association.

FDA provided a public comment period of 60 days on the proposal. However, in response to a request from a manufacturer, FDA extended the comment period an additional 60 days **Federal Register** of December 9, 1980; 45 FR 81065).

FDA received 37 letters in response to the proposal and several of these letters contained more than one comment. Eight letters expressed approval of the amendments as proposed, eight other letters expressed approval of the amendments with some reservations, and the remaining letters contained general comments or suggestions of alternative names. Because certain comments objected to the proposed changes in proper names of one or more products or upon reconsideration, FDA advises that in the final rule about 30 percent of the proper names that FDA proposed to change were not changed. For more detailed information, see table I at the end of the preamble to this final rule. Summaries of all of the comments and FDA's responses follow:

1. One comment noted a discrepancy concerning the modifier to be used with the proposed proper name of each of several blood and blood products.

FDA agrees with the comment. In several instances in the proposal, FDA identified incorrectly a proposed proper name with a modifier as the proper name. Accordingly, in the final rule FDA is excluding any modifier from the proper name of a product. Examples follow:

Proper name	Proper name with modifier
Red blood cells	Red blood cells deglycerolized.
Red blood cells	Red blood cells frozen.
Whole blood	Whole blood cryoprecipitate removed.

2. Two comments suggested new names for five products but gave no reasons why these names should be used instead of the names that FDA proposed.

Name suggested by comments	Name proposed by FDA
Albumin 96 pct. pure	Albumin.
Albumin 83 pct. pure	Plasma protein fraction.
AHF lyophilized	Antihemophilic factor.
AHF cryoprecipitated	Cyroprecipitated AHF.
Factor VIII	Antihemophilic factor and cryoprecipitated AHF.

FDA disagrees with the comments. FDA believes that the names that were suggested offer no advantages over the names that FDA proposed. Accordingly, FDA is rejecting the suggested name changes above for these products. (See also FDA's response in paragraph 29.)

3. One comment stated that proposed § 600.13 concerning retention sample requirements is not accurate because § 600.13 lists some but not all of the products in proposed § 600.15. Section 600.15 specifies temperatures of products to be maintained during shipment.

FDA disagrees with the comment. Section 600.13 lists certain products and categories of products that are exempt from the retention sample requirements. Section 600.15 is unrelated to § 600.13. Section 600.15 specifies temperatures of products to be maintained during shipment. All products shown in § 600.15 should not be listed in § 600.13, because all of the products in § 600.15 are not exempt from the retention sample requirements.

4. One comment stated that proposed § 600.15(a) does not state whether freshly collected whole blood may be shipped before the blood has cooled to 10 °C or colder, as described in proposed § 640.6(b) in FDA's proposal of October 31, 1980 (45 FR 72422).

FDA agrees that proposed § 600.15(a) should be clarified. Accordingly, in the final rule FDA is amending § 600.15(a) to incorporate transit storage temperature requirements.

5. One comment on proposed § 600.15 stated that the name Red Blood Cells should not be identified with the phrase "(liquid product)", because the phrase could easily be mistaken for a proper name, a modifier, or a qualifier.

FDA disagrees with the comment. FDA believes that the phrase "(liquid product)" that is not capitalized and is placed in parentheses helps to clarify the form of the product that is affected by the requirement and the phrase is not part of the proper name of the product. Accordingly, FDA rejects this comment.

6. Two comments on proposed § 610.53(c) stated that the dating periods are incorrect for some products. One comment stated that the dating periods for antisera are unrealistic and wasteful.

FDA disagrees with the comments. The dating periods listed in proposed § 610.53 are minimum dating periods for the products. FDA notes, however, that there could be instances where even shorter dating periods may be necessary to maintain product safety or potency. Therefore, FDA considers the "minimum dating period" to be the dating period based on usage, clinical experience, or laboratory testing which initially may be assigned to a product before the

manufacturer completes extended shelf life stability studies. As an amendment to its product license, a manufacturer may submit stability data to the Director, Center for Drugs and Biologics, to support a dating period longer than the minimum dating period shown in § 610.53. Accordingly, in the final rule FDA is changing § 610.53(a) by inserting the word "minimum" in the first sentence.

7. FDA proposed in § 610.53 to delete the 10-year dating period for Albumin (Human) packaged in hermetically sealed metal containers. Two comments suggested that the 10-year dating period for Albumin (Human) packaged in hermetically sealed metal containers be retained, because the Department of Defense still uses the product packaged in this manner.

FDA agrees with the comments. Accordingly, in the final rule FDA is retaining the 10-year dating period for Albumin (Human) packaged in hermetically sealed metal containers.

8. One comment on proposed § 610.53(c) objected to the proposal to change the name of Allergenic Extracts, Alum Precipitated, to Allergenic Extracts Adsorbed, because the manufacturers' administrative and financial costs from revising all labels and labeling of alum precipitated allergenic extracts would well exceed any expected benefit from consistency in names with other adsorbed products.

FDA now believes that only minimal benefits would result from the proposed change in the name. Accordingly, in the final rule FDA is retaining the current proper names of these products.

9. Four comments on proposed § 610.53(c) concerned the proposed proper names of the antivenins and the proposed word change of "antivenin" to "antivenom." One comment suggested the name Antivenom Black Widow Spider as an alternative to the proposed name Antivenom Widow Spider, because the proposed name suggests that this antivenom may have a broader specificity than has been demonstrated. For a similar reason, another comment objected to the proposed name Antivenom Coral Snake and suggested retaining the name Antivenin (*Micrurus fulvius*) for this product. One comment suggested adding a comma after "Copperhead" in the proposed name Antivenom Rattlesnake, Copperhead and Moccasin. One comment suggested that the current name of all antivenins be retained and that the proposed name Antivenom Rattlesnake, Copperhead and Moccasin is incorrect, because no copperhead or moccasin venom is used in the manufacture of this product. Instead, the venom of a tropical American pit viper is used in the manufacture of this antiserum.

FDA recognizes that confusion may result from changing the names of antivenins to the common names that were proposed, particularly if the products were to be exported to another country where the common name may represent a different genus or species. Thus, FDA agrees with the comments that suggested that the current proper names be retained without change. Accordingly, upon reconsideration, FDA is retaining the current names listed in the biologics regulations for these products. In addition, FDA is retaining the word "antivenin" rather than the proposed word "antivenom."

10. One comment on proposed § 610.53(c) noted that four products (Granulocytes, Pheresis; Granulocytes, Pooled; Granulocytes Platelets Pheresis; and Recovered Plasma, Pooled) that were listed in the Guideline for the Uniform Labeling of Blood and Blood Components that FDA made available in the **Federal Register** of October 31, 1980 (45 FR 72416) were not included in proposed § 610.53. Another comment suggested changing the proper name Recovered Plasma to Source Plasma, Recovered.

FDA advises that the four products identified by the comment were not licensed at the time of the proposal and thus were not included in proposed § 610.53. The three granulocyte preparations and Recovered Plasma still are unlicensed. FDA believes that the proper name Recovered Plasma is widely accepted and understood by the blood banking community and, therefore, FDA rejects the suggested name change for that product.

11. One comment on proposed § 610.53(c) suggested reversing the order of the words in the names of all immune globulins so that they could be listed together.

FDA agrees in part and disagrees in part with the comment. FDA does not believe that it is necessary to change the names of all immune globulins to list them together in the regulations. However, FDA agrees that listing the immune globulins together will aid in locating these products in the dating period listings. Accordingly, in the final rule FDA is reorganizing § 610.53 so that all immune globulin products are listed together. Likewise, FDA is reorganizing § 610.53 so that all plasma products are listed together.

12. Two comments on proposed § 610.53(c) concerned the proposed proper name Rh_o(D) Immune Globulin. One comment suggested substituting the name Rh Immune Globulin, because the product is almost universally known as Rh Immune Globulin or RhoGam. One comment stated that the proposed proper name of this product should be D(Rh_o) Immune Globulin, for consistency with the nomenclature of Blood Grouping Sera.

FDA disagrees with the comments. FDA believes that the most important part of the product name, i.e., Rh_o(D), should appear first. FDA rejects the suggested name D(Rh_o) Immune Globulin because the product is used therapeutically to prevent Rh hemolytic disease. Accordingly, in the final rule FDA is continuing to use the § 610.53(c) the current proper name Rh_o(D) Immune Globulin (Human). (See also FDA's response in paragraph 29.)

13. One comment on proposed § 610.53(c) suggested that the name "Measles and Mumps Virus Vaccine, Live" be changed by deleting the comma, to be consistent with similar products and the nomenclature in the U.S.P.

FDA agrees with the comment. FDA proposed this change in the codified text of § 610.53(c) in the proposal of October 31, 1980, but FDA mistakenly omitted it from the name change amendments listed in the preamble to the proposal. Accordingly, in the final rule FDA is identifying the product as Measles and Mumps Virus Vaccine Live.

14. One comment recommended deleting Mumps Immune Globulin from proposed § 610.53(c), because action has been taken taken by FDA to revoke product licenses for this product.

FDA agrees with the comment. After FDA published the proposal in the **Federal Register**, FDA revoked the licenses of 12 products in addition to the 30 products FDA proposed be deleted. In a final rule published in the **Federal Register** of June 8, 1982 (47 FR 24696), FDA deleted the following six products from § 610.53: Adenovirus and Influenza Virus Vaccines Combined Aluminum Hydroxide Adsorbed, Adenovirus and Influenza Virus Vaccines Combined Aluminum Phosphate Adsorbed, Adenovirus Vaccine, Mumps Immune Globulin (Human), Rocky Mountain Spotted Fever Vaccine, and Typhus Vaccine. Accordingly, in this final rule FDA is deleting the following 35 products from § 610.53: Aggregated Radio-Iodinated (I^{131}) Albumin (Human), Anti-Human Chorionic Gonadotropic Serum, Cobra Venom Solution, Cobra Venom Solution with Silicic and Formic Acids, Diphtheria and Tetanus Toxoids, Diphtheria and Tetanus Toxoids and Pertussis and Poliomyelitis Vaccine Adsorbed, Diphtheria and Tetanus Toxoids and Pertussis Vaccine, Diphtheria and Tetanus Toxoids and

Pertussis Vaccine Adsorbed and Poliomyelitis Vaccine, Diphtheria and Tetanus Toxoids and Poliomyelitis Vaccine, Diphtheria Toxoid and Pertussis Vaccine, Diphtheria Toxoid and Pertussis Vaccine Adsorbed, Fibrinogen (Human), Fibrinogen with Antihemophilic Factor (Human), Gas Gangrene Polyvalent Antitoxin, Haemophilus Influenzae Typing Serum, Histamine Azoprotein, Leukocyte Typing Serum, Lymphogranuloma Venereum Antigen, Measles Immune Globulin (Human), Modified Plasma (Bovine), Mumps Vaccine, Poliomyelitis Vaccine Adsorbed, Polyvalent modified bacterial antigens with "No U.S. Standard of Potency," Pseudomonas Polysaccharide, Radio-Chromated (Cr^{51}) Serum Albumin (Human), Radio-Iodinated (I^{125}) Serum Albumin (Human), Radio-Iodinated (I^{131}) Serum Albumin (Human), Reagent Blood Group Specific Substances A and B, Russell Viper Venom, Schick Test Control, Staphylococcus Antitoxin, Staphylococcus Toxoid, Streptokinase-Streptodornase, Tetanus and Gas Gangrene Polyvalent Antitoxin, Trichinella Extract. Also, FDA proposed to codify existing dating periods for 11 licensed products which previously had not been listed in § 610.53. After publication of the proposed rule, FDA revoked the product license for 1 of the 11 products, Anticarcinoembryonic Antigen Serum, and has issued product licenses for 14 additional products. Accordingly, in the final rule FDA is identifying in § 610.53 dating periods for the following new products: Adenovirus Vaccine Live Oral Type 4; Adenovirus Vaccine Live Oral Type 7; Anti-Inhibitor Coagulant Complex; Asparaginase; Hepatitis B Immune Globulin (Human); Hepatitis B Vaccine; Immune Globulin Intravenous (Human); Lymphocyte Immune Globulin, Anti-Thymocyte Globulin (Equine); Meningococcal Polysaccharide Vaccine Group A; Meningococcal Polysaccharide Vaccine Group C; Meningococcal Polysaccharide Vaccine Groups A and C Combined; Meningococcal Polysaccharide Vaccine Groups A, C, Y, and W135 Combined; Pertussis Vaccine Adsorbed; Pneumococcal Vaccine Polyvalent; Rabies Immune Globulin (Human); Red Blood Cells Deglycerolized; Skin Test Antigens for Cellular Hypersensitivity; Source Leukocytes; Therapeutic Exchange Plasma; Thrombin Impregnated Pad; Varicella-Zoster Immune Globulin (Human).

15. One comment on proposed § 610.53(c) suggested that the storage temperature for Liquid Plasma be included in column D under both (a) and (b).

FDA agrees that this suggested change will clarify the regulations. Accordingly, in the final rule FDA is presenting the storage temperature for Liquid Plasma in column D under both (a) and (b).

16. One comment on proposed § 610.53(c) suggested that reversing the order of the words in the proposed names of some plasma and red blood cell products would allow the proper name and common name to be the same.

FDA agrees that reversing the order of the words in the proposed proper names of some plasma products will clarify the regulations. Accordingly, in the final rule FDA is changing the following proposed proper names to read as follows:

Proposed proper name	Proper name in final rule
Plasma fresh frozen	Fresh frozen plasma.
Plasma liquid	Liquid plasma.
Plasma platelet rich	Platelet rich plasma.

17. One comment on proposed § 610.53(c) stated that the information regarding dating periods for Plasma Protein Fraction in column D were confusing and suggested that the dating period regulations for this product be consistent with the dating period for Albumin.

FDA accepts the comment. In the final rule FDA is revising the information in the dating period regulations so that the requirements regarding manufacturer's storage temperature are consistent for Plasma Protein Fraction (Human) and Albumin (Human).

18. One comment on proposed § 610.53(c) suggested reversing the order of the names of anticoagulated products, e.g., ACD Red Blood Cells and CPD Whole Blood, because the name of the product is more important than the name of the anticoagulant.

FDA disagrees with the comment. FDA sees no advantage in having the name of the anticoagulant following the name of the product. In addition, for consistency with the terminology in the U.S.P., FDA believes that the name of the anticoagulant should precede the name of the product.

19. One comment on proposed § 610.53(c) stated that the hematocrit should be less than 80 percent for 35-day dating of CPDA–1 Red Blood Cells and questioned whether this information should be added to § 610.53.

FDA disagrees with the comment. FDA believes that it is inappropriate for hematocrit levels to be included in the dating period listing in § 610.53. Rather, a blood establishment should include this information in the blood establishment's standard operating procedures and in its product license application. FDA also advises that it currently is reviewing all blood regulations and evaluating hematocrit levels.

20. Two comments noted that no provision was made in proposed § 610.53(c) for Tuberculin, Old, on a multiple puncture device and also questioned why Tuberculin, Old, containing at least 50 percent glycerin was no longer identified.

FDA agrees that Tuberculin, Old, on a multiple puncture device should have been listed in § 610.53(c) and in the final rule FDA is including this product. FDA advises that Tuberculin, Old, containing at least 50 percent glycerin was excluded from proposed § 610.53(c) because the product is no longer manufactured under license.

21. One comment on proposed § 630.10 suggested deleting the comma in the proposed name Poliovirus Vaccine Live Oral, Trivalent, as well as the comma in each of the proposed names of the three monovalent vaccines.

FDA agrees with the comment. In the final rule FDA is deleting each of the commas. FDA notes, however, that only Poliovirus Vaccine Live Oral Trivalent is licensed for distribution. FDA has licensed and is releasing the three monovalent vaccines only for use in manufacturing the trivalent product.

22. One comment on proposed § 630.80 objected to the proposed name Measles-Smallpox Vaccine Live and suggested the name "Measles Live and Smallpox Vaccine" for two reasons: (1) the hyphen is unnecessary and should be replaced by the customary word "and"; and (2) the word "Live" should be placed after "Measles," not at the end of the proper name, to distinguish it from the inactivated form.

FDA agrees with the comment. Accordingly, in the final rule FDA is changing the proper name of the product to Measles Live and Smallpox Vaccine.

23. One comment on proposed § 640.(c) and (h) stated that the term "Heparinized" in the product name "Heparinized Whole Blood" should be changed to "Heparin," to be consistent with the practice of preceding the proper name with the name of the specific anticoagulant used.

FDA agrees with the comment. Accordingly, in the final rule FDA is changing the name of the product to Heparin Whole Blood.

24. One comment on proposed § 640.5(c) stated that Rh "typing" serum should not be changed to "grouping" serum because group refers to ABO and type refers to Rh and other factors.

FDA disagrees with this comment. FDA believes that Rh now is considered a group like ABO. FDA is not changing the regulation as suggested.

25. FDA received five comments on proposed §§ 640.6 and 640.7 concerning the proposed name Whole Blood Platelets and/or Cryoprecipitate Removed. One comment stated that Whole Blood, Modified, Platelets Removed, and Whole Blood, Modified, Cryoprecipitate Removed, should not be combined into one proposed name, because many physicians would not use the product for hemophiliacs if the label stated "Platelets and/or Cryoprecipitate Removed," when in fact only the Platelets had been removed. One comment stated that the name Whole Blood Platelets and/or Cryoprecipitate Removed is more cumbersome than Whole Blood (Human) Modified and suggested the names Blood, Platelets and/or Cryoprecipitate Poor; Whole Blood, Modified; Blood, Whole Blood, Modified; or Blood, Modified, as alternatives. One comment suggested inserting a comma or dash between Whole Blood and the component removed for clarification. One comment proposed two separate names—Platelets and Platelets Cryoprecipitate Removed—while another comment suggested two other separate names—Whole Blood Platelets Removed and Whole Blood Cryoprecipitated AHF Removed.

FDA agrees that the name Whole Blood Platelets and/or Cryoprecipitate Removed is cumbersome. FDA believes that it is important for physicians treating hemophiliacs to know if the Cryoprecipitate has been removed from the product. Further, FDA believes that it is unnecessary to indicate whether platelets have been removed because the blood would have to be very fresh for the platelets to be of value. Further, FDA does not believe that a comma or dash is necessary between the proper name and the modifier because the proper name and modifier appear on a different line on the label. FDA does not believe that the comment suggesting the names Platelets and Platelet Cryoprecipitate Removed should be adopted. The suggested names do not indicate that the product is whole blood that lacks platelets and cryoprecipitate. FDA has evaluated all alternative proper names and concludes that the proper name of the product should be Whole Blood Cryoprecipitate Removed. Accordingly, in the final rule FDA is changing the proper name in §§ 640.6 and 640.7 to Whole Blood Cryoprecipitate Removed.

26. One comment on proposed § 640.20 urged retention of the name Platelet Concentrate, because it is essential to differentiate this product from Whole Blood, Platelets and/or Cryoprecipitate Removed.

FDA disagrees with this comment. FDA believes that the name Platelet Concentrate does not identify the product more clearly than the proposed name Platelets and the comment misunderstood that the second product as Whole Blood from which Platelets or Cryoprecipitate or both have been removed. Accordingly, in the final rule FDA is adopting the name Platelets as proposed.

27. One comment on proposed § 640.34(d) stated that the term cubic milliliter should be cubic millimeter and that the phrase "250,000 platelets per cubic milliliter" should be "400,000 platelets per microliter."

FDA agrees in part and disagrees in part with the comment. FDA agrees that the term "cubic milliliter" is incorrect. Indeed, in the editorial revisions FDA published in the **Federal Register** of March 29, 1983 (48 FR 13052), the term "cubic milliliter" was corrected to read "microliter." FDA disagrees that the number of platelets should be increased from 250,000 to 400,000, because this action would result in wasting otherwise useful platelet preparations that could be used for treating pediatric patients.

28. Two comments on proposed § 640.50 objected to the proposed proper name Cryoprecipitated AHF. One comment stated that the abbreviation AHF is too subjective and uninformative and urged that the name Cryoprecipitated Antihemophilic Factor be retained. Another comment stated that it is misleading to call the product Cryoprecipitated AHF because it contains fibrinogen and von Willebrand factor in addition to Antihemophilic Factor. The comment suggested the name Cryoprecipitate be used, because the term is well recognized and widely used.

FDA disagrees with the comments. FDA believes that the proposed name Cryoprecipitated AHF is clear, informative, and in keeping with the principle of reducing the length of proper names wherever possible. FDA notes that the suggested proper name Cryoprecipitate is indeed uninformative and ambiguous. The term Cryoprecipitate can be used to identify any number of biological products and is, therefore, unacceptable. Accordingly, in the final rule FDA is retaining the proposed proper name Cryoprecipitated AHF in §§ 600.13, 600.15, 606.120, 610.11, 610.12, 610.53, 640.34, 640.50, 640.52, 640.53, 640.54, 640.55, and 640.56.

29. Five comments on proposed § 640.80 noted that the proposed proper name "Albumin" was inconsistent with the name "Albumin Human" in the current U.S.P. Two comments recommended retaining the word "Human" in the proper names of fractionation products, such as albumin, because blood products of animal origin are still available.

FDA agrees with these comments. Accordingly, in the final rule FDA is retaining the word "Human" in the proper names of the following products because similar blood products of animal origin are still available: Albumin (Human), Antihemophilic Factor (Human), Fibrinolysin (Human), Hepatitis B Immune Globulin (Human), Immune Globulin (Human), Pertussis Immune Globulin (Human), Plasma Protein Fraction (Human), Rabies Immune Globulin (Human), Rh_o(D) Immune Globulin (Human), Tetanus Immune Globulin (Human), Vaccinia Immune Globulin (Human).

30. Three comments on proposed § 660.28 concerned Blood Grouping Serum products. One comment stated that Anti-Colton^b is the synonym for Anti-Co^b. One comment noted that the synonym for Anti-CDE is Anti-Rh_o' ", not Anti-Rh_o' ". One comment noted the omission of the bars over the letters in Anti-c, Anti-e, Anti-k, and Anti-s and stated that the bar could be eliminated over the letter e but should be retained for each of the letters c, s, and k to differentiate the lower case letters from the upper case letters.

FDA agrees in part and disagrees in part with the comments. FDA has considered adding Anti-Colton^b to the table in § 660.28(d) as a synonym for Anti-Co^b, but now believes that confusion and typographical errors can be avoided by not listing each Blood Grouping Serum specificity in § 610.53. Instead, FDA is amending § 610.53 to state that all liquid Blood Grouping Serum products have a minimum dating period of 2 years, whereas all dried Blood Grouping Serum products have a minimum dating period of 5 years. The second and third comments deal with typographical errors that are corrected in this final rule. FDA notes that it has already eliminated the bar over the letter e in the biologics regulations (48 FR 13025; March 29, 1983).

31. Six comments concerned the proposed effective date of the final regulation (180 days after publication of the final regulation). The comments suggested changing the effective date to: 18 months (one comment); 1 year (one

comment); 1 year or varying effective dates for different products (one comment); 1 year or when supply of labels run out (one comment); and 2 years (two comments). One comment also suggested that FDA allow the use of "mixed" labeling (both new names and former names) before the effective date.

FDA essentially agrees with the suggestions of the comments regarding the need for a later effective date for the final rule. Accordingly, FDA is changing the effective date to January 29, 1986, which is 1 year after publication of this regulation. Also, FDA is allowing manufacturers to voluntarily begin use of labeling including the new proper name of a product along with labeling including the former proper name of the product, provided that such manufacturers alert their consignees or customers of any significant inconsistencies in the proper name of their products. Any product subject to this final rule that is initially introduced or initially delivered for introduction into interstate commerce on or after January 29, 1986 shall bear labeling including the new proper name of the product established herein.

Table I

For each product subject of a proposed change in proper name that was included in the proposal of October 31, 1980; FDA is listing below the current codified name, the proposed name, and the new proper name, if any, established herein.

Current codified name	Proposed name	Revised proper name (if any) and modifier (if applicable) under final rule
Blood Products		
Normal serum albumin (human)	Albumin	Albumin (human).
Antihemophilic factor (human)	Antihemophilic factor	No change in current codified name (see preamble paragraph 29)
Cryoprecipitated antihemophilic factor (human)	Cryoprecipitated AHF	Cryoprecipitated AHF.
Factor IX complex (human)	Factor IX complex	Factor IX complex.
Fibrinolysin (human)	Fibrinolysin	No change in current codified name (see preamble paragraph 29)
Immune serum globulin (human)	Immune globulin	Immune globulin (human).
Mumps immune globulin (human)	Mumps immune globulin	Product no longer licensed (see preamble paragraph 14).
Measles immune globulin (human)	Measles immune globulin	Do.
Pertussis immune globulin (human)	Pertussis immune globulin	No change in current codified name (see preamble paragraph 29)
Single donor plasma (human)	Plasma	Plasma.
Single donor plasma (human), fresh frozen	Plasma fresh frozen	Fresh frozen plasma.
Single donor plasma (human), liquid	Plasma liquid	Liquid plasma.
Single donor plasma (human), platelet rich	Plasma platelet rich	Platelet rich plasma.
Plasma protein fraction (human)	Plasma protein fraction	No change in current codified name (see preamble paragraph 29)
Platelet concentrate (human)	Platelets	Platelets.
Rabies immune globulin (human)	Rabies immune globulin	No change in current codified name (see preamble paragraph 29)
Reagent red blood cells (human)	Reagent red blood cells	Reagent red blood cells.
Red blood cells (human)	Red blood cells	Red blood cells.
Red blood cells (human), deglycerolized	Red blood cells deglycerolized	Red blood cells deglycerolized.
Red blood cells (human), frozen	Red blood cells frozen	Red blood cells frozen.
$Rh_o1(D)$ immune globulin (human)	$Rh_o(D)$ immune globulin	No change in current codfiad name (see preamble paragraph 29)
Source plasma (human)	Source plasma	Source plasma.
Source plasma (human), liquid	Source plasma liquid	Source plasma liquid.
Source plasma (human), pooled	Source plasma pooled	Source plasma pooled.
Source plasma (human), salvaged	Source plasma salvaged	Source plasma salvaged.
Tetanus immune globulin (human)	Tetanus immune globulin	No change in current codified name (see preamble paragraph 29)
Vaccinia immune globulin (human)	Vaccinia immune globulin	Do.
Whole blood (human)	Whole blood	Whole blood.
Whole blood (human), modified	Whole blood platelets and/or cryoprecipitate removed	Whole blood cryoprecipitate removed.
Viral Products		
Measles and mumps virus vaccine, live	Measles and mumps virus vaccine live	Measles and mumps virus vaccine live.
Measles virus vaccine, live attenuated	Measles virus vaccine live	Measles virus vaccine live.
Measles, mumps, and rubella virus vaccine, live	Measles, mumps and rubella virus vaccine live	Measles, mumps, and rubella virus vaccine live.
Measles and rubella virus vaccine, live	Measles and rubella virus vaccine live	Measles and rubella virus vaccine live.
Measles-smallpox vaccine, live	Measles-smallpox vaccine live	Measles live and smallpox vaccine.
Mumps virus vaccine live	Mumps virus vaccine live	Mumps virus vaccine live.
Poliovirus vaccine live, oral, trivalent	Poliovirus vaccine live oral, trivalent	Poliovirus vaccine live oral trivalent.
Poliovirus vaccine live, oral, type I	Poliovirus vaccine live oral, type I	Poliovirus vaccine live oral type I.
Poliovirus vaccine live, oral, type II	Poliovirus vaccine live oral, type II	Poliovirus vaccine live oral type II.
Poliovirus vaccine live, oral, type III	Poliovirus vaccine live oral, type III	Poliovirus vaccine live oral type III.
Poliomyelitis vaccine	Poliovirus vaccine inactivated	Poliovirus vaccine inactivated.
Rubella and mumps virus vaccine live	Rubella and mumps virus vaccine live	Rubella and mumps virus vaccine live.
Rubella virus vaccine, live	Rubella virus vaccine live	Rubella virus vaccine live.
Adenovirus and influenza virus vaccines combined aluminum phosphate adsorbed.	Adenovirus and influenza virus vaccines combined adsorbed.	Product no longer licensed (see preamble paragraph 14)
Bacterial Products		
Anthrax vaccine, adsorbed	Anthrax vaccine adsorbed	Anthrax vaccine adsorbed.
Diphtheria and tetanus toxoids and pertussis and poliomyelitis vaccines adsorbed.	Diphtheria and tetanus toxoids and pertussis and poliovirus vaccines inactivated, adsorbed.	Product no longer licensed (see preamble paragraph 14).
Diphtheria and tetanus toxoids and pertussis vaccine adsorbed and poliomyelitis vaccine.	Diphtheria and tetanus toxoids and pertussis vaccine adsorbed and poliovirus vaccine inactivated.	Product no longer licensed (see preamble paragraph 14).
Tetanus and diphtheria toxoids adsorbed (for adult use)	Tetanus and diphtheria toxoids adsorbed for adult use	Tetanus and diphtheria toxoids adsorbed for adult use.
Antivenins		
Antivenin (crotolidae) polyvalent	Antivenom rattlesnake, copper head and moccasin	No change in current codified name (see preamble paragraph 9)
Antivenin (lactrodectus mactans)	Antivenom widow spider	Do.
Antivenin (micrurus fulvius)	Antivenom coral snake	Do.
Allergenic Extracts		
Allergenic extracts, alum precipitated	Allergenic extracts adsorbed	No change in current codified name (see preamble paragraph 8)

Accordingly, FDA is updating any applicable regulations in Parts 600 through 660 to reflect the new proper names and is updating § 610.53(a) concerning minimum dating periods. Further, FDA is making minor clarifying changes in the regulations. One of these changes includes revising the terms "Reference Measles Immune Globulin" and "Reference Poliomyelitis Immune Globulin" found in § 640.104 concerning potency of immune serum globulins to read "Reference Immune Serum Globulin". The reference standard labeled "Reference Immune Serum Globulin" contains antibodies to both measles and polio.

The agency has determined under 21 CFR 25.24(d)(10) (proposed December 11, 1979; 44 FR 71742) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Paperwork Reduction Act of 1980

FDA is continuing unchanged any collection of information requirements, as defined in the Paperwork Reduction Act of 1980, in the various sections of the biologics regulations being amended by this final rule.

The requirement for a regulatory flexibility analysis under the Regulatory Flexibility Act does not apply to this final rule because the proposed rule was issued prior to January 1, 1981, and is therefore exempt. The economic impact of this rule has been assessed in accordance with Executive Order 12291. Based on the assessment, the agency concludes that the rule does not warrant designation as a major rule under any of the criteria specified under section 1(b) of Executive Order 12291. The assessment done to make this determination in on file with the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

List of Subjects in 21 CFR Parts 600, 606, 610, 620, 630, 640, and 660

Biologics; Blood, Labeling.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201, 501, 502, 510, 701, 52 Stat. 1040–1042 as amended, 1049–1051 as amended, 1055–1056 as amended, 76 Stat. 794–795 as amended (21 U.S.C. 321, 351, 352, 360, 371)); the Public Health Service Act (secs. 351, 352, 353, 361, 58 Stat. 702–703 as amended, 81 Stat. 536 (42 U.S.C. 262, 263, 263a, 264)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Chapter I of Title 21 of the Code of Federal Regulations is amended as follows:

PART 600—BIOLOGICAL PRODUCTS: GENERAL

1. Part 600 is amended:

§ 600.13 [Amended]

a. In § 600.13 *Retention samples* by revising "Whole Blood (Human), Cryoprecipitated Antihemophilic Factor (Human), Platelet Concentrate (Human), Red Blood Cells (Human), Single Donor Plasma (Human), and Source Plasma (Human)," to read "Whole Blood, Cryoprecipitated AHF, Platelets, Red Blood Cells, Plasma, and Source Plasma".

b. In § 600.15 by revising paragraph (a) to read as follows:

§ 600.15 Temperatures during shipment.

