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Briefing on How To Use the Federal Register
For information on a briefing in Washington, DC, see announcement on the inside cover of this issue.

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FOR: Any person who uses the Federal Register and Code of Federal Regulations.

WHO: The Office of the Federal Register.

WHAT: Free public briefings (approximately 3 hours) to present:

1. The regulatory process, with a focus on the Federal Register system and the public's role in the development of regulations.
2. The relationship between the Federal Register and Code of Federal Regulations.
3. The important elements of typical Federal Register documents.
4. An introduction to the finding aids of the FR/CFR system.

WHY: To provide the public with access to information necessary to research Federal agency regulations which directly affect them. There will be no discussion of specific agency regulations.

WASHINGTON, DC

WHEN: June 23 at 9:00 am

WHERE: Office of the Federal Register Conference Room, 800 North Capitol Street NW., Washington, DC (3 blocks north of Union Station Metro)

RESERVATIONS: 202–523–4538

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Free **Electronic Bulletin Board** service for Public Law numbers, **Federal Register** finding aids, and a list of documents on public inspection is available on 202–275–1538 or 275–0920.

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Presidential Documents

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The President

Presidential Determination No. 94–28 of June 6, 1994

Assistance Program for the New Independent States of the Former Soviet Union

Memorandum for the Secretary of State

Pursuant to section 577 of the Foreign Operations, Export Financing, and Related Programs Appropriations Act, 1994 (Titles I–V of Public Law 103–87), I hereby certify that Russia and the Commonwealth of Independent States continue to make substantial progress toward the withdrawal of their armed forces from Latvia and Estonia.

You are authorized and directed to notify the Congress of this certification, and to publish it in the **Federal Register.**

William J. Clinton

THE WHITE HOUSE,
Washington, June 6, 1994.

[FR Doc. 94–14974
Filed 6–15–94; 3:38 pm]
Billing code 4710–10–M

Rules and Regulations

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MERIT SYSTEMS PROTECTION BOARD

5 CFR Part 1201

Practices and Procedures

AGENCY: Merit Systems Protection Board.

ACTION: Final Rule.

SUMMARY: The Board is amending its practices and procedures by extending the regulatory time limits for filing initial appeals, class action appeals, motions for attorney fees, initial appeals raising issues of prohibited discrimination, and requests to review final decision under negotiated grievance procedures. The time limit for filing appeals with the Federal courts, as well as the Equal Employment Opportunity Commission, is currently greater than that of the Board. This change brings the Board's practices and procedures more in line with those entities and will also have the effect of making the Board's appellate processes more accessible to Federal employees.

DATES: Effective June 17, 1994.

FOR FURTHER INFORMATION CONTACT: Robert E. Taylor, Clerk of the Board, (202) 653–7200.

SUPPLEMENTARY INFORMATION: This change in the Board's practices and procedures came about as a result of Executive Order 12866 of September 30, 1993, requiring agencies to ensure that regulations are effective, consistent, sensible, and understandable. The Board's review found that changing the time limit for filing initial appeals to its regional offices would be consistent with the legal and regulatory time limits for filing with the Federal Courts and the Equal Employment Opportunity Commission both of which can potentially review final decisions of the Board. The consistency created by this proposed change will help to eliminate possible confusion by Federal employees who file appeals with the Board.

The Board announced this change as a proposed rule at 59 FR 18764, April 20, 1994, and asked for comments. The Board received 29 comments from agency and union representatives. Twenty-two were in favor of or not opposed to the proposed amendments. There was significantly more support for the proposed amendments than opposition. While some commenters suggested alternatives to the proposed regulations, the Board has considered these suggestions and determined not to adopt them.

The Board has determined that this proposed regulatory action is not "significant" as defined by Executive Order 12866, and therefore, is not subject to review by the Office of Management and Budget.

The Board has also determined that this proposed regulatory action does not have a significant impact on a substantial number of small entities under the Regulatory Flexibility Act (Pub. L. 96354, 94 Stat. 1164, 5 U.S.C. 601–612).

List of Subjects in 5 CFR Part 1201

Administrative practice and procedure, Civil Rights, Government employees. Accordingly, 5 CFR part 1201 is amended as follows:

PART 1201—[AMENDED]

1. The authority citation for part 1201 continues to read as follows:

Authority: 5 U.S.C. 1204 and 7701 unless otherwise noted.

2. Section 1201.22 is amended by removing the number "20" in the first sentence of paragraph (b); and by adding in its place the number "30"; and by removing the number "25" from the second sentence of paragraph (b); and by adding in its place the number "35".

3. Section 1201.23 is amended by revising the "EXAMPLE:" paragraph to read as follows:

§ 1201.23 Computation of time.

* * * * *

Example: If an employee receives a decision notice that is effective on July 1, the 30-day period for filing an appeal starts to run on July 2. The filing ordinarily would be timely only if it is made by July 31. If July 31 is a Saturday, however, the last day for filing would be Monday, August 2.

4. Section 1201.27 is amended by removing the number "25" from the second sentence in paragraph (b); and adding in its place the number "35"; and by removing the number "25" from the last sentence is paragraph (b); and adding in its place the number "35".

§ 1201.37 [Amended]

5. Section 1201.37 is amended by removing the numbers "20" and "25" from the second sentence in paragraph (a)(3); and adding in their place the numbers "30" and "35" respectively.

§ 1201.154 [Amended]

6. Section 1201.154 is amended by removing the number "20" in paragraph (a); and adding in its place the number "30"; by removing the number "20" from paragraph (b)(1); and by adding in its place the number "30"; and by removing the number "25" from paragraph (d); and adding in its place the number "35".

Dated: June 14, 1994.

Robert E. Taylor,

Clerk of the Board.

[FR Doc. 94–14859 Filed 6–16–94; 8:45 am]

BILLING CODE 7400–01–M

5 CFR Part 1209

Practices and Procedures for Appeals and Stay Requests of Personnel Actions Allegedly Based on Whistleblowing

AGENCY: Merit Systems Protection Board.

ACTION: Final rule.

SUMMARY: The Board is amending its Practices and Procedures for Appeals and Stay Requests of Personnel Actions Allegedly Based on Whistleblowing. This amendment extends the time limit for filing an appeal of an agency action where the appellant first files a request for a stay of that action. This change will bring the filing time in initial whistleblower cases into line with filing times in the Board's appellate jurisdiction cases and will also have the effect of making the Board's appellate processes more accessible to Federal employees.

DATES: Effective June 17, 1994.

FOR FURTHER INFORMATION CONTACT: Robert E. Taylor, Clerk of the Board, (202) 653–7200.

SUPPLEMENTARY INFORMATION: This change came about as a result of

Executive Order 12866, September 30, 1993, requiring agencies to insure that regulations are effective, consistent, sensible, and understandable. The Board's review found that changing the time limit for filing initial appeals to its regional offices would be consistent with the legal and regulatory time limits for filing with the Federal courts and the Equal Employment Opportunity Commission both of which can potentially review final decisions of the Board. The consistency created by this proposed change will help to eliminate possible confusion by Federal employees who file appeals with the Board.

The Board proposed the amendments to its practices and procedures at 59 FR 18502, April 19, 1994, and requested comments. The Board received 29 comments from agency and union representatives. Twenty-two were in favor of or not opposed to the amendments. While some commenters suggested alternatives to the proposed regulations, the Board has considered these suggestions and determined not to adopt them.

The Board has determined that this proposed regulatory action is not "significant" as defined by Executive Order 12866, and therefore, is not subject to review by the Office of Management and Budget.

The Board has also determined that this proposed regulatory action does not have a significant impact on a substantial number of small entities under the Regulatory Flexibility Act (Pub. L. 96354, 94 Stat. 1164, 5 U.S.C. 601–612).

List of Subjects in 5 CFR Part 1209

Administrative practice and procedure, Civil rights, Government employees.

Accordingly, 5 CFR part 1209 is amended as follows:

PART 1209—[AMENDED]

1. The authority citation for part 1209 continues to read as follows:

Authority: 5 U.S.C. 1204, 1221, 2302(b)(8) and 7701.

§ 1209.5 [Amended]

2. Section 1209.5 is amended by removing the number "20" in paragraph (c); and by adding in its place the number "30".

Dated: June 14, 1994.

Robert E. Taylor,

Clerk of the Board.

[FR Doc. 94–14860 Filed 6–16–94; 8:45 am]

BILLING CODE 7400–01–M

DEPARTMENT OF AGRICULTURE

Soil Conservation Service

7 CFR Part 658

Farmland Protection Policy

AGENCY: Soil Conservation Service, USDA.

ACTION: Final rule.

SUMMARY: This rule amends part 658 of title 7 of the Code of Federal Regulations which implements the Farmland Protection Policy Act (FPPA). The amendments contained in this rule are necessary to enable the Department of Agriculture to effectively implement the FPPA, as amended. They request reports by federal agencies, recognize the statutory authority of a governor of a state to bring legal actions to enforce the FPPA, provide policy direction regarding federal assistance and federal programs, and they restore a subsection of the existing rule that was omitted from publication by clerical error.

EFFECTIVE DATE: This rule becomes effective June 17, 1994.

FOR FURTHER INFORMATION CONTACT: Lloyd E. Wright, Director, Basin and Area Planning, Soil Conservation Service, PO Box 2890, Washington, DC 20013, telephone 202–720–2847.

SUPPLEMENTARY INFORMATION: The regulations of the United States Department of Agriculture (the Department) implementing the Farmland Protection Policy Act (FPPA) are contained in 7 CFR part 658. A proposed rule, setting forth several amendments to these regulations, was published for public comment on January 14, 1987, at 52 FR 1465. The comment period closed February 27, 1987, during which time nineteen sets of comments were received from five federal agencies; four state agencies; seven national organizations in the agricultural, resource conservation, and planning fields; one county board of supervisors; and two individuals.

The proposed rule, as discussed below, contained six amendments to the Department's existing regulations. Of these six amendments, three were being proposed as a result of the specific changes in the FPPA that Congress had enacted in section 1255 of the Food Security Act of 1985, Public Law 99–198, 99 Stat. 1518. Another amendment to the existing rule was to correct a clerical mistake. These four amendments, with minor changes, are made final by this rule.

The two remaining amendments, of the six included in the proposed rule, were not responses to any new direction enacted by Congress, but were the Department's proposals to change its policy in the interpretation of FPPA provisions. These two amendments were a departure from the policy that the Department had announced when the existing regulations were promulgated on July 5, 1984, 49 FR 27716. The existing sections of part 658 that would be changed by these two amendments are §§ 658.2(a) and 658.3(c). The rationale underlying the provisions of the existing regulations is set forth in the preamble of the final rule publication, which is found at 49 FR 27716–27724. The rationale for the proposed changes is set forth in the preamble of the proposed rule at 52 FR 1465–1468. After reviewing the policy considerations that led to the adoption of the existing regulations in 1984, as well as considering the proposed changes and the public comments to the proposed rule, the Department has concluded that the proposed amendments to § 658.2(a) should be adopted with some additional interpretive clarification, as discussed below.

In addition, the Department has concluded that § 658.3(c) should be amended as proposed to comport with the authority of a governor of a state to take action to enforce the provisions of the FPPA with regard to a policy or program of the affected state for the protection of farmland.