* * * * *

(a) *Products.*

Product	Temperature
Cryoprecipitated AHF	– 18 °C or colder.
Measles and rubella virus vaccine live.	10 °C or colder.
Measles live and smallpox vaccine.	Do.
Measles, mumps, and rubella virus vaccine live.	Do.
Measles and mumps virus vaccine live.	Do.
Measles virus vaccine live	Do.
Mumps virus vaccine live	Do.
Fresh frozen plasma	– 18 °C or colder.
Liquid plasma	° to 10 °C.
plasma	– 18 °C or colder.
Platelet rich plasma	Between 1 and 10 °C if the label indicates storage between 1 and 6 °C, or all reasonable methods to maintain the temperature as close as possible to a range between 20 and 24 °C, if the label indicates storage between 20 and 24 °C.
Platelets	Between 1 and 10 °C if the label indicates storage between 1 and 6 °C, or all reasonable methods to maintain the temperature as close as possible to a range between 20 to 24 °C, if the label indicates storage between 20 and 24 °C.
Poliovirus vaccine live oral trivalent.	0 °C or colder.
Poliovirus vaccine live oral type I.	Do.
Poliovirus vaccine live oral type II.	Do.
Poliovirus vaccine live oral type III.	Do.
Red blood cells (liquid product).	Between 1 and 10 °C.
Red blood cells frozen	– 65 °C or colder.
Rubella and mumps virus vaccine live.	10 °C or colder.
Rubella virus vaccine live	Do.
Smallpox vaccine (liquid product).	0 °C or colder.
Source plasma	– 5 °C or colder.
Source plasma liquid	10 °C or colder.
Whole blood	Blood that is transported from the collecting facility to the processing facility shall be transported in an environment capable of continuously cooling the blood toward a temperature range of 1 ° to 10 °C, or at a temperature as close as possible to 20 ° to 24 °C for a period not to exceed 6 hours. Blood transported from the storage facility shall be placed in an appropriate environment to maintain a temperature range between 1 to 10 °C during shipment.
Yellow fever vaccine	0 °C or colder.

* * * * *

PART 606—CURRENT GOOD MANUFACTURING PRACTICE FOR BLOOD AND BLOOD COMPONENTS

2. Part 606 is amended:

a. By revising the part heading to read as set out above.

§ 606.120 [Amended]

b. In § 606.120 *Labeling* in paragraph (b)(2) by revising "Source Plasma (Human)" to read "Source Plasma" and in paragraph (b)(9) by revising "Cryoprecipitated Antihemophilic Factor (Human)" to read "Cryoprecipitated AHF" and "Source Plasma (Human)" to read "Source Plasma".

PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS

3. Part 610 is amended:

§ 610.11 [Amended]

a. In § 610.11 *General safety* in paragraph (g) by revising "Whole Blood (Human)," "Red Blood Cells (Human)," "Cryoprecipitated Antihemophilic Factor (Human)," "Platelet Concentrate (Human)," and "Single Donor Plasma (Human)" to read "Whole Blood," "Red Blood Cells," "Cryoprecipitated AHF," "Platelets," and "Plasma", respectively.

§ 610.12 [Amended]

b. In § 610.12 *Sterility* in paragraph (g)(4) removing "Leukocyte Typing Serum" and by revising "Whole Blood (Human)," "Cryoprecipitated Antihemophilic Factor (Human)," "Platelet Concentrate (Human)," "Red Blood Cells (Human)," "Single Donor Plasma (Human)," and "Source Plasma (Human)," to read "Whole Blood," Cryoprecipitated AHF," "Platelets," "Red Blood Cells," "Plasma," and "Source Plasma", respectively, and in paragraph (g)(7) by removing, "and Fibrinogen (Human)" and by revising

"Normal Serum Albumin (Human)," to read "Albumin (Human) and".

§ 610.13 [Amended]

c. In § 610.13 *Purity* in paragraph (a)(2)(ii) by revising "Measles Virus Vaccine, Live, Attenuated; Measles-Smallpox Vaccine, Live; Rubella Virus Vaccine, Live;" to read "Measles Virus Vaccine Live, Measles Live and Smallpox Vaccine, Rubella Virus Vaccine Live,"; in paragraph (a)(2)(iii) by revising "Modified Plasma (Bovine); Thrombin; Fibrinogen; Streptokinase; and Streptokinase-Streptodornase;" to read "Thrombin and Streptokinase;" in the introductory text of paragraph (b) by revising "Cryoprecipitated Antihemophilic Factor (Human); Single Donor Plasma (Human); Source Plasma (Human);" to read "Cryoprecipitate; Plasma; Source Plasma;" in paragraph (b)(1)(i) by removing the phrase "and at least 30 milligrams for Fibrinogen (Human)"; and in paragraph (b)(1)(ii) by removing "Streptokinase-Streptodornase, Aggregated Radio-Iodinated (I^{131}) Albumin (Human), Radio-Chromated (Cr^{51}) Serum Albumin (Human), Radio-Iodinated (I^{125}) Serum Albumin (Human), and Radio-Iodinated (I^{131}) Serum Albumin (Human),".

§ 610.15 [Amended]

d. In § 610.15 *Constituent materials* in paragraph (a) by revising "Poliovirus Vaccine, Live, Oral" to read "Poliovirus Vaccine Live Oral".

§ 610.51 [Removed]

e. By removing § 610.51 *Periods of cold storage.*

§ 610.52 [Removed]

f. By removing § 610.52 *Dating period.*

g. By revising § 610.53, to read as follows:

§ 610.53 Dating periods for licensed biological products.

(a) *General.* The minimum dating periods in paragraph (c) of this section are based on data relating to usage, clinical experience, or laboratory tests that establish the reasonable period beyond which the product cannot be expected to yield its specific results and retain its safety, purity, and potency, provided the product is maintained at the recommended temperatures. The standards prescribed by the regulations in this subchapter are designed to ensure the continued safety, purity, and potency of the products and are based on the dating periods set forth in paragraph (c) of this section. Package labels for each product shall recommend storage at the stated temperatures.

(b) *When the dating period begins.* The dating period for a product shall begin on the date of manufacture, as prescribed in § 610.50. The dating period for a combination of two or more products shall be no longer than the dating period of the component with the shortest dating period.

(c) *Table of dating periods.* In using the table in this paragraph, a product in column A may be stored by the manufacturer at the prescribed temperature and length of time in either column B or C, plus the length of time in column D. The dating period in column D shall be applied from the day the product leaves the manufacturer's storage, provided the product has not exceeded its maximun storage period, as prescribed in column B or C. If a product is held in the manufacturer's storage beyond the period prescribed, the dating period for the product being distributed shall be reduced by a corresponding period.

Product	Manufacturer's storage period 1 to 5 °C (unless otherwise stated)	Manufacturer's storage period 0 °C or colder (unless otherwise stated)	Dating period after leaving manufacturer's storage when stored at 2 to 8 °C (unless otherwise stated)
A	B	C	D
Adenovirus vaccine live oral	6 months	Not applicable	6 months.
Albumin (human)	3 years	do	(a) 5 years.
	do	do	(b) 3 years, provided labeling recommends storage at room temperature, no warmer than 37 °C.
	Not applicable	do	(c) 10 years, if in a hermetically sealed metal container and provided labeling recommends storage between 2 and 8 °C.
Allergenic extracts labeled "No U.S. Standard of Potency":			
1. With 50 percent or more glycerin	3 years	do	3 years.
2. With less than 50 percent glycerin	18 months	do	18 months.
3. Products for which cold storage conditions are inappropriate.	Not applicable	do	18 months (from date of manufacture), provided labeling recommends storage at 30 °C or colder.
4. Powders and tablets	do	do	5 years (from date of manufacture), provided labeling recommends storage at 30 °C or colder.
5. Freeze-dried products:			
a. Unreconstituted	do	do	4 years (from date of manufacture).
b. Reconstituted	do	do	18 months (cannot exceed 4-year unreconstituted dating period plus an additional 12 months).
Allergenic Extracts, alum precipitated labeled "No. U.S. Standard of Potency".	18 months	do	18 months.
Anthrax vaccine adsorbed	2 years	do	1 year.
Antibody to hepatitis B surface Antigen:			
1. Antibody to hepatitis B surface antigen	6 months	do	6 months.
2. Lyophilized coated red blood cells	do	do	Do.
3. Enzyme conjugated products	do	do	Do.
Iodinated (I^{125})	Not applicable	do	45 days (from date of manufacture).
Antihemophilic factor (human)	do	do	1 year (from date of manufacture).
Antihuman globulin liquid	do	do	2 years.
Anti-inhibitor coagulant complex			2 years at 4 °C ±2 °C.
Antirabies serum	1 year	2 years	2 years.
Antivenin (*crotalidae*) polyvalent	do	do	5 years with an initial 10 percent excess of potency, provided labeling recommends storage at 37 °C or colder.
Antivenin (*latrodectus mactans*)	do	do	5 years with an initial 10 percent excess of potency.
Antivenin (*Micrurus fulvius*)	do	do	5 years with an initial 10 percent excess of potency.
Asparaginase	Not applicable	do	18 months from the date of the last valid potency test.
BCG vaccine	1 year	Not applicable	6 months.

Product	Manufacturer's storage period 1 to 5 °C (unless otherwise stated)	Manufacturer's storage period 0 °C or colder (unless otherwise stated)	Dating period after leaving manufacturer's storage when stored at 2 to 8 °C (unless otherwise stated)
A	B	C	D
Blood Grouping Serums:			
1. Liquid	Not applicable	Not applicable	2 years.
2. Dried	1 year	2 years	5 years.
Blood group substance AB	do	do	2 years.
Blood group substance A	do	do	Do.
Blood group substance B	do	do	Do.
Botulism antitoxin	do	do	5 years with an initial 20 percent excess of potency.
Cholera vaccine	do	Not applicable	18 months.
Coccidioidin	do	do	3 years.
Collagenase	Not applicable	do	4 years (from date of manufacture), provided labeling recommends storage at 37 °C or colder.
Cryoprecipitated AFH	do	do	12 months from the date of collection of source blood, provided labeling recommends storage at −18 °C or colder.
Diphtheria Antitoxin:			
1. Liquid	1 year	2 years	5 years with an initial 20 percent excess of potency.
2. Dried	do	do	5 years with an initial 10 percent excess of potency.
Diphtheria and tetanus toxoids and pertussis vaccine adsorbed	do	do	18 months.
Diphtheria and tetanus toxoids, absorbed	do	do	2 years.
Diphtheria toxin for schick test	do	do	1 year.
Diphtheria toxoid	do	do	2 years.
Diphtheria toxoid adsorbed	do	do	Do.
Diphtheria toxoid-schick test control	Not applicable	Not applicable	1 year.
Factor IX complex	do	do	1 year (from date of manufacture).
Fibrinolysin (human)	1 year	2 years	2 years.
Fibrinolysin and desoxyridonuclease combined (bovine)	do	do	3 years, provided labeling recommends storage at 30 °C or colder.
Fibrinolysin and desoxyribonuclease combined (bovine) with chloramphenicol	do	do	3 years, provided labeling recommends storage at 30 °C or colder.
Hepatitis B surface antigen:			
1. Unlyophilied coated red blood cells	Not applicable	do	14 days (from date of manufacture).
2. Iodinated (^{125}I) product	do	do	45 days (from date of manufcture).
3. Enzyme conjugated product	6 months	do	6 months
Histoplasmin	1year	do	2 years.
Immunoglobulins:			
1. Hepatitis B immune globulin (human)	Not applicable	do	1 year.
2. Immune globulin (human)	3 years	do	3 years.
3. Immune globulin intravenous (human)	1 year	do	1 year.
4. Lymphocyte immune globulin, anti-thymocyte globulin (equine).	Not applicable	Not applicable	2 years.
5. Pertussis immune globulin (human)	3 years	do	3 years from date the dried or frozen bulk product is placed in final solution.
6. Rabies immune globulin (Human)	1 year	do	1 year.
7. Rh_0(D) immune globulin (human)	6 months	do	6 months.
8. Tetanus immune globuline (human)	1 year	do	3 years with an initial 10 percent excess of potency.
9. Vaccinia immune globulin (human)	3 year	do	3 years.
10. Vari-cella-zoster immune globulin (human)	1 year	do	1 year.
Hepatitis B vaccine	2 years at 2 to 8 °C	Not applicable	3 years.
Influenza virus vaccine	1 year	do	18 months.
Limulus amebocyte lysate	Not applicable	Not applicable	18 months (from date of manufacture).
Measles, mumps, and rubella virus vaccine live	do	1 year (−20 °C or colder)	1 year.
Measles and mumps virus vaccine live	do	do	1 year.
Measles and rubella virus vaccine live	do	do	Do.
Measles live and smallpox vaccine	Not applicable	do	1 year (from date of manufacture).
Measles virus vaccine live	do	do	1 year.
Meningococcal polysaccharide vaccine group A:			
1. Final bulk powder	do	2 years (−20 °C or colder)	Not applicable.
2. Final container	Not applicable	3 years (−20 °C or colder)	2 years (−20 °C or colder).
Meningococcal polysaccharide vaccine group C:			
1. Final bulk powder	do	2 years (−20 °C or colder)	Not applicable.
2. Final container	do	3 years (−20 °C or colder)	2 years (−20 °C or colder).
Meningococcal polysaccharide vaccine groups A and C combined.	do	do	Do.
Meningococcal polysaccharide vaccine groups vaccine groups A, C, Y, and W135 combined.	do	do	do.
Mumps skin test antigen	1 year	do	18 months.
Mumps virus vaccine live	Not applicable	1 year (−20 °C or colder)	1 year.
Normal horse serum	1 year	2 years	5 years.
Pertussis vaccine	do	Not applicable	18 months.
Pertussis vaccine adsorbed	do	do	Do.
Plague vaccine	do	do	Do.
Plasma products:			
1. Fresh frozen plasma	Not applicable	do	1 year from date of collection of source blood (−18 °C or colder).
2. Liquid plasma	do	do	(a) 26 days from date of collection of source blood (between 1 and 6 °C). (b) 40 days from date of collection of source blood only when CPDA-1 solution is used as the anticoagulant (between 1 and 6 °C).
3. Plasma	do	do	5 years from date of collection of source blood (−18 °C or colder).
4. Platelet rich plasma	do	do	72 hours from time of collection of source blood, provided labeling recommends storage (20 to 24 °C or between 1 and 6 °C). 5 days if certain approved containers are used (20 to 24 °C).

Product	Manufacturer's storage period 1 to 5 °C (unless otherwise stated)	Manufacturer's storage period 0 °C or colder (unless otherwise stated)	Dating period after leaving manufacturer's storage when stored at 2 to 8 °C (unless otherwise stated)
A	B	C	D
5. Source leukocytes	do	do	In lieu of expiration date, the collection date shall appear on the label.
6. Source plasma	do	do	10 years (at the recommended storage temperature stated on the label).
7. Therapeutic exchange plasma	do	do	10 years.
Plasma protein fraction (human)	1 year	do	(a) 5 years. (b) 3 years provided labeling recommends storage at room temperature, no warmer than 30 °C.
Platelets	Not applicable	do	72 hours from time of collection of source blood, provided labeling recommends storage at 20 to 24 °C or between 1 and 6 °C. 5 days if certain approved containers are used (20 to 24 °C).
Pneumococcal vaccine polyvalent:			
1. Final bulk powder	do	15 months after potency assay (−20 °C or colder).	Not applicable.
2. Final container	do	Not applicable	2 years (after date of manufacture).
Poliovirus vaccine inactivated	1 year	do	1 year.
Poliovirus vaccine live oral trivalent:			
1. Frozen	Not Applicable	1 year (−10 °C or colder)	1 year, provided labeling recommends storage at a temperature which will maintain ice continuously in a solid state.
2. Liquid	do	Not applicable	30 days, provided labeling recommends storage between 2 and 8 °C and container has been unopened.
Poliovirus vaccine live oral type I:			
1. Frozen	do	1 year (−10 °C or colder)	1 year, provided labeling recommends storage at a temperature which will maintain ice continuously in a solid state.
2. Liquid	do	Not applicable	30 days, provided labeling recommends storage between 2 and 8 °C and container has been unopened.
Poliovirus vaccine live oral type II:			
1 Frozen	do	1 year (−10 °C or colder)	1 year, provided labeling recommends storage at a temperature which will maintain ice continuously in a solid state.
2. Liquid	do	Not applicable	30 days, provided labeling recommends storage between 2 and 8 °C and container has been unopened.
Poliovirus vaccine live oral type III:			
1 Frozen	do	1 year (−10 °C or colder)	1 year, provided labeling recommends storage at a temperature which will maintain ice continuously in a solid state.
2. Liquid	do	Not applicable	30 days, provided labeling recommends storage between 2 and 8 °C and container has been unopened.
Polyvalent bacterial antigens with "No U.S. Standard of Potency" liquid.	1 year	Not applicable	18 months.
Polyvalent bacterial vaccines with "No U.S. Standard of Potency" liquid.	do	do	Do.
Rabies Vaccine:			
1 Dried	do	2 years	Do.
2. Liquid	3 months	Not applicable	6 months.
Reagent red blood cells	Not applicable	do	35 days from earliest date of collection.
ACD red blood cells	do	do	(a) 21 days from date of collection of source blood, provided labeling recommends storage between 1 and 6 °C and the hermetic seal is not broken during processing. (b) 24 hours after plasma removal, provided labeling recommends storage between 1 and 6 °C and the hermetic seal is broken during processing.
CPD red blood cells	do	do	(a) 21 days from date of collection of source blood, provided labeling recommends storage between 1 and 6 °C and the hermetic seal is not broken during processing. (b) 24 hours after plasma removal, provided labeling recommends storage between 1 and 6 °C and the hermetic seal is broken during processing.
CPDA-1 red blood cells	do	do	(a) 35 days from date of collection of source blood, provided labeling recommends storage between 1 and 6 °C and the hermetic seal is not broken during processing. 24 hours after plasma removal, provided labeling recommends storage between 1 and 6 °C and the hermetic seal is broken during processing.
Red blood cells deglycerolized	do	do	24 hours after removal from storage at −65 °C or colder, provided labeling recommends storage between 1 and 6 °C.
Red blood cells frozen	do	do	3 years from date of collection of source blood, provided labeling recommends storage at −65 °C or colder.
Rubella and mumps virus vaccine live	do	1 year (−20 °C or colder)	1 year.
Rubella virus vaccine live	do	°C.	Do.
Skin test antigens for cellular hypersensitivity	6 months	Not applicable	Do.

Product A	Manufacturer's storage period 1 to 5 °C (unless otherwise stated) B	Manufacturer's storage period 0 °C or colder (unless otherwise stated) C	Dating period after leaving manufacturer's storage when stored at 2 to 8 °C (unless otherwise stated) D
Smallpox Vaccine:			
1. Liquid	Not applicable	9 months (−10 °C or colder, if product is maintained as glycerinated or equivalent vaccine in bulk or final containers).	3 months, provided labeling recommends storage at 0 °C or colder.
2. Dried	6 months	Not applicable	18 months.
Streptokinase	do	2 years	Do.
Tetanus and diphtheria toxoids adsorbed for adult use	1 year	Not applicable	2 years.
Tetanus antitoxin:			
1. Liquid	do	2 years	5 years with an initial 20 percent excess of potency.
2. Dried	do	do	5 years with an initial 10 percent excess of potency.
Tetanus toxoid adsorbed	do	do	2 years.
Thrombin	do	do	3 years.
Thrombin impregnated pad	Not applicable	Not applicable	1 year, or 6 months at 20 to 24 °C.
Tuberculin:			
1. Purified protein derivative, diluted	6 months	do	1 year.
2. Old or purified protein derivative, dried on multiple puncture device:	1 year (not to exceed 30 °C; do not refrigerate).	do	2 years, provided labeling recommends storage at a temperature not to exceed 30 °C. Do not refrigerate.
3. Old on multiple puncture device	do	do	Do.
Typhoid vaccine	1 year	do	18 months.
ACD whole blood	Not applicable	do	21 days from date of collection, provided labeling recommends storage between 1 and 6 °C.
CPD whole blood	do	do	Do.
CPDA-1 whole blood	do	do	35 days from date of collection, provided labeling recommends storage between 1 and 6 °C.
Heparin whole blood	do	do	48 hours from date of collection, provided labeling recommends storage between 1 and 6 °C.
Yellow fever vaccine	do	1 year (−20 °C or colder)	1 year, provided labeling recommends storage at 5 °C or colder.

(d) *Exemptions.* Exemptions or modifications shall be made only upon written approval, in the form of an amendment of the product license, issued by the Director, Office of Biologics Research and Review (HFN-800), Center for Drugs and Biologics.

PART 620—ADDITIONAL STANDARDS FOR BACTERIAL PRODUCTS

4. Part 620 is amended:

§ 620.4 [Amended]

a. In § 620.4 *Potency test* in paragraph (g) by revising "Poliomyelitis Vaccine" to read "Poliovirus Vaccine Inactivated".

Subpart C—[Amended]

b. By revising the heading of Subpart C to read "Subpart C—Anthrax Vaccine Adsorbed".

§ 620.20 [Amended]

c. In § 620.20 by revising the section heading to read "§ 620.20 *Anthrax Vaccine Adsorbed*" and in the text by revising "Anthrax Vaccine, Adsorbed" to read "Anthrax Vaccine Adsorbed".

PART 630—ADDITIONAL STANDARDS FOR VIRAL VACCINES

5. Part 630 is amended:

Subpart A—[Reserved]

a. By revising the heading of Subpart A to read "Subpart A—Poliovirus Vaccine Inactivated".

§ 630.1 [Amended]

b. In § 630.1 by revising the section heading to read "§ 630.1 *Poliovirus Vaccine Inactivated*" and in the text of paragraphs (a) and (c) by revising "Poliomyelitis Vaccine" to read "Poliovirus Vaccine Inactivated".

§ 630.2 [Amended]

c. In § 630.2 by revising the section heading to read "*Poliovirus Vaccine Inactivated*" and in paragraph (e)((3) by revising "poliomyelitis vaccine" to read "Poliovirus Vaccine Inactivated".

§ 630.3 [Amended]

d. In § 630.3 *Potency test* in the introductory paragraph by revising "poliomyelitis vaccine" to read Poliovirus Vaccine Inactivated".

§ 630.4 [Amended]

e. In § 630.4 *Tests for safety* in paragraph (b)((1) by revising "poliomyelitis vaccine" to read "poliovirus vaccine" and in paragraph (e)(5)((ii) by revising "poliomyelitis" to read "poliovirus".

§ 630.6 [Amended]

f. In § 630.6 *Equivalent methods* in the text by revising "poliomyelitis vaccine" to read "Poliovirus Vaccine Inactivated".

Subpart B—[Amended]

g. By revising the heading of Subpart B to read "Subpart B—Poliovirus Vaccine Live Oral".

h. In § 630.10 in paragraphs (a) and (b)(2) by revising "Poliovirus Vaccine, Live, Oral" to read "Poliovirus Vaccine Live Oral" and by revising the section heading to read "*§ 630.10 Poliovirus Vaccine Live Oral.*"

* * * * *

§ 630.12 [Amended]

i. In § 630.12 *Animal source; quarantine; personnel* in paragraphs (a)(1) and (b) by revising "Poliovirus Vaccine, Live, Oral" to read "Poliovirus Vaccine Live Oral".

§ 630.13 [Amended]

j. In § 630.13 by revising the section heading to read "*§ 630.13 Manufacture of Poliovirus Vaccine Live Oral.*"

§ 630.18 [Amended]

k. In § 630.18 *Equivalent methods* in the text by revising "Poliovirus Vaccine, Live, Oral," to read "Poliovirus Vaccine Live Oral".

Subpart D—[Amended]

1. By revising the heading of Subpart D to read "Subpart D—Measles Virus Vaccine Live".

§ 630.30 [Amended]

m. In § 630.30 by revising the section heading to read "§ 630.30 *Measles Virus Vaccine Live*" and in paragraphs (a) and (b)(2) by revising "Measles Virus Vaccine, Live, Attenuated," to read "Measles Virus Vaccine Live".

§ 630.36 [Amended]

n. In § 630.36 *General requirements* in paragraph (d) by revising "Measles Virus Vaccine, Live, Attenuated," to read "Measles Virus Vaccine Live".

§ 630.37 [Amended]

o. In § 630.37 *Equivalent methods* in the text by revising "Measles Virus Vaccine, Live, Attenuated," to read "Measles Virus Vaccine Live".

Subpart F—[Amended]

p. By revising the heading of Subpart F to read "Subpart F—Mumps Virus Vaccine Live".

§ 630.50 [Amended]

q. In § 630.50 by revising the section heading to read "§ 630.50 *Mumps Virus Vaccine Live*" and in paragraphs (a) and (b)(2) by revising "Mumps Virus Vaccine, Live," to read "Mumps Virus Vaccine Live".

§ 630.51 [Amended]

r. In § 630.51 *Clinical trials to qualify for license* in the text by revising "Mumps Virus Vaccine, Live," to read "Mumps Virus Vaccine Live".

§ 630.52 [Amended]

s. In § 630.52 by revising the section heading to read "§ 630.52 *Manufacture of Mumps Virus Vaccine Live*".

§ 630.56 [Amended]

t. In § 630.56 *General requirements* in paragraph (b) by revising "Mumps Virus Vaccine, Live," to read "Mumps Virus Vaccine Live" and in paragraph (e) by revising "Mumps Virus Vaccine, Live" to read "Mumps Virus Vaccine Live".

§ 630.57 [Amended]

u. In § 630.57 *Equivalent methods* in the text by revising "Mumps Virus Vaccine, Live," to read "Mumps Virus Vaccine Live".

Subpart G—[Amended]

v. By revising the heading of Subpart G to read "Subpart G—Rubella Virus Vaccine Live".

§ 630.60 [Amended]

w. In § 630.60 by revising the section heading to read "§ 630.60 *Rubella Virus Vaccine Live*" and in paragraph (a) by revising "Rubella Virus Vaccine, Live" to read "Rubella Virus Vaccine Live" and in paragraph (d)(1) by revising "Rubella Virus Vaccine, Live," to read "Rubella Virus Vaccine Live".

§ 630.61 [Amended]

x. In § 630.61 *Clinical trials to qualify for license* in the text by revising "Rubella Virus Vaccine, Live," to read "Rubella Virus Vaccine Live".

§ 630.62 [Amended]

y. In § 630.62 *Production* in paragraph (b) by revising "Rubella Virus Vaccine, Live" to read "Rubella Virus Vaccine Live".

§ 630.66 [Amended]

z. In § 630.66 *General requirements* in paragraph (b) by revising "Rubella Virus Vaccine, Live," to read "Rubella Virus Vaccine Live" and in paragraph (d) by revising "Rubella Virus Vaccine, Live" to read "Rubella Virus Vaccine Live".

§ 630.67 [Amended]

aa. In § 630.67 *Equivalent methods* in the text by revising "Rubella Virus Vaccine, Live" to read "Rubella Virus Vaccine Live".

Subpart I—[Amended]

bb. By revising the heading of Subpart I to read "Subpart I—Measles Live and Smallpox Vaccine".

§ 630.80 [Amended]

cc. In § 630.80 by revising the section heading to read "§ 630.80 *Measles Live and Smallpox Vaccine*" and in paragraph (a) by revising "Measles-Smallpox Vaccine, Live" to read "Measles Live and Smallpox Vaccine".

§ 630.84 [Amended]

dd. In § 630.84 *Potency tests* in the introductory paragraph by revising "Measles-Smallpox Vaccine, Live," to read "Measles Live and Smallpox Vaccine".

§ 630.87 [Amended]

ee. In § 630.87 *Equivalent methods* in the text by revising "Measles-Smallpox Vaccine, Live" to read "Measles Live and Smallpox Vaccine".

PART 640—ADDITIONAL STANDARDS FOR HUMAN BLOOD AND BLOOD PRODUCTS

5. Part 640 is amended:

Subpart A—[Amended]

a. By revising the heading of Subpart A to read "Subpart A—Whole Blood".

§ 640.1 [Amended]

b. In § 640.1 by revising the section heading to read "§ 640.1 *Whole blood*" and in the text by revising "Whole Blood (Human)" to read "Whole Blood".

§ 640.2 [Amended]

c. In § 640.2 *General requirements* in paragraph (a) by revising "Whole Blood (Human)" to read "Whole Blood".

§ 640.3 [Amended]

d. In § 640.3. in paragraphs (a) and (f) by revising "Whole Blood (Human)" to read "Whole Blood".

§ 640.4 [Amended]

e. In § 640.4 *Collection of the blood* in paragraphs (c) and (h) by revising "Heparinized Whole Blood (Human)" to read "Heparin Whole Blood" and in paragraph (i) by revising "Platelet Concentrate (Human)" and "platelet concentrate" to read "Platelets" and "platelets", respectively.

§ 640.5 [Amended]

f. In § 640.5 *Testing the blood* in paragraphs (a) through (e) by revising "Whole Blood (Human)" to read "Whole Blood" and in paragraph (c) by revising "Anti-Rh_o (Anti-D) Typing Serum" to read "Anti-D Blood Grouping Serum".

§ 640.6 [Amended]

g. § 640.6 by revising the section heading to read "§ 640.6 *Modifications of Whole Blood*" and in the introductory paragraph by revising "Whole Blood (Human)" to read "Whole Blood" and in paragraph (c) by revising "Whole Blood (Human), modified," to read "Whole Blood Cryoprecipitate Removed".

§ 640.7 [Amended]

h. In § 640.7 *Labeling* in the introductory text of paragraph (g) by revising "Whole Blood (Human), Modified" to read "Whole Blood Cryoprecipitate Removed" and in paragraph (g)(1) by revising "Modified" to read "Cryoprecipitate Removed".

Subpart B—[Amended]

i. By revising the heading of Subpart B to read "Subpart B—Red Blood Cells".

§ 640.10 [Amended]

j. In § 640.10 by revising the section heading to read "§ 640.10 *Red Blood Cells*" and in the text by revising "Red Blood Cells (Human)" to read "Red Blood Cells".

§ 640.11 [Amended]

k. In § 640.11 *General requirements* in paragraph (a) by revising "Red Blood Cells (Human)" to read "Red Blood Cells".

§ 640.12 [Amended]

l. In § 640.12 *Suitability of donor* in the text by revising "Red Blood Cells (Human)" to read "Red Blood Cells".

§ 640.13 [Amended]

m. In § 640.13 *Collection of the blood* in paragraph (b) by revising "Whole Blood (Human)" to read "Whole Blood".

§ 640.15 [Amended]

n. In § 640.15 *Pilot samples* in paragraphs (a) and (d) by revising "Red Blood Cells (Human)" to read "Red Blood Cells".

§ 640.16 [Amended]

o. In § 640.16 *Processing* in paragraph (a) by revising "red blood cells (human)" to read "Red Blood Cells" and in paragraph (c) by revising "Red Blood Cells (Human)" to read "Red Blood Cells".

§ 640.17 [Amended]

p. In § 640.17 *Modifications for specific products* in the text by revising "Red Blood Cells (Human)" to read "Red Blood Cells" and by revising "Red Blood Cells (Human), Frozen" to read "Red Blood Cells Frozen".

§ 640.18 [Amended]

q. In § 640.18 *Labeling* in the introductory paragraph by revising "Red Blood Cells (Human)" to read "Red Blood Cells"; in paragraph (a) by revising "Whole Blood (Human)" to read "Whole Blood"; in paragraph (b) by revising "Red Blood Cells (Human), Frozen, and Red Blood Cells (Human), Deglycerolized" to read "Red Blood Cells Frozen and Red Blood Cells Deglycerolized"; and in paragraph (d) by revising "Whole Blood (Human)" to read "Whole Blood".

Subpart C—[Amended]

r. By revising the heading of Subpart C to read "Subpart C—Platelets".

§ 640.20 [Amended]

s. In § 640.20 by revising the section heading to read "§ 640.20 *Platelets*" and in paragraphs (a) and (b) by revising "Platelets Concentrate (Human)" to read "Platelets".

§ 640.22 [Amended]

t. In § 640.22 *Collection of source material* in paragraph (a) by revising "Platelet Concentrate (Human)" to read "Platelets".

§ 640.23 [Amended]

u. In § 640.23 *Testing the blood* in paragraph (a) by revising "Platelet Concentrate (Human)" to read "Platelets".

§ 640.24 [Amended]

v. In § 640.24 *Processing* in paragraphs (a) and (e) by revising "Platelet Concentrate (Human)" to read "Platelets"; in paragraph (b) by revising "platelet concentrate is" to read "platelets are"; and in paragraph (d) by revising "platelet concentrate" to read "platelets".

§ 604.25 [Amended]

w. In § 640.25 *General requirements* in paragraph (a), the introductory text of paragraph (c), and paragraph (c) (1) and (2) by revising "Platelet Concentrate (Human)" to read "Platelets".

Subpart D—[Amended]

x. By revising the heading of Subpart D to read "Subpart D—Plasma".

§ 640.30 [Amended]

y. In § 640.30 by revising the section heading to read "§ 640.30 *Plasma*", in paragraphs (a) and (b) by revising "Single Donor Plasma (Human)" to read "Plasma", and in paragraph (b)(2) by revising "Whole Blood (Human)" to read "Whole Blood".

§ 640.32 [Amended]

z. In § 640.32 *Collection of source material* in paragraph (a) by revising "Single Donor Plasma (Human); Single Donor Plasma (Human), Fresh Frozen; and Single Donor Plasma (Human), Liquid," to read "Plasma, Fresh Frozen Plasma, and Liquid Plasma"; and by revising "Single Donor Plasma (Human), Platelet Rich" to read "Platelet Rich Plasma".

§ 640.33 [Amended]

aa. In § 640.33 *Testing the blood* in paragraph (b) by revising "Single Donor Plasma (Human)" to read "Plasma".

§ 640.34 [Amended]

bb. In § 640.34 *Processing* in paragraph (a) by revising "Single Donor Plasma (Human)" to read "Plasma" and "Single Donor Plasma (Human), Liquid" to read "Liquid Plasma"; in paragraph (b) by revising "Single Donor Plasma (Human), Fresh Frozen" to read "Fresh Frozen Plasma"; in paragraph (c) by revising "Single Donor Plasma (Human), Liquid" to read "Liquid Plasma"; in paragraph (d) by revising "Single Donor Plasma (Human), Platelet Rich" to read "Platelet Rich Plasma"; in the introductory text of paragraph (e) by revising "Single Donor Plasma (Human)" to read "Plasma" and by revising "Platelet Concentrate (Human) and/or Cryoprecipitated Antihemophilic Factor (Human) from Single Donor Plasma (Human)" to read "Platelets and/or Cryoprecipitated AHF from Plasma"; in paragraph (e)(1) by revising "Platelet Concentrate (Human)" to read "Platelets" and "Single Donor Plasma (Human), Fresh Frozen" to read "Fresh Frozen Plasma"; in paragraph (e)(2) by revising "Cryoprecipitated Antihemophilic Factor (Human)" to read "Cryoprecipitated AHF" and "Single Donor Plasma (Human)" to read "Plasma"; in paragraph (e)(3) by revising "Platelet Concentrate (Human) and Cryoprecipitated Antihemophilic Factor (Human)" to read "Platelets and Cryoprecipitated AHF" and "Single Donor Plasma (Human)" to read "Plasma"; and in paragraph (g)(2) by revising "Single Donor Plasma (Human), Platelet Rich; and Single Donor Plasma (Human), Liquid" to read "Platelet Rich Plasma and Liquid Plasma".

§ 640.35 [Amended]

cc. In § 640.35 *Labeling* in the introductory paragraph by revising "Single Donor Plasma (Human)" to read "Plasma" and in paragraph (s) by changing the proper name "Whole Blood (Human)" to read "Whole Blood".

Subpart F—[Amended]

dd. By revising the heading of Subpart F to read "Subpart F—Cryoprecipitate".

§ 640.50 [Amended]

ee. In § 640.50 by revising the section heading to read "§ 640.50 *Cryoprecipitated AHF*" and in paragraphs (a) and (b) by revising "Cryoprecipitated Antihemophilic Factor (Human)" to read "Cryoprecipitated AHF".

§ 640.52 [Amended]

ff. In § 640.52 *Collection of source material* in paragraph (a) by revising "Cryoprecipitated Antihemophilic Factor (Human)" to read "Cryoprecipitated AHF" and "Platelet Concentrate (Human)" to read "Platelets".

§ 640.53 [Amended]

gg. In § 640.53 *Testing the blood* in paragraphs (a) and (c) by revising "Cryoprecipitated Antihemophilic Factor (Human)" to read "Cryoprecipitated AHF".

§ 640.54 [Amended]

hh. In § 640.54 *Processing* in paragraphs (a)(3) and (b)(1) and (3) by revising "Cryoprecipitated

Antihemophilic Factor (Human)" to read "Cryoprecipitated AHF".

§ 640.55 [Amended]

ii. In § 640.55 *U.S. Standard preparation* in the text by revising "Cryoprecipitated Antihemophilic Factor (Human)" to read "Cryoprecipitated AHF".

§ 640.56 [Amended]

jj. In § 640.56 *Quality control test for potency* in paragraphs (a), (b), and (c)(1) by revising "Cryoprecipitated Antihemophilic Factor (Human)" to read "Cryoprecipitated AHF".

Subpart G—[Amended]

kk. By revising the heading of Subpart G to read "Subpart G—Source Plasma".

§ 640.60 [Amended]

ll. In § 640.60 by revising the section heading to read "§ 640.60 *Source Plasma*" and in the text by revising "Source Plasma (Human)" to read "Source Plasma".

§ 640.63 [Amended]

mm. In § 640.63 *Suitability of donor* in paragraph (a) by revising "Source Plasma (Human)" to read "Source Plasma".

§ 640.64 [Amended]

nn. In § 640.64 by revising the section heading to read "§ 640.64 *Collection of blood for Source Plasma*" and in paragraphs (a) and (c) by revising "Source Plasma (Human)" to read "Source Plasma".

§ 640.67 [Amended]

oo. In § 640.67 *Test for hepatitis B surface antigen* by revising "Source Plasma (Human)" to read "Source Plasma".

§ 640.68 [Amended]

pp. In § 640.68 *Processing* in paragraphs (a), (b), and (c) by revising "Source Plasma (Human)" to read "Source Plasma".

§ 640.69 [Amended]

qq. In § 640.69 *General requirements* in paragraph (a), (b), and (c) by revising "Source Plasma (Human)" to read "Source Plasma".

§ 640.70 [Amended]

rr. In § 640.70 *Labeling* in the introductory text of paragraph (a) by revising "Source Plasma (Human)" to read "Source Plasma" and in paragraph (b) by revising "Source Plasma (Human)" to read "Source Plasma" and by revising "Source Plasma (Human) Salvaged" to read "Source Plasma Salvaged".

§ 640.71 [Amended]

ss. In § 640.71 *Manufacturing responsibility* in the introductory texts of paragraphs (a) and (b) and in paragraph (b) (1) and (2) by revising "Source Plasma (Human)" to read "Source Plasma".

§ 640.72 [Amended]

tt. In § 640.72 *Records* in paragraphs (a)(1) and (b) by revising "Source Plasma (Human)" to read "Source Plasma".

§ 640.74 [Amended]

uu. In § 640.74 by revising the section heading to read "§ 640.74 *Modification of Source Plasma*" and in paragraphs (a) and (b) by revising "Source Plasma (Human)" to read "Source Plasma" and in paragraph (b) by revising "Liquid Source Plasma (Human)" to read "Source Plasma Liquid".

§ 640.75 [Amended]

vv. In § 640.75 *Alternate procedures* in the text by revising "Source Plasma (Human)" to read "Source Plasma".

ww. In § 640.76 in paragraphs (a), (b), and (c) by revising "Source Plasma (Human)" to read "Source Plasma" and by revising "Source Plasma (Human) Salvaged" to read "Source Plasma Salvaged".

Subpart H—[Amended]

xx. By revising the heading of Subpart H to read "Subpart H—Albumin (Human)".

§ 640.80 [Amended]

yy. In § 640.80 by revising the section heading to read "§ 640.80 *Albumin (Human)*" and in paragraph (a), introductory text of (b), and paragrah (b)(1) by revising "Normal Serum Albumin (Human)" to read "Albumin (Human)".

§ 640.81 [Amended]

zz. In § 640.81 *Processing* in paragraphs (e) and (g) by revising "Normal Serum Albumin (Human)" to read "Albumin (Human)".

§ 640.82 [Amended]

aaa. In § 640.82 *Tests on final product* in paragraph (f) by revising "Normal Serum Albumin (Human)" to read "Albumin (Human)".

bbb. In § 640.85 in the introductory paragraph by revising "Normal Serum Albumin (Human)" to read "Albumin (Human)".

§ 640.86 [Amended]

ccc. In § 640.86 *Equivalent methods* by revising "Normal Serum Albumin (Human)" to read "Albumin (Human)".

Subpart J—[Amended]

ddd. By revising the heading of Subpart J to read "Subpart J—Immune Globulin (Human)".

§ 640.100 [Amended]

eee. In § 640.100 by revising the section heading to read "§ 640.100 *Immune Globulin (Human)*" and in paragraphs (a) and (b) by revising "Immune Serum Globulin (Human)" to read "Immune Globulin (Human)".

§ 640.101 [Amended]

fff. In § 640.101 *General requirements* in paragraph (e)(3) by revising "Measles Virus Vaccine, Live, Attenuated" to read "Measles Virus Vaccine Live" and in the introductory text of paragraph (f) by revising "Immune Serum Globulin (Human)" to read "Immune Globulin (Human)".

§ 640.102 [Amended]

ggg. In § 640.102 by revising the section heading to read "§ 640.102 *Manufacture of Immune Globulin (Human)*" and in paragraph (d) by revising "Immune Serum Globulin (Human)" to read "Immune Globulin (Human)".

§ 640.104 [Amended]

hhh. In § 640.104 *Potency* in paragraphs (b)(2) and (c)(1) by revising "Reference Measles Immune Globulin" to read "Reference Immune Serum Globulin"; in paragraph (b)(2) by revising "Measles Virus Vaccine, Live, Attenuated" to read "Measles Virus Vaccine Live"; and in paragraphs (b)(3) and (c)(2) by revising "Reference Poliomyelitis Immune Globulin" to read "Reference Immune Serum Globulin".

PART 660—ADDITIONAL STANDARDS FOR DIAGNOSTIC SUBSTANCES FOR LABORATORY TESTS

7. Part 660 is amended:

§ 660.23 [Amended]

a. In § 660.23 *Red blood cell preparations* in paragraph (a) by revising "Reagent Red Blood Cells (Human)" to read "Reagent Red Blood Cells".

b. In § 660.25 by revising paragraph (a)(5)(iii), to read as follows:

§ 660.25 Potency test without reference preparations.

* * * * *

(a) * * *

(5) * * *

(iii) For Anti-U, Anti-Kp^a, Anti-Kp^c, Anti-Js^a, Anti-Js^b, Anti-Fy^b, Anti-N, Anti Le^a, Anti-Le^b, Anti-Di^a, Anti-Mg, Anti-

Jk^b, Anti-Xg^a, Anti-Co^b, and Wr^a at least 2+ reaction with undiluted serum.

* * * * *

c. In § 660.28 by revising paragraph (d), to read as follows:

§ 660.28 Labeling.

* * * * *

(d) *Names of antibodies.*

Blood group designation for container label	Optional synonym for package label and package insert
Anti-A	None.
Anti-A_1	Do.
Anti-B	Do.
Anti-A, B	Do.
Anti-Di^a	(Anti-$Diego^a$).
Anti-Fy^a	(Anti-$Duffy^a$).
Anti-Fy^b	(Anti-$Duffy^b$).
Anti-I	None.
Anti-Jk^a	(Anti-$Kidd^a$).
Anti-Jk^b	(Anti-$Kidd^b$).
Anti-Js^a	(Anti-Sutter).
Anti-Js^b	(Anti-Matthews).
Anti-K	(Anti-Kell).
Anti-k	(Anti-Celiano).
Anti-Kp^a	(Anti-Penney).
Anti-Kp^b	(Anti-Rautenborg).
Anti-Le^a	(Anti-$Lewis^a$).
Anti-Le^b	(Anti-$Lewis^b$).
Anti-M	None.
Anti-N	Do.
Anti-M^a	(Anti-Gilfeather).
Anti-P_1	None.
Anti-D	(Anti-Rh_o).
Anti-CD	(Anti-Rh_o').
Anti-DE	(Anti-Rh_o'').
Anti-CDE	(Anti-Rh_o''').
Anti-C	(Anti-rh').
Anti-E	(Anti-rh'').
Anti-c	(Anti-hr').
Anti-e	(Anti-hr'').
Anti-C^w	(Anti-rh^w).
Anti-S	None.
Anti-s	Do.
Anti-U	Do.
Anti-Wr^a	(Anti-$Wright^a$).
Anti-Js^a	(Anti-Sutter).
Anti-Co^b	(Anti-$Colton^b$).
Anti-Xg^a	None.

Effective date. Any product subject to this final rule that is initially introduced or initially delivered for introduction into interstate commerce on or after January 29, 1986 shall bear labeling including the new proper name of the product established herein.

(Secs. 201, 501, 502, 510, 701, 52 Stat. 1040–1042 as amended, 1049–1051 as amended, 1055–1056 as amended, 76 Stat. 794–795 as amended (21 U.S.C. 321, 351, 352, 360, 371); secs. 351, 352, 353, 361, 58 Stat. 702–703 as amended, 81 Stat. 536 (42 U.S.C. 262, 263, 263a, 264))

Dated: January 18, 1985.

Frank E. Young,

Commissioner of Food and Drugs.

[FR Doc. 85–2001 Filed 1–28–85; 8:45 am]

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Federal Register

Tuesday
January 29, 1985

Part V

Department of Labor

Mine Safety and Health Administration

30 CFR Parts 56 and 57

Metal and Nonmetal Mine Safety and Health; Radiation Standards; Proposed Rule

DEPARTMENT OF LABOR

Mine Safety and Health Administration

30 CFR Parts 56 and 57

Metal and Nonmetal Mine Safety and Health, Radiation Standards

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Advance Notice of proposed rulemaking.

SUMMARY: The Mine Safety and Health Administration (MSHA) invites public participation in its review of existing metal and nonmetal radiation standards (30 CFR 57.5–37 through 47). The Agency has identified specific issues with respect to possible regulatory action. Written comments are solicited.

The purpose of this review is to evaluate the adequacy of the existing standards in providing appropriate protection for workers exposed to radiation hazards in surface and underground operations.

DATE: All written comments should be submitted by April 1, 1985.

ADDRESS: Comments should be sent to Patricia W. Silvey, Director, Office of Standards, Regulations and Variances, MSHA, 4015 Wilson Boulevard, Arlington, Virginia 22203.

FOR FURTHER INFORMATION CONTACT: Patricia W. Silvey, Director, Office of Standards, Regulations and Variances, MSHA (703) 235–1910.

SUPPLEMENTARY INFORMATION:

I. Background

MSHA radiation protection standards for underground metal and nonmetal mines appear in 30 CFR 57.5–37 through 57.5–47. Current MSHA standards limit the maximum permissible concentration of radon daughters to 1.0 WL (30 CFR 57.5–39)[1] and limit the maximum calendar year exposure to 4.0 WLM (3 CFR 57.5–38).[2]

The agency promulgated a 1.0 WL maximum permissible concentration standard on February 25, 1970, 35 FR 3672. On May 25, 1971 (36 FR 9480), the Environmental Protection Agency (EPA) issued its Federal radiation protection guidance for radon daughters, which specified a maximum exposure limit of 4.0 WLM per year. That guidance was implemented for underground mines in 30 CFR 57.5–42, which automatically incorporated EPA recommendations, 35 FR 18591 (December 8, 1980). In 1976, the Mining Enforcement and Safety Administration, MSHA's predecessor agency, explicitly adopted the current 1.0 WL and 4.0 WLM per year standards set out in 30 CFR 57.5–39 and 30 CFR 57.5–38 respectively, 41 FR 23616 (June 10, 1976), as corrected in 41 FR 28266 (July 9, 1976).

On April 21, 1980, MSHA received a petition requesting an emergency temporary standard for radon daughter exposure. MSHA had requested the assistance of the National Institute for Occupational Safety and Health (NIOSH) to review the literature in this area. On July 14, 1980, MSHA received an interim NIOSH study which reviewed selected scientific papers. This study indicated there is evidence of excess health risk at and below the 120 WLM cumulative exposure limit. (Cumulative exposure was computed based on the maximum exposure of 4 WLM for each of 30 years working life.) NIOSH is undertaking additional research prior to its submission of a final report in response to an MSHA request for a more comprehensive review of the literature and assessment of risk. A number of risk assessments prepared by scientific authorities have become available, including:

(1) Evaluation of Occupational Environmental Exposures to Radon and Radon Daughters in the United States. NCRP Report No. 78, May 31, 1984. National Council on Radiation Protection and Measurements;

(2) Lung Cancer Risk Assessment of Radon-Exposed Miners on the Basis of a Proportional Hazard Model by W. Jacobi, H.G. Paretzke, F. Schindel. International Conference on Occupational Radiation Safety in Mining, October 14–18, 1984, Toronto, Ontario, Canada;

(3) Risk Estimates for the Health Effects of Alpha Radiation, Duncan C. Thomas and K.G. McNeill, by Atomic Energy Control Board, INFO–0081, September 1982, Ottawa, Canada; and

(4) Lung Cancer Mortality Among U.S. Uranium Miners: A Reappraisal, by A.S. Whittemore and A. McMillan, Journal of National Cancer Institute, Vol. 71, No. 3, September 1983.

MSHA has been working with the U.S. Bureau of Mines (Department of Interior) to analyze the cost of ventilating uranium mines at various levels of exposure and to develop techniques to improve exposure measurements. In addition, MSHA is evaluating standards and compliance methods of other countries.

Based on MSHA's review of technical literature, scientific studies, and its enforcement experience, the Secretary has determined that the petition for an emergency temporary standard does not meet the statutory criteria required for issuance of an emergency temporary standard under section 101(b)(1) of the Federal Mine Safety and Health Act of 1977. The parties to this petition are being notified. However, to assure that an appropriate level of health protection is maintained, MSHA will continue its review of existing radiation standards in light of the new information which has become available. In addition, the Agency seeks information concerning the radiation hazards in uranium mills and other facilities where radioactive sources or equipment may be present such as radioactive density gauges and analytical X-ray machines. The ANPR is a part of this process.

Upon completion of a comprehensive analysis of the comments and any other information received, MSHA will determine the adequacy of its existing radiation standards and initiate any appropriate rulemaking.

The Environmental Protection Agency (EPA) has initiated regulatory action concerning radon-222 emissions from underground uranium mines. MSHA intends to coordinate the review of its current standards with EPA to assure that Federal actions are consistent and provide an appropriate level of health protection for all persons exposed to radiation hazards.

II. Public Participation

Interested persons are encouraged to submit comments on any of the issues listed below and other issues dealing with the protection of miners from the hazards of radiation.

Comments may address alternatives to the existing regulatory requirements, including specific regulatory language, the continued need for standards, the elimination of duplicative standards, conflicts with other Federal or state regulations, the impact of specific standards on small businesses, and recordkeeping and reporting requirements. Persons are also encouraged to submit estimates related to the costs of complying with existing standards and costs and effectiveness related to any alternatives submitted.

As part of this review and in addition to the statutory rulemaking requirements of the Federal Mine Safety and Health Act of 1977, MSHA will also be evaluating its standards in accordance with Executive Order 12291, Executive

[1] A "working level" (WL) is a standard measure of radon daughter concentration in air. It is an expression of potential alpha energy. One WL is any combination of radon daughters per liter of air that will result in the emission of 1.3×10^5 Mev (million electron volts) of alpha energy in their decay through Polonium-214 (RAC') (130,000 Mev per liter).

[2] A "working level month" (WLM) is a standard measurement of cumulative exposure. A WLM is an exposure equivalent to 1 WL for 173 hours.

Order 12498, the Regulatory Flexibility Act, and the Paperwork Reduction Act.

III. Specific Issues Identified for Comment

1. Risk Assessment

- What is the relationship and the associated uncertainty between cumulative lifetime radon daughter exposure at or below 120 WLM and the lifetime risk of lung cancer or other biological response?
- What methodology (absolute or relative risk) should be used to arrive at the risk relationship and uncertainty and how do factors such as smoking and exposure to other carcinogens affect this relationship and uncertainty?
- Would a linear, non-threshold model extrapolating from elevated exposure levels (a few hundred working level months or more) be the most appropriate model to predict average lifetime lung cancer risks from exposure to radon daughters?
- Should the risk relationship be modified in some fashion to account for cell repair or other factors?
- Is cancer cell type a valid and reliable method of differentiating cancer attributable to radon daughters from cancer due to other occupational and environmental exposures?
- What is the best estimate of the latency period and how should the question of the latency period be incorporated into the risk assessment model?
- Does latency vary with cigarette smoking or with total exposure or exposure rate?
- How should exposure to thoron daughters, external gamma radiation, respirable and nonrespirable ore dust, and radon gas be incorporated into the risk assessment model?

2. Epidemiological Studies and Dosimetry

- To what extent do any existing epidemiological studies provide a reliable estimate of risk of lung cancer from exposure to radon daughters?
- How valid and reliable are outcome data (lung cancer) in each study?
- What limitations should be applied to interpreting the available epidemiological studies? Should any of the studies be excluded partly or wholly due to inadequacies in design or conduct?
- What impact does exposure rate below 4 WLM per year have on risk?
- Which studies are most useful in assessing risk at or below 120 cumulative working level months of exposure?
- How do these studies factor the reliability of dosimetry into their confidence intervals for a risk coefficient?
- Have the studies used the appropriate comparison population and why?
- If the epidemiological study includes exposure to thoron daughters, external gamma radiation, respirable and nonrespirable ore dust, and radon gas, can these be separated out to give an assessment of risk from radon daughters only? Is it necessary to separate them out?
- Does the possible presence of another carcinogen such as asbestos, arsenic, nickel, or chromium affect the reliability of the study?
- How can inconsistencies among results of epidemiological studies be explained?

3. Effects of Smoking

- What is the effect of smoking on the risk of lung cancer in miners exposed to randon daughters?
- Is the effect additive, multiplicative, or is there some other relationship?
- Would a cessation of smoking be likely to result in a lowering of lung cancer risk from the combined effect of smoking and exposure to radon daughters?
- Would miners who refrained from smoking only during working hours be likely to experience lower lung cancer risks?

4. Exposure Limit

- How should the results of a quantitative risk assessment be used in arriving at an exposure limit?
- Should the exposure limit be based on separate limits for radon daughters, thoron daughters, ore dust and external gamma radiation exposure, or should it be based on a single limit which combines the four exposures?
- Should all mines and ore processing mills be subject to the same exposure limit?

5. Records

- What criteria should be used to determine when records of employee exposure to radon and thoron daughters, ore dust and external gamma radiation should be required?
- What types of records should be required? For what purpose?
- Where should these records be stored and for what time period?

6. As Low as Reasonably Achievable (ALARA)

- How can the concept of "as low as reasonably achievable" be implemented through a regulation?

7. Sampling and Monitoring Methods

- Are existing sampling and exposure monitoring methods sufficiently sensitive, accurate and reliable? If not, what methods would be more suitable?
- What criteria should be the basis for a sampling strategy?
- If the annual exposure limit were to include exposure to ore dust and external gamma radiation, what would be the appropriate sampling monitoring methods?
- What are appropriate methods for time weighting exposure using area monitoring or grab sampling methods?

8. Awareness of Hazards

- What labels, signs or other forms of warning are necessary to apprise miners of the hazards of radiation?
- What training should miners receive regarding the hazards of radiation?

9. Mine Medical Program

- Would medical screening and surveillance requirements be appropriate for miners exposed to radiation? If so, what procedures should be used and for what purposes?

10. Feasibility

- If it is determined that there is a need to increase protection afforded underground miners, what would you recommend as the most feasible approach? Compare alternative approaches in terms of cost and relative effectiveness.
- What technology could be used to lower exposure to radon daughters? Is the technology practical and feasible?
- Is it practical to meet a lower standard by use of administrative controls? If so, what is the overall effect on public health and the numbers of people at risk?
- What specific costs are involved in lowering the exposure to radon daughters? If ventilation is used to reduce radon daughter concentration what is the additional ventilation cost to reduce radon daughter exposure by increments of 1 WLM?
- What is the relationship between reducing emissions of radon daughters into the atmosphere and reducing exposure of miners to radon daughters? EPA is examining containment of mine air thorugh bulkheading, barricading and sealing as means of reducing emissions of radon daughters into the atmosphere. How would increased use of these techniques impact the exposure to miners?
- Would existing sampling methods and exposure monitoring procedures be adequate to measure a lower annual radon daughter exposure limit?

List of Subjects in 30 CFR Parts 56 and 57

Mine safety and health, Radiation protection.

Dated: January 18, 1985.

David A. Zegeer,

Assistant Secretary for Mine Safety and Health.

[FR Doc. 85-2011 Filed 1-23-85; 2:41 pm]

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federal register

Tuesday
January 29, 1985

Part VI

Environmental Protection Agency

Protest Appeals of Recipients' Procurement Actions Under Federal Assistance Agreements; Subject Index List of EPA Regional Administrator Protest Appeal Determinations Issued During 1983

ENVIRONMENTAL PROTECTION AGENCY

[FRL-2765-7]

Protest Appeals of Recipients' Procurement Actions Under Federal Assistance Agreements; Subject Index List of EPA Regional Administrator Protest Appeal Determinations Issued During 1983

This notice publishes the subject index list of bid protest appeal decisions issued by EPA Regional Administrators during 1983. These determinations were made pursuant to the EPA protest procedures set forth at 40 CFR 35.939 (assistance awarded prior to May 12, 1982), 40 CFR Part 33, May 12, 1982 Interim Final Rules (assistance awarded between May 12, 1982 and March 28, 1983) and 40 CFR Part 33, March 28, 1983 Final Rules (assistance awarded after March 28, 1983).

This the sixth EPA subject index and lists only the decisions for the year stated. The first index, listing Regional Administrator protest appeal determinations issued during the period 1974 through 1977, was published at 43 FR 29086–95 (July 5, 1978). This was supplemented by the index of 1978 determinations published at 44 FR 25812–18 (May 2, 1979), the index of 1979 determinations published at 45 FR 58770–74 (September 4, 1980), the index of 1980 determinations published at 46 FR 30476–80 (June 8, 1981) and the index of 1981 and 1982 determinations published at 49 FR 36004 (September 13, 1984).

In 1983, EPA Regional Administrators issued 70 appeal determinations and 6 determinations of reconsideration requests. The determinations are cited informally with the names of the assistance recipients and protestors shortened and abbreviated for administrative convenience. Each entry begins by identifying the year the appeal was decided and the sequential determination number for that year. This number is not part of the preferred citation which should state the following: Grantee, State, (EPA Region —, date of determination) (Protest of ———).

Copies of specific protest appeal determinations may be examined at or obtained from the EPA Office of Regional Counsel or from the Office of General Counsel in EPA headquarters.

For further information contact: J. Kent Holland Jr., Esquire; Grants, Contracts, and General Law Division (LE–132–G), Office of General Counsel, United States Environmental Protection Agency, Washington, D.C. 20460; (202) 382–5313.

Dated: January 15, 1985.

Gerald H. Yamada,

Acting General Counsel (LE–130).

A/E Procurement

83:04 Globe, AZ (IX, 1–25–83) (*Brown & Caldwell*) (prior EPA approval required).

83:04 Globe, AZ [Reconsideration] (IX, 4–11–83) (*Brown & Caldwell*) (prices and identities of proposers publicly disclosed).

Ambiguity

83:08 Hamilton, MT (VIII, 2–8–83) (*4G Plumbing & Heating, Inc.*) (MBE requirements unclear as to responsiveness).

83:27 Port Arthur, TX (V, 5–12–83) (*Robert Bossow, Inc.*) (unclear bid evaluation method harmless error where no reliance by or prejudice to bidder).

83:36 Bentonville, AR (VI, 6–14–83) (*Archer Henry Const., Co.*) (harmless error where no prejudice to bidder).

83:64 Los Angeles, CA (IX, 11–25–83) (*C K Pump & Dewatering Corp.*) (ambiguous MBE requirements cause for rejecting all bids).

83:68 Tri-City, OR (X, 12–9–83) (*Dresser Industries, Inc.*) (to determine if specifications restrictive consider extrinsic factors like trade custom).

Award-Prime Contract

83:59 Puerto Rico, PR (II, 10–18–83) (*Longo—Puerto Rico, Inc.*) (no right to public contract).

Bids

A. General

83:07 Oklahoma City, OK (VI, 2–4–83) (*D.J. Domas, Inc.*) (duplicate copies of bid required by IFB).

83:09 Covington, GA (IV, 2–9–83) (*Griffin Const., Co., & Ethridge Brothers Const., Inc.*) (must be signed and bidder clearly identified).

83:15 Union City, OH (V, 3–8–83) (*Mote Const., Co.*) (separate bids required for two related projects with different IFBs).

83:21 Chester, CT (I, 4–7–83) (*Maple Hill Const., Co.*) (unsigned bid responsive where accompanied by signed bid bond) (failure to indicate authority of signatory not fatal if sufficient evidence of authority).

B. Addenda

83:21 Chester, CT (I, 4–7–83) (*Maple Hill Const. Co.*) (addenda not submitted but acknowledged in writing prior to bid opening).

83:34 New Concord, OH (V, 6–10–83) (*Adams Robinson Enterprise, Inc.*) (failure to acknowledge addendum made bid nonresponsive).

83:69 Conroe, TX (VI, 12–13–83) (*KNC, Inc.*) (verbal addenda generally prohibited) (inadequate time to consider addenda).

C. Alternative

83:10 Needles, CA (IX, 2–10–83) (*Hefley Bros., Corp.*) (principal bid not rendered nonresponsive by nonresponsiveness of alternate bid) (must be rational performance basis for grantee switching selected alternative).

83:36 Bentonville, AR (VI, 6–14–83) (*Archer Henry Const., Co.*) (choice between equal alternatives based on cost).

D. Deduct items

83:06 Western Carolina, SC (IV, 2–2–83) (*Ashbrook-Simon-Hartley*) (grantee review of low bidder's deduct equipment).

83:15 Union City, OH (V, 3–8–83) (*Mote Const., Co.*) (deduct cannot be considered unless all bidders had opportunity to offer deduct).

83:36 Bentonville, AR (VI, 6–14–83) (*Archer Henry Const., Co.*) (deductive alternates used where grantee knows material changes in scope of services may occur).

83:47 Topeka, KS (VII, 7–21–83) (*Walters-Morgan, Inc.*) (where bids on two separate projects opened same day combined bid deduction offered by bidder is unacceptable).

E. Extension of Bids

83:59 Puerto Rico, PR (II, 10–18–83) (*Longo—Puerto Rico, Inc.*) (revival of expired bid not in public interest).

F. Qualified

83:46 Palatine, IL (V, 7–19–83) (*Di Paolo-Rossetti, Joint Venture*) (offer to deduct amount if given two separate contracts is a conditional bid).

83:51 Santa Barbara, CA (IX, 8–15–83) (*Namtec Corp. & Union Engineering Co.*) (warranty provisions).

G. Unbalanced

83:66 Boston, MA (I, 12–9–83) (*Schiavone Const., Co.*) (penny bidding not per se unbalanced and nonresponsive).

Bid Evaluation

83:04 Globe, AZ [Reconsideration] (IX, 4–11–83) (*Brown & Caldwell*) (must clearly state method and criteria).

83:06 Western Carolina, SC [Reconsideration] (IV, 5–6–83)

(*Ashbrook-Simon-Hartley*) (no right to contract but right to be fairly judged under performance specifications).

83:11 LaPorte, TX (VI, 2–18–83) (*Jess Lovelace Cosnt., Co.*) (estimated quantities of work must be reasonable) (award of unit price contract may not be based on total prices on alternative means of performance).

83:21 Chester, CT (I, 4–7–83) (*Maple Hill Const., Co.*) (deference to exercise of discretion by public official).