I. Background

The FPPA was enacted as Subtitle I, sections 1539–1549, of Title XV of the Agriculture and Food Act of 1981, Public Law 98–98, 7 U.S.C. 4201–4209. In enacting the FPPA, Congress found that the Nation's farmland was "a unique natural resource" and that each year, "a large among of the Nation's farmland" was being "irrevocably converted from actual or potential agricultural use to nonagricultural use," in many cases as a result of action taken or assisted by the federal government. The FPPA directs federal agencies to identify and take into account the adverse effects of federal programs on the preservation of farmland; consider alternative actions, as appropriate, that could lessen such adverse effects; and assure that such federal programs, to the extent practicable, are compatible with state government, local government, and private programs and policies to protect farmland.

In order to guide the federal agencies in implementing the FPPA, section 1541(a) of the Act, 7 U.S.C. 4202(a), directs the Department of Agriculture, in cooperation with other departments, agencies, independent commissions,

and other units of the federal government, to "develop criteria for identifying the effects of Federal programs on the conversion of farmland to nonagricultural uses." The Department issued these criteria in its current rule implementing the FPPA at 7 CFR 658.4 and 658.5. The FPPA also authorizes the Department to provide technical assistance to federal, state, and local government agencies to develop programs or policies to limit the conversion of productive farmland to nonagricultural uses, and this is covered in the current rule at 7 CFR 658.7.

In addition, section 1542 of the FPPA, 7 U.S.C. 4203, requires "each department, agency, independent commission, or other unit of the Federal Government" to review its laws, administrative rules, policies and procedures "to determine whether any provision thereof will prevent" the federal entity "from taking appropriate action to comply fully" with the FPPA, and to "develop proposals for action to bring its programs, authorities, and administrative activities into conformity with the purpose and policy" of the FPPA.

The Act does not expressly require a federal agency to modify any project solely to avoid or minimize the effects of conversion of farmland to nonagricultural uses. The Act merely requires that, before taking or approving any action that would result in conversion of farmland as defined by the FPPA, the federal agency examine the effects of that action using the criteria which the Department of Agriculture has supplied and, if there are adverse effects, to consider alternatives to lessen those effects. Once the agency has completed this examination, it may proceed with a project that would convert farmland to nonagricultural uses.

As originally enacted, the FPPA contained a prohibition against the use of the Act as a basis for litigation. Section 1548 states that the FPPA "shall not be deemed to provide a basis" for any litigation "challenging a Federal project, program or other activity that may affect farmland." 7 U.S.C. 4209. In the 1985 amendments to the FPPA, Congress amended this section to allow the governor of a state to bring a suit to enforce compliance with section 1542 (7 U.S.C. 4202) and related regulations.

II. Discussion of the Existing Regulations to Implement the FPPA

The current regulations were promulgated principally to enable federal agencies, with the help of the Soil Conservation Service (SCS), to measure the adverse effects, if any, of their programs and projects on farmland. The SCS has developed a Farmland Conversion Impact Rating Form, Form AD–1006, for this purpose. A federal agency considering a project on or affecting farmland completes and submits a Form AD–1006 to a local SCS office. The SCS determines if the proposed site or sites contain farmland subject to the FPPA, i.e., farmland that is "prime," "unique," or of "statewide or local importance," as defined by the FPPA. If SCS determines that the site or sites are not subject to the Act, SCS returns the form to the agency with that determination noted.

However, if SCS determines that the FPPA applies, SCS measures the "relative value" of the site or sites as farmland on a scale of 0 to 100, enters this score on the Form AD–1006 and returns the form to the federal agency. At this stage, the agency prepares a site assessment using twelve criteria set forth in the rule. After scoring each of the criteria and arriving at a total site assessment score, up to a maximum of 160 points, the agency adds this site assessment score to the "relative value" score that was supplied by the SCS on the Form AD–1006. The higher the combined score, the more suitable the site would be for protection as farmland. On the other hand, if a site receives a combined score of less than 160 points, the regulation recommends that it be given only "a minimal level of consideration for protection" and that additional sites do not need to be evaluated as alternatives.

Although the primary purpose of the Department's regulations implementing the FPPA was to impart these criteria and the guidelines for their use by agencies, the rule, in addition, established the Department's policy as to the farmlands that are subject to the FPPA, and as to the effect that the FPPA could have on private parties and nonFederal units of government applying for federal assistance to convert farmland to nonagricultural uses.

With regard to the first matter, the FPPA's definition of "prime farmland," excludes "land already in or committed to urban development or water storage." Section 1540(c)(1)(A), 7 U.S.C. 4201(c)(1)(A). The current regulation, § 658.2(a), provides that prime farmland is "committed to urban development or water storage" if a local zoning code or ordinance or current local comprehensive land use plan designated this land for commercial or industrial use or for residential use that is not intended at the same time to protect farmland.

With regard to the second issue, the current regulation, § 658.3(c), sets forth the Department's determination that the FPPA does not authorize a federal agency to withhold assistance to a project solely because that project was going to convert farmland to nonagricultural uses.

III. Discussion of the Amendments to the Existing Regulations

A. The Two Amendments Necessary for the Annual FPPA Report to Congress

Section 1546 of the FPPA, as enacted in 1981 (99 Stat. 1343–1344), required the Secretary of Agriculture to report to Congress on the progress made in implementing the FPPA. Only one report was required; and it was due within one year after the date of enactment, December 22, 1981. Section 1546 provided that the report should include information on:

(1) The effects, if any, of federal programs, authorities, and administrative activities with respect to the protection of United States farmland; and

(2) The results of the reviews of existing policies and procedures required under section 1542(a) of the Act.

As amended by section 1255 of the Food Security Act of 1985, section 1546 (7 U.S.C. 4207) now requires an annual report due at the beginning of each calendar year. The existing regulation, which was published prior to the amendment of section 1546, does not include any provisions for an annual report to Congress. Further, under the existing regulation, once agencies have completed their site assessments on the Farmland Conversion Impact Rating Form (Form AD–1006), they retain these forms and proceed to make their own decisions regarding the use of the site for the project in question. They do not make a regular practice of returning the form or a copy of it to SCS. Thus, SCS receives no record of the agency's use of the form or the agency's ultimate decision on the project.

Similarly, the existing regulation does not require a federal agency to report regularly to the Department on the progress made with the review of current provisions of law, administrative rules and regulations, and policies and procedures applicable to the federal agency to determine whether any provision thereof will prevent such unit of the federal government from taking appropriate action to comply fully with the provisions of the FPPA. This review is required by section 1502(a) of the Act, 7 U.S.C. 4203(a).

Now that the Act requires an annual report that includes both the effects of federal activities on the protection of farmland and the reviews undertaken by agencies, it is necessary for the Department to modify its existing regulations. Accordingly, the proposed rule in 1987 included two amendments to the existing regulations to enable the Department to carry out its reporting obligations.

The first of these amendments would have added a new § 658.4(g) to request federal agencies to return a copy of their completed Form AD–1006 to SCS after a final decision on a project has been made. This amendment received support in comments from all nongovernmental organizations and individuals, from the State of Rhode Island Statewide Planning Program, and from the Clarke County (Virginia) Board of Supervisors. However, the response was different from federal and state agencies that work with Form AD–1006 and would be responsible for returning it to the SCS.

Two federal agencies, the Federal Highway Administration (FHWA) and the Department of Housing and Urban Development (HUD), and the Michigan Department of Transportation and that of Oklahoma expressed concern that this requirement would generate additional, burdensome paperwork. The FHWA suggested that only those forms in which the selected site had a score of more than 160 be returned to SCS. HUD proposed to advise SCS of any tracts of farmland for which financing of housing subdivisions was being approved, but said it would be hard-pressed to return a Form AD–1006 for each action taken by HUD, especially those involving individual mortgage insurance.

The Michigan Department of Transportation and that of Oklahoma made comments that were almost identical to one another. On federally supported highway projects requiring environmental assessments or impact statements, the Form AD–1006 is included in such documentation and SCS receives a copy of the final document. Lesser projects, on the other hand, do not require an environmental assessment or impact statement, because they are often categorically excluded from review by regulations implementing the National Environmental Policy Act. These projects "usually require only minor amounts of right-of-way and thus have a very minimal impact on prime farmland," the Oklahoma Department of Transportation stated. Both Michigan and Oklahoma objected to having to submit Form AD–1006 on these types of projects.

The Department recognizes that this change in its regulation may increase the paperwork requirement on federal public works and other federally, assisted programs that are already burdened with reporting requirements. Congress, however, directed that each year the Department is to report on the effects federal programs and actions are having on farmland, and the Department believes that collecting the Form AD–1006 data generated by the affected federal agencies is the best way to compile this information.

The Department has made changes in the final rule to reduce reporting burdens. Under the current rule, SCS determines whether the site or sites in question are of the type of farmland subject to the FPPA. Even in cases where SCS determines the FPPA does not apply and SCS returns a Form AD–1006 to the referring agency, further tracking of agency decisionmaking is carried out with a report back to SCS on the final decision regarding the initial referral. New procedures set forth in § 658.4(g), give agencies the option of referring questions of FPPA applicability to SCS or of making these determinations themselves, and in cases where SCS makes a negative determination, there is no further tracking of matters in which none of the alternatives involve farmland subject to the FPPA.

The second amendment to the existing regulations related to the annual reporting function is a new § 658.7(d). This new paragraph (d) will require each federal agency to report to the Chief of SCS the agency's progress during the prior fiscal year in reviewing its authorities, internal rules, policies and procedures, and the agency's development of proposals to bring its programs, authorities, and administrative activities into conformity with the FPPA, pursuant to section 1542 of the FPPA, 7 U.S.C. 4203.

This second amendment drew a pattern of comments similar to those offered for amendment one. The organizations and individuals who generally supported the amendments in the proposed rule were in support of this subsection. However, three of the federal agencies that would be required to make these yearly reports to SCS were critical.

The Farmers Home Administration (FmHA) proposed that once an agency has demonstrated that its programs, authorities, and administrative activities are in compliance with the FPPA, it should not be required to make an annual report. Rather, The FmHA asserted, such an agency should be requested to report only in a year in which it either plans to change its FPPA compliance process or undertakes a new program that may be subject to the FPPA.

The FHWA commented that a single report from an agency should be sufficient until any future revisions to the FPPA or the SCS regulations are made.

The Tennessee Valley Authority (TVA) asked for additional guidance concerning the type of information in the report, and recommended that the annual report be an assessment of the progress made in implementing the FPPA, without excessive and burdensome documentation of specific farmland conversion or protection activities.

The Department has incorporated the suggestion offered by the FmHA in the final rule. Although the request for an annual report will remain, once the agency has completed the review of its policies and procedures and revised them as needed to comply with the Act, no additional reports are requested. In years in which the agency has changed its FPPA compliance process, a report is requested.