83:24 Oklahoma City, OK [Reconsideration] (VI, 5–23–83) (*Fiberglass Engineered Products, Inc.*) (ambiguous experience clause requirement).

83:27 Port Arthur, TX (V, 5–12–83) (*Robert Bossow, Inc.*) (IFB unclear as to low alternative and deduction to be evalauted—harmless error).

83:30 St. Albans, WV (III, 5–27–83) (*Ralph B. Carter Co.*) (must be clearly stated method).

83:36 Bentonville, AR (VI, 6–14–83) (*Archer Henry Const., Co.*) (ambiguous IFB description harmless error if no reliance by bidder).

83:45 Casper, WY (VIII, 7–6–83) (*Shawnee Const., Inc.*) (must award based on stated criteria).

83:48 Heber Spring, AR (VI, 8–2–83) (*Trigon Engineering Co.*) (operation and maintenance costs, cost-effectiveness considered).

83:51 Santa Barbara, CA (IX, 8–15–83) (*Namtec Corp. & Union Engineering Co.*) (failure to follow evaluation criteria by waiving specifications).

83:60 Tri-City, OR (X, 10–20–83) (*Donald M. Drake Co.*) (bid evaluated on component item amounts not summary total).

Bid Shopping

83:13 Sandpoint, ID (X, 3–3–83) (*Lydig Const., Co.*) (subcontractor listing as material term).

Bidders

83:06 Western Carolina, SC (IV, 2–2–83) (*Ashbrook-Simon-Hartley*) (where specifications required supplier to submit equipment for review through prime contractor grantee may refuse to review equipment directly offered).

Bonds

83:02 Columbus, OH (V, 1–12–83) (*Cobey Metro—Waste Compositing Systems, Inc.*) (5 year bond not unduly restrictive if available at nonburdensome cost).

83:03 Columbus, OH [Reconsideration] (V, 6–6–83) (*Cobey Metro—Waste Composting System, Inc.*) (review of numerous EPA decisions concerning bonds) (must prove rational basis for bond requirement if protestor shows effect on competition) (5 year bond requirement deemed reasonable).

83:41 MDS, Chicago, IL (V, 6–24–83) (*Premier Electrical Const., Co.*) (summary dismissal of protest where bid bond not extended).

Burden of Proof

83:01 Spearfish, SD (VIII, 1–11–83) (*Rickel Manufacturing Co.*) (grantee must prove exclusionary specification based on minimum performance needs).

83:03 Columbus, OH [Reconsideration] (V, 6–6–83) (*Cobey Metro—Waste Compositing System, Inc.*) (grantee must prove rational basis for experience and bonding requirements if protestor shows adverse effect).

83:16 Halstead, Hutchinson, KS (VII, 3–9–83) (*Charles E. Stevens*) (protestor's burden to prove intent to bid).

83:27 Port Arthur, TX (V, 5–12–83) (*Robert Bossow, Inc.*) (bidder failed to prove reliance on ambiguity).

83:39 Philadelphia, PA (III, 6–22–83) (*Fisher & Porter Co.*) (shifting burden).

83:43 Toledo, OH (V, 6–29–83) (*Industrial Pump & Equipment Corp.*) (protestor must show specification not minimum performamce).

83:63 Monterey CA (IX, 11–4–83) (*Power Systems*) (successful supplier cannot prove specifications excluded it).

83:68 Tri-City, OR (X, 12–9–83) (*Dresser Industries, Inc.*) (shifting burden where restrictive specification alleged did not exclude equipment).

83:69 Conroe, TX (VI, 12–13–83) (*KNC, Inc.*) (protestor must show prejudice to competition).

Choice of Law

A. General

83:34 New Concord, OH (V, 6–10–83) (*Adams Robinson Enterprise, Inc.*) (EPA reliance on grantee interpretation of state and local law).

83:51 Santa Barbara, CA (IX, 8–15–83) (*Namtec Corp. & Union Engineering Co.*) (under State law warranty qualification did not negate express warranty).

83:53 New Haven, CT (I, 8–19–83) (*Blakeslee arpaia Chapman, Inc.*) (interpretation of local law—deference to City's legal opinion).

83:61 Johnston, OH (V, 10–24–83) (*Zimpro, Inc.*) (protestor barred from immediate protest where issues primarily determined by state law).

83:66 Boston, MA (I, 12–9–83) (*Schiavone Const., Co.*) (deference to grantee interpretation where State law unclear and no overriding federal principle).

B. Local Law

83:07 Oklahoma City, OK (VI, 2–4–83) (*D.J. Domas, Inc.*) (requiring submission of duplicate copies of bids).

C. State Law

83:05 Morton, MS (IV, 1–25–83) (*Associated Cosnt., Inc.*) (City attorney opinion on state licensing requirement).

83:13 Sandpoint, ID (X, 3–3–83) (*Lyding Const., Co.*) (listing subcontractors required, no overriding federal interest).

Conflict of Interest

83:29 Fargo, ND (VIII, 5–18–83) (*Van Bergen & Markson, Inc.; The Gray Engineering Group, Inc. & Conservatek, Inc.*) (Code of Conduct must be maintained by grantee) (potential conflict where City official engaged in contracting business).

Engineering Judgment

83:20 Los Angeles, CA (IX, 3–28–83) (*Solar Turbines, Inc.*) (basic design decision not protestable where based on performance needs).

83:23 Jerseyville, IL (V, 4–14–83) (*Clow Corp.*) (must show rational basis for using brand name specification).

83:30 St. Albans, WV (III, 5–27–83) (*Ralph B. Carter Co.*) (performance tests of equipment).

83:37 Central Valley, UT (VIII, 6–17–83) (*American Surfpac, Inc.*) (choice of filter media not basic design and may be protested).

83:55 Brazos River, TX (VI, 9–23–83) (*Jeffery Manufacturing Div.*) (technical features need not be only choice available if rational) (reliability requirements consideration).

Experience Requirements

83:02 Columbus, OH (V, 1–12–83) (*Cobey Metro—Waste Composting Systems, Inc.*) (experience clause justified by complexity of the equipment and innovative technology) (supplier standing under Part 35 to challenge clause and determination of inadequate experience).

83:03 Columbus, OH [Reconsideration] (V, 6–6–83) (*Cobey Metro—Waste Composting System, Inc.*) (only must prove rational basis for experience requirement if protestor shows competition affected).

83:24 Oklahoma City, OK (VI, 4–29–83) (*D.J. Domas, Inc.*) (general clause requiring experience installing similar equipment—no bond alternative).

83:24 Oklahoma City, OK [Reconsideration] (VI, 5–23–83) *(Fiberglass Engineered Products, Inc.)*

(requiring unspecific period of experience is ambiguous).

83:38 Sacramento, CA (VIII, 6–17–83) (*Power Machine Co.*) (must be justified).

E.E.O.

83:12 Le Clarie, IA (VII, 2–23–83) (*C. Iber & Sons, Inc.*) (submittal of documents after bid opening).

Harmless Error

83:55 Haysville, KS [Reconsideration] (VII, 2–14–83) (*Walker Process Corp.*) (procedural error by not distributing engineer's letter).

83:03 Columbus, OH [Reconsideration] (V, 6–6–83) (*Cobey Metro—Waste Composting System, Inc.*) (incorrect EPA conclusion that grantee had authority to use a sole source.

83:27 Port Arthur, TX (V, 5–12–83) (*Robert Bossow, Inc.*) (where reliance on unclear bid evaluation method).

83:36 Bentonsville, AR (VI, 6–14–83) (*Archer Henry Const., Co.*) (ambiguous IFB description of bid evaluation method).

83:48 Heber Spring, AR (VI, 8–2–83) (*Trigon Engineering Co.*) (no prejudice resulted from imperfect bid evaluation process).

Invitation for Bids

A. Addenda

83:16 Halstead, Hutchinson, KS (VII, 3–9–83) (*Charles E. Stevens*) (where addenda had no connection with bid preparation no harm in short notice period).

83:69 Conroe, TX (VI, 12–13–83) (*KNC, Inc.*) (verbal addenda generally prohibited) (inadequate time to consider addenda).

Jurisdiction

83:04 Globe, AZ (IX, 1–25–83) (*Brown & Caldwell*) (grantee procurement action premature where prior EPA approval of A/E contract not obtained).

83:11 LaPorte, TX (VI, 2–18–83) (*Jess Loveless Const., Co.*) (reprocuremnt of services after contractor quits job).

83:33 Joplin, MI (IX, 6–6–83) (*Advanco Constructors, Inc.*) (summary dismissal where protest based solely on Federal Procurement regulations not adopted by EPA regulations).

83:37 Central Valley, UT (VIII, 6–17–83) (*American Surfpac, Inc.*) (selection of filter media not broad design decision—protestable).

83:57 Sod Run, Harford County, MD (III, 10–7–83) (*CESCO, Inc.*) (equipment substitution not protestable).

83:58 Evanston, WY (VIII 10–18–83) (*WesTech Engineering, Inc.*) (equipment substitution by contractor not protestable procurement action).

83:61 Johnstown, OH (V, 10–24–83) (*Zimpro, Inc.*) (subcontractor substitution by contractor not protestable).

83:63 Monterey, CA (IX, 11–4–83) (*Power Systems*) (contract obligations not addressable in bid protest).

83:66 Boston, MA (I, 12–9–83) (*Schiavone Const. Co.*) (violation of State law not protestable unless contravening federal requirement).

License

83:05 Morton, MS (IV, 1–25–83) (*Associated Const., Inc.*) (license requirement affects responsibility not responsiveness).

Listing Subcontractors and Equipment

83:13 Sandpoint, ID (X, 3–3–83) (*Lydig Const., Co.*) (required by state law) (follow Part 35 determinations).

83:17 Patapsco, MD (III, 3–17–83) (*J. Vinton, Schafer & Sons, Inc.*) (failure to list MBEs did not render bid nonresponsive).

83:21 Chester, CT (I, 4–7–83) (*Maple Hill Const., Co.*) (subcontractor listing not matter of responsiveness unless clear IFB).

83:22 San Jose, CA (IX, 4–11–83) (*Johnson Controls, Inc.*) (equipment listing responsibility matter under Part 33 unless IFB clear to contrary).

83:26 Waynesburg [Stark County], OH (V, 5–12–83) (*Robert Bossow, Inc.*) (bid may be accepted and contractor required to do substitution).

83:28 Des Moines, WA (X, 5–18–83) (*Will Const. Co. Inc.*) (listing MBE subcontractor responsibility matter).

83:32 Los Angeles, CA (IX, 6–6–83) (*Advanco Constructors, Inc.*) (bid not deemed nonresponsive for listing more than one subcontractor).

83:35 Pleasant Hill, IL (V, 6–10–83) (*State Mechanical Contractors, Inc.*) (because bidder required to perform to specifications and substitute equipment if necessary, listing nonconforming equipment is not nonresponsive).

83:44 Streetsboro, Ravenna, OH (V, 7–1–83) (*Robert Bossow, Inc.*) (substitution of noncomplying equipment) (listing errors not grounds for rejection).

83:44 Streetsboro, Ravenna, OH [Reconsideration] (V, 8–26–83) (*Robert Bossow, Inc.*) (bid accepted and contractor required to substitute equipment).

83:49 MSD, Chicago, IL (V, 8–2–83) (*Door Systems of Elk Grove*) (not grounds for rejection where IFB required listing) (listing to list MBEs).

83:51 Santa Barbara, CA (IX, 8–15–83) (*Namtec Corp. & Union Engineering Co.*) (may accept bid and required equipment substitution).

Local Preference

83:29 Fargo, ND (VIII, 5–18–83) (*Van Bergen & Markson, Inc.; The Gray Engineering Group, Inc. & Conservatek, Inc.*) (procedures or practices creating preference prohibited).

Minority Business Enterprise (MBE) (See Responsibility and Responsiveness for Other Determinations)

83:08 Hamilton, MT (VIII, 2–8–83) (*4G Plumbing & Heating, Inc.*) (positive efforts satisfied by meeting goal) (MBE rejected by prime for business reasons not discriminatory motive).

83:14 MSD Chicago, IL (V, 3–4–83) (*R. Rudnick & Co., Inc. & Namat Const., Co.*) (prime receives MBE subcontractor credit only for work actually done by MBE) (where bid met MBE goal on its face but MBE not bonafide, evaluate contractor pre-bid opening positive efforts).

83:17 Patapsco, MD (III, 3–17–83) (*J. Vinton, Schafer & Sons, Inc.*) (bidder may demonstrate positive efforts until contract award).

83:25 Onondaga County, NY (II, 5–9–83) (*Herbert F. Darling, Inc.*) (responsibility challenged where MBE goal not met in bid and good faith efforts not demonstrated) (post-bid determination of good faith efforts ripe for appeal when award announced).

83:26 Waynesburg [Stark County], OH (V, 5–12–83) (*Robert Bossow, Inc.*) (ambiguous MBE requirements requires resolicitation due to effect on competition).

83:28 Des Moines, WA (X, 5–18–83) *(Will Const., Co., Inc.)* (MBE responsibility curable after bid opening).

83:34 New Concord, OH (V, 6–10–83) *(Adams Robinson Enterprise, Inc.)* (where IFB unequivocally required bidder state MBE offer, failure to do so nonwaivable).

83:35 Pleasant Hill, IL (V, 6–10–83) *(State Mechanical Contractors, Inc.)* (documentation of positive efforts made bid responsive though no MBE participation proposed).

83:46 Palatine, IL (V, 7–19–83) *(Di Paolo-Rossetti, Joint Venture)* (IFB made self certification affidavit and 20 day advertising matters of responsiveness).

83:49 MSD, Chicago, IL (V, 8–2–83) *(Door Systems of Elk Grove)* (MBE subcontractor listing not material to bid).

83:64 Los Angeles, CA (IX, 11–25–83) *(C K Pump & Dewatering Corp.)* (ambiguous MBE requirements cause to reject all bids).

Mistake

83:10 Needles, CA (IX, 2–10–83) *(Hefley Bros., Corp.)* (where bidder alleges mistake he cannot waive right to have bid rejected unless absent mistake he would be low bidder).
83:36 Bentonville, AR (VI, 6–14–83) *(Archer Henry Const., Co.)* (correction of math error displacing another bidder) (bidder cannot compel upward correction of competitor's bid).
83:45 Casper, WY (VIII, 7–8–83) *(Shawnee Const., Inc.)* (not necessarily require finding bid nonresponsive, bidder must be given chance to verify apparent mistake).
83:60 Tri-City, OR (X, 10–20–83) *(Donald M. Drake Co.)* (where mistake not claimed reconciliation clause waived).

Negotiated Procurement

83:04 Globe, AZ [Reconsideration] (IX, 4–11–83) *(Brown & Caldwell)* (prices and identities of proposers publicly disclosed) (right to revise proposal) (essential to have clear statement of evaluation criteria and method).

Prequalification

83:02 Columbus, OH (V, 1–12–83) *(Cobey Metro—Waste Composting Systems, Inc.)* (time between notification of prequalification and bid opening is discretionary) (supplier not entitled to "marketing" time).
83:23 Jerseyville, IL (V, 4–14–83) *(Clow Corp.)* (not required to seek prequalification before protesting unduly restrictive specifications).
83:62 Wayne, NB (VII, 10–31–83) *(Envirex, Inc.)* (specifications interpreted restrictively caused rejection of prequalified supplier).
83:68 Tri-City, OR (X, 12–9–83) *(Dresser Industries, Inc.)* (failure to timely submit equipment information).

Procedure

83:01 Spearfish, SD (VIII, 1–11–83) *(Rickel Manufacturing Co.)* (decision affirmed for different reasons than supplied by grantee).
83:02 Columbus, OH (V, 1–12–83) *(Cobey Metro—Waste Composting Systems, Inc.)* (summary dismissal not justified by failure to notice parties).
83:08 Hamilton, MT (VIII, 2–8–83) *(4G Plumbing & Heating, Inc.)* (grantee duty to afford opportunity to present arguments).
83:13 Sandpoint, ID (X, 3–3–83) *(Lydig Const., Co.)* (appeal premature before grantee issues decision) (applicability of Part 33 regulations).
83:14 MSD Chicago, IL (V, 3–4–83) *(R. Rudnick & Co., Inc. & Namat Const., Co.)* (hearing notice).
83:16 Halstead, Hutchinson, KS (VII, 3–9–83) *(Charles E. Stevens)* (GAO decisions used).
83:22 San Jose, CA (IX, 4–11–83) *(Johnson Controls, Inc.)* (GAO decisions used).
83:23 Jerseyville, IL (V, 4–14–83) *Clow Corp.)* (citing Part 35 instead of Part 33 regulations not fatal) (failure to seek prequalification not failure to exhaust administrative remedies where futile).
83:29 Fargo, ND (VIII, 5–18–83) *(Van Bergen & Markson, Inc.; The Gray Engineering Group, Inc. & Conservatek, Inc.)* (where IFB improperly included Part 35 regulations EPA applied Part 33 regulations with same result).
83:31: Younstown, OH (V, 5–31–83) *(Floyd Brown Associates)* (new issues may not be raised on appeal) (no allegation how action violated regulations).
83:37 Central Valley, UT (VIII, 6–17–83) *(American Surfpac, Inc.)* (telegraphic notice perfecting appeal).
83:38 Sacramento, CA (VIII, 6–17–83) *(Power Machine Co.)* (adequate notice where regulations not cited).
83:41 MSD, Chicago, IL (V, 6–24–83) *(Premier Electrical Const., Co.)* (bid bond extension during protest).
83:48 Heber Spring, AR (VI, 8–2–83) *(Trigon Engineering Co.)* (few EPA restraints on manner grantee decides protest).
83:49 MSD, Chicago, IL (V, 8–2–83) *(Door Systems of Elk Grove)* (grantee dismissal for failure to attend hearing and present detailed written statement).
83:51 Santa Barbara, CA (IX, 8–15–83) *(Namtec Corp. & Union Enginnering Co.)* (failure to reference regulations and notify parties not fatal).
83:61 Johnstown, OH (V, 10–24–83) *(Zimpro, Inc.)* (specific regulations not cited).

Rational Basis Test

83:01 Spearfish, SD (VIII, 1–11–83) *(Rickel Manufacturing Co.)* (no rational basis for liquid cooled pump).
83:18 Perryville, MD (III, 3–21–83) *(Lyco Wastewater Equipment Division)* (no performance basis for rejecting RBC equipment).
83:20 Los Angeles, CA (IX, 3–28–83) *(Solar Turbines, Inc.)* (engineering design to use four turbines).
83:23 Jerseyville, IL (V, 4–14–83) *(Clow Corp.)* (for using brand name or equal specifications instead of stating technical requirements).
83:38 Sacramento, CA (VIII, 6–17–83) *(Power Machine Co.)* (defer to grantee where it and protester have credible cases).
83:41 MSD, Chicago, IL (V, 6–24–83) *(Premier Electrical Const., Co.)* (setting period for bid bond extension).
83:55 Brazo River, TX (VI, 9–23–83) (*Jeffery Manufacturing Div.*) (technical requirements need not be only available choice).
83:62 Wayne, NB (VII, 10–31–83) (*Envirex, Inc.*) (speculation of equipment failure) (post ward equipment substitution not required by subcontractor price—no effect in prime's price).
83:66 Boston, MA (I, 12–9–83) (*Schiavone Const., Co.*) (interpretation of state law).
83:68 Tri-City, OR (X, 12–9–83) (*Dresser Industries, Inc.*) (specifications to achieve uniformity in blowers by requiring single manufacturer).

Reconsideration

82:55 Haysville, KS [Reconsideration] (VII, 2–14–83) (*Walker Process Corp.*) (affirmed 10–13–82 decision) (inherent authority of EPA).
83:63 Elk Pinch, WV [Reconsideration] (III, 1–7–83) (*Kappe Associates, Inc.*) (cannot raise new argument based on same facts).
83:03 Columbus, OH [Reconsideration] (V, 6–6–83) (*Cobey Metro-Waste Composting System, Inc.*) (affirmed prior decision—no legal error).
83:06 Western Carolina, SC [Reconsideration] (IV, 5–6–83) (*Ashbrook-Simon-Hartley*) (affirmed prior decision).
83:24 Oklahoma City, OK [Reconsideration] (VI, 5–23–83) (*Fiberglass Engineered Products, Inc.*) (affirmed prior decision—no new facts).
83:37 Central Valley, UT [Reconsideration] (VIII, 9–22–83) (*American Surfpac, Inc.*) (affirmed 83:42—summarily dismissed as untimely).
83:44 Streetsboro, Ravenna, OH [Reconsideration] (V, 8–26–83) (*Robert Bossow, Inc.*) (affirmed prior decision—no legal error shown).

Regulations

83:29 Fargo, ND (VIII, 5–18–83) (*Van Bergen & Markson, Inc.; Gray Engineering Group, Inc. & Conservatek, Inc.*) (where IFB incorrectly included Part 35 regulations EPA applied Part 33).
83:46 Palatine, IL (V, 7–19–83) (*Di Paolo-Rossetti, Joint Venture*) (grantee opted to use interim Part 33 by reference in IFB).

83:66 Boston, MA (I, 12–9–83) (*Schiavone Const., Co.*) (grantee indicated Part 33 applied by reference in IFB).

Rejection of All Bids

83:07 Oklahoma City, OK (VI, 2–4–83) (*D.J. Domas, Inc.*) (all bids may be rejected if in best interest to EPA and grantee).

83:22 San Jose, CA (IX, 4–11–83) (*Johnson Controls, Inc.*) (protestable procurement action) (must be good cause, PRM 78–8 example of good cause).

83:26 Waynesburg [Stark County], OH (V, 5–12–83) (*Robert Bossow, Inc.*) (ambiguous MBE requirements).

83:60 Tri-City, OR (X, 10–20–83) (*Donald M. Drake Co.*) (not good cause for rejection where prejudicial ambiguity).

83:64 Los Angeles, CA (IX, 11–25–83) (*C K Pump & Dewatering Corp.*) (ambiguity in MBE requirements).

Responsibility

83:02 Columbus, OH (V, 1–12–83) (*Cobey Metro-Waste Composting Systems, Inc.*) (inadequate experience).

83:05 Morton, MS (IV, 1–25–83) (*Associated Const., Inc.*) (failure to obtain license).

83:10 Needles, CA (IX, 2–10–83) (*Hefley Bros., Corp.*) (affirmative determination not reversed by EPA unless fraud, bad faith or violation of objective standards of responsibility).

83:14 MSD Chicago, IL (V, 3–4–83) (*R. Rudnick & Co., Inc. & Namat Const., Co.*) (contractor must demonstrate positive efforts if it fails to meet MBE goal) (EPA may reverse affirmative determination if grantee fails to consider all relevant information).

83:17 Patapsco, MD (III, 3–17–83) (*J. Vinton, Schafer & Sons, Inc.*) (failure to attach MBE documentation) (positive efforts may be cured anytime before contract award).

83:28 Des Moines, WA (X, 5–18–83) (*Will Const., Co., Inc.*) (MBE form incomplete).

83:42 Eastern Avenue Baltimore, MD (V, 6–28–83) (*Allied Contractors, Inc.*) (MBE requirements can be met by satisfying goal or showing good faith efforts).

83:45 Casper, WY (VIII, 7–8–83) (*Shawnee Const., Inc.*) (MBE requirements).

83:49 MSD, Chicago, IL (V, 8–2–83) (*Door Systems of Elk Grove*) (MBE subcontractor listing).

83:50 Detroit, MI (V, 8–2–83) (*Dynamic Const., Co., Inc.*) (MBE requirements positive efforts demonstrated after bid opening)

83:52 Berkeley, CA (IX, 8–16–83) (*Gerl Const., Co.*) (MBE requirements).

83:53 New Haven, CT (I, 8–19–83) (*Blakeslee Arpaia Chapman, Inc.*) (local affirmative action agreement).

Responsiveness

83:01 Spearfish, SD (VIII, 1–11–83) (*Rickel Manufacturing Co.*) (pump not capable of meeting specified cubic feet per minute is nonresponsive).

83:09 Covington, GA (IV, 2–9–83) (*Griffin Const., Co., & Ethridge Brothers Const., Inc.*) (bid signing, bidder identity and bid bonds).

83:10 Needles, CA (IX, 2–10–83) (*Hefley Bros., Corp.*) (principal bid not rendered nonresponsive by failure to bid on alternate).

83:13 Sandpoint, ID (X, 3–3–83) (*Lydig Const. Co.*) (subcontractor listing).

83:15 Union City, OH (V, 3–8–83) (*Mote Const., Co.*) (separate bids required for two related projects with different IFBs).

83:19 Oklahoma City, OK (VI, 3–25–83) (*Envirex, Inc.*) (bid nonresponsive due to qualifications to liquidated damages, time and warranty clauses).

83:21 Chester, CT (I, 4–7–83) (*Maple Hill Const., Co.*) (unsigned bid responsive where accompanied by signed bid bond) (addenda not submitted but written acknowledgement prior to bid opening).

83:22 San Jose, CA (IX, 4–11–83) (*Johnson Controls, Inc.*) (equipment listing requirement not matter of responsiveness under Part 33) (nonconforming equipment did not make bid nonresponsive where grantee can require substitution).

83:34 New Concord, OH (V, 6–10–83) (*Adams Robinson Enterprise, Inc.*) (MBE forms and information) (where addendum not acknowledged bid nonresponsive).

83:35 Pleasant Hill, IL (V, 6–10–83) (*State Mechanical Contractors, Inc.*) (MBE documentation satisfied) (bid listing nonconforming equipment is responsive; substitution permitted).

83:44 Streetsboro, Ravenna, OH (V, 7–1–83) (*Robert Bossow, Inc.*) (bid listing nonconforming equipment is responsive substitution permitted).

83:46 Palatine, IL (V, 7–19–83) (*Di Paolo-Rossetti, Joint Venture*) (MBE information and 20 day advertising required by IFB cannot be waived as immaterial) (self certification affidavits).

83:50 Detroit, MI (V, 8–2–83) (*Dynamic Const., Co., Inc.*) (acknowledged bid addendum but did not adjust bid).

83:51 Santa Barbara, CA (IX, 8–15–83) (*Namtec Corp. & Union Engineering Co.*) (material, technical and commercial terms cannot be waived) (bid cannot be clarified after bid opening).

83:56 Los Angeles, CA (IX, 9–30–83) (*Bailey Controls Co.*) (exception to contract conditions and bid bond amount nonresponsive).

83:69 Conroe, TX (VI, 12–13–83) (*KNC, Inc.*) (inclusion of extraneous information in bid OK where bid terms not qualified).

83:70 Contra Costa, CA (IX, 12–16–83) (*Perkin—Elmer*) (principal bid not rendered nonresponsive by submittal of uninvited alternate).

Review

83:24 Oklahoma City, OK [Reconsideration] (VI, 5–23–83) (*Fiberglass Engineered Products, Inc.*) (EPA may reexamine and overrule decisions made by delegated State agency).

83:60 Tri-City, OR (X, 10–20–83) (*Donald M. Drake Co.*) (rational basis standard of EPA review).

Specifications

A. General

83:39 Philadelphia, PA (III, 6–22–83) (*Fisher & Porter Co.*) (must not include requirements unrelated to minimum performance needs).

83:48 Heber Spring, AR (VI, 8–2–83) (*Trigon Engineering Co.*) (operation and maintenance costs of equipment).

83:70 Contra Costa, CA (IX, 12–16–83) (*Perkin—Elmer*) (bidder could not rely on oral interpretation of specifications when IFB required they be in writing).

B. Brand Name or Equal

83:23 Jerseyville, IL (V, 4–14–83) (*Clow Corp.*) (used as disguised sole source) (can only be used if rational basis for not stating technical requirements) (must state salient features).

C. Sole Source

83:23 Jerseyville, IL (V, 4–14–83) (*Clow Corp.*) (brand name or equal specifications satisfied by only one supplier).

83:37 Central Valley, UT (VIII, 6–17–83) (*American Surfpac, Inc.*) (where two manufacturers able to bid on equipment, not sole source).

83:38 Sacramento, CA (IX, 6–17–83) (*Power Machine Co.*) (EPA may review sole source even if State agency prior approval) (not justified to reduce spare parts and maintenance through standardization).

83:39 Philadelphia, PA (III, 6–22–83) (*Fisher & Porter Co.*) (catalog design features which can be met by only one manufacturer).

83:62 Wayne, NB (VII, 10–31–83) (*Envirex, Inc.*) (grantee directed particular equipment be substituted after prime contract award).

D. Unduly Restrictive

83:01 Spearfish, SD (VIII, 1–11–83) (*Rickel Manufacturing Co.*) (requiring liquid cooled pump exceeded minimum performance needs).
83:06 Western Carolina, SC (IV, 2–2–83) (*Ashbrook-Simon-Hartley*) (engineer is to establish minimum performance needs and specifications should be performance based).
83:18 Perryville, MD (III, 3–21–83) (*Lyco Wastewater Equipment Division*) (RBC equipment arbitrarily rejected) (must not include requirements that are not performance related).
83:23 Jerseyville, IL (V, 4–14–83) (*Clow Corp.*) (requiring RBC be air driven not minimum performance need) (competition adversely affected—not cured by manufacturer of described item and not cured by ability of others to create copy item).
83:30 St. Albans, WV (III, 5–27–83) (*Ralph B. Carter Co.*) (performance test allegedly made specifications restrictive as applied).
83:38 Sacramento, CA (IX, 6–17–83) (*Power Machine Co.*) (limitation of type of filter media not unduly restrictive where two suppliers).
83:39 Philadelphia, PA (III, 6–22–83) (*Fisher & Porter Co.*) (proprietary design features) (specifications cannot be modified through private agreement involving testing).
83:43 Toledo, OH (V, 6–29–83) (*Industrial Pump & Equipment Corp.*) (pumps selected for lower capital and reapir costs and less installation space).
83:48 Heber Spring, AR (VI, 8–2–83) (*Trigon Engineering Co.*) (nonexcluded bidder cannot protest specifications).
83:51 Santa Barbara, CA (IX, 8–15–83) (*Namtec Corp. & Union Engineering Co.*) (grantee willingness to waive requirement indicates specifications overstated minimum needs).
83:55 Brazos River, TX (VI, 9–23–83) (*Jeffery Manufacturing Div.*) (shifting burden of proof) (technical features need not be only possible choice so long as rational).
83:62 Wayne, NB (VII, 10–31–83) (*Envirex, Inc.*) (by requiring equipment substitution grantee restrictively applied specifications).
83:68 Tri-City, OR (X, 12–9–83) (*Dresser Industries, Inc.*) (temperature rise specifications for blower equipment to lower operating costs rationally based) (specifications to achieve uniformity in blowers requiring single manufacturer).
83:70 Contra Costa, CA (IX, 12–16–83) (*Perkin—Elmer*) (exact compliance with design specifications must be determined from face of bid without extrinsic evidence) (post bid evaluation of equipment not permitted where not provided for by IFB).

Standing

83:02 Columbus, OH (V, 1–12–83) (*Cobey Metro—Waste Composting Systems, Inc.*) (supplier protest experience requirements and grantee determination of inadequate experience).
83:03 Columbus, OH (V, 1–12–83) (*Zimpro, Inc.*) (subcontractor not listed by prime lacks direct financial interest).
83:08 Hamilton, MT (VIII, 2–8–83) (*4G Plumbing & Heating, Inc.*) (MBE subcontractor offeror may protest prime's actions).
83:16 Halstead, Hutchinson, KS (VII, 3–9–83) (*Charles E. Stevens*) (protester burden to show intent to bid).
83:18 Perryville, MD (III, 3–21–83) (*Lyco Wastewater Equipment Division*) (RBC supplier may protest specifications which prevented prime from awarding it contract).
83:22 San Jose, CA (IX, 4–11–83) (*Johnson Controls, Inc.*) (low bidder affected by decision to reject all bids).
83:29 Fargo, ND (VIII, 5–18–83) (*Van Bergen & Markson, Inc.; The Gray Engineering Group, Inc. & Conservatek, Inc.*) (subcontractor may protest substitution dictated by grantee).
83:30 St. Albans, WV (III, 5–27–83) (*Ralph B. Carter Co.*) (subcontractor may protest City rejection of its equipment).
83:38 Sacramento, CA (IX, 6–17–83) (*Power Machine Co.*) (subcontractor protested specifications).
83:43 Toledo, OH (V, 6–29–83) (*Industrial Pump & Equipment Corp.*) (supplier alleging sole source) (Part 33 regulations).
83:51 Santa Barbara, CA (IX, 8–15–83) (*Namtec Corp. & Union Engineering Co.*) (supplier protested specifications and prime's responsiveness).
83:56 Los Angeles, CA (IX, 9–30–83) (*Bailey Controls Co.*) (to protest competitor's responsiveness bidder must be responsive).
83:57 Sod Run, Harford County, MD (III, 10–7–83) (*CESCO, Inc.*) (equipment substitution not protestable).
83:58 Evanston, WY (VIII, 10–18–83) (*WesTech Engineering, Inc.*) (equipment substitution not protestable).
83:62 Wayne, NB (VII, 10–31–83) (*Envirex, Inc.*) (prequalified supplier may protest grantee directed substitution).
83:63 Monterey, CA (IX, 11–4–83) (*Power Systems*) (successful supplier cannot protest specifications).
83:68 Tri-City, OR (X, 12–9–83) (*Dresser Industries, Inc.*) (where protester can meet specifications no basis for protest).

Sua Sponte Review

83:01 Spearfish, SD (VIII, 1–11–83) (*Rickel Manufacturing Co.*) (authority to review unduly restrictive specifications).
83:08 Hamilton, MT (VIII, 2–8–83) (*4G Plumbing & Heating, Inc.*) (where appeal summarily dismissed EPA may review merits to provide guidance).
83:11 LaPorte, TX (VI, 2–18–83) (*Jess Lovelace Const., Co.*) (where integrity of procurement system at issue).
83:24 Oklahoma City, OK [Reconsideration] (VI, 5–23–83) (*Fiberglass Engineering Products, Inc.*) (experience clause—integrity of procurement).
83:41 MSD, Chicago, IL (V, 6–24–83) (*Premier Electrical Const., Co.*) (strictly discretionary).
83:60 Tri-City, OR (X, 10–20–83) (*Donald M. Drake Co.*) (EPA may raise issue not addressed by any party).

Subcontract—Award

83:08 Hamilton, MT (VIII, 2–8–83) (*4G Plumbing & Heating, Inc.*) (contractor rejected MBE subcontractor for business reasons).
83:29 Fargo, ND (VIII, 5–18–83) (*Van Bergen & Markson, Inc.; The Gray Engineering Group, Inc. & Conservatek, Inc.*) (business reasons for substituting subcontract).
83:24 Oklahoma City, OK [Reconsideration] (VI, 5–23–83) (*Fiberglass Engineered Products, Inc.*) (anticipated receipt of contract not protected by Fifth Amendment due process).
83:57 Sod Run, Harford County, MD (III, 10–7–83) (*CESCO, Inc.*) (equipment substitution by contractor not protestable).
83:58 Evanston, WY (VIII, 10–18–83) (*WesTech Engineering, Inc.*) (equipment substitution not protestable).
83:61 Johnstown, OH (V, 10–24–83) (*Zimpro, Inc.*) (subcontractor substitution by contractor not protestable).

Subcontractor Listing (See Listing Subcontractor) Summary Dismissal

83:19 Oklahoma City, OK (VI, 3–25–83) (*Envirex, Inc.*) (where protest by bidder who qualified bid was obviously frivolous).

83:33 Joplin, MI (IX, 6–6–83) (*Advanco Constructors, Inc.*) (where protest relies on Federal Procurement regulations not adopted by EPA regulations).

83:40 Elkhart, IN (V, 6–22–83) (*Penn equipment & Tool Corp.*) (based on timeliness).

83:66 Boston, MA (I, 12–9–83) (*Schiavone Const., Co.*) (where no alleged violation of EPA regulation).

Time Limitations

83:01 Spearfish, SD (VIII, 1–11–83) (*Rickel Manufacturing Co.*) (mailed appeal must be received within one week).

83:02 Columbus, OH (V, 1–12–83) (*Cobey Metro—Waste Composting Systems, Inc.*) (documents must be promptly filed following mailgram notice and protest).

83:08 Hamilton, MT (VIII, 2–8–83) (*4G Plumbing & Heating, Inc.*) (communications between protestor and EPA do not excuse untimely filing of appeal).

83:22 San Jose, CA (IX, 4–11–83) (*Johnson Controls, Inc.*) (clock not started by engineer's communication to bidder concerning adequacy of equipment).

83:25 Onondaga County, NY (II, 5–9–83) (*Herbert F. Darling, Inc.*) (appeal of post bid determination of good faith MBE efforts ripe when award announced).

83:28 Des Moines, WA (X, 5–18–83) (*Will Const., Co., Inc.*) (protester's burden of proving timeliness).

83:31 Youngstown, OH (V, 5–31–83) (*Floyd Brown Associates*) (must challenge evaluation criteria before submitting proposal).

83:38 Sacramento, CA (IX, 6–17–83) (*Power Machine Co.*) (protest after bid opening where specification not clearly restrictive on its face) (rejection of equipment started clock).

83:39 Philadelphia, PA (III, 6–22–83) (*Fisher & Porter Co.*) (good faith negotiations delayed clock).

83:40 Elkhart, IN (V, 6–22–83) (*Penn Equipment & Tool Corp.*) (strictly construed 1 week).

83:43 Toledo, OH (V, 6–29–83) (*Industrial Pump & Equipment Corp.*) (sole source must be protested before bid opening).

83:50 Detroit, MI (V, 8–2–83) (*Dynamic Const., Co., Inc.*) (timely where no knowledge of grantee intent to award to competitor).

83:51 Santa Barbara, CA (IX, 8–15–83) (*Namtec Corp. & Union Engineering Co.*) (7 days to protest restrictive specifications) (nonresponsive bid must be protested within 1 week of learning of award) (oral notice of City Council meeting starts appeal clock).

83:54 Dorchester, MD (III, 9–20–83) (*F.E. Meyers Co.*) (specifications must be protested prior to bid opening).

83:55 Brazos River, TX (VI, 9–23–83) (*Jeffery Manufacturing Div.*) (where protester reasonably believed equipment met specifications protest may be filed after bid opening).

83:58 Evanston, WY (VIII, 10–18–83) (*WesTech Engineering, Inc.*) (protester risks late delivery of express mail protest appeal).

83:60 Tri-City, OR (X, 10–20–83) (*Donald M. Drake Co.*) (telegraphic notice received after close of business deemed timely).

83:63 Monterey, CA (IX, 11–4–83) (*Power Systems*) (protest of specifications).

Waiver

83:05 Morton, MS (IV, 1–25–83) (*Associated Const., Inc.*) (license requirement waived as technicality).

83:07 Oklahoma City, OK (VI, 2–4–83) (*D.J. Domas, Inc.*) (grantee must have rational basis for refusing to waive minor informalities).

83:09 Covington, GA (IV, 2–9–83) (*Griffin Const., Co., & Ethridge Brothers Const., Inc.*) (discretionary authority of grantee cannot be compelled by bidder).

83:32 Los Angeles, CA (IX, 6–6–83) (*Advanco Constructors, Inc.*) (irregularities in listing subcontractors must be waived as minor where IFB did not make it matter of responsiveness).

83:34 New Concord, OH (V, 6–10–83) (*Adams Robinson Enterprise, Inc.*) (failure to acknowledge receipt of addendum not waivable where material).

83:40 Elkhart, IN (V, 6–22–83) (*Penn Equipment & Tool Corp.*) (minor deviations involving bid bond surety form caused no competitive advantage).

83:46 Palatine, IL (V, 7–19–83) (*Di Paolo-Rossetti, Joint Venture*) (where MBE requirements are responsiveness matters, waiver not permitted).

83:68 Tri-City, OR (X, 12–9–83) (*Dresser Industries, Inc.*) (bidder waives protest issue by not submitting evidence).

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federal register

Tuesday
January 29, 1985

Part VII

Department of Health and Human Services

Office of Human Development Services

Head Start Program; Availability of Fiscal Year 1985 Financial Assistance and Request for Applications; Notice

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Human Development Services

[Program Announcement No. 13600.851]

Head Start Program; Availability of FY 1985 Financial Assistance and Request for Applications

AGENCY: Administration for Children, Youth and Families (ACYF), Office of Human Development Services (OHDS), Department of Health and Human Services (DHHS).

ACTION: Announcement of availability of Fiscal Year 1985 financial assistance and request for applications to establish a body to develop and operate a national program for accreditation or approval of Child Development Association (CDA) training and assessment programs and administer a national CDA credential program.

SUMMARY: The Administration for Children, Youth and Families (ACYF), OHDS, announces that competing applications will be accepted for financial assistance through a cooperative agreement to develop and operate a national program for the accreditation or approval of CDA training and assessment programs and to administer the national CDA credential program. The level of Federal support for a 30-month grant period will not exceed $2 million.

This cooperative agreement is intended to restructure the current CDA program by establishing a new structure responsible for the setting of standards for CDA training programs, the accreditation or approval of these training programs, and the issuance of the CDA credential. Specifically, this new structure will:

(1) Establish and maintain standards for CDA training;

(2) Establish a process for national accreditation or approval of CDA training institutions, patterned after the successful experience of other professions in the human services field;

(3) Award the CDA credential to successful candidates;

(4) Establish a fee structure adequate to support the CDA accreditation/approval and the credential programs.

DATE: The closing date for receipt of applications is April 1, 1985.

FOR FURTHER INFORMATION CONTACT: Clennie Murphy, Acting Associate Commissioner, Administration for Children, Youth and Families, (202) 755–2987.

SUPPLEMENTARY INFORMATION:

Statutory Authority

Human Services Reauthorization Act, Pub. L. 98–588, (Oct. 30, 1984) Section 106 amending Section 648 of the Head Start Act, 42 U.S.C. 9843.

Program Purpose

The Head Start program is designed to provide comprehensive developmental services primarily to low income preschool children, age three to the age of compulsory school attendance, and their families. To aid enrolled children to obtain their full potential, Head Start programs provide comprehensive health, nutritional, educational, social and other services. The Head Start Act was originally enacted in 1965. The current Head Start Act was enacted by Subchapter B of Chapter 8 of Title VI of the Omnibus Budget Reconciliation Act of 1981, Pub. L. 97–35, and reauthorized by the Human Services Reauthorization Act, Pub. L. 98–558.

Background of the CDA Program

In an effort to increase the number of competent staff in child care programs, the Child Development Associate (CDA) program was initiated in 1971 through a task force of early childhood education and child development specialists convened by the Office of Child Development, ACYF's predecessor agency. During the period from 1972 to 1975, the task force developed an innovative, comprehensive plan for training, assessing, and issuing credentials to child care staff that has grown into the CDA program. During this period the CDA Competency Standards, and the Assessment and Credential Award System described below were developed. In addition, 13 pilot CDA training programs were funded to develop curriculum materials consistent with the CDA Competency Standards. The system became operational in 1975, and, except for a short interval, has been in continuous operation with support from ACYF and fees for assessments and credentials paid by persons seeking the CDA credential.

The CDA program was designed to provide performance-based training and assessment, leading to the CDA credential. The CDA Competency Standards, have served as the foundation for training and assessment. The Compentency Standards include the evaluation of the candidate's ability to:

(1) Establish and maintain a safe, healthy learning environment;

(2) Advance physical and intellectual competence of the childen;

(3) Support social and emotional development and to provide guidance and discipline in the care centers or classrooms;

(4) Establish positive and productive relationships between families and children or families and child care providers;

(5) Ensure a well-run, purposeful program responsive to participant needs; and

(6) Maintain a commitment to professionalism.

Within these six areas, the CDA candidate must demonstrate thirteen specific functional areas. In addition, a person who works in a bilingual program and has demonstrated bilingual competence in either the center-based, home visitor, or family day care setting may become a Child Development Associate with a Bilingual Specialization.

An estimated 6,000 individuals participate in CDA training each year through approximately 200 training institutions with CDA programs. ACYF provides approximately $6 million per year to Head Start grantees to support Head Start staff participation in CDA training. ACYF has also developed CDA training materials that many of the CDA training programs are using today.

While CDA training is provided by many institutions, CDA assessments are conducted through one body—the CDA National Credential Program. The performance-based assessments are conducted by Local Assessment Teams (LAT). They occur in the community where the CDA candidate works. The LAT is comprised of the candidate, an advisor, a parent/community representative and a CDA representative. This team observes the candidate's work, collects information from the parents of the children in the candidate's care, reviews the education, background experience, training of the candidate, and then decides on the candidate's competence. All members of the team must agree in order for the candidate to earn the CDA credential. Documentation on the candidate and the recommendations from the LAT are reviewed by the CDA National Credential Program. If all procedures have been followed, the recommendations made by the LAT are accepted and the CDA credential is awarded. Approximately 3,000 assessments are conducted each year.

The CDA credential is national professional credential awarded to individuals on behalf of the National CDA Credential Program. Currently, the CDA Credential Commission, whose membership consists of representatives of national professional associations from the early childhood development

field, is the policy making body for the CDA program.

Current candidates for the CDA credential pay fees to the CDA National Credential Program for the assessment and the credential, including a $25 application fee, a $250 assessment fee, a $50 credential fee and a $50 credential five-year renewal fee. The actual cost for each assessment is in excess of $600. The difference between income from fees and actual costs has been subsidized by Federal grants to the National Credential Program. Bank Street College of Education currently administers the CDA National Credential Program under a Federal grant which expires in August, 1985.

In recent years, ACYF and some private foundations have provided financial support to expand the CDA program to new populations. The program is now available to home visitors, center-based providers working with infants and toddlers, and family day care providers. This expansion increases the number of persons likely to seek the CDA credential and enhances the potential for improving the quality of child care services throughout the country.

Goals and Objectives

The promotion of the supply of quality child care continues to be a high priority of the Federal government. As the number of working mothers has increased, Federal efforts have been directed at encouraging employers to address the day care needs of their employees. Working parents now benefit from Federal tax credits for child care. The CDA program is a Federally-initiated effort which has made a significant contribution to improving the quality of Head Start and other child care programs.

With society's growing concern for the quality of pre-school child care, we believe that expansion of the CDA program is timely and necessary. The centralized structure of the CDA program limits the ability to expand the program and maintain high quality with a fee structure affordable to candidates. Therefore ACYF proposes to restructure the program. Presently CDA training is provided by an estimated 200 institutions nationwide. There are no common standards or curricula for this training. We believe that the child care field needs to address these issues by establishing and applying national standards for CDA training and assessment programs.

Scope of This Program Announcement

This program announcement is intended to solicit proposals for the development and operation of a national program for accreditation or apporval of CDA training and assessment programs and the administration of a national CDA credential program.

Scope of Work

The successful applicant will be responsible for:

1. Development of an approval or accreditation process including: (a) broad-based participation by the early childhood education and child care fields; (b) utilization of individuals experienced in operating CDA training programs; (c) review of existing CDA and related training practices, policies, standards, and fee structure; (d) establishment of quality standards for CDA training and assessment programs; (e) initial implementation and operation of the approval or accreditation process within the first year.

2. Development of a process to shift responsibility from the National Credential Program to training institutions for conducting individual assessments. Within the first year, provisional approval should be provided to as many local programs as possible so that the shift in responsibility can begin. During this transitional period, the successful applicant should conduct assessments only in those areas where there is no approved CDA training and assessment program. Training institutions shall include costs for the assessment in their tuition and fees. By the end of 18 months, no local assessments shall be conducted by the successful applicant with Federal funds.

3. The successful applicant will award the CDA credential, maintain a central registry of CDAs, administer the CDA renewal system, set policy for the program and refer prospective candidates to local programs no later than September 1, 1985.

Bank Street College will manage the credential award process under an existing grant through June 1985. During July and August of 1985 continuity in services to candidates in the system must be ensured.

4. Establishment of a fee structure which will generate sufficient income to permit operation of the national accreditation and credential programs after the completion of the Federal funding period.

5. Promotion of the CDA program nationally, including working with State and local governments to include the CDA credential in their licensing standards.

Eligible Applicants

Eligible applicants must be non-profit institutions or organizations with relevant experience and demonstrated capability to complete the project as described.

Available Funds

HDS expects to award up to $1 million for the first 12 months of this cooperative agreement and an additional $1 million over the following 18 months.

Recipient Share of the Project

Recipients are required to provide a 15% non-Federal share or in-kind contribution.

Application Content

The Administration for Children, Youth and Families is requesting applicants to prepare an application which will address the following:

A. The technical approach to each of the tasks in the scope of work. The technical approach should provide a complete plan of activities including a time frame for each task

B. The applicant's capability to meet the goals and objectives of the announcement. The capability statement should describe all necesary personnel, facilities, materials and services.

C. A detailed budget for the first year. The budget should include estimates for both expenditures and income.

Availability of Forms

Application for a financial assistance award under this program announcement must be submitted on the standard forms provided for this purpose at the end of this program announcement.

Criteria for Review and Evaluation of Financial Assistance Application

Competing applications for financial assistance will be reviewed and evaluated against the following criteria.

- Process for developing quality standards and implementing an accreditation or approval process for CDA training and assessment. (25 points)

Viability of overall approach to quality standards development; extent of projected participation of early childhood education and child care field and CDA profession, including existing CDA training programs; thoroughness of detail in describing task activities; understanding of what is entailed in accreditation or approval of training and assessment programs; understanding of role of CDA in child care and statement of philosophy of CDA accreditation or approval; comprehensiveness of areas identified in which standards will be developed; viability of overall approach

to implementation and operation; adequacy of plans for promoting the accreditation or approval process; assurance that the accreditation or approval process will begin operation within the first year.

• Developing a process for shifting responsibility for assessments from the national credential program to training institutions. (15 points)

Viability of overall approach; adequacy of transitional plans ensuring assessment will be available to qualified individuals without interruption; statement of principles to guide this process; adequacy of monitoring system over CDA assessments.

• Plans for operating a national credential program for CDAs. (15 points)

Viability of overall approach to operate a credential program, maintain a central registry of CDAs, administer the CDA renewal system, set policy for the program and refer prospective candidates to local programs no later than September 1, 1985.

• Establishment of a financial plan to become independent of direct Federal support while maintaining a reasonable fee schedule affordable to prospective candidates. (20 points)

• Promoting CDA. (10 points)

Creativity and thoroughness of planning for promotion of the CDA program. Involvement of profession in increasing the acceptance and recognition of the CDA credential.

• Experience in the establishment and operation of both accreditation of credential processes. (15 points)

While not a condition for funding, special consideration will be given to applicants who demonstrate a capability and likelihood of completing the project substantially earlier than the proposed 30-month project period and/or for substantially less Federal funding than the proposed $2 million.

Application Submission

At a minimum, one signed original and two copies of the application are required. However, an additional three copies would be helpful in expediting the review process. Applications, including all attachments, must be submitted to William McCarron, Chief, Grants Management Office, OHDS Grants and Contracts Management Division, North Building, Room 1296, 330 Independence Avenue, S.W., Washington, D.C. 20201.

Application Consideration

Applications which are complete and conform to the requirements of this program announcement are subject to a competitive review and evaluation by qualified individuals. The results of the review will assist the Associate Commissioner of the Head Start Bureau to determine which applicant will be recommended for funding. The Commissioner of ACYF will approve the final selection.

After the Commissioner has approved the final selection, unsuccessful applicants will be notified in writing of this final decision. The successful applicant will be notified through the issuance of a Notice of Financial Assistance Awarded which sets forth the amount of funds awarded, the budget period for which support is given, and the total period for which project support is contemplated.

Notification Under Executive Order 12372

This program is covered under Executive Order (E.O.) 12372, "Intergovernmental Review of Federal Programs," and 45 CFR Part 100, "Intergovernmental Review of Department of Health and Human Services Programs and Activities." State Processes or directly affected State, area-wide, regional, and local officials and entities have 60 days to comment on the application, starting from the deadline date for applications submission to HDS. Each State has established a State Single Point of Contact (SPOC) to fulfill the requirements of E.O. 12372. Applicants must submit required material to the SPOCs so that HDS can obtain comments from the SPOCs as part of the award process. (Applications for programs to be administered directly by Federally recognized Indian tribes are exempt from the requirements of E.O. 12372.) Applicants should contact their SPOC as soon as possible to alert them of the prospective applications and receive specific instructions regarding the process. Required material should be sent to the SPOC as early as possible. SPOCs will submit their comments directly to Clennie H. Murphy, Jr. Associate Commissioner, Head Start Bureau, Administration for Children, Youth and Families, P.O. Box 1182, Washington, D.C. 20013. HDS will notify the State of any application received which has no indication that the State Process has had an opportunity for review.

Closing Date for Receipt of Application

The closing date for receipt of applications is April 1, 1985. Applications may be mailed or hand delivered to: William McCarron, Chief, Grants Management Office, HDS Grants and Contracts Management Division, 330 Independence Ave., SW, Room 1296–N Bldg., Washington, D.C. 20201.

Applications shall be considered as meeting the deadline if they are either:

1. Received on or before the deadline date at the HDS Grants and Contracts Management Office, or

2. Sent on or before the deadline date and received by the granting agency in time to be considered during the competitive review and evaluation process. (Applicants are cautioned to request a legibly dated U.S. Postal Service postmark or to obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.)

Late applications: Applications which do not meet these criteria are considered late applications and will not be considered in the current competition.

Hand-delivered applications: Hand-delivered applications are accepted at the HDS Grants and Contracts Management Office during the normal working hours of 8:30 A.M. to 5:00 P.M. Monday through Friday.

(Catalog of Federal Domestic Assistance Program Number 13.600, Project Head Start)

Dated: January 18, 1985.

Dodie Livingston,

Commissioner, Administration for Children, Youth and Families.

Approved: January 24, 1985.

Dorcas R. Hardy,

Assistant Secretary for Human Development Services.

Appendix A.—State Single Point of Contact List

Alabama

Mrs. Donna J. Snowden, SPOC, Alabama State Clearinghouse, Alabama Department of Economic and Community Affairs, 3465 Norman Bridge Road, Post Office Box 2939, Montgomery, Alabama 36105–0939

Arizona

Office of Economic Planning and Development, State of Arizona

Note.—Correspondence & questions concerning this state's E.O. 12372 process should be directed to: Jo Stephens, Director, Local Government Assistance, ATTN: Arizona State Clearinghouse, 1700 West Washington, Rm. 205, Phoenix, Arizona 85007, Tel. (602) 255–5004.

Arkansas

State Clearinghouse, Office of Intergovernmental Services, Department of Finance and Administration, P.O. Box 3278, Little Rock, Arkansas 72203, Tel. (501) 371–2311

California

Office of Planning and Research, 1400 Tenth Street, Sacramento, California 95814, Tel. (916) 445–0282

Colorado

State Clearinghouse, Division of Local Government, 1313 Sherman Street, Rm. 520, Denver, Colorado 80203, Tel. (303) 866–2156.

Connecticut

Gary E. King, Under Secretary, Comprehensive Planning Division, Office of Policy and Management, Hartford, Connecticut 06106–4459

Note.—Correspondence & questions concerning this state's E.O. 12372 process should be directed to: Intergovernmental Review Coordinator, Comprehensive Planning Division, Office of Policy and Management, 80 Washington Street, Hartford, Connecticut 06106–4459, Tel. (203) 566–4298.

Delaware

Executive Department, Thomas Collins Building, Dover, Delaware 19903, Attn: Franchine Booth, Tel. (302) 736–4204

Florida

Ron Fahs, Executive Office of the Governor, Office of Planning and Budgeting, The Capitol, Tallahassee, Florida 32301, Tel. (904) 488–8114.

Georgia

Charles H. Badger, Administrator, Georgia State Clearinghouse, 270 Washington Street, S.W., Atlanta, Georiga, 30334, Tel. (404) 656–3855.

Hawaii

Kent M. Keith, Director, Department of Planning and Economic Development, P.O. Box 2359, Honolulu, Hawaii 96804
For Information Contact: Hawaii State Clearinghous, Tel. (808) 548–3085.

Illinois

Tom Berkshire, Office of the Governor, State of Illinois, Springfield, Illinois 62706, Tel. (217) 782–6639.

Indiana

Ms. Susan J. Kennell, State Budget Agency, 212 State House, Indianapolis, Indiana 46204, Tel. (317) 232–5604

Iowa

Office for Planning and Programming, Capital Annex, 523 East 12th Street, Des Moines, Iowa 50319, Tel. (515) 281–6483.

Kansas

Kansas Department of Human Resources, Office of The Secretary, Attention: Judy Krueger, 401 Topeka Avenue, Topeka, Kansas 66603, Tel. (913) 296–5075.

Kentucky

Kentucky State Clearinghouse, 2nd Floor, Capital Plaza Tower, Frankfort, Kentucky 40601, Tel. (502) 564–2382.

Louisiana

Michael J. Jefferson, Dept. of Urban & Community Affairs, Office of State Clearinghouse, P.O. Box 44455, Capitol Station, Baton Rouge, Louisiana 70804, Tel. (504) 925–3722

Maine

State Planning Office, Attn: Intergovernmental Review Process, State House Station No. 38, Augusta, Maine 04333, Tel. (207) 289–3154.

Maryland

Guy W. Hagar, Director, Maryland State Clearinghouse for Intergovernmental Assistance, Department of State Planning, 301 West Preston Street, Baltimore, Maryland 21201–2365, Tel. (301) 383–7875

Massachusetts

Executive Office of Communities and Development, 100 Cambridge Street, Rm. 1401, Boston, Massachusetts 02202, Tel. (617) 727–7078.

Michigan

Carol Hoffman, Director, Office of Business and Community Development, Michigan Department of Commerce, P.O. Box 30004, Lansing, Michigan 48909, Tel. (517) 373–0933.

Mississippi

Office of Federal State Programs, Department of Planning and Policy, 1504 Walter Sillers Bldg., 500 High Street, Jackson, Mississippi 39202.
For Information Contact: Mr. Marlan Baucum. Department of Planning and Policy, Tel. (601) 359–3069.

Minnesota

Thomas N. Harren, Minnesota State Planning Agency, Capitol Square Building—Room 101, 550 Cedar Street, St. Paul, Minnesota 55101, Tel. (612) 296–3698.

Missouri

Missouri Federal Assistance Clearinghouse, Office of Administration, Division of Budget and Planning, Room 129 Capitol Building, Jefferson City, Missouri 65102, Tel. (314) 751–4834 or 751–2345.

Montana

Agnes Fipperian, Intergovernmental Review Clearinghouse, c/o Office of the Lieutenant Governor, Capitol Station, Helana, Montana 59620, Tel. (406) 444–5522.

Nebraska

Policy Research Office, P.O. Box 94601, Room 1321, State Capitol, Lincoln, Nebraska 68509, Tel. (402) 471–2414.

Nevada

Ms. Linda A. Ryan, Director, Office of Community Services, Capitol Complex, Carson City, Nevada 89710, Tel. (702) 885–4420

Note.—Correspondence and questions concerning this state's E.O. 12372 process should be directed to: John Walker, Clearinghouse Coordinator, Tel. (702) 885–4420

New Hampshire

David G. Scott, Acting Director, New Hampshire Office of State Planning, 2½ Beacon Street, Concord, New Hampshire 03301, Tel. (603) 271–2155

New Jersey

Mr. Barry Skokowski, Director, Division of Local Government Services, Department of Community Affairs, CN 803, 363 West State Street, Trenton, New Jersey 08625, Tel. (609) 292–6613

Note.—Correspondence and questions concerning this state's E.O. process should be directed to: Nelson S. Silver, State Review Process, Division of Local Government Services—CN 803, Trenton, New Jersey 08625–0803, Tel. (609) 292–9025

New Mexico

Peter C. Pence, Director, Department of Finance and Administration, State of New Mexico, 515 Don Gaspar, Santa Fe, New Mexico 87503, Tel. (505) 827–3885

New York

Director of the Budget, New York State

Note.—Correspondence and questions concerning this state's E.O. 12372 process should be directed to: New York State Clearinghouse, Division of the Budget, State Capitol, Albany, New York 12224, Tel. (518) 474–1605

North Carolina

Mrs. Chrys Baggett, Director, State Clearinghouse, Department of Administration, 116 West Jones Street, Raleigh, North Carolina 27611, Tel. (919) 733–4131

North Dakota

Office of Intergovernmental Assistance, Office of Management and Budget, 14th Floor—State Capitol, Bismarck, North Dakota 58505, Tel. (701) 224–2094

Ohio

State Clearinghouse, Office of Budget and Management, 30 East Broad Street, Columbus, Ohio 43215

For Information Contact: Mr. Leonard E. Roberts, Deputy Director, Tel. (614) 466–0699

Oklahoma

Office of Federal Assistance Management, 4545 North Lincoln Blvd., Oklahoma City, Oklahoma 73105, Tel. (405) 528–8200

Oregon

Intergovernmental Relations Division, State Clearinghouse, Executive Building, 155 Cottage Street, N.E., Salem, Oregon 97310, Tel. (503) 373–1998

Pennsylvania

Pennsylvania Intergovernmental Council, P.O. Box 1288, Harrisburg, Pennsylvania 17108, ATTN: Charles Griffiths, Executive Director, Tel. (717) 783–3700

Rhode Island

Daniel W. Varin, Chief, Rhode Island Statewide Planning Program, 265 Melrose Street, Providence, Rhode Island 02907, Tel. (401) 277–2656

South Carolina

Danny L. Cromer, Grant Services, Office of the Governor, 1205 Pendleton Street, Room 477, Columbia, South Carolina 29201, Tel. (803) 758–2417

South Dakota

Ieff Stroup, Commissioner of the Bureau of Intergovernmental Relations, Second Floor, Capitol Building, Pierre, South Dakota 57501, Tel. (605) 773–3661

Tennessee

Tennessee State Planning Office, 1800 James K. Polk Building, 505 Deaderick Street, Nashville, Tennessee 37219, Tel. (615) 741–1676

Texas

Bob McPherson, State Planning Director, Office of the Governor, Austin, Texas 78711, Tel. (512) 475–6156

Utah

Michael B. Zuhl, Director, Office of Planning and Budget, State of Utah, 116 State Capitol Building, Salt Lake City, Utah 84114, Tel. (801) 533–5245

Vermont

State Planning Office, Pavilion Office Building, 109 State Street, Montpelier, Vermont 05602, Tel. (802) 828–3326

Virginia

Robert H. Kirby, Intergovernmental Review Officer, Department of Planning and Budget, Post Office Box 1422, Richmond, Virginia 23211, Tel. (804) 786–1921

Washington

Ken Black, Washington Department of Community Development, Ninth and Columbia Building, Olympia, Washington 98504, Tel. (206) 753–2200

West Virginia

Mr. Fred Cutlip, Director, Community Development Division, Governor's Office of Economic and Community Development, Building #6, Room 553, Charleston, West Virginia 25305, Tel. (304) 348–4010

Wisconsin

Secretary Doris J. Hanson, Wisconsin Department of Administration, 101 South Webster Street—GEF 2, Madison, Wisconsin 53702, Tel. (608) 266–1212

Wyoming

Wyoming State Clearinghouse, State Planning Coordinator's Office, Capitol Building, Cheyenne, Wyoming 82002, Tel. (307) 777–7574

Virgin Islands

Federal Programs Office, Office of the Governor, The Virgin Islands of the United States, Charlotte Amalie, St. Thomas 00801, Tel. (809) 774–6511

District of Columbia

Pauline Schneider, Director, Office of Intergovernmental Relations, Room 416, District Building, Washington, DC 20004, Tel. (202) 727–6265

Puerto Rico

Nelson Soto, President, Puerto Rico Planning Board, P.O. Box 4119 Minilla Station, San Juan, Puerto Rico 00940, Tel. (809) 724–7900

Northern Mariana Islands

Planning and Budget Office, Office of the Governor, Saipan, CM 96950

Appendix B.—Instructions for Applying for Federal Assistance From HDS Programs

(OMB 0980–0016, Expires: 2/85, Clearance Pending: 2/88)

INTRODUCTION

Use of Forms

The forms included in this "kit" shall be used to apply for all new discretionary grants and cooperative agreements awarded by the Office of Human Development Services. They shall also be used to request supplemental assistance, proposed changes or amendments, and request continuation or refunding for previously approved grants or cooperative agreements from the Office of Human Development Services. An original and two copies of the forms should be submitted to the responsible grants management office. If an item cannot be answered or does not appear to be related or relevant to the assistance required, write "NA" for not applicable.