As for the concern expressed by the TVA, the scope of the agencies' reports to SCS under the new § 658.7(d) is that which is established in section 1542 of the FPPA and which is set forth in the unchanged sections of the existing regulations, 7 CFR 658.7(a) and (b). In other words, the annual reports the agencies are to submit to SCS are to be limited to the reviews of laws, regulations, policies, and procedures that the agencies have conducted under section 1542(a) of the FPPA and the proposals for action, if any, that the agency has developed pursuant to section 1542(b). In addition, SCS will be receiving data from the agencies on their individual project decisions involving farmland, but this data will come from the various AD–1006 forms that the agencies are to return to SCS after making their action decisions.

B. Amendment to Recognize Change in Limitation on Litigation

Section 1255(b) of the Food Security Act of 1985, 99 Stat. 1518, amended section 1548 of the FPPA, 7 U.S.C. 4209, which originally prohibited states, local governments, and private parties using the FPPA as a basis to bring actions challenging Federal activities. Prior to the amendment, the language of section 1548 was as follows:

This subtitle shall not be deemed to provide a basis for any action, either legal or equitable, by any State, local unit of government, or any persons challenging a

Federal project, program, or other activity that may affect farmland. 95 Stat. 1344.

As amended, section 1548 (7 U.S.C. 4209) now reads as follows:

This subtitle shall not be deemed to provide a basis for any action, either legal or equitable, by any state, local unit of government, or any persons challenging a Federal project, program, or other activity that may affect farmland. 95 Stat. 1344.

This subtitle shall not be deemed to provide a basis for any action, either legal or equitable, by any person or class of persons challenging a Federal project, program, or other activity that may affect farmland: Provided, that the Governor of an affected State where a State policy or program exists to protect farmland may bring an action in the Federal district court of the district where a Federal program is proposed to enforce the requirements of section 1541 of this subtitle and regulations issued pursuant thereto.

Accordingly, § 658.3(d) of the existing regulation, which is simply a restatement of section 1548 in its original form, needs to be amended to conform with section 1548, as amended. None of the commenting parties expressed opposition to the proposal for this change in the regulation, and it is incorporated in this rule.

C. Amendment to restore § 658.7(b)

When 7 CFR part 658 was published as a final rule in 1984, it was intended to include § 658.7(b), which simply incorporates the provision of section 1542(b) of the Act requiring the federal agencies to develop proposals for action to bring their programs, authorities, and administrative activities into conformity with the FPPA. However, in the draft of the rule submitted to the **Federal Register**, paragraph (b) was inadvertently omitted, leaving a gap between § 658.7(a) and § 658.7(c) as they appeared in the published rule at 49 FR 27727. The proposed rule of January 14, 1987 included an amendment to restore this missing paragraph. None of the commenting parties expressed opposition to this correction, and it is incorporated in the final rule.

D. Amendment to Change Definition of "Prime Farmland Committed to Urban Development of Water Storage"

The FPPA does not include all farmland under its protection. In section 1540(c), 7 U.S.C. 4201(c), the specific farmland covered by the FPPA is defined. This is farmland that is either "prime farmland," "unique farmland," or "farmland, other than prime or unique farmland, that is of statewide or local importance." Each one of these terms is further defined and qualified in the FPPA and, in the definition of "prime farmland, there is an exclusion of "land already in or committed to urban development or water storage." Federal agencies are not required to consider the impact of their projects on prime farmland that is "already in or committed to urban development or water storage," even if this land would otherwise fall within the definition of "prime farmland."

In developing the existing regulations, the Department adopted standards for determining if prime farmland is "already in urban development" and whether land, although not "in urban development," was nevertheless "committed to urban development." Under § 658.2(a) of the current regulation, prime farmland which had been zoned for nonagricultural use by a state or local government with jurisdiction over the land, or which was designated in a current state or local land use plan for nonagricultural use, is regarded as "committed to urban development." This would mean that projects on prime farmland in those areas would not have to be analyzed by agencies for their effect on prime farmland.

The Department noted in the preamble to the 1984 final rule, at 49 FR 27720, that land use planning and zoning "are prerogatives of state and local government, not the Federal Government," and supplied the following rationale for the conclusion that prime farmland under nonagricultural zoning or planning was excluded from the FPPA:

If a federal agency were required by the Act to assess the impacts of a project on prime farmland not yet in urban development but already designated by the state or local government for urban development through planning or zoning, the only purpose of the requirement would be for that agency to weigh alternative sites that would lessen the impact of the project on farmland. If the agency, based on its assessment pursuant to the Act, should then decide to refrain from building its project on the proposed site, it would be declining itself to use the proposed site for urban development when local or state planning or zoning had already declared urban uses to be acceptable on the site. This would be an intrusion by the Federal Government in the function of land use planning of state and local governments.

In the proposed rule, the Department offered for public comment a proposal that would abrogate the Department's previous interpretation of this question. In the definition of "prime farmland," there would no longer be an exclusion based solely on the designation of the land in a land use plan or zoning code or ordinance for nonagricultural uses. The proposed rule amendment would provide that once a project site had been analyzed and given a combined score of 160 points or less, it would be considered "committed to urban development" and thus no longer covered by the FPPA.

The preamble to the 1987 proposed rule, at 52 FR 1466–1467, cited three reasons for introducing these changes. First, it stated that the existing definition "is inconsistent with the definitions of prime farmland used in almost all other State and Federal programs which use the definition." Second, it noted that the existing definition requires the SCS district conservationists to review local plans and land use regulations and that many of them do not have the background in land use planning to make the proper determinations as to whether a given project site is truly "committed to urban development." Third, because land "committed to urban development" is excluded in the FPPA's definition of "prime farmland" but not from the FPPA's definitions of farmland that is "unique" or "of statewide or local importance," it is an anomaly that this type of "prime farmland" can be so easily and categorically put outside the reach of the FPPA while farmland that is "unique" or "of statewide or local importance" is covered by the FPPA despite the existence of zoning designations or land use plans that would allow urban development of such lands.

The comments on the proposed rule were sharply divided on whether the Department should change the identification of farmland "committed to urban development." The American Farmland Trust "strongly" supported the proposed change, calling the existing rule "confusing and inconsistent with the intent of the legislation." The Natural Resources Defense Council (NRDC) also supported the proposed change since it did not approve of farmland being excluded from the FPPA's coverage just because local land-use plans or zoning ordinances would allow urban development on it. This, the NRDC stated, would be an "arbitrary 'grandfather' exclusion * * * even where there is no current nonagricultural development and the prospect of future nonagricultural development is highly speculative." The American Land Resource Association agreed with the proposed change, claiming that the existing rule worked "inadequately" for protection of prime farmland and caused "unnecessary confusion among Federal agencies implementing the FPPA." The Farmers Home Administration and the Rhode Island Statewide Planning Program supported the change. Other

commenting parties agreed with the change as part of their general support of all the amendments being proposed.

However, the Department of Housing and Urban Development (HUD), the Federal Highway Administration (FHWA), and the Michigan Department of Transportation opposed making the change in the Department's interpretation of farmland "committed to urban development." In particular, HUD devoted the principal thrust of its comments to this provision, objecting "strongly" to the change and outlining the importance of retaining the Department's current interpretation that land under planning or zoning for nonagricultural use was "committed to urban development." HUD stated:

> This procedure ignores and undermines a local government's land use decisions made through zoning, comprehensive planning, and subdivision regulations which are adopted to guide and direct urban development and growth * * * By changing the definition of 'farmland committed to urban development' and requiring a Farmland Conversion Impact Rating (AD–1006) be prepared, which must result in an aggregated score of 160 points or less before it is considered 'farmland committed to urban development,' certainly qualified USDA as taking a "big brother" approach to local land use plans and decisions.

HUD explained that whenever an application for project assistance is submitted to HUD, it must receive approval of local authorities. Since 1985, HUD's principal method for issuing mortgage insurance on single, family homes in housing subdivisions has been to wait until the local government has approved the subdivision plan and construction of the necessary streets and water and sewer systems. Under the existing rule, HUD would not have to analyze this land as "prime farmland" under FPPA. HUD argued that under the proposed rule, it would be required to complete the AD–1006 form on this land, which it termed a "useless exercise" at that point.

Aside from the mechanics of the proposed amendment, HUD made these comments about the general problem of farmland protection measures that the agency might undertake:

> In the single family housing program (which actions are most likely to be on the fringes of urban areas), preservation of farmland would require that we would have to either be involved in the local planning and zoning process at the earliest conceptual stages or by prohibitive and restrictive regulations which would withhold assistance for projects which had converted farmland to nonagricultural uses. Taking either action could easily be interpreted as an indirect way to regulate the use of private land or affect the property rights of the owners of such lands. We do not believe that to be the intent of Congress. Putting a penalty on the land, either directly or indirectly, could result in creating a greater housing shortage, especially for low and moderate income families who are the primary users of HUD mortgage housing programs.

The FHWA, likewise, objected to the proposal on the grounds that it would require preparation of a site assessment on every project that requires rights-of-way. This would require "an enormous amount of time and resources to be provided by Federal, State and/or local agencies" and in many cases there would be "no apparent justification." FHWA suggested that the same exclusion of farmland "committed to urban development" that the Department has applied to "prime farmland" should be applied to the other two categories in the FPPA, "unique" farmland and farmland "of local or statewide importance."

The Michigan Department of Transportation had similar objections. It explained that the current rule "screens out many projects and constitutes a real time savings * * * If the local entities have designated the land for other uses, it doesn't warrant a high degree of protection as resource base at the federal level." On the other hand, if the rule were changed, it would require site assessments of "each project that required rights-of-way."

As noted in the preamble to the proposed rule at 52 FR 1467, the zoning and land use plans that are applicable to a particular site will be considered in conjunction with other criteria that are designed to assess the degree to which the site is committed to urban development. In this way, the prerogatives of state and local government, as exercised in zoning codes and land use plans, will play a role in determining whether a site should be given further FPPA review. Because the amended regulations will neither prohibit the providing of federal assistance to convert farmland nor preclude the conversion of farmland through non-federal means, the Department believes that the amended rule, as proposed, will not interfere with local land use planning, and will assure that prime farmlands will, to the full extent of the law, be given appropriate consideration.

Under the current regulation, sites that contain prime farmland that otherwise would have been exempted due to being "in or committed to urban development" would have still been covered by the FPPA if the site also contained lands of statewide or local importance. The exclusion of lands "in or committed to urban development" would have limited effect. After consideration of the comments, the Department is amending the rule to apply the exemption for farmland "in or committed to urban development" to all four types of farmland. It is clear from the comments provided by a number of federal agencies that they are already applying the exemption to all four types of farmland. Section 658.2(a) is being revised to remove the word "prime" before the word "farmland," thereby, making the exemption apply to all farmland.

An AD–1006 for a site that is located in urban areas need not be sent to SCS for evaluation. In addition, some agencies would like to use available mapped information to make their determinations without sending a Form AD–1006 to SCS. To facilitate the use of such information, § 658.2(a) will be revised to clarify that farmland "already in" urban development or water storage may be identified by an area shown as "urbanized area" (UA) on the Census Bureau map, or shown as an urban tint outline or urban area map on U.S.G.S. topographical maps, or shown as urban-built-up on the USDA Important Farmland Maps. Areas shown as white on the USDA Important Farmland Maps are not farmland and, therefore, are not subject to the Act. In addition, § 658.4(a) is being amended to clarify that federal agencies may determine whether or not a site contains farmland as defined in § 658.2(a) without sending a Form AD–1006 to SCS. Where SCS is asked to complete the land evaluation portion of Form AD–1006 before the Federal agency completes the site assessment portion, and SCS determines that the site is subject to the FPPA, then when SCS returns the form to the agency for completion of the site assessment portion, SCS will at the same time provide the agency with the requested information and data necessary for the Federal agency to complete and score the site assessment factor questions, and where the agency chooses to complete the site assessment portion of the form first, SCS will cooperate in providing timely information and data to enable the Federal agency to score the site assessment factor questions.