Applications

Applicants for new awards and competing continuations are required to submit a complete application which consists of Parts I (SF–424) through Part V. Applicants for new projects must include completed Standard Forms 441, Civil Rights Assurance and HHS—641, Rehabilitation Act Assurance. Applicants for additional funding (such as a non-competing continuation or supplemental grant) or amendments to a previously submitted application should include only affected pages. Previously submitted pages whose information is still current need not be resubmitted. Additionally, applicants for certain HDS programs may be subject to Executive Order 12372, Intergovernmental Review of Federal Programs (see Attachments 1 and 2). These applicants must follow the instructions provided relative to Executive Order 12372 coverage where appropriate, as listed on page 11.

Submission of Applicants

(1) Non-competing Continuation Grants—Applicants for continuation grants must submit these forms not later than 90 days prior to the budget period end date.

(2) New Projects and Competing Continuations—Applicants for Assistance to support new projects or for competing continuations should refer to program announcements for information regarding deadline dates for submission of forms.

Instructions for Completion of Part I (SF–424)

Section I

Applicants shall complete all items in Section I. If an item is not applicable, write "NA". If additional space is needed, insert an asterisk (*) and use Section IV. An explanation follows for each item.

Items

1. Mark appropriate box. Preapplication and application are described in OMB Circular A–102 and HDS program instructions. Use of the SF–424 as a Notice of Intent is at State option. HDS does not require Notice of Intent.

2a. Applicant's own control number, if desired.

2b. Date Section I is prepared.

3a. For a program covered by Executive Order 12372, enter the number assigned, if any, by the State Point of Contact Office. Applications submitted to OHDS must contain this identifier, if provided by the State Point of Contact. Note: Item 22 of this form must be completed for programs covered by E.O. 12372.

3b. Date identifier is assigned by State.

4a.–4h. Enter legal name of applicant/recipient, name of primary organizational unit which will undertake the assistance activity, complete address of applicant, and name and telephone number of person who can provide further information about this request.

IF THE PAYEE WILL BE OTHER THAN THE APPLICANT, ENTER IN THE REMARKS SECTION "PAYEE". THE PAYEE'S NAME, DEPARTMENT OR DIVISION, COMPLETE ADDRESS AND EMPLOYER IDENTIFICATION NUMBER AND DHHS ENTITY NUMBER.

If an individual's name and/or title is desired on the payment instrument, the name/or title of the designated individual must be specified.

5. Enter Employer Identification Number of applicant as assigned by the Internal Revenue Service. If the applicant organization has been assigned a DHHS Entity Number consisting of the IRS employer identification number prefixed by "1" and suffixed by a two-digit number, enter the full Entity Number. If applicant has other grants with DHHS and has been assigned a Payee Identification Number, enter PIN in parenthesis ( ) beside employer identification number.

6a. Enter the Catalog of Federal Domestic Assistance number assigned to program under which assistance is requested. If more than one program (e.g., joint funding) enter "multiple" and explain in Section IV remarks. If unknown, cite Public Law or U.S. Code.

6b. Enter the program title from Catalog of Federal Domestic Assistance. Abbreviate if necessary.

7. Enter title and appropriate description of project. For Notification of Intent, continue in Section IV if necessary to convey proper description. If project affects particular sites as, for example, construction or real property projects, attach a map showing the project location.

8. Enter appropriate letter to designate grantee type—"City" includes town, township or other municipality. If the grantee is other than that listed, specify type on "Other" line e.g., Council of Government.

Note.—Nonprofit organizations which have not previously received HDS program support must submit proof of nonprofit status.

9. Enter Governmental unit where significant and meaningful impact could be observed. List only largest unit or units is affected, such as State, county, or city. If entire unit is affected, list it rather than subunits.

10. Identify estimated number of persons *directly* benefiting from project, as described in the program narrative.

11. All applicants for new, competing continuation and non-competing continuation grants should enter the letter "A". And applicants for supplemental grant funding should enter the letter "B".

12. Enter amount requested or to be contributed during the initial funding/budget period by each contributor. Where allowable the value of inkind contributions should be included. If the action is a change in dollar amount of existing grant (a revision or augumentation), indicate only the amount of the change. For decreases, enclose the amount in parentheses. If both basic and supplemental amounts are included, breakout in Section IV. For multiple program funding use totals and show program breakdowns in remarks. Item definitions: 12a, amount requested from Federal Government; 12b, amount applicant will contribute; 12c, amount from State, if applicant is not a State; 12d, amount from local government, if applicant is not a local government; 12e, amount from any other sources, explain in Section IV. Note: Applicants for research grants should complete 12a and 12f only.

13a. Self explanatory.

13b. Enter the district(s) where most of actual work will be accomplished. If city-wide or State-wide covering several districts, write "city-wide" or "State-wide".

14. Enter appropriate letter. Definitions are:

A. *New.* A submittal for the first time for a new project or project period (includes competing continuations).

B. *Renewal.* Not applicable to HDS grant programs.

C. *Revision.* A modification to project after the initial funding/budget period and within the approved project period.

D. *Continuation.* Support for a non-competing continuation project after the initial funding/budget period and within the approved project period.

E. *Augumentation.* (Referred to elsewhere in these instructions and in other HDS publications as a "supplemental"). An application for additional funds for a project previously awarded funds in the same funding/budget period. Project nature and scope unchanged.

15. Enter approximate date project is expected to begin. If initial budget period is other than 12 months, check item 21 and explain in Part IV.

16. Enter estimated number of months to complete project after Federal funds are available.

17. Complete only for revisions (item 14c), or augumentations (Supplements) (Item 14e).

18. Date application/preapplication must be submitted to HDS in order to be eligible for funding consideration.

19. Name and address of the Federal agency to which this request is addressed. Indicate as clearly as possible the name of the office to which the application will be delivered.

20. Enter existing Federal grant identification number if this is not a new request and directly relates to a previous Federal action. Otherwise write "NA".

21. Check appropriate box as to whether Section IV of form contains remarks and/or additional remarks are attached.

Section II

Applicants will always compete either item 22a or 22b *and* items 23a and 23b. An explanation follows for each item.

22a. Complete if application is subject to Executive Order 12372 (State review and comment).

Note.—All written comments submitted by or through the State Contact must be attached, if available. Applicants are advised of the delay of funding near the end of the fiscal year, if a timely notification to the State Contact is not made.

22b. Check if application is not subject to E.O. 12372.

23a. Name and title of authorized representative of legal applicant.

23b. Self explanatory. *Note:* Authorized representative signature cannot be signed by designee.

Note.—Applicant completes only sections I and II. Section III is completed by Federal agencies.

Instructions for Completion of Part II

Negative answers will not require an explanation unless the responsible HDS program office requests more information at a later date. All "Yes" answers must be explained on a separate page in accordance with these instructions.

Item 1—Provide the name of the governing body establishing the priority system and the priority rating assigned to this project. If the priority rating is not available, give the approximate date that it will be obtained.

Item 2—Provide the name of the agency or board which issued the clearance and attach the documentation of status or approval. If the clearance is not available, give the approximate date that it will be obtained.

Item 3—Furnish the name of the approving agency and the approval date. If the approval has not been received, state approximately when it will be obtained.

Item 4—Show whether the approved comprehensive plan is State, local or regional; or, if none of these, explain the scope of the plan. Give the location where the approved plan is available for examination, and state whether this project is in conformance with the plan. If the plan is not available, explain why.

Item 5—Show the population residing or working on the Federal installation who will benefit from this project. (Federally recognized Indian reservations are not "Federal Installations")

Item 6—Show the percentage of the project work that will be conducted on Federally-owned land or leased land. Give the name of the Federal installation and its location.

Item 7—Briefly describe the possible beneficial and/or harmful effect on the environment because of the proposed project. If an adverse environmental effect is anticipated, explain what action will be taken to minimize it.

Item 8—State the number of individuals, families, businesses, or farms this project will displace. Federal agencies will provide separate instructions, if additional data is needed.

Item 9—Show the Catalog of Federal Domestic Assistance number, the program number, the type of assistance, the status, the amount of each project where there is related previous, pending or anticipated assistance from another funding source.

Instructions for Completion of Part III

This form is designed so that application can be made for funds to support one or more functions or activities. Generally, HHS funded programs do not require a breakdown by function or activity. Therefore, only Line 1 need be completed. However, Head Start, funded by the Administration for Children, Youth and Families requires that activities commonly identified by program accounts be displayed separately on individual lines (Lines 1–4 under Section A and Columns 1–4 under Section B).

Since HDS programs award funds to support activities for budget periods which are generally 12 months in duration, Section A, B, C, and D must provide budget information for the requested budget period. Section E should reflect the need for Federal assistance in subsequent budget periods.

Applicants for research grants are not required to complete information items related to non-Federal share. Rather, research cost sharing shall be negotiated separately with the funding office.

Section A—Budget Summary

Lines 1–4

Col. (a): For applications pertaining to a single grant program and *not* requiring a functional, activity or program account breakout enter on Line 1 under Column (a) the Federal Domestic Assistance Catalog program title (See attached listing). For "Head Start", enter the activities (program accounts) name and number for which funds are being requested on separate lines.

Col. (b): Enter appropriate Catalog of Federal Domestic Assistance number. For "Head Start", enter the activities (program accounts) name and number for which funds are being requested on separate lines.

Col. (c)–(g): For *new applications*, leave Columns (c) and (d) blank. For each line entry, enter in Columns (e), (f), and (g) the appropriate amounts needed to support the project for the first budget period. Applicants for research grant should make no entries in Column (f).

For *non-competing*, or *competing continuation applications*, enter in Columns (c) and (d) the estimated amounts for funds which will remain unobligated at the end of the current budget period. Enter in columns (e), (f), and (g) the appropriate amounts needed to support the project for the new budget period. (Applicants for research grants should make no entries in Columns (d) or (f). Column (g) should equal the total to Column (e) and Column (f).

For *augumentation* (supplements) and changes to existing grants, leave Columns (c) and (d) blank and enter in Columns (e) and (f) the amount of increase or decrease of Federal and non-Federal funds, as appropriate. Enter in Column (g) the new total budgeted amount (Federal and non-Federal) which includes the previously authorized total budgeted amounts for the current budget period plus or minus, as appropriate, the amounts shown in Columns (e) and (f). The amount(s) in Columns (g) should not equal the sum of the amounts in Columns (e) and (f). Applicants for research grants should make no entries in columns (d) or (f).

Line 5

Enter the totals for all columns completed.

Section B—Budget Categories—Column 1–5

In the Column heading (1) through (4), enter the same titles of the grant programs and/or program accounts shown on Lines 1 through 4, Column (a), Section A. For each grant program or activity (program account) entered in Columns (1) through (4) enter the total requirements for *Federal funds* by object class categories and enter total in Column 5.

Allowability of costs are governed by applicable cost principles set forth in Subpart Q of 45 CFR Part 74 and the HDS Grants Administration Manual.

Personnel—Line 6a: Enter the total costs of salaries and wages of applicant/grantee staff. Do not include costs of consultants or personnel costs of delegate agencies. (See Section F, Line 21, for additional requirements).

Fringe Benefits—Line 6b: Enter the total costs of fringe benefits unless treated as part of an approved indirect cost rate. Provide break-down of amounts and percentages that comprise fringe benefit costs.

Travel—Line 6c: Enter total costs of out-of-town travel for employees of the project. Do not enter costs for consultant's travel or local transportation. Provide justification for requested travel costs. (See Line 6h and Section F, Line 21, for additional instructions).

Equipment—Line 6d: Enter the total costs of all equipment to be acquired by the project. "Equipment" means an article of tangible personal property having a useful life of more than two years and an acquisition cost of $500 or more per unit. An applicant may use its own definition of equipment, provided that such a definition would at least include all tangible personal property as defined in the preceeding sentence. (See Section F, Line 21 for additional requirements).

Supplies—Line 6e: Enter the total costs of all tangible personal property (supplies) other than that included on line 6d.

Contractual—Line 6f: Enter the total costs of all contracts, including (1) procurement contracts (except those which belong on other lines such as equipment, supplies, etc.), and, (2) contracts agreements with secondary recipient organizations including delegate agencies. Also include any contracts with organizations for the provision of technical assistance. Do not

include payments to individuals on this line. Attach a list of contractors indicating the name of the organization; the purpose of the contract; statement (scope) of work; period of performance; and the estimated dollar amount of the award. If the Name of Contractor, Scope of Work and estimated total is not available or has not been negotiated, include in Line h, "Other". (Note: Whenever the applicant/grantee intends to delegate part or all of the program to another agency, the applicant must submit sections A and B of Part III, Budget Section, completed for each delegate agency by agency title, along with the required supporting information referenced in the applicable instructions. The total cost of all such agencies will be part of the amount shown on Line 6(f). Provide back-up documentation identifying Name of contractor, purpose of contract and major cost elements.

Construction—Line 6g: Enter the costs of alterations or renovation. Provide narrative justification and break-down or costs. New construction is unallowable.

Other—Line 6h: Enter the total of all other costs. Such costs, where applicable, may include, but are not limited to, insurance, food, medical and dental costs, (noncontractual), fees and travel paid directly to individual consultants, local transportation (all travel which does not require per diem is considered local travel), space and equipment rentals, printing and publication, computer use, training costs including tuition and stipends, training service costs including wage payments to individuals and supportive service payments, and staff development costs.

Total Direct Charges—Line 6i: Show the totals of Lines 6(a) through 6(h).

Indirect Charges—Line 6j: Enter the total amount of indirect costs. If no indirect costs are requested enter "none". This line should be used only when the applicant (except local governments) has an indirect cost rate approved by the Department of Health and Human Services. If rate has recently been approved, please enclose a copy of current rate. Local governments shall enter the amount of indirect costs determined in accordance with HHS requirements. In the case of training grants to other than State or local governments, the reimbursement of indirect costs will be limited to the lesser of actual indirect costs or 8 percent of the amount allowed for direct costs exclusive of any equipment charges, rental of space, tuition and fees, post-doctoral training allowances, contractual items, and alteration and renovations. It should be noted that when an indirect cost rate is requested, these costs included in the indirect cost pool should not be also charged as direct costs to the grant.

Total—Line 6k: Enter the total amounts of Lines 6(i) and 6(j). For all new competing and non-competing continuation applications, the total amount shown in Column (5), Line 6(k), should be the same as the amount shown in Section A, Column (e), Line 5.

For all supplements or changes, the total of the amount shown in Columns (1) through (4) should equal the amount shown in Section A, Line 5(e). The amount shown in Column (5) should include the cumulative total of the previously approved Federal share for the current budget period plus or minus, as appropriate, the increase or decrease of Federal fund.

Program Income—Line 7: Enter the estimated amount of income, if any, expected to be generated from this project. Do not add or subtract this amount from the total project amount. Show, in the program narrative statement, the nature and source of income.

Section C—Non-Federal Resources

Line 8–11: Enter amounts of non-Federal resources that will be used to support the project. (Applicants for research grants should not complete this Section but will negotiate appropriate cost sharing arrangements with the funding office). Provide a brief explanation, on a separate sheet, showing the type of contribution, and whether it is in cash or in-kind. If in-kind, is allowable and included, show the basis for computation including:

(1) Numbers and types of volunteers and rates at which their services are valued;

(2) Valuation of donated space (use only) including number of square feet and value assigned per square foot; and

(3) Determination of depreciation and use allowance for grantee-owned space; [Include statement whether space was purchased or constructed, totally or in part with federal funds for items (2) and (3)].

(4) Type and value of other in-kind contributions expected.

Column (a): Enter the program title or activities (program accounts) as in Column (a) Section A.

Column (b): Enter the amount of cash and in-kind contributions to be made by the applicant.

Column (c). Enter the State contribution. If the applicant is a State agency, enter the non-Federal funds to be contributed by the State other than the applicant State agency.

Column (d): Enter the amount of cash and in-kind contributions to be made from all other sources.

Column (e): Enter the totals of Columns (b), (c), and (d).

Line 12— Enter total of each of Columns (b) through (e). The amount in Column (e) should be equal to the amount on Line 5, Column (f), Section A.

Section D—Forecasted Cash Needs

Line 13— Enter the amount of Federal cash needed for this grant, by quarter, during the budget period.

Line 14— Enter the amount of cash from all other sources needed by quarter during the budget period. (Applicants for research grants should not complete this line).

Line 15— Enter the totals of amounts on Line 13 and 14.

Section E—Budget Estimates of Federal Funds Needed for Balance of Projects

*Line 16–19—*Enter in Column (a) the same program title or activities (program accounts) as in Column (a) Section A. For new or competing continuation or non-competing continuation grant applications, enter in the proper columns amounts of Federal funds which will be needed to complete the program or project over the succeeding budget periods (usually in years). Do not enter current year budget amount; enter second, third, fourth, and fifth year budget estimate needs. This Section need not be completed for Headstart applicants with indefinite project periods or for revisions or supplements for the current budget period which do not increase the general level of support.

*Line 20—*Enter the totals of each of the Columns (b) through (e).

Section F—Other Budget Information

*Line 21—*Use this space to fully explain and justify the major items included in the budget categories shown in Section B. Include sufficient detail to facilitate determination of allowability, relevance to the project, and cost benefits. Particular attention must be given to the explanation of any requested direct cost budget item which requires explicit approval by the HDS program office. Budget items which require identification and justification shall include, but not be limited to, the following:

1. Salary amounts and percentage of time worked for those key individuals who are identified in the project narrative;

2. Any foreign travel;

3. A list of all equipment (See Part III, Section B, Line 6d) and estimated cost of each item to be purchased. Need for equipment must be supported in program narrative;

4. Contractual: Major items or groups of smaller items; and

5. Other: group and major categories, e.g., consultants, local transportation, space rental, training allowances, staff training, computer equipment, etc. Provide a complete break-down of all costs that make up this category.

Line 22—Enter the type of indirect rate (provisional, final fixed) that will be in effect during the funding period, the estimated amount of the base to which the rate is applied and the total indirect expense. Also, enter the date HDS approved the rate, where applicable. Attach a copy of rate agreement if recently approved.

Line 23—Provide any other explanations required or deemed necessary.

Attachment 1

EXECUTIVE ORDER 12372 COVERAGE

1. General

Executive Order 12372, "Intergovernmental Review of Federal Programs," provides for the State and local government coordination and review of proposed Federal financial assistance. Certain applicants for HDS grants must comply with the provisions of E.O. 12372 and 45 CFR Part 100, "Intergovernmental Review of Department of Health and Human Services Programs and Activities." The following table provides a listing of all HDS assistance programs identified by Catalog of Federal Domestic Assistance Number (CFDA), and shows those programs and activities which are covered by E.O. 12372 and those which are exempt from coverage.

Federally recognized Indian Tribes are exempt from the provisions and requirements of E.O. 12372 (see 48 FR 29196 dated June 24, 1983).

States may design their own processes for reviewing and commenting on proposed Federal assistance under certain Federal programs. States adopting a review process under the E.O. will have designated a State official or organization to act as the State's "Single Point of Contact" (SPOC) for sending official State recommendations to HDS Applicants with projects subject to E.O. 12372 review must adhere to the requirements of their State processes.

2. Procedures for New and Competing Continuation Applications

E.O. 12372 requires applicants for new and competing continuation grants and cooperative agreements to coordinate their plans at the State and local levels through the State SPOC. Names and addresses of the State SPOC are listed in the **Federal Register** announcement soliciting applications or in the application kit. A current listing can also be obtained from the regional or headquarters grants management office. Potential applicants should contact their State SPOC at the earliest feasible time and notify them of their intent to apply for Federal assistance. Many State offices have their own notification forms and instructions, and applicants should obtain this material directly from them.

Applications submitted to HDS must respond to the E.O. 12372 Certification, Item 22 on Standard Form 424. HDS will notify the State SPOC of any application covered by E.O. 12372 that does not indicate that the State contact has had an opportunity to review it. Therefore, failure to notify the State of the proposed application to HDS may result in a delay of funding as HDS will not make an award without assurance of compliance with this process.

State SPOC offices have sixty (60) days after the HDS deadline date for the receipt of applications in which to review and resolve problems with the applicant and submit comments to HDS.

3. Procedures for Non-Competing Continuation Applications

Applicants for non-competing continuations of awards covered by E.O. 12372 must contact the State SPOC regarding their application at the earliest possible time. Applications submitted to HDS must respond to the E.O. 12372 Certification, Item 22 on the Standard Form 424. HDS will notify the State SPOC of the receipt of any covered program application which has no indication that the State process has had an opportunity for review.

The closing date for submission of State comments is thirty (30) days after the deadline date for receipt of applications. Applicants are advised to make claer to the SPOC that they are applying for a non-competing continuation award with a thirty day rather than a sixty (60) day review period.

Attachment 2

Catalog of Federal domestic assistance number	Discretionary grants	Mandatory or formula grants
HDS Programs and Activities Covered by Executive Order 12372		
13.600	Head Start—Basic Head Start Program, Research, Training and Technical Assistance, Demonstration, and Pilot Projects.	
13.623	Runaway Youth—all projects.	
13.628	Child Abuse and Neglect Prevention and Treatment—All projects.	State Child Abuse and Neglect Prevention and Treatment.
13.630		Developmental Disabilities—Basic Support and Advocacy.
13.631	Developmental Disabilities Special Projects.	
13.633		Aging—Title III-A & III-B, Grants for Supportive Services and Senior Centers.
13.635		Aging—Title III-C, Nutrition Services.
13.645		Child Welfare Services—Title IV-B State Grants.
13.646		Work Incentive Program (WIN).
HDS Programs and Activities Not Covered by Executive Order 12372		
13.608	Child Welfare Research & Demonstration Section 426 of Social Security Act (SSA).	
13.612	Native American Programs—Financial Assistance.	
13.632	Developmental Disabilities—University Affiliated Facilities and Satellite Centers.	
13.647	Social Services Research and Demonstration—Section 1110 of SSA.	
13.648	Child Welfare Services (426) Training.	
13.652	Adoption Opportunities—Research & Demonstration.	
13.655	Aging—Title VI, Grants to Indian Tribes.	
13.658		Title IV-E—Foster Care.
13.659		Title IV-E—Adoption Assistance.
13.661	Native American Programs—Research, Demonstration, and Evaluation.	
13.662	Native American Programs—Training and Technical Assistance.	
13.667		Social Services Block Grant.
13.668	Aging—Title IV, Research, Demonstration, & Training.	

BILLING CODE 4130-01-M

APPENDIX C

OMB Approval No. 0348-0006

FEDERAL ASSISTANCE

1. TYPE OF SUBMISSION (Mark appropriate box)
- ☐ NOTICE OF INTENT (OPTIONAL)
- ☐ PREAPPLICATION
- ☐ APPLICATION

2. APPLICANT'S APPLICATION IDENTIFIER — a. NUMBER; b. DATE (Year month day) 19

3. STATE APPLICATION IDENTIFIER — NOTE: TO BE ASSIGNED BY STATE — a. NUMBER; b. DATE ASSIGNED (Year month day) 19

Leave Blank

SECTION I—APPLICANT/RECIPIENT DATA

4. LEGAL APPLICANT/RECIPIENT
- a. Applicant Name
- b. Organization Unit
- c. Street/P.O. Box
- d. City
- e. County
- f. State
- g. ZIP Code
- h. Contact Person (Name & Telephone No.)

5. EMPLOYER IDENTIFICATION NUMBER (EIN)

6. PROGRAM (From CFDA) — a. NUMBER ☐☐*☐☐☐ MULTIPLE ☐; b. TITLE

7. TITLE OF APPLICANT'S PROJECT (Use section IV of this form to provide a summary description of the project.)

8. TYPE OF APPLICANT/RECIPIENT
A—State; B—Interstate; C—Substate Organization; D—County; E—City; F—School District; G—Special Purpose District; H—Community Action Agency; I—Higher Educational Institution; J—Indian Tribe; K—Other (Specify):
Enter appropriate letter ☐

9. AREA OF PROJECT IMPACT (Names of cities, counties, states, etc.)

10. ESTIMATED NUMBER OF PERSONS BENEFITING

11. TYPE OF ASSISTANCE
A—Basic Grant; B—Supplemental Grant; C—Loan; D—Insurance; E—Other
Enter appropriate letter(s) ☐☐

12. PROPOSED FUNDING

a. FEDERAL	$	.00
b. APPLICANT		.00
c. STATE		.00
d. LOCAL		.00
e. OTHER		.00
f. Total	$	.00

13. CONGRESSIONAL DISTRICTS OF: a. APPLICANT; b. PROJECT

14. TYPE OF APPLICATION
A—New; B—Renewal; C—Revision; D—Continuation; E—Augmentation
Enter appropriate letter ☐

15. PROJECT START DATE (Year month day) 19

16. PROJECT DURATION (Months)

17. TYPE OF CHANGE (For 14c or 14e)
A—Increase Dollars; B—Decrease Dollars; C—Increase Duration; D—Decrease Duration; E—Cancellation; F—Other (Specify):
Enter appropriate letter(s) ☐☐☐

18. DATE DUE TO FEDERAL AGENCY ► (Year month day) 19

19. FEDERAL AGENCY TO RECEIVE REQUEST
- a. ORGANIZATIONAL UNIT (IF APPROPRIATE)
- b. ADMINISTRATIVE CONTACT (IF KNOWN)
- c. ADDRESS

20. EXISTING FEDERAL GRANT IDENTIFICATION NUMBER

21. REMARKS ADDED ☐ Yes ☐ No

SECTION II—CERTIFICATION

22. THE APPLICANT CERTIFIES THAT► To the best of my knowledge and belief, data in this preapplication/application are true and correct, the document has been duly authorized by the governing body of the applicant and the applicant will comply with the attached assurances if the assistance is approved.
- a. YES, THIS NOTICE OF INTENT/PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON: DATE _____
- b. NO, PROGRAM IS NOT COVERED BY E.O. 12372 ☐ OR PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW ☐

23. CERTIFYING REPRESENTATIVE — a. TYPED NAME AND TITLE; b. SIGNATURE

24. APPLICATION RECEIVED (Year month day) 19

25. FEDERAL APPLICATION IDENTIFICATION NUMBER

26. FEDERAL GRANT IDENTIFICATION

SECTION III—FEDERAL AGENCY ACTION

27. ACTION TAKEN
- ☐ a. AWARDED
- ☐ b. REJECTED
- ☐ c. RETURNED FOR AMENDMENT
- ☐ d. RETURNED FOR E.O. 12372 SUBMISSION BY APPLICANT TO STATE
- ☐ e. DEFERRED
- ☐ f. WITHDRAWN

28. FUNDING

a. FEDERAL	$	.00
b. APPLICANT		.00
c. STATE		.00
d. LOCAL		.00
e. OTHER		.00
f. TOTAL	$	.00

29. ACTION DATE► (Year month day) 19

30. STARTING DATE (Year month date) 19

31. CONTACT FOR ADDITIONAL INFORMATION (Name and telephone number)

32. ENDING DATE (Year month date) 19

33. REMARKS ADDED ☐ Yes ☐ No

NSN 7540-01-008-8162
PREVIOUS EDITION IS NOT USABLE

424-103

STANDARD FORM 424 PAGE 1 (Rev. 4-84)
Prescribed by OMB Circular A-102

OMB NO. 0348-0006

PART II
PROJECT APPROVAL INFORMATION

Item 1.
Does this assistance request require State, local regional, or other priority rating?
_____ Yes _____ No
Name of Governing Body _____
Priority Rating _____

Item 2.
Does this assistance request require State, or local advisory, educational or health clearances?
_____ Yes _____ No
Name of Agency or Board _____
(Attach Documentation)

Item 3.
Does this assistance request require State, local, regional or other planning approval?
_____ Yes _____ No
Name of Approving Agency _____
Date _____

Item 4.
Is the proposed project covered by an approved comprehensive plan?
_____ Yes _____ No
Check one: State ☐ Local ☐ Regional ☐
Location of Plan _____

Item 5.
Will the assistance requested serve a Federal installation?
_____ Yes _____ No
Name of Federal Installation _____
Federal Population benefiting from Project _____

Item 6.
Will the assistance requested be on Federal land or installation?
_____ Yes _____ No
Name of Federal Installation _____
Location of Federal Land _____
Percent of Project _____

Item 7.
Will the assistance requested have an impact or effect on the environment
_____Yes _____ No
See instructions for additional information to be provided.

Item 8.
Will the assistance requested cause the displacement of individuals, families, businesses, or farms?
_____ Yes _____ No
Number of:
Individuals _____
Families _____
Businesses _____
Farms _____

Item 9.
Is there other related assistance on this project previous, pending, or anticipated
_____Yes _____ No
See instructions for additional information to be provided.

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PART III - BUDGET INFORMATION

SECTION A - BUDGET SUMMARY

Grant Program, Function or Activity (a)	Federal Catalog No. (b)	Estimated Unobligated Funds		New or Revised Budget		
		Federal (c)	Non-Federal (d)	Federal (e)	Non-Federal (f)	Total (g)
1.		$	$	$	$	$
2.						
3.						
4.						
5. TOTALS		$	$	$	$	$

SECTION B - BUDGET CATEGORIES

6. Object Class Categories	- Grant Program, Function or Activity				Total
	(1)	(2)	(3)	(4)	(5)
a. Personnel	$	$	$	$	$
b. Fringe Benefits					
c. Travel					
d. Equipment					
e. Supplies					
f. Contractual					
g. Construction					
h. Other					
i. Total Direct Charges					
j. Indirect Charges					
k. TOTALS	$	$	$	$	$
7. Program Income	$	$	$	$	$

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SECTION C - NON-FEDERAL RESOURCES

(a) Grant Program	(b) APPLICANT	(c) STATE	(d) OTHER SOURCES	(e) TOTALS
8.	$	$	$	$
9.				
10.				
11.				
12. TOTALS	$	$	$	$

SECTION D - FORECASTED CASH NEEDS

	Total for 1st Year	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
13. Federal	$	$	$	$	$
14. Non-Federal					
15. TOTAL	$	$	$	$	$

SECTION E - BUDGET ESTIMATES OF FEDERAL FUNDS NEEDED FOR BALANCE OF THE PROJECT

(a) Grant Program	FUTURE FUNDING PERIODS (YEARS)			
	(b) FIRST	(c) SECOND	(d) THIRD	(e) FOURTH
16.	$	$	$	$
17.				
18.				
19.				
20. TOTALS	$	$	$	$

SECTION F - OTHER BUDGET INFORMATION
(Attach Additional Sheets if Necessary)

21. Direct Charges:

22. Indirect Charges:

23. Remarks:

PART IV PROGRAM NARRATIVE (Attach per instruction)

PART V

ASSURANCES

The Applicant hereby assures and certifies that he will comply with the regulations, policies, guidelines and requirements, including 45 CFR Part 74, and OMB Circulars No. A-102 and A-110, as they relate to the application, acceptance and use of Federal funds for this federally-assisted project. Also the Applicant assures and certifies to the grant that:

1. It possesses legal authority to apply for the grant; that a resolution, motion or similar action has been duly adopted or passed as an official act of the applicant's governing body, authorizing the filing of the application, including all understandings and assurances contained therein, and directing and authorizing the person identified as the official representative of the applicant to act in connection with the application and to provide such additional information as may be required.

2. It will comply with Title VI of the Civil Rights Act of 1964 (P.L. 88-352) and in accordance with Title VI of that Act, no person in the United States shall, on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be otherwise subjected to discrimination under any program or activity for which the applicant receives Federal financial assistance and will immediately take any measures necessary to effectuate this agreement.

3. It will comply with Title VI of the Civil Rights Act of 1964 (42 USC 2000d) prohibiting employment discrimination where (1) the primary purpose of a grant is to provide employment or (2) discriminatory employment practices will result in unequal treatment of persons who are or should be benefiting from the grant-aided activity.