E. Amendment to Allow an Agency to Either Provide or Deny Assistance to a Project to Convert Farmland

The existing regulations, at § 658.3(c), interpret the extent to which an agency can use the FPPA as a basis for denying assistance to a project that would convert farmland. The paragraph reads as follows:

The Act and these regulations do not authorize the Federal Government in any way to regulate the use of private or nonfederal land, or in any way affect the property rights of owners of such land. The Act and these regulations do not provide authority for the withholding of federal assistance to convert farmland to nonagricultural uses. In case where either a private party or a nonfederal unit of government applies for federal assistance to convert farmland to a nonagricultural use, the federal agency should use the criteria set forth in this part to identify and take into account any adverse effects on farmland of the assistance requested and develop alternative actions that could avoid or mitigate such adverse effects. If, after consideration of the adverse effects and suggested alternatives, the applicant wants to proceed with the conversion, the federal agency may not, on the basis of the Act or these regulations, refuse to provide the requested assistance.

The proposed rule contained an amendment that would change the Department's interpretation of the effect of the FPPA by revising this paragraph significantly. This amendment would drop the second sentence. In the closing sentence, instead of retaining the language that the federal agency "may not, on the basis of the Act or these regulations, refuse to provide the requested assistance," the new language would state that the agency, after doing the required analysis and following its internal policies or procedures, would be free to deny as well as provide the assistance. See 52 FR 1467.

The rationale for this proposed change, as stated in the preamble to the proposed rule at 52 FR 1466, is that the FPPA leaves to the discretion of each agency "the determination of whether the providing or the denial of Federal assistance for farmland conversion will, in a given situation, comply with the policy and purpose of the FPPA." It was further noted that the rule, as presently written, "may be misread as a limitation on the previously described discretion provided by Congress to Federal agencies," and thus the amendment was needed "to recognize that discretion and the general process through which it is exercised."

Under the current regulation, when private landowners as well as state and local governments apply for assistance for a project involving the conversion of farmland subject to the FPPA, the federal agency is required to examine the effects of the project and alternatives but may not, based on the FPPA, refuse to provide the assistance. The amendment in the proposed rule would avoid making this analysis a pointless exercise by removing the rigid restriction on agency deliberations and allowing the agency to use the FPPA analysis as a basis for withholding assistance to the project in order to achieve the policies and objectives of the Act.

None of the parties who commented raised opposition to this proposal to change the existing regulation. A number of them supported it vigorously or proposed that it be made even stronger. The FmHA suggested the rule should provide that "if a clear alternative exists to avoiding a proposed conversion of important farmland and the applicant for Federal assistance is unwilling to pursue such an alternative, the Federal agency cannot provide financial assistance." FmHA went on to argue that if the FPPA did not impose this "affirmative duty" on agencies to deny assistance, "then other significant provisions of the Act become meaningless, such as (1) the ability of a governor to bring action in Federal district court to enforce the requirements of the FPPA, and (2) the requirement that each Federal agency identify and report to Congress any provisions of law, administrative rules, regulations, policies, and procedures applicable to it which prevent it from complying fully with the FPPA. What can governors enforce, what possible legislative or regulatory conflicts can exist, if the FPPA allows a Federal agency total discretion in deciding whether or not to finance an unnecessary conversion of important farmland?"

The Natural Resources Defense Council, the American Land Resource Association, and the American Farmland Trust also supported the change and, like the FmHA, proposed that it contain requirements that federal assistance be withheld from nonagricultural development in cases where alternatives mitigating or avoiding prime farmland conversion are available.

The Department, after considering the comments, believes that the proposed rule amendment is necessary to achieve the intent of Congress under the FPPA and, therefore, adopts that amendment in this rule. The amended § 658.3(c) allows the various federal agencies to consider the particular facts relating to their proposed assistance activities and to decide, in light of the policies of the FPPA and their own authorities, which reasonable alternative action will best achieve their mission and comply with the FPPA.

In similar deference to the agency discretion provided by the FPPA, the Department has determined not to accept the recommendations for a complete withholding of federal assistance to convert farmland in situations where alternatives exists to avoid or mitigate the effects of conversion. There may be, specific situations, compelling reasons of national, state, or local importance that would outweigh the protective policies of the Act. The federal agencies, in exercising the responsibility provided by the FPPA, can best analyze the facts of those situations, and their discretion to do so should not be unnecessarily constrained.

The Department notes that the Congress, during deliberations on proposed amendments to the FPPA as part of the Food Security Act of 1985, Public Law 99–198, considered and rejected a ban on federal assistance to convert farmland in situations where reasonable alternatives to conversion exist. See H.R. Conf. Rep. No. 447, 99th Cong., 1st Sess. 472 (1985), reprinted in 1985 U.S. Code Cong. & Admin. News 2398. The final rule allows the intentions of Congress, as expressed in the FPPA and in the 1985 deliberations, to be carried out.

During consideration of the comments received on the proposed rule and in interagency discussions within the Department, a misunderstanding of the scope of the analysis required by the FPPA and the regulations surfaced. This related to the extent to which federal agencies are required to identify and assess the potential for future conversion of farmland as a result of present activities and assistance.

As with other natural resource or environmental evaluations, such as the analyses required by the National Environmental Policy Act, the scope of the review must be related to the scope of the activity under consideration. In complying with the requirements of section 1542 of the Act (7 U.S.C. 4203) that each federal agency review its programs, authorities, policies, and procedures and take appropriate measures to assure that they conform with the purposes of the FPPA, an agency may properly consider the broader implications that its programs and policies have toward the potential for future conversions of farmland to nonagricultural uses. However, in considering whether a specific project or assistance activity of the agency will result in the irreversible conversion of farmland, the focus will be on those direct and indirect effects of the activity that can be reasonably identified and evaluated. In a review of a specific activity which does not contain proposals for, nor necessarily lead to, future activities that may convert farmland, the potential activities may be too general or speculative to adequately identify and usefully consider The

scope of each evaluation is determined by the scope of the objectives and facts of the agency activity under consideration.

It should be noted that the guidance provided in § 658.3(c), as amended by this rule, regarding the providing of federal assistance to convert farmland clearly applies beyond situations where a federal agency has been requested to provide assistance. Federal activities that are the result of federal initiatives, rather than requests for federal assistance, necessarily involve the same farmland protection policy considerations. In a situation where a Federal agency is contemplating an action that would convert farmland to a nonagricultural use and which is not the result of a direct request for federal assistance, the federal agency may decide, after conducting the analysis required by the FPPA, not to proceed with the action in order to achieve the objectives of the FPPA.

Implementation of the policy objectives of the FPPA in the manner discussed above and as contained in this final rule not only respects the traditional deference to state and local land use decisionmaking reflected in the FPPA, but also comports with and furthers the principles of federalism contained in Executive Order No. 12612 of October 26, 1987, 52 FR 41685. Local zoning and land use plans will be considered in determining if a site has been committed to urban development. Further, a federal agency may support state and local efforts to protect farmland by deciding not to provide federal assistance that would be used to convert farmland.

The wording of § 658.3(c) has been slightly modified from that of the proposed rule to clarify that any agency policies or procedures for implementing the Act may be considered by an agency in deciding how to proceed with an activity.

F. Additional Considerations

Some federal agencies raised concerns as to actions subject to the Act. The current regulation, at § 658.2(c), provides an exemption for federal permitting, licensing, or rate approval programs. Federal regulatory activities are not considered as federal assistance that could convert farmland. Therefore, federal regulatory activities are exempted from the Act. For example, in cases where a Clean Water Act section 404 permittee is required by the Corps of Engineers to perform compensatory mitigation on farmed wetland, thereby converting the wetland actual or potential use of farmland to a nonagricultural use, that conversion is not subject to FPPA. In complying with § 658.7 (a) and (b), Federal agencies may identify those programs that they determine are not subject to the Act and provide details on how other programs will be implemented consistent with the Act.

As further clarification, it should be noted that only those actions that will or could convert farmland to nonagricultural uses are subject to the Act. Assistance provided to purchase, maintain, renovate, or replace a structure that already exists is not subject to the Act, because any conversion of farmland took place at the time the structure was constructed. The addition of minor new ancillary structures, such as garages or sheds, to *serve* existing structures is also not included under the Act. Even in cases where loans are made for new houses, that action is not subject to the FPPA if the request for assistance and commitment by the federal agency was made after the house was constructed. Likewise, once one Federal agency has performed an analysis under the FPPA for the conversion of a site, that agency's or a second Federal agency's determination with regard to additional assistance or actions on the same site do not require additional, redundant FPPA analysis. Section 658.4(h) is being added to the final rule to reflect this clarification.

Several federal agencies cited concern for the application of the FPPA to land acquisitions by these agencies, providing temporary, intermediate ownership by the Federal Government such as through foreclosure, the acquisition of assets of an insolvent thrift institution or through forfeiture in criminal law enforcement proceedings. They expressed concern for potential conflicts between their statutory responsibilities to obtain prompt, high value disposal of these assets and the analysis procedures required under the FPPA.

The definition of "Federal program" in the FPPA, 7 U.S.C. 4201(c)(4), extends the coverage of the FPPA to "acquiring, managing, or disposing of Federal lands and facilities." If an agency determines that its program does not result in a sufficient acquisition of legal or equitable title by the United States to characterize the property as "Federal land or facilities," then the agency may exclude such land through its own policies and procedures for implementing the FPPA.

However, the Department has determined that an interpretive clarification of the term "Federal land and facilities" as used in the definition of "Federal programs" covered by the FPPA would be useful. In that regard, the Department believes that the use of the word "Federal" to modify the words "land and facilities" indicates an intent by Congress to focus the scope of federal programs covered by the FPPA to lands and facilities acquired or managed by federal agencies as necessary proprietary elements of federal programs, such as national forests, national parks, or military bases. The use of the modifier "Federal" is significant; if the intent was to include the acquisition, management, or disposal of any land or facility by a federal agency, regardless of the purpose of the use of the land or facility, Congress could have omitted the modifier and simply stated, "acquiring, managing, or disposing of lands and facilities."

Accordingly, the Department has amended the definition of "Federal program" contained in § 658.2(c) to clarify that, for the purposes of the FPPA and these regulations, the phrase "acquiring, managing, or disposing of federal lands and facilities" refers to lands and facilities that are acquired, managed, or were used by a federal agency specifically in support of a federal activity or program. It does not include lands or facilities that are acquired, managed, or disposed of by a federal agency as the incidental result of actions by that agency through which the agency has temporary ownership or custody of the land or facility, such as acquisition pursuant to a lien for delinquent taxes, the exercise of conservatorship or receivership authority, or the exercise of civil or criminal law enforcement forfeiture or seizure authority.

The Department has also incorporated in the definition of "Federal program" interpretive clarification that loan guarantees or loan insurance of the construction of buildings or other structures is covered by the phrase "undertaking, financing, or assisting construction or improvement projects" contained in the definition of "Federal program." This interpretation was previously provided in the preamble of the final rule that promulgated the current regulations. See 49 FR 27720, July 5, 1984. Further in this regard, the Department has clarified that the acquisition, management, and disposal of land or facilities that a federal agency obtains as the result of foreclosure or other actions taken under a loan, loan guarantee, or other financial assistance proved by the agency directly and specifically for that property or facility is likewise within the definition of "Federal program."

A federal agency may develop and use procedures to implement the FPPA for its loan, loan guarantee, or other financial assistance programs on either a specific project/loan basis or on the basis of an entire program. Further, if an agency has conducted a FPPA review of a loan or other financial assistance for the conversion of farmland and the agency or any other federal agency subsequently acquires the property related to that assistance, the previously conducted FPPA review will be sufficient to constitute compliance with the FPPA for the management an eventual disposal of the property.

More importantly, an agency may develop and use specific policies and procedures for the management and disposal of property acquired through foreclosure, forfeiture, or other such means that taken into consideration its primary statutory authorities regarding such properties. Clearly, these determinations can be best made by the particular agencies involved through their respective FPPA policies and procedures, in consideration of the statutory requirements under which they operate. The Department will consult with agencies, pursuant to section 1542 of the FPPA, 7 U.S.C. 4203, to address these concerns.

Some federal agencies would like to exempt certain sites related to the expansion of existing linear projects that would convert only a few acres of farmland but would avoid the conversion of a large number of acres. Some statewide LESA systems currently include exemptions of 10 acres per bridge and 3 acres per mile on existing highways. The construction of bridges and widening of existing highways is a farmland protection method. USDA will consult with Federal Highway Administration, on actions that are designed to improve existing linear projects so as to avoid the conversion of land that would occur if a new linear project were to be constructed.

This rule has been reviewed under USDA procedures established in accordance with provisions of Departmental Regulations 1512–1 and has been designated "non-major."

It has been determined that this action will not have an economic impact on the economy of $100 million or more; result in a major increase in costs or prices for consumers, individual industries, federal, state, or local government agencies, or geographic regions; or result in significant adverse effects on competition; employment, investment, productivity, innovation, or on the ability of U.S.-based enterprises to compete with foreign, based enterprises in domestic or export markets.

This rule does not contain information collection requirements that require approval by the Office of Management and Budget under 44 U.S.C. 3501 et seq.

This document has been prepared in the Office of the Secretary, USDA, with the assistance of the Basin and Area Planning Division of the Soil Conservation Service.

List of Subjects in 7 CFR Part 658

Agriculture, Farmland, Soil conservation.

Accordingly, part 658 of title 7 of the Code of Federal Regulations is amended as follows:

PART 658—[AMENDED]

1. The authority citation for part 658 is revised to read:

Authority: 7 U.S.C. 4201–4209.

2. Section 658.2 is amended by revising paragraphs (a) and (c) to read as follows:

§ 658.2 Definitions.

(a) *Farmland* means prime or unique farmlands as defined in section 1540(c)(1) of the Act or farmland that is determined by the appropriate state or unit of local government agency or agencies with concurrence of the Secretary to be farmland of statewide of local importance. "Farmland" does not include land already in or committed to urban development or water storage. Farmland "already in" urban development or water storage includes all such land with a density of 30 structures per 40-acre area. Farmland already in urban development also includes lands identified as "urbanized area" (UA) on the Census Bureau Map, or as urban area mapped with a "tint overprint" on the USGS topographical maps, or as "urban-built-up" on the USDA Important Farmland Maps. Areas shown as white on the USDA Important Farmland Maps are not "farmland" and, therefore, are not subject to the Act. Farmland "committed to urban development or water storage" includes all such land that receives a combined score of 160 points or less from the land evaluation and site assessment criteria.

* * * * *

(c) *Federal program* means those activities or responsibilities of a Federal agency that involve undertaking, financing, or assisting construction or improvement projects or acquiring, managing, or disposing of Federal lands and facilities.

(1) The term "Federal program" does not include:

(i) Federal permitting, licensing, or rate approval programs for activities on private or non-Federal lands; and

(ii) construction or improvement projects that were beyond the planning stage and were in either the active design or construction state on August 4, 1984.

(2) For the purposes of this section, a project is considered to be "beyond the planning stage and in either the active design or construction state on August 4, 1984" if, on or before that date, actual construction of the project had commenced or:

(i) acquisition of land or easements for the project had occurred or all required Federal agency planning documents and steps were completed and accepted, endorsed, or approved by the appropriate agency;

(ii) a final environmental impact statement was filed with the Environmental Protection Agency or an environmental assessment was completed and a finding of no significant impact was executed by the appropriate agency official; and

(iii) the engineering or architectural design had begun or such services had been secured by contract. The phrase "undertaking, financing, or assisting construction or improvement projects" includes providing loan guarantees or loan insurance for such projects and includes the acquisition, management and disposal of land or facilities that a Federal agency obtains as the result of foreclosure or other actions taken under a loan or other financial assistance provided by the agency directly and specifically for that property. For the purposes of this section, the phrase "acquiring, managing, or disposing of Federal lands and facilities" refers to lands and facilities that are acquired, managed, or used by a Federal agency specifically in support of a Federal activity or program, such as national parks, national forests, or military bases, and does not refer to lands and facilities that are acquired by a Federal agency as the incidental result of actions by the agency that give the agency temporary custody or ownership of the lands or facilities, such as acquisition pursuant to a lien for delinquent taxes, the exercise of conservatorship or receivership authority, or the exercise of civil or criminal law enforcement forfeiture or seizure authority.

* * * * *

3. Section 658.3 is amended by revising paragraphs (c) and (d) to read as follows:

§ 658.3 Applicability and exemptions.

* * * * *

(c) The Act and these regulations do not authorize the Federal Government in any way to regulate the use of private or nonfederal land, or in any way affect the property rights of owners of such land. In cases where either a private party or a nonfederal unit of government applies for federal assistance to convert farmland to a nonagricultural use, the federal agency should use the criteria set forth in this part to identify and take into account any adverse effects on farmland of the assistance requested and develop alternative actions that would avoid or mitigate such adverse effects. If, after consideration of the adverse effects and suggested alternatives, the landowners want to proceed with conversion, the federal agency, on the basis of the analysis set forth in § 658.4 and any agency policies or procedures for implementing the Act, may provide or deny the requested assistance. Only assistance and actions that would convert farmland to nonagricultural uses are subject to this Act. Assistance and actions related to the purchase, maintenance, renovation, or replacement of existing structures and sites converted prior to the time of an application for assistance from a federal agency, including assistance and actions related to the construction of minor new ancillary structures (such as garages or sheds), are not subject to the Act.

(d) Section 1548 of the Act, as amended, 7 U.S.C. 4209, states that the Act shall not be deemed to provide a basis for any action, either legal or equitable, by any person or class of persons challenging a federal project, program, or other activity that may affect farmland. Neither the Act nor this rule, therefore, shall afford any basis for such an action. However, as further provided in section 1548, the governor of an affected state, where a state policy or program exists to protect farmland, may bring an action in the federal district court of the district where a federal program is proposed to enforce the requirements of section 1541 of the Act, 7 U.S.C. 4202, and regulations issued pursuant to that section.

4. Section 658.4 is amended by revising paragraphs (a) and (c)(2), and by adding two new paragraphs (g) and (h) to read as follows:

§ 658.4 Guidelines for use of criteria.

* * * * *

(a) An agency may determine whether or not a site is farmland as defined in § 658.2(a) or the agency may request that SCS make such a determination. If an agency elects not to make its own determination, it should make a request to SCS on Form AD–1006, the Farmland Conversion Impact Rating Form, available at SCS offices, for determination of whether the site is farmland subject to the Act. If neither the entire site nor any part of it are subject to the Act, then the Act will not apply and SCS will so notify the agency. If the site is determined by SCS to be subject to the Act, then SCS will measure the relative value of the site as farmland on a scale of 0 to 100 according to the information sources listed in § 658.5(a). SCS will respond to these requests within 10 working days of their receipt except that in cases where a site visit or land evaluation system design is needed, SCS will respond in 30 working days. In the event that SCS fails to complete its response within the required period, if further delay would interfere with construction activities, the agency should proceed as though the site were not farmland.

* * * * *

(c) * * *

(2) Sites receiving a total score of less than 160 need not be given further consideration for protection and no additional sites need to be evaluated.

* * * * *

(g) To meet reporting requirements of section 1546 of the Act, 7 U.S.C. 4207, and for data collection purposes, after the agency has made a final decision on a project in which one or more of the alternative sites contain farmland subject to the FPPA, the agency is requested to return a copy of the Form AD–1006, which indicates the final decision of the agency, to the SCS field office.

(h) Once a Federal agency has performed an analysis under the FPPA for the conversion of a site, that agency's, or a second Federal agency's determination with regard to additional assistance or actions on the same site do not require additional redundant FPPA analysis.

5. Section 658.7 is amended by redesignating paragraph (b) as paragraph (c) and adding paragraphs (b) and (d) to read as follows:

§ 658.7 USDA assistance with Federal agencies' reviews of policies and procedures.

* * * * *

(b) Section 1542(b) of the Act, 7 U.S.C. 4203, requires, as appropriate, each department, agency, independent commission, or other unit of the Federal Government, with the assistance of the Department of Agriculture, to develop proposals for action to bring its programs, authorities, and administrative activities into conformity with the purpose and policy of the Act.

* * * * *

(d) To meet the reporting requirements of section 1546 of the Act, 7 U.S.C. 4207, and for data collection purposes, each Federal agency is requested to report to the Chief of the Soil Conservation Service by November 15th of each year on progress made during the prior fiscal year to implement sections 1542 (a) and (b) of the Act, 7 U.S.C. 4203 (a) and (b). Until an agency fully implements those sections, the agency should continue to make the annual report, but may omit the report upon full implementation. However, an agency is requested to file an annual report for any future year in which the agency has substantially changed its process for compliance with the Act.

Dated: June 8, 1994.

Mike Espy,

Secretary of Agriculture.

[FR Doc. 94–14548 Filed 6–16–94; 8:45 am]

BILLING CODE 3410–16–M

Agricultural Marketing Service

7 CFR Parts 916 and 917

[Docket No. FV94–916–2–IFR]

Nectarines and Peaches Grown in California; Revision of Container Pack Requirements for Fresh Nectarines and Peaches

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Interim final rule with request for comments.

SUMMARY: This rule revises the pack requirements for volume-filled containers of nectarines and peaches grown in California shipped to the fresh market. This rule is designed to provide handlers with more flexibility in packing fresh nectarines and peaches consistent with established packing practices, and is needed to help the California nectarine and peach industries maintain the quality of fruit shipped to the fresh market. This rule is in the interest of producers, handlers, and consumers of these fruits.

DATES: Effective on June 17, 1994. Comments which are received by July 18, 1994 will be considered prior to issuance of any final rule.