4. It will comply with requirements of the provisions of the Uniform Relocation Assistance and Real Property Acquisition Act of 1970 (P.L. 91-646) which provides for fair and equitable treatment of persons displaced as a result of Federal and federally-assisted programs.

5. It will comply with the provisions of the Hatch Act which limit the political activity of employees.

6. It will comply with the minimum wage and maximum hours provisions of the Federal Fair Labor Standards Act, as they apply to hospital and educational institution employees of State and local governments.

7. It will establish safeguards to prohibit employees from using their positions for a purpose that is or gives the appearance of being motivated by a desire for private gain for themselves or others, particularly those with whom they have family, business, or other ties.

8. It will give the sponsoring agency or the Comptroller General through any authorized representative the access to and the right to examine all records, books, papers, or documents related to the grant.

9. It will comply with all requirements imposed by the Federal sponsoring agency concerning special requirements of law, program requirements, and other administrative requirements.

10. It will insure that the facilities under its ownership, lease or supervision which shall be utilized in the accomplishment of the project are not listed on the Environmental Protection Agency's (EPA) list of Violating Facilities and that it will notify the Federal grantor agency of the receipt of any communication from the Director of the EPA Office of Federal Activities indicating that a facility to be used in the project is under consideration for listing by the EPA.

The phrase "Federal financial assistance" includes any form of loan, grant, guaranty, insurance payment, rebate, subsidy, disaster assistance loan or grant, or any other form of direct or indirect Federal assistance.

11. It will comply with the flood insurance purchase requirements of Section 102(a) of the Flood Disaster Protection Act of 1973, Public Law 93-234, 87 Stat. 975, approved December 31, 1976. Section 102(a) requires, on and after March 2, 1975, the purchase of flood insurance in communities where such insurance is available as a condition for the receipt of any Federal financial assistance for construction or acquisition purposes for use in any area that has been identified by the Secretary of the Department of Housing and Urban Development as an area having special flood hazards.

12. It will assist the Federal grantor agency in its compliance with Section 106 of the National Historic Preservation Act of 1966 as amended (16 U.S.C. 470), Executive Order 11593, and the Archeological and Historic Preservation Act of 1966 (16 U.S.C. 469a-1 et seq.) by (a) consulting with the State Historic Preservation Officer on the conduct of investigations, as necessary, to identify properties listed in or eligible for inclusion in the National Register of Historic Places that are subject to adverse effects (see 36 CFR Part 800.8) by the activity and notifying the Federal grantor agency of the existence of any such properties, and by (b) complying with all requirements established by the Federal grantor agency to avoid or mitigate adverse effects upon such properties.

13. Applicants for the Administration for Native Americans Programs, hereby certify in accordance with 45 CFR 1336.53, that the financial assistance provided by the Office of Human Development Services for the specified activities to be performed under this program, will be in addition to, and not in substitution for, comparable activities provided without Federal assistance.

14. It will comply with the Age Discrimination Act of 1975 which provides that: No person in the United States shall, on the basis of age be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any program or activity for which the applicant receives Federal financial assistance.

15. It will comply with Section 504 of the Rehabilitation Act of 1973, as amended (29 U.S.C. 794), all requirements imposed by the applicable HHS regulation (45 C.F.R. Part 84), and all guidelines and interpretations issued pursuant thereto.

[FR Doc. 85-2192 Filed 1-28-85; 8:45 am]
BILLING CODE 4130-01-C

federal register

Tuesday
January 29, 1985

Part VIII

Department of Transportation

Federal Aviation Administration

14 CFR Parts 21, 25, and 36

Proposed Revision of Standards Governing the Noise Certification of Aircraft; Proposed Rulemaking

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 21, 25 and 36

[Docket No. 23340; Notice No. 85-2]

Proposed Revision of Standards Governing the Noise Certification of Aircraft

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of Proposed Rulemaking (NPRM).

SUMMARY: This notice proposes to revise certain provisions of the regulations prescribing requirements for aircraft noise certification to make them more understandable and easier to use. This proposal also contains substantive regulatory changes needed to simplify test requirements or minimize paperwork and recordkeeping requirements placed upon applicants by the current requirements. In large part, this proposal is based on the body of good engineering practice that has developed over the thirteen years since the original adoption of Part 36. These proposals also result from comments received from the general public and aviation industry in response to a Petition for Rulemaking from the Aerospace Industries Association of America. This proposal is part of the President's regulatory reform program to simplify regulations and reduce paperwork burdens.

DATE: Comments must be recieved on or before April 24, 1985.

ADDRESSES: Send comments on the rule in duplicate to:

Federal Aviation Administration, Office of the Chief Counsel, Attn: Rules Docket (AGC-204), Docket No. 23340, 800 Independence Avenue, SW., Washington, D.C. 20591;

Or deliver comments in duplicate to:

FAA Rules Docket, Room 916, 800 Independence Avenue, SW., Washington, D.C. 20591

Comments may be examined in the Rules Docket, weekdays except Federal Holidays, between 8:30 a.m., and 5:00 p.m.

FOR FURTHER INFORMATION CONTACT: Mr. Richard Tedrick, Noise Policy and Regulatory Branch (AFE-110), Noise Abatement Division, Office of Environment and Energy, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, D.C. 20591; telephone (202) 755-9027.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposals. Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposals. Communications should identify the regulatory docket or notice number and be submitted in duplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket No. 23340." The postcard will be date/time stamped and returned to the commenter. All communications received before the specified closing date for comments will be considered by the Administrator before taking action on the proposed rule. The proposals contained in this notice may be changed in the light of comments received. All comments submitted will be available for examination in the Rules Docket both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

Any person may obtain a copy of this notice of proposed rulemaking (NPRM) by submitting a request to the Federal Aviation Administration, Office of Public Affairs, Attention: Public Information Center, APA-430, 800 Independence Avenue, SW., Washington, D.C. 20591, or by calling (202) 426-8058. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRMs should also request a copy of Advisory Circular No. 11-2 which describes the application procedure.

Synopsis of the Proposal

Part 36 of the Federal Aviation Regulations (14 CFR Part 36) contains noise standards for aircraft type and airworthiness certification. As the part is currently organized, Subparts B and C and Appendices A, B and C apply to transport category large airplanes and subsonic turbojet powered airplanes regardless of category. This Notice proposes to revise these sections of the Part to better reflect the actual technical basis for noise certification of aircraft. Substantive changes are proposed in the testing and in the recordkeeping and reporting requirements. As proposed, the Federal Aviation Administration (FAA) believes that while there would be a substantial cost reduction accrued as a result of these proposals, there will be no net increase or decrease in stringency for any class of aircraft. The FAA also believes that no increase or decrease in aircraft noise levels would result from the adoption of these proposals.

Changes in Test Requirements

The FAA proposes to make a number of changes to the noise certification test requirements to simplify the procedures, to clarify the content or intent of the tests, to update equipment specifications to better accommodate the use of modern digital electronics, and to further reduce the number of full flight tests conducted solely for approval of relatively minor aircraft modifications. One such change involves dropping from four to two the minimum number of sideline noise measuring stations used to define the maximum sideline noise. By placing the remaining microphones on either side of the point where the jet aircraft reaches 1000 feet altitude, the maximum noise can be determined at significantly lower costs for equipment, installation, calibration and data reduction.

Similarly, relative humidity and wind limits on test conditions would be opened up to maximize available test sites and usable days at those sites. The humidity limit, critical to the absorption of sound with distance, would be increased for those applicants using higher-precision instruments, while the proposed wind limit increase is based on experience. The requirement which specifies the location of the meteorological instrumentation is clarified to require that the weather be measured in the vicinity of the noise measuring stations, rather than at the nearest airport.

A number of technical changes are proposed to the analyzer specifications and to the data reporting requirements to facilities the use of a wider variety of instrumentation, particularly the newer digital analyzers. Further, because recent computer processing advances make it possible to use data closer to the ambient noise floor and in some cases to reconstruct data where parts of the spectrum are below the ambient, greater flexibility is proposed for the FAA in approving test and analysis procedures.

One of the major impacts of these proposals would be to provide clearer guidelines on the use of non-flight, supplemental tests to meet Part 36 regulatory requirements. The cost of noise certification of a single jet aircraft type often runs from several hundred thousand dollars to well over a million. Where a long production run of a complex and sophisticated aircraft is anticipated, this cost is generally insignificant when compared to the total development cost of the project. However, to meet the increasingly competitive nature of aviation in this decade, aircraft manufacturers have shortened production runs of standard models and now produce families of related short production run versions. A number of the changes in this proposal would make it easier to collect a flight data base of sufficient quality and breadth from the first aircraft in such a family that other related aircraft can be noise certificated using that data base supplemented by only relatively simple and inexpensive tests and analyses. For instance, under this proposal noise data from static tests conducted at either the engine or aircraft manufacturer's ground facilities may be approved, as appropriate, by FAA certificating authorities.

Changes in Documentation Requirements

It is anticipated that the documentation requirements on indsutry and on individual applicants would be reduced as a result of this proposal. These changes would improve the responsiveness of the FAA to initiatives from the private sector and would result in lower expenditures in manpower and effort by the Government in the review and approval of certification documents.

The changes already discussed in eliminating requirements for prior FAA approval of certain test procedures should greatly simplify the paperwork prior to the test, as well as simplify the test itself. As proposed in this notice, Part 36 would retain the requirement for an approved test plan, albeit a simpler one. Similarly, the certification report which contains the engineering data supporting the certification would also continue.

The paperwork after certification, however, is where this proposal will have its greatest effect. Currently, Part 36 requires that Airplane Flight Manuals (AFM) must contain all procedures that are employed in the flight test, the certificated noise levels, any weight limitations that were required to meet the noise level requirements, and "other information for the flight crew." While this did not appear to be an onerous burden at the time Part 36 was adopted, the FAA has found a number of situations where these seemingly simple requirements have resulted in an outlandish distortion of the legitimate functions of the AFM. Several large commercial jet aircraft types have certificated more than five thousand different versions each. As a result, the AFMs contain hundreds of pages of noise "information." Under these circumstances, it is often extremely difficult to identify which data are applicable to any particular airplane on a given day. However, a copy of the AFM is currently required to be carried on board every airplane.

After careful consideration of the issue, the FAA believes that it is appropriate to consider simplification in the Airplane Flight Manual reporting requirements. The AFM is a required document providing information necessary for the safe operation of the airplane. Aircraft weight limits or operating configurations required to meet Part 36 certification are placed in the limitations section of the AFM. However beyond this, the FAA now feels that only a minimum requirement for a Part 36 compliance statement and the takeoff, approach, and sideline noise levels for that specific airplane hardware configuration are necessary. Thus, the FAA proposes to clarify Parts 25 and 36 to preclude the continuing inclusion of needless inappropriate information in the Airplane Flight Manual.

Other Changes

The acoustical changes provisions of Part 21 would be clarified by specifically excepting from the noise certification requirements several temporary configurations and conditions used for maintenance. Since none of these conditions represents the permanent configuration of any aircraft type, the FAA feels that this action is consistent with Section 611 of the Federal Aviation Act (as amended).

Numerous references to obsolete dates and conditions would be removed to shorten and simplify Part 36 and several sections would be retitled more appropriately. All these proposed changes would aid in the clarification of both the rule and its intent.

Regulatory History

Since its adoption in November 1969, FAR Part 36 has been the basis for all Federal aircraft noise regulations in the United States. That regulation was structured to provide a firm, consistent foundation for subsequent rulemaking activities to abate and control aircraft noise. Part 36, therefore, includes precise instructions concerning the acquisition, processing, and documentation of noise data from inflight aircrtaft. As originally promulgated, Part 36 applied only to turbojet aircraft and propeller-driven transport category airplanes over 12,500 pounds maximum gross weight.

In 1975, noise certification standards for propeller-driven small airplanes were added. The noise level requirements for certain new turbojets and transport category airplanes were lowered in 1977. These lower noise level standards were applied in 1978 to derivations of older aircraft types. Standards for Concorde supersonic transport airplanes were also adopted in 1978.

Amendment 36-9, which was adopted in 1978, widely revised the test and analysis specifications contained in Appendices A and B of Part 36. The specifications were expanded to include technical details that had been omitted from the original publication. An example of this was the addition of a section on the calibration of acoustical test equipment. Other changes were made to bring FAR Part 36 into agreement with international standards on noise measurement and with the procedures adopted for noise certification by the International Civil Aviation Organization (ICAO).

On October 28, 1982, the FAA published for public comment a petition from the Aerospace Industries Association of America (AIA), on behalf of its member aircraft manufacturers, for amendment of FAR Parts 21 and 36. A discussion of the issues raised by this petition follows.

Petition for Rulemaking

Although this Notice is largely based upon an eighteen month review project initiated as a part of the Administration's regulatory reform program, the Notice was also influenced by a Petition for Rulemaking (47 FR 47854; October 28, 1982). This petition, from the Aerospace Industries Association of America (AIA) on behalf of its member aircraft manufacturers, was for amendment of Parts 21 and 36 of the Federal Aviation Regulations (14 CFR Parts 21 and 36). The AIA petition concerned the rules for turbojet airplanes and proposed: (a) Retaining the basic noise requirements that must be met for airplane noise certification; (b) deleting the detailed noise measurement and analysis specifications from the rule and issuing Advisory Circulars containing compliance demonstration techniques currently approved by the FAA; (c) simplifying procedures for noise

information reporting requirements in the Airplane FLight Manual; and (d) amending the acoustical change provisions of 14 CFR Part 21 to eliminate multiple compliance requirements such as demonstrations for non-standard operating configurations and alternative takeoff thrust options.

In response to the petition, the FAA opened Docket No. 23340 and accepted public comments and data until January 20, 1983. To assist the FAA in its review, comments were invited on ten specific issues raised in the petition. The following summary of the comments submitted to the Docket and the disposition of the issues is organized accordingly.

1. *Ways in which the "Regulation by Objective" (RBO) concept could be implemented within the framework and objectives of Parts 21 and 36.*

The majority of respondents (9 of 14 or 64%) felt that the present noise certification process must be maintained in order to retain the integrity of the certification process. However, a number of these respondents felt that certain segments of Parts 36 and 21 should be streamlined and updated to include new certification techniques recently introduced. It was felt that RBO would seriously undermine the technical validity of noise certification, hence lead to an eventual decline in noise standards. Many opponents to the AIA proposal felt that until RBO becomes a firm commitment on the part of the FAA, a program as such would not be "workable." Two respondents commented on the present "immature and unproven status" of the RBO.

Several respondents felt the AIA petition was directed only toward easing the burden of noise certification for the larger transport category planes and did not address specific noise certification issues pertinent to other types of aircraft, such as executive jet aircraft.

After considering these comments, the FAA is concerned that RBO (at least in this particular petition) was not adequately explained and detailed. Since the petition lacked specificity, commenters on both sides of the issue were left to their imaginations and to discuss their respective philosophies of regulation. The proposals contained in this Notice are more specific and cannot be labeled "Regulation by Objective." However, this is largely immaterial, since the proposals represent the best of current practice and thirteen years of experience by both FAA and industry.

2. *Cost savings and/or impacts that could be realized by adoption of RBO.*

Those in favor of the RBO approach to noise certification approved of it specifically because of the cost savings. No respondent offered any specific figures on potential cost savings, using instead AIA estimates. The AIA had previously estimated that up to 50% of noise certification costs could be saved in demonstration flight time alone. Additional savings were projected in administrative costs both to the FAA and to manufacturers.

However, opposing views were concerned about whether the cost savings would be worth the possible degradation of the noise certification process. For instance, one commenter claimed that "if measurement and analyses standards are stipulated in an Advisory Circular they will have to be regarded as negotiable and subject to possible relaxation and the international acceptability of FAA noise certification may as a result be called into question. This would place additional burdens upon the manufacturer."

The FAA shares the concerns expressed here. While it is important to minimize costs for both industry and Government, it is vital that the validity and reputation of U.S. noise certification actions should not be diminished. Further, the FAA does not want the process to create or to widen any differences between U.S. and ICAO aircraft noise certification levels or stringencies. The AIA petition, on this point, expressed the desire that the changes they recommended be carefully coordinated to eliminate already existing differences.

This Notice proposes to update specific certification measurement and analysis procedures on the basis of both national and international experience. The choice of procedures within the broad framework of FAR Part 36 and the responsibility of documenting the certification using those procedures would still be with the aircraft manufacturers under this proposal. The FAA would continue to approve Test Plans and ensure that the plan was followed in obtaining the certificated noise levels. However, the use of more modern equipment, instrumentation and methods would provide cost savings. Further, simplifications in the requirements (such as reductions in the number of sideline measurements) and increased use of supplemental tests (such as engine static tests in certifications of families of aircraft) would result in significant cost savings.

3. *Need for the Airplane Flight Manual (AFM) to document the results of noise certification.*

Nine of the fourteen respondents to the Docket commented upon this issue. About half of these felt that the elaborate noise level data currently included as part of the Flight Manual serve no operational purpose whatsoever. One commentator mentioned that there are certain other items which have direct effect on operations which are left out of the Flight Manual; hence there should be no need to include noise data. Four commenters felt that noise data could be better disseminated through other channels, such as advisory circulars, type certificate data sheets (TCDS), or the aviation safety analysis system.

A number of commentators in favor of retaining the noise certification documentation in the Flight Manual believed the manual could be simplified to eliminate irrelevant information, such as detailed enumeration of noise demonstration conditions. Several respondents suggested that a different noise unit such as the A-weighted decibel would be more responsive to airport user needs than the Effective Perceived Noise Level used for certification procedures.

The five respondents in favor of the continued use of the Flight Manual felt that the Flight Manual, containing official FAA noise data, is the most readily available and detailed document concerning noise level data. The Flying Tigers comments specifically questioned whether current information, though "questionable in usefulness," would be readily available through other means.

An association of business aircraft owners and operators expressed strong opposition to deleting the aircraft noise levels from the AFM. In fact, they went on to suggest that the AFM data should be expanded to provide the noise levels in at least one additional noise unit and to provide these data at "various conditions of weight, power." However, the various manufacturers' associations did not agree. They felt that very few airport authorities use or understand the noise data which are currently in the manual and thus "the requirement to publish the FAR 36 certification data in the AFM provides no useful data to the pilot in operations of the aircraft and should be deleted."

The FAA, after careful consideration of all of these comments and opinions, agrees that some simplification and clarification of the Airplane Flight Manual documentation requirements is necessary. Specifically, there does not appear to be any need to continue to use this forum to publish the flight operational procedures used during the noise certification tests. Therefore, it is proposed to eliminate that requirement. Beyond this, recent FAA experience indicates that there is wide variation in flight manuals between various

companies and that this variation largely results from lack of clarity in the current rule language. Accordingly, the FAA is proposing specific wording to eliminate this problem.

4. *Alternatives to the Airplane Flight Manual for documenting noise certification.*

The respondents on this issue suggested several alternatives to the AFM for documenting noise certification. An association of U.S. air carriers suggested that one possible alternative "would be an Engineering Report from the applicant to the FAA, with a letter response from FAA signifying that all noise certification requirements have been met."

Both the AIA and the General Aviation Manufacturers Association (GAMA) recommended the use of FAA Advisory Circulars which are designed for quick and easy updating. GAMA noted that Advisory Circulars have "the advantage of making more data available at one time, to a large number of people." They went on to suggest that additional data formats might be developed to present data resulting from use of low noise operating procedures. While the FAA endorses this suggestion, the expansion of the present Advisory Circular format does not require rulemaking action and will be considered separately.

5. *Excepting "nonstandard configurations" and derated engines from individual noise certification action.*

The majority of respondents felt that exceptions should be allowed for all multiple configuration demonstrations. They believed that sound differences are "inperceptible" and may be discernable only through analysis and not measurement. Comment was made that no other ICAO members state requires noise certification for different configurations. The British Civil Aviation Authority agrees with the AIA provided that the configuration is only temporary in nature. The CAA maintains that the environmental impact of such aircraft configurations is small.

Those opposing the exception feel that significant differences exist between different configurations, specifically between standard and stretched versions and between different engine complements. The Airport Operators Council International (AOCI) considers the AIA proposal "completely unrealistic." According to the opponents, basing compliance on a single reference airplane configuration and on one takeoff and landing procedure does not appear warranted based on past observations. The Flying Tigers object "vigorously" to the AIA proposal to eliminate noise certification at alternate thrust ratings. It has been their experience that alternate thrust ratings "can be of significant value when planning noise sensitive takeoffs at less than maximum takeoff gross weight."

The FAA believes that some of the comments cited above are based upon a misinterpretation of the petitioner's intent. It is the FAA's view that the AIA intended to seek an exception for configurations that, by their very nature, would not constitute the standard, or normal, operating configuration of the aircraft. One such configuration would be that where an engine is ferried from one point to another (presumably for maintenance purposes) by fastening it to the outside of the airplane in a location not normally occupied by an engine. To the extent that such configurations can be identified unambiguously, the FAA intends to except them.

6. *Means for simplifying the definition of and documentation for "acoustical changes."*

Only four respondents specifically addressed this proposal. One commentator agreed "in principle" since they were not directly affected. The other comment was a further reiteration from AIA of their initial proposal. The third, Mr. Edward Gaydos, believes that a derivative design "which incorporates the same engine-nacelle combination as the parent design, should not be expected to have noise levels greater than the parent design . . . and therefore should not be considered an acoustical change."

The FAA endorses these suggestions in principle.This Notice proposes to simplify the requirements somewhat while preserving the data quality of the present Part 36 requirements.

Since the petition did not propose specific simplifications, the public was unable to provide specific comments. However, the publication of this Notice will provide the public with the opportunity to comment on a series of definite proposals.

7. *Simplified (or alternative) noise test procedures and methods for correcting test results to Part 36 standard day conditions.*

Again, only four comments were received on this issue. Those commentors associated with aircraft manufacturing supported the idea of simplifying the existing test procedures. In part, this position reflected a concern for the cost of conducting the noise certification tests themselves. However, the major thrust of the argument was that, regardless of cost, knowledge of factors affecting noise measurements has increased significantly over the fifteen years that airplanes have been subject to noise certification requirements.

Only one commentor, a foreign certification authority, flatly opposed the concept of simplification citing the long record of reliability of the present methods and objecting to any deviation from international standards adopted by ICAO. Another foreign certification authority expressed, "with qualifications," approval of the principal of simplification. However, their comments also expressed preference for an evolutionary process in developing equivalent procedures rather than a sudden shift to vaguer, more generalized requirements.

After consideration of all these comments, the FAA agrees with the last cited commenter. It is obvious on the basis of nearly fifteen years' experience that the current test and correction procedures can and should be opened up somewhat. The proposals contained herein are intended to do exactly that. They are intended to lower the cost and complexity of noise certification while making no changes in the accuracy or reliability of the noise values derived from those tests.

8. *Coordination and comparison with the international noise certification procedures (ICAO Annex 16).*

Overwhelming support was given to coordinating FAA and ICAO standards. A point of discussion was the leadership position taken by the FAA in implementing of ICAO standards. The question is not whether coordination should exist between the two organizations, but whether the AIA proposal, if accepted by the FAA, will appeal to ICAO membership. Those respondents favoring the AIA proposal felt the FAA should lead the way in encouraging ICAO to adopt similar proposals.

Opponents of the AIA proposal believed that the amendments would only cause disagreement among the two organizations, thus hindering cooperation. The Dutch government was prompted to say, "it could well be that the American aircraft manufacturers will be faced with a problem with regard to the acceptance by foreign aviation authorities of their compliance demonstration to the ICAO Annex 16 requirements."

The FAA believes that commenters' stated objections to the AIA proposals lie principally with the concept of RBO. Since RBO is not included in this NPRM, the FAA expects that the expressed concerns about international harmony should be moot. Further, many of the three dozen specific proposed word

changes to Part 36 are intended to eliminate minor wording differences that have grown up over the years between the two standards. As a result, it is expected that this Notice will be generally viewed as a significant step toward international harmonization.

9. *Effectivity and applicability of the proposed rule.*

Only those in favor of the proposal commented on the issue of applicability. They believed the rules should be effective upon issuance applicable to any new type aircraft for which an application was initiated after the date the amended rule was issued. Under the petition, only certifications of large transport category airplanes and subsonic turbojet airplanes would be affected. GAMA felt the "concept" of the proposed rule change could also be applied to small propeller-driven airplanes.

10. *Stringency and technical validity of noise certification and noise data collected under the proposed rule modifications.*

Since actual noise limits would not have been altered by the AIA proposal, those in favor of the proposal believed that no change would occur in the stringency and technical validity of noise certification. One respondent mentioned that stringency and technical validity are not necessarily related. The proponents belief that data quality "may even improve" due to new techniques was disputed by the opponents. These commentators believed that questions may arise concerning a specific noise test due to different noise gathering techniques, thus creating a lack of faith in the FAA's noise certification process. Some even saw the AIA proposal as the beginning of the dismantling of existing noise rules and limits under the guise of regulation by objective.

The FAA does not see it that way. While the AIA petition was vague in many respects, the FAA does not believe that its purpose was to dismantle or impede U.S. aircraft noise certification. Such a result would be counterproductive and would cause more problems than the slight savings would justify. However, the noise certification rules do not appear to be a suitable candidate for conversion to RBO. Accordingly, this Notice proposes specific wording changes to outmoded, outdated, and unclear regulatory passages, rather than the fundamental sweeping changes necessary to incorporate RBO.

Need for Regulation

Because FAR Part 36 has been regarded generally as both fair and reasonable, the noise certification program in the United States has been effective in maintaining a balance between legitimate environmental concerns and development of economically viable aircraft. However, as with any regulation, there has gradually arisen a need to review and overhaul the regulation in order to maintain that balance. In this particular instance, the need arises mainly from two developments.

The first is the recognition that many of the time-phased noise certification requirements that were originally written into Part 36 or introduced in subsequent amendments are simply no longer pertinent to anyone. This is particularly true of requirements that were based on the original date of application for new or amended type certificates. As amendments were added, applicants who had applied prior to the effective date of the amendment were "grandfathered" so as to not place undue burden on those who, in good faith, had already begun development. However, as those applicants completed their programs the need for such grandfathering provisions disappeared. Accordingly, many of the amendments proposed in this Notice are to delete such outdated provisions and to renumber or restructure the remaining sections. This action will greatly clarify the intent and application of the Part.

A second impetus to the proposed revisions comes from changes in the aircraft industry itself. Partly as a result of airline deregulation, airplane manufacturers have found it necessary to certificate and deliver more specialized versions of the same aircraft type. This has the effect of developing families of related short production run aircraft. Since there is no technical reason for requiring each version to be individually flight tested, Part 36 needs amendment to allow new, alternative, simpler tests (such as engine static tests) and analysis procedures. Related simplifications are also necessary in the documentation requirements to minimize paperwork burdens on the private sector. In the case of the Aircraft Flight Manual, it is also necessary to clarify the requirements for the noise section to ensure that only data pertinent to the specific aircraft are included.

Discussion of the Proposal

Acoustical Change

In the United States, noise certification of aircraft is an integral part of the total airworthiness certification process. The requirement to meet FAR Part 36 noise standards is triggered by the airworthiness certification procedures of Part 21. This is very specifically true of acoustical changes. These are changes to the aircraft type design which might affect the noise emission characteristics of the aircraft. The definition of acoustical change and the requirement to meet Part 36 standards for certain types of design changes meeting that definition are in Part 21. Therefore, in proposing to modify the acoustical change requirements for certain aircraft, the FAA proposes to modify § 21.93(b) of FAR Part 21.

Specifically, the FAA proposes to exempt from the definition of acoustical change for turbojet aircraft and transport category large aircraft (a) gear down flight with one or more retractable landing gear during the entire flight and (b) spare engine and nacelle carriage external to the skin of the airplane and the return of the pylon or other external mount. These two conditions add considerable drag to the aircraft and are only flown in unusual circumstances. For example, external spare engine and nacelle carriage is generally only necessary to support the unscheduled maintenance of a disabled aircraft. Because it is uneconomic to fly extended periods with the severely increased drag imposed by either of the two proposed exemption conditions, the FAA does not believe that they should be subject to the same noise certification requirements as permanent, in-service configurations.

Aircraft Flight Manual

Over the past several years, there has been some concern that the aircraft operational limits, if any, that are estabished as a result of FAR 36 type certification are not being expressed properly in the Aircraft Flight Manual (AFM) when combined with the airworthiness limitations. To clarify the intent of the existing regulations, it is proposed to add clarifying language in Part 25 (where the other AFM requirements are listed) and in Part 36. The Part 25 change would clarify the maximum certificated weight of the airplane when it is necessary to limit the maximum gross weight in order to meet the noise limits of Part 36.

Similarly, Part 36 would be amended to clarify that there can only be one takeoff, one approach, and one sideline noise value developed and reported as the certificated values in the AFM. If the manufacturer wants to put noise numbers for other conditions in the AFM, they must be segregated and identified as information separate from the certificated noise levels values. While this Notice does not propose to

change this requirement, it more clearly states its intent. It is also proposed to clarify use of the terms, Stage 1, Stage 2, and Stage 3 airplanes, by categorically stating that each airplane must be one or another but may not be identified as complying with more than one Stage.

Obsolete Dates and Conditions

Numerous reference to dates and conditions that are no longer pertinent to present and future applicants for type certification would be removed under this proposal. The intent here is to simplify Part 36 to make it easier for applicants to determine which, if any, provisions apply directly to them. With the removal of these references and sections, it will be necessary to renumber certain sections of Part 36.

Certification Reports

Among the existing documentation requirements is one for a technical data report on the certification tests and results. This Notice would clarify Section 36.1501 to better describe the information necessary to be included and would for the first time specifically allow inclusion of data from supplemental tests (such as ground-based static tests of engines). This increased flexibility is intended to allow wider use of cost-saving equilvalent procedures as long as the data can be analyzed to yield results that would be the same as if the aircraft had been completely flight tested. No increase in documentation requirements will result—only better definition of the requirements, themselves.

Test Requirements

This Notice would simplify noise certification test requirements in several ways. In each case, the intent of the proposed change would be to lower the cost of certification without diluting the quality of the noise data used for certification. In some cases, the costs would be lowered by widening the acceptable weather window during which tests may be conducted. This would lower costs to both industry and government by minimizing delays which presently tie up equipment, aircraft and personnel for days while waiting for specific weather conditions. One proposal would allow the temperature and relative humidity limits to be increased in those cases where relative humidity is measured by a more accurate instrument. Another weather-related proposal would increase the allowable average wind from 10 knots to 12 knots and the crosswind from 5 knots to 7 knots. The maximum wind velocity could not exceed 15 knots with a limit of 10 knots crosswind. This Notice also proposes to clarify that the weather should be measured in the vicinity of the noise measuring stations, rather than at the nearest airport.

A number of changes are proposed in the technical specifications for the electronic equipment used in the collection and analysis of the noise data. These changes follow closely the standards adopted by the International Civil Aviation Organization (ICAO) and should minimize costs where manufacturers have to certificate to both ICAO and U.S. standards.

The major change to the Part 36 test requirements from this Notice would be to change the sideline microphone array specified in Section A36.1(b) of Appendix A. The FAA proposes to change the required minimum number of microphones from four to two. These would be placed on either side of the point where the jet aircraft reaches 1000 feet altitude to determine the maximum noise. Because of the difficulties encountered by applicants in finding appropriate test sites that can accommodate the larger present array, the FAA believes that this particular proposal will significantly ease regulatory burdens.

Data Correction and Analysis

Section A36.5 of Appendix A would be amended to clarify the information that is needed to correct the data to standard reference conditions. Specifically, only those engine performance parameters relevant to noise generation, such as net thrust, engine pressure ratio, exhaust temperatures, and fan or compressor rotational speeds, would be reported. The meteorological requirements would be clarified to acknowledge that the FAR Part 36 reference atmosphere should be considered homogeneous. Aircraft sound pressure levels under the proposal would need to exceed the ambient background noise by only 3 decibels instead of the present 5 decibels. The proposal would even allow lower signal-to-noise ratio if the method for separating the signal from the noise is approved by the FAA. Several other amendments to Appendices A and B of FAR 36 are proposed that would make relatively minor changes to mathematical constants in the correction procedures or that would make minor revisions in the description of the procedures. These are considered to be clarifying, not substantive, in nature.