ADDRESSES: Interested persons are invited to submit written comments concerning this rule. Comments must be sent in triplicate to the Docket Clerk, Fruit and Vegetable Division, AMS, USDA, P.O. Box 96456, Room 2523–S,

Washington, DC 20090–6456; or by facsimile at 202–720–5698. All comments should reference the docket number and the date and page number of this issue of the Federal Register and will be made available for public inspection at the office of the Docket Clerk during regular business hours.

FOR FURTHER INFORMATION CONTACT: Gary D. Rasmussen, Marketing Specialist, Marketing Order Administration Branch, Fruit and Vegetable Division, AMS, USDA, P.O. Box 96456, Room 2523–S, Washington, DC 20090–6456; telephone: (202) 720–5331; or Terry Vawter, California Marketing Field Office, Marketing Order Administration Branch, Fruit and Vegetable Division, AMS, USDA, 2202 Monterey Street, Suite 102B, Fresno, California, 93721; telephone: (209) 487–5901.

SUPPLEMENTARY INFORMATION: This rule is issued under Marketing Agreement and Marketing Order Nos. 916 and 917 (7 CFR parts 916 and 917) regulating the handling of nectarines and peaches grown in California, hereinafter referred to as the orders. The orders are effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the Act.

The Department of Agriculture (Department) is issuing this rule in conformance with Executive Order 12866.

This rule has been reviewed under Executive Order 12778, Civil Justice Reform. This rule is not intended to have retroactive effect. This rule will not preempt any state or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with the Secretary a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. A handler is afforded the opportunity for a hearing on the petition. After the hearing the Secretary would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction in equity to review the Secretary's ruling on the petition, provided a bill in equity is filed not later than 20 days after the date of the entry of the ruling.

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA), the Administrator of the Agricultural Marketing Service (AMS) has considered the economic impact of this action on small entities. The purpose of the RFA is to fit regulatory actions to the scale of business subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf.

Thus, both statutes have small entity orientation and compatibility.

There are about 300 California nectarine and peach handlers subject to regulation under the orders covering nectarines and peaches grown in California, and about 1,800 producers of these fruits in California. Small agricultural producers have been defined by the Small Business Administration (13 CFR 121.601) as those having annual receipts of less than $500,000, and small agricultural service firms are defined as those whose annual receipts are less than $5,000,000. A majority of these handlers and producers may be classified as small entities.

The Nectarine Administrative Committee (NAC) recommended that the pack requirements for volume-filled containers of California nectarines be revised, and the Peach Commodity Committee (PCC) recommended that the pack requirements for volume-filled containers of California peaches be revised. These committees meet prior to and during each season to review the rules and regulations effective on a continuous basis for California nectarines and peaches under the orders. These committee meetings are open to the public, and interested persons may express their views at these meetings. The Department reviews committee recommendations and information, as well as information from other sources, and determines whether modification, suspension, or termination of the rules and regulations would tend to effectuate the declared policy of the Act.

Section 916.350 (7 CFR 916.350, as amended at 59 FR 15838) specifies container and pack requirements for fresh nectarine shipments. Paragraph (a)(1) of § 916.350 specifies that nectarines in any closed package or container, except master containers of consumer packages and individual consumer packages, shall be packed in accordance with "standard pack". "Standard pack" is defined in paragraph (b) of § 916.350 as having the same meaning as set forth in the United States Standards for Grades of Nectarines (7 CFR 51.3145 through 51.3160). Under the definition of "standard pack", nectarines packed in certain containers must be tightly packed and the containers must be "well filled". "Well filled" means that the container is properly filled, allowing no movement of its contents, and the container should have its contents in firm contact with the cover. This rule revises § 916.350 by adding a new proviso to paragraph (a)(1) specifying that the nectarines in any such container need only be filled to within one inch of the top of the container. This rule also removes the proviso in paragraph (a)(1) of § 916.350 reading "That nectarines in any container shall be fairly uniform in size", because such requirements are included within the definition of "standard pack" in the United States Standards for Grades of Nectarines, and therefore are not needed in this paragraph.

Section 917.442 (7 CFR 917.442, as amended at 59 FR 15840) specifies container and pack requirements for fresh peach shipments. Paragraph (a)(1) of § 917.442 specifies that peaches in any closed package or container, except master containers of consumer packages and individual consumer packages, shall be packed in certain containers in accordance with "standard pack". "Standard pack" is defined in paragraph (b) of § 917.442 as having the same meaning as set forth in the United States Standards for Grades of Peaches (7 CFR 51.1210 through 51.1223). Under the definition of "standard pack", peaches in certain containers must be tightly packed and the containers must be "well filled". "Well filled" means that the level of the fruit must be slightly higher than the top edge of the container and the peaches are held firmly in place. This rule revises § 917.442 by adding a new proviso to paragraph (a)(1) specifying that the peaches in any such container need only be filled to within one inch of the top of the container.

The NAC and PCC recommended these revised pack requirements for fresh nectarines and peaches in volume-filled containers after a comprehensive review of changes in the nectarine and peach industry packing practices over the years, and the need to make appropriate changes in the pack requirements. When the pack requirements were established, most containers were of a place-pack or a tray-pack type, but at the present time substantial quantities of nectarines and peaches are shipped in volume-filled containers throughout the entire range

of sizes packed. This revision will provide handlers with more flexibility in selecting the appropriate size container for certain volume-filled packs without potential bruise damage to the fruit. Under current packing conditions, nectarines and peaches of certain varieties and sizes are sometimes bruised when packed in accordance with "standard pack", because the fruit extends above the top of the container and is damaged when the lid is attached. There are a combination of factors contributing to this situation, including: (1) Handlers must pack a specific quantity of fruit, in terms of minimum weight, in certain containers, and some handlers prefer to pack precisely this quantity in each such container; (2) the volume of fruit packed in a particular container varies depending on the variety and size of fruit for a given pack weight; (3) handlers maintain a limited number of different size containers in inventory; and (4) handlers pack most of their fruit at the well matured stage of maturity, and such fruit is susceptible to bruising when packed too tight. This revision will enable handlers to pack their nectarines and peaches with up to one inch space between the top of the fruit and the top of the container, and result in less bruising of the fruit due to excessively tight packs.

This rule reflects the committees' and the Department's appraisal of the need to revise the pack requirements for California nectarines and peaches in volume-filled containers, as specified. The Department's determination is that this rule will have a beneficial impact on producers, handlers, and consumers of California nectarines and peaches.

This rule revises pack requirements for fresh California nectarines and peaches in volume-filled containers, enabling handlers to pack such fruit consistent with desirable packing practices, and is needed to help the California nectarine and peach industries maintain the quality of fruit shipped to the fresh market. This rule is designed to establish and maintain orderly marketing conditions for these fruits in the interest of producers, handlers, and consumers.

Based on the above, the Administrator of the AMS has determined that this rule will not have a significant economic impact on a substantial number of small entities.

After consideration of all relevant matters presented, the information and recommendations submitted by the committees, and other information, it is found that the rule, as hereinafter set forth, will tend to effectuate the declared policy of the Act.

Pursuant to 5 U.S.C. 553, it is also found and determined, upon good cause, that it is impracticable, unnecessary and contrary to the public interest to give preliminary notice prior to putting this rule into effect, and that good cause exists for not postponing the effective date of this rule until 30 days after publication in the **Federal Register** because: (1) Shipment of the 1994 season crop of fresh California nectarines and peaches is currently underway; (2) this rule relaxes pack requirements for both nectarines and peaches; (3) California nectarine and peach handlers are aware of these revised pack requirements recommended by the committees at public meetings, and they will need no additional time to comply with such requirements; and (4) the rule provides a 30-day comment period, and any written comments received will be considered prior to any finalization of this interim final rule.

List of Subjects

7 CFR Part 916

Marketing agreements, Nectarines, Reporting and recordkeeping requirements.

7 CFR Part 917

Marketing agreements, Peaches, Pears, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR Parts 916 and 917 are amended as follows:

PART 916—NECTARINES GROWN IN CALIFORNIA

1. The authority citation for 7 CFR part 916 continues to read as follows:

Authority: 7 U.S.C. 601–674.

2. Section 916.350 is amended by revising paragraph (a)(1) to read as follows:

§ 916.350 California nectarine container and pack regulation.

(a) * * *

(1) Such nectarines when packed in any closed package or container, except master containers of consumer packages and individual consumer packages, shall conform to the requirements of standard pack: *Provided,* That nectarines in any such volume-filled container need only be filled to within one inch of the top of the container.

* * * * *

PART 917—FRESH PEARS AND PEACHES GROWN IN CALIFORNIA

1. The authority citation for 7 CFR Part 917 continues to read as follows:

Authority: 7 U.S.C. 601–674.

2. Section 917.442 is amended by revising paragraph (a)(1) to read as follows:

§ 917.442 California peach container and pack regulation.

(a) * * *

(1) Such peaches when packed in any closed package or container, except master containers of consumer packages and individual consumer packages, shall conform to the requirements of standard pack: *Provided,* That peaches in any such volume-filled container need only be filled to within one inch of the top of the container.

* * * * *

Dated: June 9, 1994.

Eric M. Forman,

Deputy Director, Fruit and Vegetable Division.

[FR Doc. 94–14742 Filed 6–16–94; 8:45 am]

BILLING CODE 3410–02–P

Rural Electrification Administration

7 CFR Parts 1753 and 1755

RIN 0572–AA20

REA Form 525, Central Office Equipment Contract (Including Installation)

AGENCY: Rural Electrification Administration, USDA.

ACTION: Final rule.

SUMMARY: The Rural Electrification Administration (REA) hereby amends its regulations on Telecommunications Standards and Specifications for Materials, Equipment and Construction to add a Central Office Equipment Contract (Including Installation) and to announce a general revision of REA Form 525, Central Office Equipment Contract (Including Installation). REA is updating this contract in order to incorporate technological changes.

EFFECTIVE DATE: July 18, 1994.

FOR FURTHER INFORMATION CONTACT: John J. Schell, Chief, Central Office Equipment Branch, Telecommunications Standards Division, Rural Electrification Administration, room 2836, South Building, USDA, Washington, DC 20250–1500, telephone number (202) 720–0671.

SUPPLEMENTARY INFORMATION:

Executive Order 12866

This final rule has been determined to be not-significant for purposes of Executive Order 12866 and therefore has not been reviewed by OMB.

Executive Order 12372

This final rule is excluded from the scope of Executive Order 12372, Intergovernmental Consultation. A Notice of Final Rule entitled Department Programs and Activities Excluded from Executive Order 12372 (50 FR 47034) exempts REA and RTB loans and loan guarantees, and RTB bank loans, to governmental and nongovernmental entities from coverage under this Order.

Executive Order 12778

This final rule has been reviewed under Executive Order 12778, Civil Justice Reform. This final rule: (1) Will not preempt any state or local laws, regulations, or policies; (2) Will not have any retroactive effect; or (3) Will not require administrative proceedings before parties may file suit challenging the provisions of this rule.

Regulatory Flexibility Act Certification

The Administrator of REA has determined that this final rule will not have a significant impact on a substantial number of small entities as defined by the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The changes to the Central Office Equipment Contract in this final rule are updates which have been made so that REA telephone borrowers can continue to provide their subscribers with the most up-to-date and efficient telephone service.

Information Collection and Recordkeeping Requirements

The reporting and recordkeeping requirements contained in this final rule have been submitted to the Office of Management and Budget (OMB) in accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*). Comments concerning these requirements should be directed to the Department of Agriculture, Clearance Office, Officer of Information Resources Management, room 404–W, Washington, DC 20250, and to the Office of Information and Regulatory Affairs of OMB, Attention: Desk Officer for USDA, room 3201, NEOB, Washington, DC 20503. When OMB has approved the information and recordkeeping requirement contained in this final rule, REA will publish an amendment to this final rule to add the OMB control number and statement to the regulatory text.

National Environmental Policy Act Certification

The Administrator of REA has determined that this final rule will not significantly affect the quality of the human environment as defined by the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*). Therefore, this action does not require an environmental impact statement or assessment.

Catalog of Federal Domestic Assistance

The program described by this final rule is listed in the Catalog of Federal Domestic Assistance Programs under No. 10.851, Rural Telephone Loans and Loan Guarantees, and 10.852, Rural Telephone Bank Loans. This catalog is available on a subscription basis from the Superintendent of Documents, the United States Government Printing Office, Washington, DC 20402.

Background

The proposed rule for 7 CFR 1755.525 was first published in the **Federal Register** as a 7 CFR part 1762 proposed rule on October 29, 1989, at 54 FR 43429. Since that time part 1762 has been incorporated into part 1755. Due to the pertinence of the comments received REA decided to incorporate many of them into the document. The revised rule was published as a 7 CFR part 1755 proposed rule on March 14, 1991, at 56 FR 10827 with a 60 day comment period. During this period comments and suggestions were received from six major manufacturers of central office equipment. Many useful comments and suggestions were received and many of them have been incorporated into the revised Form 525 Contract.

The last revision to the Form 525 Contract was September 1966. Since that date, significant changes have been made in the telephone industry. The profound advancement in central office equipment technology has made possible many new services on a cost effective basis. Divestiture and competition, legislation and regulation have brought about many changes in the conduct of telecommunications business. The revised Form 525 Contract incorporates these changes into the Central Office Equipment Contract. The main changes to the Contract are new requirements that: (1) Provide for a software license, (2) provide for patent, copyright, and trademark infringement protection, (3) provide a cap on consequential damages, and (4) provide Equal Employment Opportunity requirements. In addition, it revises and updates provisions for (1) delivery and installation of equipment, (2) inspection and testing of the completed installations, (3) payments to the contractor, (4) insurance, (5) liquidated damages, and (6) completion of the project. This action will make it possible for REA telephone borrowers to continue to provide their subscribers with the most modern and efficient telephone service.

REA has issued a series of 7 CFR chapter XVII parts which serve to implement the policies, procedures, and requirements for administering its loan and loan guarantee programs and the loan documents and security instruments which provide for and secure REA financing. The technical change to 7 CFR part 1753 updates the number of days allowed for acceptance testing in order to conform with REA Form 525 Central Office Equipment Contract (Including Installation). The revision to 7 CFR part 1755 codifies REA Form 525, Central Office Equipment Contract (Including Installation). The 7 CFR part 1755 also describes where copies of the contract may be obtained. REA telephone borrowers are required to use the REA Form 525 Contract where major central office facilities are being procured and installed under contract. The present REA Form 525 has become outdated due to technological advancements and other reasons. Advanced technology and equipment concepts have introduced new issues. Contract terms and obligations need to be modified and updated to more accurately reflect present business practices. Some representative issues addressed in updating this contract are: Expansion of patent infringement protection to include copyrights, trademarks, etc.; software right-to-use licensing terms; warranty coverage; use of information; consequential damages; delays in project; liquidated damages; bonding and insurance; independent contractor provisions; and support of discontinued products. All these additions and changes have been made so that REA telephone borrowers can continue to provide their subscribers with the most up-to-date and efficient telephone service.

Comments

Public comments were received from Alcatel Network Systems, Inc., AT&T Network Systems, Mitel Public Switching, Northern Telecom Inc., Redcom Laboratories, Inc., and Seimens Stromberg-Carlson. The comments, recommendations and responses are summarized as follows:

General Comments

One commenter remarked that a telephone central office switch is a computer and should be purchased using a supply type contract rather than a construction contract and therefore, REA Form 525 should not apply.

Response: REA feels that due to the very complex nature and individuality

of each central office and the immense amount of coordination and development that must be done prior to, during, and after the installation a supply type contract would not be a suitable instrument to achieve the desired results. Further, REA feels a supply type contract does not provide the Borrower the same degree of protection as the REA Form 525 Contract. This lack of protection could be devastating to the Borrower and consequently, jeopardize REA loan security. The required use of REA Form 525, Central Office Equipment Contract (Including Installation), remains.

Notice and Instructions to Bidders

Item 4: One commenter remarked that the Owner should be responsible for providing a notice that the state requires a license for bidding, if such a requirement exists.

Response: Since the Bidder is the party who ultimately will have to abide by the State's licensing requirements, REA believes the Bidder should bear the responsibility for determining whether a license is required for bidding.

Item 6: One commenter remarked that the method of bidding in the existing REA Form 525 makes bid bonds optional and the proposed REA Form 525 removes this option. They feel that the option should remain.

Response: The existing REA Form 525, Notice and Instructions to Bidders, Item 5, and the proposed REA Form 525, Notice and Instructions to Bidders, Item 6, specifically state that each proposal must be accompanied by a Bid Bond or a certified check. No other option exists. The wording in both documents is essentially the same.

Item 14: (b) One commenter remarked that this requirement adds complexity and administrative burden because the manufacturers are already required to comply with REA Form 525, Article VI.

Response: Item 14(b) is required by the Office of Federal Contract Compliance Programs (OFCCP) requirement.

Bidder's Proposal To Engineer, Furnish, Deliver, and Install Equipment, Materials and Software

Article I, Bid Price

Section 1: Two commenters questioned the use of the term "Delivery Acceptance" in column five of this section.

Response: Column five is the time in calendar days between approval of the Contract and delivery of equipment. The term "Acceptance" has been removed from this column to more clearly define the requirement.

Section 1: One commenter remarked that there should be some instruction as to how to identify each project.

Response: REA agrees. REA has added Note 3 to Article I, section 1, as an instruction to leave a blank line between each Project listed in section 1.

Section 3: One commenter remarked that the word "substantial" should be replaced and one commenter remarked that the language "The Owner * * * may * * * make reasonable changes, additions to or subtractions from the Specifications * * *" is ambiguous and should be changed.

Response: This is the same language that is in the existing REA Form 525 Contract. It has worked well in the past and REA does not feel there is a need to change it.

Article II, Delivery and Installation

Section 1: One commenter remarked that the draft REA Form 525 made the Completion of Installation of the essence. The commenter feels that Completion of the Project should be of the essence, since liquidated damages are measured from that event.

Response: Completion of Installation is a scheduled date that must be met. The scheduled date for the Completion of the Project, as shown in Article I, Section 1, Column 7, is established by adding 60 days to the Completion of Installation. Liquidated Damages are measured from the scheduled date for Completion of the Project. Actual Completion of the Project may be a date earlier or later than the scheduled date of Completion of the Project as defined in Article VII, Section 1, Definitions. Therefore, REA believes that Completion of Installation must be of the essence.

Section 1: One commenter remarked that if a remote switching terminal is scheduled independently of a central office, the Contract should reflect this as a separate Project.

Response: Article I, Section 1, and the Contract in general, regard a central office, including all associated remote switching terminals, to be an indivisible unit for delivery, payment, turnover, closeout, liquidated damages, and other purposes. A host office and its remotes are interdependent and alterations to one may affect the others. Therefore, REA regards a host office and all associated remotes as one item under the Contract.

Section 1: One commenter remarked that the reference to "the satisfaction of the Owner and the Administrator" is a subjective standard and should be removed.

Response: If the language in question is deleted, the Section would require unconditional adherence to the terms of the Contract. The language is included here to allow the possibility of latitude, where the Owner and REA agree.

Section 3: One commenter had the following remarks:

(i) In the first sentence the wording "give sufficient supervision to" should be changed to "supervise."

(ii) Also, this commenter feels the language "using Bidder's best skill and attention" is onus and unenforceable and should be deleted.

(iii) The commenter also feels the second sentence should be expanded to include the following language "but that the failure of the Bidder to discover these items shall not create any obligation or liability on the part of the Bidder, nor relieve the Owner of its performance or responsibilities."

Response: REA feels that the existing language is appropriate. REA disagrees with the expansion of the second sentence since REA believes it is reasonable for the Bidder to be responsible for the fulfillment of the Contract requirements.

Section 4: One commenter had the following remarks:

(i) The reference to "manufacturing" in the first paragraph should be replaced with "other than cost information or any other information from which cost could be derived."

(ii) The commenter also suggests the language "each central office (and its associated remote switching terminals), feature or service" be replaced with the word "Project" as a potential exists for a remote to be scheduled as a separate Project.

(iii) In addition, the commenter feels the word "nonperformance" in the fourth paragraph should be replaced with "failure to satisfactorily resolve all such deficiencies as previously listed on the REA Form 517."

Response:

(i) REA feels the language in the first paragraph offers sufficient protection to the Bidder as written. This language has not been changed.

(ii) As previously responded to, Article I, Section 1, and the Contract in general, regard a central office, including all associated remote switching terminals, to be an indivisible unit. However, in the interest of brevity, this language has been replaced with the word "Project."

(iii) REA agrees and has revised Article II, section 4, paragraph 4 to include the suggested language.

Section 4: One commenter remarked that the fourth paragraph of this Section imposes an artificial thirty (30) day requirement for correction of deficiencies. They suggest the Section

be amended to require corrections within thirty (30) days of receipt of the REA Form 517 from the Borrower or by the scheduled date for Completion of the Project, whichever is longer.

Response: REA feels this Section offers the Bidder and the Borrower equal protection by imposing specific time limits for the Borrower's tests and the Bidder's corrections. This language has not been changed.

Section 7: One commenter remarked that the first paragraph of this Section should be modified to permit the Bidder either to correct the defect within 30 days or to agree with the Borrower during such 30 days on a course of correction reasonably designed to cure the defect.

Response: REA agrees. This Section has been revised to allow an extension of time if agreed upon by the Owner and REA.

Section 7: One commenter remarked that refund and credit options should be included in the event a defect cannot reasonably be corrected.

Response: Such a provision would give the Bidder the right to simply "buy back" equipment or software when a problem is encountered. To the Borrower, this means that essential features or capability could be lost and would remain unavailable for the entire useful life of new switching equipment. The resulting reduction in value of the Contract to the borrower cannot be predicted. This option has not been added to Form 525.

Section 7: One commenter remarked that minor "bugs" are inherent in all software and should not rise to the level of warranty defects.

Another commenter remarked that the Form 522 Specifications and not other technical material provided by the Bidder should be the standard for software warranty.

Response: REA feels the performance of the software must be in accordance with the Form 522 Specifications and Bidder documentation.

The Bidder documentation is furnished to assist the borrower in the operation, administration and maintenance of the switch.