Regulatory Impact Evaluation

The FAA conducted a detailed regulatory evaluation which is included in the regulatory docket. This evaluation reviews all proposed changes to Parts 21 and 36. The FAA determined that this NPRM is consistent with the objectives of Executive Order 12291 as part of the President's Regulatory Reform Program to reduce regulatory burdens on the public. This NPRM imposes no additional costs on the Federal Government.

The amendments proposed in the NPRM would provide benefits in the aggregate to the aviation public. These amendments would provide general benefits to the aviation public by deleting obsolete requirements, updating equipment requirement with respect to the state-of-the-art, updating and clarifying the text, and relaxing certain documentation requirements. The regulations would be more concise and easier to understand. In addition, these proposed amendments to Part 36 are expected to provide several other benefits to the general public, including: commonality and a more logical progression of the rules, reduced complexity, and deletion of redundancies and obsolete compliance dates. These changes will provide a regulation that is easier to read and understand, and will therefore, reduce the amount of study time for person who are responsible for knowing and complying with the regulation. No additional costs are expected to result from the proposed rule changes.

Therefore, it is certified that this proposal is not a major rule under E.O. 12291, and is not significant pursuant to DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979).

The FAA invites comments on the regulatory evaluation which is included in the Docket. A copy of the initial regulation evaluation may be examined in the public docket or obtained from the person identified under the caption **"FOR FURTHER INFORMATION CONTACT."**

Regulatory Flexibility Determination

As detailed in the evaluation, all but four of the proposed changes to Part 36 are editorial or clarifying changes. Three of the four other changes result only in minimal benefits. The other proposal is a change to § A36.1(b) which will lower the cost with no change in benefit. Any economic savings would be minor—approximately $5000 per aircraft certification. Only three aircraft manufacturers and less than twelve aircraft modifiers fall under the definition of small entities. Thus, the change could not be construed to have a significant economic impact on a substantial number of entities.

Therefore, it is certified that the proposal, if enacted, will not have

significant economic impact on a substantial number of "small intities" under the criteria of the Regulatory Flexibility Act.

Environmental Analysis

Pursuant to Department of Transportation "Policies and Procedures for Considering Environmental Impacts" (FAA Order 1050.1C), the FAA has determined that this proposal would not constitute a major Federal action significantly affecting the quality of the human environment. The proposed changes are either technical of clarifying in nature and would neither raise nor lower aircraft noise levels. Therefore, no environmental assessment or environmental impact statement was prepared.

List of Subjects

14 CFR Parts 21 and 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

14 CFR Part 36

Aircraft, Noise control.

The Proposed Amendments

PART 21—[AMENDED]

Accordingly, the Federal Aviation Administration proposes to amend Part 36 of the Federal Aviation Regulations (14 CFR Part 25.25 and in 36) in part as follows:

§ 21.93 [Amended]

1. Section 21.93(b) would be amended to revise paragraph (b)(2) to read as follows:

* * * * *

(b) * * *

(2) Turbojet powered airplanes (regardless of category). For airplanes to which this paragraph applies, "acoustical changes" do not include changes in type design that are limited to one of the following—

(i) Gear down flight with one or more retractable landing gear down during the entire fight, or

(ii) Spare engine and nacelle carriage external to the skin of the airplane (and return of the pylon or other external mount), or

(iii) Time-limited engine and/or nacelle changes, where the airplane may not be operated for a period of more than 90 days unless compliance with the applicable acoustical change provisions of Part 36 of this chapter is shown for that change in type design.

* * * * *

PART 25—[AMENDED]

§ 25.25 [Amended]

2. Section 25.25 would be amended by adding ";or" to the end of paragraph (a)(2) by adding a new paragraph (a)(3) to read as follows:

(a) * * *

(3) The highest weight at which compliance is shown with the certification requirements of Part 36 of this chapter.

* * * * *

PART 36—[AMENDED]

3. Section 36.1 would be amended to add a new paragraph (g) to read as follows:

§ 36.1 Applicabilty and definition.

* * * * *

(g) For purposes of showing compliance with this Part for transport category large airplanes and turbojet airplanes regardless of category, each airplane must be shown to be either a Stage 1, a Stage 2, or a Stage 3 airplane and may not be identified as complying with more than one Stage.

* * * * *

§ 36.7 [Amended]

4. Section 36.7(c)(1) would be amended by revising the last sentence to read as follows:

* * * * *

(c) * * *

(1) * * * The tradeoff provisions of Section C36.5(b) of Appendix C of this Part may not be used to increase the Stage 1 noise levels, unless the resulting aircraft qualifies as a Stage 2 airplane.

* * * * *

5. Section 36.7 (d) and (e) would be revised to read as follows:

* * * * *

(d) Stage 2 airplanes. If an airplane is a Stage 2 airplane prior to the change in type design, in addition to the provisions of paragraph (b) of this section, the following apply:

(1) Airplanes with high bypass ratio turbojet engines. For an airplane that has turbojet engines with a bypass ratio of 2 or more before a change in type design—

(i) The airplane after the change in type design may not exceed either (A) each Stage 3 noise limit by more than 3 EPNdB, or (B) each Stage 2 noise limit, whichever is lower;

(ii) The tradeoff provisions of Section C36.5(b) of Appendix C of the Part may be used in determining compliance under this paragraph with respect to the Stage 2 noise limit or to the Stage 3 plus 3 EPNdB noise limits, as applicable; and

(iii) During the takeoff and sideline noise test conducted before the change in type design, the quietest airworthiness approved configuration available for the highest approved takeoff weight must be used.

(2) Airplanes that do not have high bypass ratio turbojet engines. For an airplane that does not have turbojet engines with a bypass ratio of 2 or more before a change in type design—

(i) The airplane may not be a Stage 1 airplane after the change in type design; and

(ii) During the takeoff and sideline noise tests conducted before the change in type design, the quietest airworthiness approved configuration available for the highest approved takeoff weight must be used.

(e) Stage 3 airplanes. If an airplane is a State 3 airplane prior to the change in type design, in addition to the provisions of paragraph (b) of this section, the following apply:

(1) If compliance with Stage 3 noise levels is not required before the change in type design, the airplane must—

(i) Be a Stage 2 airplane after the change in type design and compliance must be shown under the provisions of paragraph (d)(1) or (d)(2) of this section, as appropriate; or

(ii) Remain a Stage 3 airplane after the change in type design and compliance must be shown under the provisions of paragraph (e)(2) of this section.

(2) If compliance with Stage 3 noise levels is required before the change in type design, the airplane must be a Stage 3 airplane after the change in type design.

* * * * *

6. Section 36.201(b) would be revised to read as follows:

* * * * *

(b) For applications for type certification for subsonic transport category large airplanes and all subsonic turbojet powered airplanes, it must be shown that the noise levels of the airplane are no greater than the Stage 3 noise limits prescribed in section C36.5(a)(3) of Appendix C of this Part.

* * * * *

§ 36.201 [Amended]

7. Section 36.201 (c) and (d) would be removed.

8. Section 36.1501 would be revised to read as follows:

§ 36.1501 Procedures, noise levels and other information.

(a) All procedures, weights, configurations, and other information or data that are employed for obtaining the certificated noise levels prescribed by

this Part must be developed and approved, including equivalent procedures used for flight, test, and analysis. This must include noise levels achieved during type certification.

(b) Where supplemental test data are approved for modification or extension of an existing flight data base, such as acoustic data from engine static tests used in the certification of acoustical changes, the test procedures, physical configuration, and other information and procedures that are employed for obtaining the supplemental data must be developed.

§ 36.1581 [Amended]

9. Section 36.1581(a) would be amended by adding the following subparagraphs (1) and (2):

(a) * * *

(1) For transport category large airplanes and turbojet powered airplanes, the noise level information must be one value each for takeoff, sideline, and approach as defined and required by Appendix C of this Part, along with the associated maximum takeoff weight, maximum landing weight, and configuration.

(2) For propeller driven small airplanes the noise level information must be one value for flyover as defined and required by Appendix F of this Part, along with the associated maximum takeoff weight and configuration.

* * * * *

10. Existing § 36.1581(b) would be redesignated (c), existing paragraph (c) removed, and a new paragraph (b) added to read as follows:

* * * * *

(b) If supplemental operational noise level information is included in the approved portion of the Airplane Flight Manual, it must be segregated, identified as information in addition to the certificated noise levels, and clearly distinguished from the information required under 36.1581(a).

* * * * *

11. Section 36.1581 is further amended by redesignating paragraphs (d) and (e) as (e) and (f), respectively, and by adding a new paragraph (d) to read as follows:

* * * * *

(d) For transport category large airplanes and turbojet powered airplanes, for which the weight used in meeting the takeoff or landing noise requirements of this Part is less than the maximum weight established under the applicable airworthiness requirements, those lesser weights must be furnished, as operating limitations, in the operating limitations section of the Airplane Flight Manual. Further, the maximum takeoff weight must not exceed the takeoff weight that is most critical from a takeoff noise standpoint.

* * * * *

The following changes are made to Appendix A to Part 36:

12. Section A36.1(b) would be amended to revise paragraph (1) to read as follows:

* * * * *

(b) * * * (1) Tests to show compliance with established aircraft noise certification levels must consist of a series of takeoffs and approaches (or stabilized flight path segments thereof) during which measurements must be taken at noise measuring stations located at the measuring points prescribed in § C36.3 of Appendix C of this Part. Each recorded segment must include measurements throughout the entire time period in which the recorded signal is within 10 dB of PNLTM.

* * * * *

13. Section A36.1(b) would be amended to revise paragraph (7) to read as follows:

* * * * *

(b) * * *

(7) A minimum of two noise measuring stations, symmetrically positioned about the test flight track, must be used to define the maximum sideline noise with respect to location and level as required by § C36.3 of Appendix C of this Part. For turbojet powered aircraft, the maximum sideline noise may be assumed to occur at the point (or its approved equivalent) along the extended centerline of the runway where the aircraft reaches 1000 feet (305 meters) altitude. For aircraft powered by other than turbojet engines, the altitude for maximum sideline noise must be determined experimentally.

* * * * *

14. Section A36.1(c) would be amended to revise paragraphs (3) and (4) to read as follows:

* * * * *

(c) * * *

(3) Relative humidity and ambient temperature over that portion of the sound propagation path between the aircraft and a point 10 meters above the ground at the noise measuring station is such that the sound attenuation in the one-third octave band centered at 8 kHz is not greater than 12 dB/100 meters and the relative humidity is between 20 and 95 percent, inclusively. However, if the dew point and dry bulb temperature used for obtaining relative humidity are measured with a device which is accurate to within ±0.5°C, the sound attenuation rate shall not exceed 14 dB/100 meters in the one-third octave band centered at 8 kHz.

(4) Average wind velocity 10 meters above ground does not exceed 12 knots and the crosswind component does not exceed 7 knots. The average wind shall be determined using a thirty-second averaging period spanning the 10 dB down time interval. Maximum wind velocity 10 meters above ground does not exceed 15 knots and the crosswind component does not exceed 10 knots during the 10 dB down time interval.

* * * * *

15. Section A36.1(d) would be amended to remove subparagraphs (5)(iii) and (7)(iii).

16. Section A36.3 would be amended by redesignating paragraphs (c)(2) (ii), (iii) and (iv) as (c)(2) (iii), (iv) and (v), respectively, by revising (c)(2)(i), and by adding a new (c)(2)(ii) to read as follows:

* * * * *

(c) * * *

(2) * * *

(i) After an adequate "warm-up" period, at least as long as that specified by the equipment manufacturer, the system output for constant acoustical input shall change by not more than 0.3 dB within any one hour nor by more than 0.4 dB within 5 hours.

(ii) The variation of microphone and preamplifier system sensitivity within an angle of ±30 degrees of grazing (60–120 degrees from the normal to the diaphragm) must not exceed the following values:

Frequency (Hz)	Change in sensitivity (dB)
45 to 1120	1
1120 to 2240	1.5
2240 to 4500	2.5
4500 to 7100	4
7100 to 11200	5

The variation of microphone sensitivity in the plane of the diaphram must not exceed ±0.5 dB over the same frequency range.

17. Section A36.3(d) would be amended to revise paragraphs (2), (5), and (6) to read as follows:

* * * * *

(2) A set of 24 consecutive one-third octave filters must be used. The first filter of the set must be centered at a geometric mean frequency of 50 Hz and the last filter at 10,000 Hz.

(i) The output of each filter must contain less than 0.5 dB ripple.

(ii) The correction for effective bandwidth relative to the response at the center frequency response for each one-third octave band filter must be determined by measuring the filter response to sinusoidal signals at a minimum of 20 frequencies equally spaced between the two adjacent preferred one-third octave frequencies or by using an approved equivalent procedure.

* * * * *

(5) The averaging properties of the integrator must be tested as follows:

(i) White noise must be passed through the 200 Hz one-third octave band filter and the output fed in turn to each detector/integrator. The standard deviation of the measured levels must than be determined from a large number of samples of the filtered white noise taken at intervals of not less than 5 seconds. The value of the standard deviation must be within the interval 0.45±0.06dB for a probability limit of 95 percent. (An approved equivalent method may be substituted for this

test on those analyzers where the test signal cannot readily be fed directly to each detector/integrator.)

(ii) For each detector/integrator, the response to a sudden onset or interuption of a constant amplitude sinusoidal signal at the respective one-third octave band center frequency must be measured at sampling times 0.5, 1.0, 1.5 and 2.0 seconds after the onset or interruption. The rising responses must be the following amounts below the steady-state level:

0.5 seconds	4.0±1.0 dB
1.0 seconds	1.75± 0.75 dB
1.5 seconds	1.0± 0.5 dB
2.0 seconds	0.6± 0.5 dB

(iii) The falling response must be such that the sum of the decibel readings (below the initial steady-state level) and the coresponding rising response reading is 6.5±1.0 dB, at each sampling time.

(iv) Analyzers using true integration cannot meet the requirements of (i), (ii), and (iii) directly, because their overall average time is greater than the sampling interval. For these analyzers, compliance must be demonstrated in terms of the equivalent output of the data processor. Further, in cases where readout and resetting require a dead-time during acquisition, the percentage loss of the total data must not exceed one percent.

(6) The sampling interval between successive readouts shall not exceed 500 milliseconds and its precise value must be known to within ±1 percent. The instant in time by which a readout is characterized, shall be the midpoint of the average period. (The averaging period is defined as twice the effective time constant of the analyzer.)

* * * * *

18. Section A36.3(e) would be amended to revise the first sentence of paragraph (7) to read as follows:

(e) * * *

(7) A performance calibration analysis of each piece of calibration equipment, including pistonphones, reference microphones, and voltage insert devices, must have been made during the six calendar months * * *

* * * * *

19. Section A36.5(b) would be amended to revise subparagraphs (5)(vi) and (vii) to read as follows:

* * * * *

(b) * * *

(5) * * *

(vi) Engine performance parameters relevant to noise generation, such as net thrust, engine pressure ratio, exhaust temperatures, and fan or compressor rotational speeds.

(vii) Aircraft flight path (altitude versus distance and lateral deviation from flight track in feet).

* * * * *

20. Section A36.5(c)(1) would be amended by adding the word "homogeneous" ahead of the words "atmospheric conditions."

* * * * *

21. Section A36.5(c) would be amended to revise subparagraph (2)(i) to read as follows:

* * * * *

(c) * * *

(2) * * *

(i) Maximum landing weight, except as provided in 36.1581(c) of this Part;

* * * * *

22. Section A36.5(d) would be amended to revise the first sentence of paragraph (3) to read as follows:

* * * * *

(d) * * *

(3) Aircraft sound pressure levels within the 10 dB-down points (described in section B36.9 of Appendix B) must exceed the mean background sound pressure levels determined under section A36.3(f)(3) by at least 3 dB in each one-third octave band * * *

* * * * *

23. Section A36.5(d) would be amended to add new subparagraphs (4)(5) to read as follows:

* * * * *

(d) * * *

(4) Where more than seven one-third octaves are within 3 dB of the ambient noise levels a time/frequency interpolation of the noise data shall be performed using an approved procedure.

(5) If equivalent test procedures, different from the reference procedures are used, the test procedures and all methods for adjusting the results to the reference procedures must be approved by the FAA. The amounts of adjustments must not exceed 16 EPNdB on take-off and 8 EPNdB on approach, and if the adjustments are more than 8 EPNdB and 4 EPNdB respectively, the resulting numbers must not be within 2 EPNdB of the appropriate Appendix C noise levels including tradeoffs.

* * * * *

24. Section A36.5(e) would be amended to substitute the word "mean" for the word "average" for every use in this section and add a new paragraph (4) to read as follows:

* * * * *

(e) * * *

(4) If equivalent procedures are to be used to certificate several airplane configurations of the same type from noise tests of a single airplane, the test procedures and analysis methods must be approved by the FAA. The request for approval must identify the noise measurement test procedures and data base, the airplane configurations, procedures and analysis methods, the method for establishing the 90 percent confidence limit for each noise certification level, and the proposed equivalent procedures.

* * * * *

25. Section A36.9 would be amended to revise paragraph (b)(1) to read as follows:

* * * * *

(b) * * *

(1) The wind velocity, temperature and relative humidity measurements required under this Part must be measured in the vicinity of the noise measuring stations. The location of the meteorological measurements must be approved by the FAA as representative of those atmospheric conditions existing near the surface over the geographical area in which aircraft noise measurements are made. In some cases, a fixed meteorological station (such as those found at airports or other facilities) may meet this requirement.

* * * * *

26. Section A36.9 would be amended to revise paragraph (d)(2) to read as follows:

* * * * *

(d) * * *

(2) If the atmospheric absorption coefficients do not vary over the sound propagation path by more than ±1.65 dB/1000 ft (±0.5 dB/100 meters) in the 3150 Hz one-third octave band from the value of the absorption coefficients derived from the meteorological measurement obtained at 10 meters above the surface, the mean of the values of the atmospheric absorption coefficients at the altitude of the aircraft and at 10 meters above the surface may be used to determine the atmospheric attenuation rates for each one-third octave band. The resulting atmospheric attenuation rate may be used to compute the PNLT correction under section A36.11(d) of this appendix.

* * * * *

27. Section A36.11(a) would be amended to remove from subparagraph (3)(v) the phrase "in the form of curves or tables giving the variation of EPNL with approach angle."

28. Section A36.11(e) introductory text would be amended to revise the first sentence to read, "If the measured takeoff and approach flight paths do not conform to those prescribed as the corrected and reference flight paths, respectively, under § A36.11 (b) and (c) it will be necessary to apply duration corrections to the EPNL values calculated from the measured data."

29. Section A36.11(e) would be amended to revise the formula only in paragraphs (1), (2) and (3) to read as follows:

* * * * *

(1) *Takeoff flight path.* For the takeoff flight path shown in Figure A3, the correction term is calculated using the formula—

$$\Delta 2 = -7.5 \log (KR/KRc)$$

* * * * *

(2) *Approach flight path.* For the approach flight path shown in Figure A6, the correction term is calculated using the formula—

$$\Delta 2 = -7.5 \log (NT/393)$$

* * * * *

(3) *Sideline flight path.* For the sideline flight path, the correction term is calculated during the formula—

$$\Delta 2 = -7.5 \log (LX/LXc)$$

* * * * *

30. Section A36.11 is amended by revising paragraph (f) introductory text,

(f)(1), (f)(2) and (f)(2)(ii) to read as follows:

* * * * *

(f) *Nonstandard location correction.* All takeoff and approach noise measurements must be conducted at the measuring points prescribed in § 36.1 of Appendix C, except where it is necessary to bring the measurement station closer to the aircraft flight path to ensure recording the complete flyover noise/time record required by § B36.9(f) of Appendix B of this Part (i.e., a flyover noise/time record which includes the required period before and after the 10 dB-down point from PNLTM). The EPNL value computed from these measurements must be corrected to the value that would have occurred at the prescribed measuring points under one of the following procedures:

(1) *Simplified procedure.* Unless the amount of adjustment exceeds 8 dB on takeoff or 4 dB on approach, or the correction results in a final EPNL value which is within 1.0 dB of the noise levels . . . prescribed in Appendix C of this part, the following correction procedure must be used:

(2) *Integrated procedure.* If the amount of adjustment exceeds 8 dB on takeoff or 4 dB on approach, or the correction results in a final EPNL value which is within 1.0 dB of the noise levels . . . prescribed in Appendix C of this part, the following correction procedure must be used:

(ii) After the measured ½-second spectra have been corrected to the measuring points prescribed in § 36.1 of Appendix C, the remaining noise evaluation . . . must be conducted under the procedures prescribed in Appendix B of this part, including the appropriate reference thrust and airspeed corrections.

31. Section B36.5(h) would be amended by removing the word "zero", and by adding in place thereof the phrase "one and a half".

32. Table B–2 would be revised as shown:

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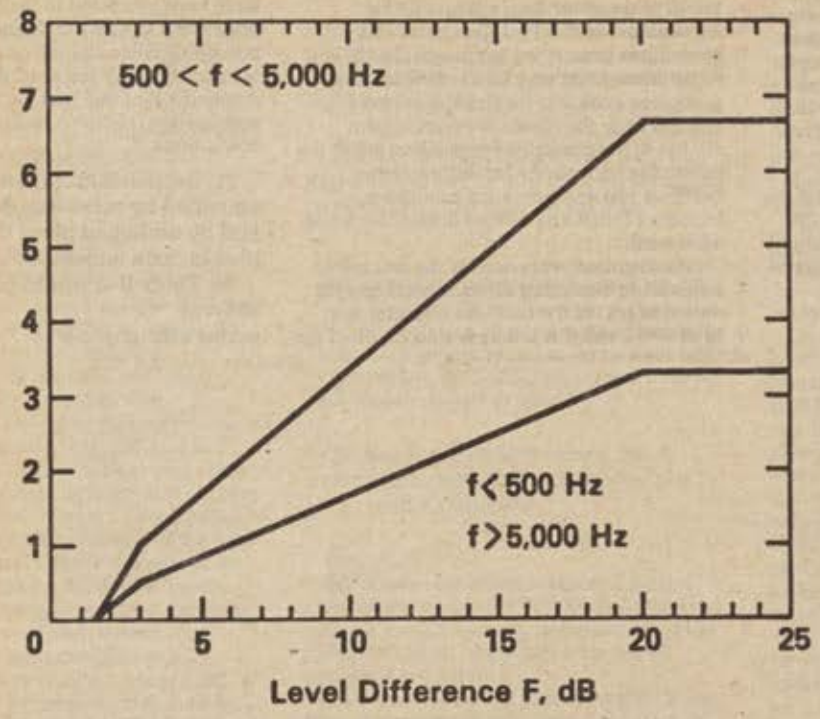
Table B2 — Tone Correction Factors



Frequency f, Hz	Level Difference F, dB	Tone Correction C, dB
50 ≤ f < 500	1½* ≤ F < 3	F/3 − ½
	3 ≤ F < 20	F/6
	20 ≤ F	3½
500 ≤ f ≤ 5,000	1½* ≤ F < 3	2 F/3 − 1
	3 ≤ F < 20	F/3
	20 ≤ F	6 2/3
5,000 < f ≤ 10,000	1½* ≤ F < 3	F/3 − ½
	3 ≤ F < 20	F/6
	20 ≤ F	3 1/3

*See Step 8

33. Section B36.9(c) would be amended to revise the definition of Δt as follows:

* * * * *

$\Delta t = 0.5$ sec. (or the approved sampling time interval), and

* * * * *

34. Section B36.9(f) would be revised to read as follows:

* * * * *

(f) The aircraft testing procedures must include the 10 dB-down points in the flyover noise/time record.

* * * * *

35. Section B36.11 would be amended to add a paragraph (c) to read as follows:

* * * * *

(c) If, during a test flight, one or more peak values of PNLT are observed which are within 2 dB of PNLTM, the value of EPNL shall be calculated for each, as well as for PNLTM. If any EPNL value exceeds the value at the moment of PNLTM, the maximum value of such exceedance must be added as a further adjustment to the EPNL calculated from the measured data.

36. Section B36.13 would be amended to revise paragraphs (a) and (b), Figure B3, and by adding Table B4 to read as follows:

* * * * *

(a) The relationship between sound pressure level and perceived noisiness given in Table B1 is illustrated in Figure B3. The variation of log (n) with SPL for a given one-third octave band can be expressed by straight lines as shown in Figure B3.

(1) the slopes of the straight lines M(b), M(c), M(d) and M(e);

(2) the intercepts of the lines on the SPL axis, SPL (b) and SPL (c); and

(3) the co-ordinates of the discontinuities, SPL (a) and log n(a); SPL (d) and log $n = -1.0$; and SPL (e) and log $n = \log (0.3)$.

(b) The important aspects of the mathematical formulation are:

(1) SPL > SPL (a)
$n = \text{antilog } [M(c) (SPL - SPL(c))]$

(2) SPL (b) < SPL < SPL (a)
$n = \text{antilog } [M(b) (SPL - SPL(c))]$

(3) SPL (e) < SPL < SPL (b)
$n = \text{antilog } [M(e) (SPL - SPL(b))]$

(4) SPL (d) < SPL < SPL (e)
$n = 0.1 \text{ antilog } [M(d) (SPL - SPL(d))]$

* * * * *

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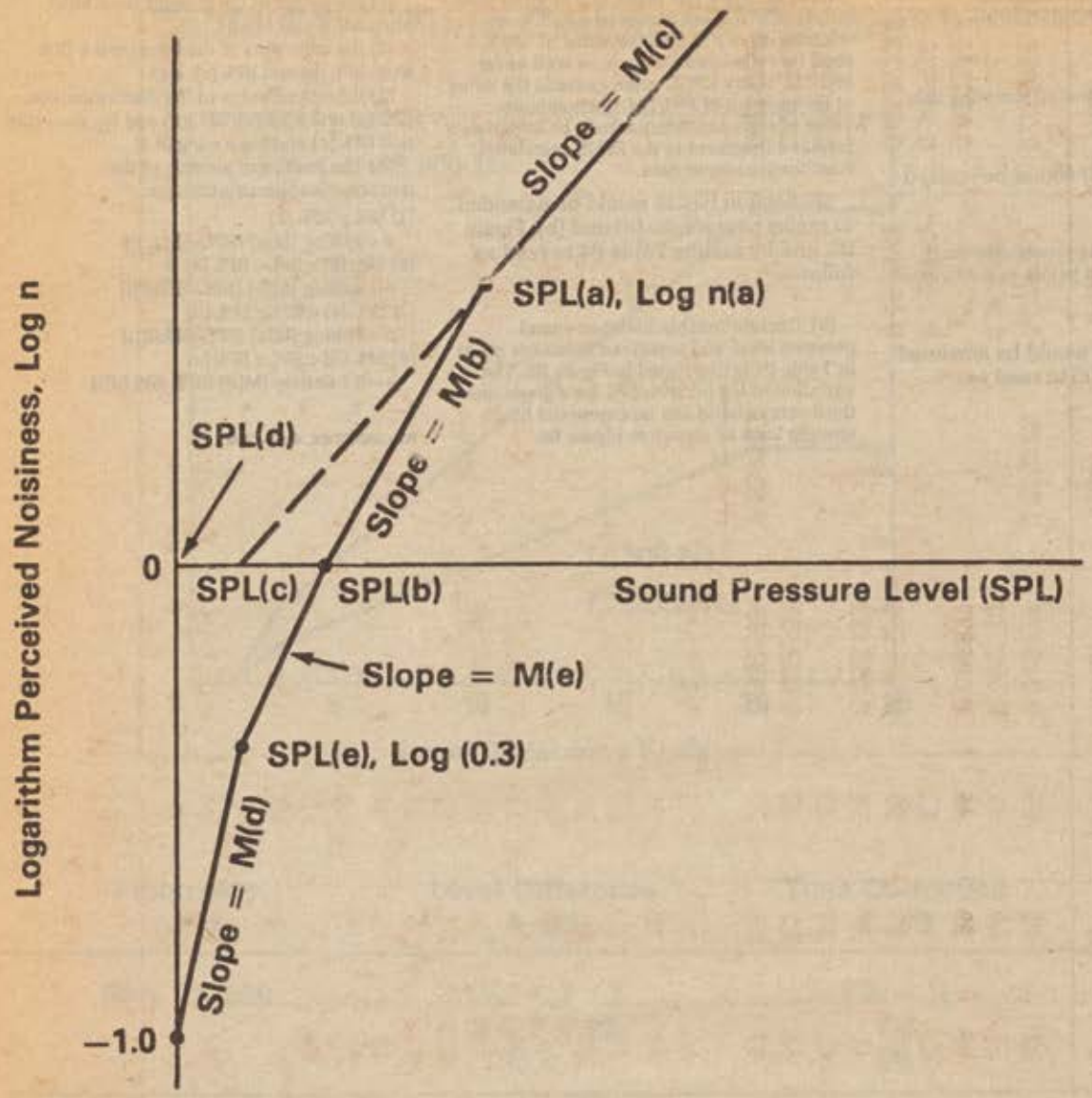

Fig. B3. Perceived Noisiness As a Function of Sound Pressure Level.

Table B4 Constants for Mathematically Formulated NOY Values

Band (i)	f Hz	SPL (a)	SPL (b)	SPL (c)	SPL (d)	SPL (e)	M(b)	M(c)	M(d)	M(e)
1	50	91.0	64	52	49	55	0.043478	0.030103	0.079520	0.058098
2	63	85.9	60	51	44	51	0.040570	↕	0.068160	"
3	80	87.3	56	49	39	46	0.036831		"	0.052288
4	100	79.9	53	47	34	42	"		0.059640	0.047534
5	125	79.8	51	46	30	39	0.035336		0.053013	0.043573
6	160	76.0	48	45	27	36	0.033333		↕	"
7	200	74.0	46	43	24	33	"			0.040221
8	250	74.9	44	42	21	30	0.032051			0.037349
9	315	94.6	42	41	18	27	0.030675	0.030103		0.034859
10	400	∞	40	40	16	25	0.030103			↕
11	500	↕	40	40	16	25	↕			
12	630		40	40	16	25				
13	800		40	40	16	25				
14	1000		40	40	16	25			0.053013	
15	1250		38	38	15	23	0.030103	Not	0.059640	0.034859
16	1600		34	34	12	21	0.029960	Applicable	0.053013	0.040221
17	2000		32	32	9	18	↕		"	0.037349
18	2500		30	30	5	15			0.047712	0.034859
19	3150		29	29	4	14			"	↕
20	4000		29	29	5	14			0.053013	
21	5000		30	30	6	15			"	0.034859
22	6300	∞	31	31	10	17	0.029960		0.068160	0.037349
23	8000	44.3	37	34	17	23	0.042285	0.029960	0.079520	"
24	10000	50.7	41	37	21	29	"	"	0.059640	0.043573

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Appendix C is amended as follows:

37. Section C36.5 would be amended to remove paragraph (c).

38. Section C36.7 would be retitled *Takeoff Reference and Test Limitations.*

39. Section C36.7 would be amended to delete paragraph (d) and to redesignate paragraphs (e) and (f) as (d) and (e), respectively.

40. Section C36.9 would be retitled *Approach Reference and Test Limitations*

41. Section C36.9 would be amended to remove paragraph (d) and to redesignate paragraphs (e) and (f) as (d) and (e), respectively.

Note.—For the reasons discussed earlier in the preamble, the FAA has determined that this document: (1) involves a proposed regulation which is not major under Executive Order 12291, (2) is not a significant rule pursuant to the Department of Transportation Regulatory Policies and Procedures (44 FR 11034; February 26, 1979), and (3) it is certified under the criteria of the Regulatory Flexibility Act that this proposed rule, if promulgated, will not have a significant economic impact on a substantial number of entities. In addition, this proposal, if adopted, would have little or no impact on trade opportunities for U.S. firms doing business overseas or for foreign firms doing business in the United States.

Issued in Washington, D.C., on November 13, 1984.

John E. Wesler,

Director of Environment and Energy.

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