Section 7: Three commenters remarked that this Section should be rewritten to add disclaimers and exclusive remedies and to limit the Bidder's liabilities and limit the Owner's remedies.

Response: REA believes that the language as stated divides the risks equitably.

Section 7(a): One commenter remarked that the reference to "a central office and its associated remote switching terminals" be deleted and replaced with the words "each Project."

Response: As previously responded to, this language has been replaced with the word "Project."

Section 7(b): Three commenters remarked that the warranty period for software should be shortened.

Response: REA requires a five (5) year warranty period because software is information based and defects in seldom used programs would not be detected until the program is used. REA believes that over a 5 year period even seldom used programs would be used and any defects corrected.

Section 7(e): One commenter remarked that exceptions to the warranty in the subsection should also include fire, explosions, power failures, force majeure, and equipment which is normally consumed in operation, such as fuses.

Response: The warranty must cover losses of whatever nature, resulting from causes covered by the warranty provided for in the formal Contract.

Section 7(f): One commenter requested that the period after the word "Owner" in the last line in the subsection be deleted and the words "during the warranty period, thereafter, all such costs and risk of shipping shall be borne by the Owner." be added.

Response: The first paragraph of the Section specifically defines these conditions as applying "Throughout the warranty period * * *." REA does not feel additional language is required to further define this.

Article III, Payments and Releases of Lien

Section 1(a),(b): One commenter remarked that these subsections are unfair as written. Each central office and its associated remotes should be treated separately for payment purposes to allow the Bidder to get paid for his investment in a timely manner.

Response: Article I, Section 1, and the Contract in general, regard a central office, including all associated remote switching terminals, to be an indivisible unit for delivery, payment, turnover, closeout, liquidated damages, and other purposes. A host office and its remotes are interdependent and alterations to one may affect the others. Therefore, REA regards a host office and all associated remotes as one item under the Contract.

Section 1(c): One commenter remarked that the phrase "Completion of the Contract" in this subsection should be changed to read "Completion of the Project." This would enable the Bidder to receive the final ten percent (10%) for each Project as it is satisfactorily completed.

Response: These have been the standard REA Contract terms for many years. REA feels it offers sufficient protection to the Borrower that the Contract will be completed in a satisfactory manner, while allowing the Bidder a return on its investment prior to satisfactory completion of the Contract. Also, the Bidder can receive the final ten percent (10%) of a Project if the partial closeout procedure is allowed.

Section 1(a), (b), (c): One commenter remarked that unproven features and capabilities should not delay payments for the Project.

Response: Unproven features and capabilities are listed as separate Projects in Article I, section 1, with separate time frames for delivery and installation of features and capabilities that cannot be provided at the time of Completion of the Project. If separate schedules are not part of the Contract, delays in delivery would cause delays in payments for the entire Project. This encourages a Bidder's disclosures as required in Article V, section 2.

Section 1(e): One commenter remarked that the subsection should be reworded to require the Owner to pay the Bidder for each central office if the subsection is not struck out.

Response: REA agrees with this comment. The language in Section 1(e) has been changed to require the Owner to strike out this section if the partial closeout procedure is not to be allowed.

Section 2: One commenter remarked that this section references a "Waiver and Release of Liens," a "Certificate of Contractor" and a "Certificate of Contractor and Indemnity Agreement" but these documents were not made public at the time, consequently, they reserve their right to comment after they are issued.

Response: The documents referred to by the commenter are existing and have not been revised. If any changes are made to the aforementioned documents they will be published as a Proposed Rule and comments will be requested at that time.

Article IV, Particular Undertakings of the Bidder

Section 1(b): Two commenters remarked that this Section is unfair to the Bidder. They feel that the Bidder should only be responsible for damages caused by the Bidder and that the Borrower is in a much better position to protect its site, and guard against fire, flood and theft.

Response: The Bidder is required by law to have insurance from

commencement to completion of the Contract. The Bidder also has charge and control of all work, equipment, materials and software to be done or used therein. Therefore, REA feels the Bidder is in a better position during this time period to protect itself against risk of loss.

Section 3: One commenter remarked that commercial insurance is unnecessary. Specifically, the coverage limits required are within the "deductible" for large companies. Thus the risk is self retained.

Response: Insurance requirements for contractors are set forth in 7 CFR part 1788, subpart C, Insurance for Contractors, Engineers and Architects. Generally, this regulation is intended to set minimum coverage requirements for companies of all sizes.

Section 5: One commenter remarked that the 525 Contract should be modified to include a Uniform Software Agreement.

Response: REA agrees. A Uniform Software License was drafted and published for comments on May 20, 1993, at 58 FR 29363, and was published as a final rule on April 14, 1994, at 59 FR 17675. The final rule will be an addendum to any 525 or 545 Contract that requires a license.

Section 6: One commenter remarked that some guarantees may not be transferable or assignable by the Bidder and this Section should be subject to any applicable restrictions on transfer or assignment.

Response: Article IV, section 6 has been revised to allow for restrictions on transfer of warranties. However, regardless of restrictions upon transfer or assignment, the warranty coverage defined in Article II, section 7, is required.

Section 7: Two commenters remarked that a buy back option should be allowed for infringement of intellectual property rights.

Response: Such a provision would give the Bidder the right simply to "buy back" equipment or software when a copyright problem is encountered. To the Owner, this means that essential features or capability could be lost and would remain unavailable for the entire useful life of the new switching equipment. The resulting reduction in value of the Contract to the Owner cannot be predicted, and often would be greater than the amount the Owner paid for the price of the infringing equipment or software.

Section 7: One commenter remarked that this Section should be limited to United States patents, trademarks, copyrights and trade secrets.

Response: REA believes this would not provide sufficient protection.

Section 7: One commenter remarked that the Bidder should be allowed to take pro-active steps to avoid an injunction, rather than always having to react to an injunction after it is imposed.

Response: This section merely states the action the Bidder must take to protect the Owner after the use of the equipment or software is enjoined. It does not proscribe any action the Bidder may wish to take to protect its own interests and the Owner's interests before the injunction is granted.

Article V, Remedies

Section 2: Three commenters remarked that the cap on liquidated damages is excessive and unrelated to any actual damage.

Response: REA believes that if a limit is to be set it should not be less than the price of the affected central office and all associated remote switching units. This in many cases will be less than the total Contract price. This Section also instructs the Owner to notify the Bidder in writing how the liquidated damages were computed.

Section 2: One commenter remarked that previous draft versions of the 525 Central Office Equipment Contract better defined "placed in service" and assumes liquidated damages are applied based on that date.

Response: REA believes that the wording "used by the Owner to earn revenue" more clearly defines "placed in service." Article V, sections 2 and 5, and Article VII, section 1, Definitions, clearly state that liquidated damages can only be assessed and are the exclusive remedy when the Bidder has failed to complete the Project on time and are not based on when a central office is placed in service.

Section 2: One commenter remarked that the Bidder should not be assessed liquidated damages based on the entire Project when a only a portion is delayed.

Response: As stated previously, the central office and all associated remote switching terminals are a unit for the purposes of this Contract. Liquidated damages are measured from "Completion of Project." This gives the Bidder an incentive to complete the Project in a timely manner. If liquidated damages were assessed on each individual part of a Project, then in some cases the incentive to finish the Project on time would be removed.

Section 2: One commenter remarked that liquidated damages should not apply to features or capabilities that are not fully developed or do not have a verifiable satisfactory field performance because they have been accepted by the Owner and by definition they are unproven. It was also felt that even if they are not exempt, liquidated damages should not apply if the central office has been placed in service.

Response: The Owner allowed these unproven features to be bid based on a time period established by the Bidder for the availability of these features. A Bidder's responsibility to provide the features or capabilities bid on, in the time period established by the Bidder, cannot be diminished by notifying the Owner that they are not going to be available in the time promised. The language in Article V, section 2, remains.

Liquidated damages on unproven features are a measure of revenue that would be lost by that feature not being available on time. It does not have a bearing on, and should not be associated with, revenue from the rest of the Project that is in service. If it was as suggested in the comment, then it would be a penalty to the Owner in lost revenue for the Bidder not completing the feature or capability as scheduled.

Section 2: One commenter remarked that additional language be added after the word "Provided," to clarify this provision. It was also felt that the last line of this section seemed inappropriate and should be deleted.

Response: REA feels the existing language clearly identifies the intent of this provision. Also, a Bidder's responsibility to complete the Project as originally bid should not be diminished because of neglect by the Bidder to notify the Owner of unproven or unavailable features or capabilities. The last sentence remains.

Section 3: Four commenters remarked on this section. From the comments received, it appears this section is still of great concern to the equipment manufacturers. The comments and recommendations received are summarized below:

(i) Two commenters remarked that ten times the Contract price is excessive. Three commenters remarked that they should be able to disclaim consequential damages. Two commenters remarked that that much exposure is probably not insurable but if it was, the premiums would be excessive and would be passed on to the Owner. One commenter recommended that consequential damages be the lesser of five times the purchase price of the affected central office and its associated remote terminals, or $5.0 million.

(ii) One commenter recommended that the Owner retain the liability since the Owner is in a better position to prevent losses by properly maintaining

its network. One commenter felt that consequential damages should only be available during the warranty period.

Response:

(i) The existing Form 525 does not limit the liability for incidental or consequential damages. REA's intent is to place a limit of liability on consequential and incidental damages, except for personal injury or tangible property damage, which will: enable Bidders to insure for a risk of known limit; provide Owners with protection against losses related to product failure; protect the government's loan security; and serve as a standard that Bidders and Owners alike can expect to see on every Contract so competitive bidding can be facilitated. REA has established a liability limit of ten times the total Contract amount, which will result in a limit in the range of $2.5 million to $10 million for typical REA Contracts.

(ii) Consequential damages provide a measure of protection from loss due to product failure or other causes related to the Bidder's performance. Since the risk of loss still exists after the warranty period, consequential damages must also be available.

Section 5: One commenter remarked that in order to make the proposed draft consistent with the suggested addition of exclusive remedies language in other sections, some minor language adjustments are needed for this section.

Response: REA has not added exclusive remedy language so no language adjustments were made.

Section 5: One commenter remarked that cumulative remedies should not apply for a normal warranty claim. The warranty provisions of the Contract provide for a remedy and course of conduct in the event of a product failure.

Response: The warranty provisions may not fully protect the Borrower in some situations. For example, a defective component, serviced under Article II, section 6, could cause a consequential damages claim. The language in section 5 is unchanged.

Article VI, Equal Employment

One commenter remarked that a number of large national employers have made direct arrangements with the Office of Federal Contract Compliance Programs (OFCCP) relating to the procedures to be followed in connection with EEO policies and language should be added to this Article VI to cover separately negotiated arrangements.

Response: The language in Article VI, was provided by the Office of Federal Contract Compliance Programs (OFCCP), and cannot be changed by REA.

Article VII, Miscellaneous

Section 1: One commenter felt the definition of Software should be expanded to clarify that Software means the Software provided to the Owner by the Bidder hereunder and the words "and similar design level documentation" should be inserted after the words "source code" in this subsection. It was also felt that the definition of Project should be expanded to include remote switching terminal(s).

Response: REA feels the definition of the term "Software" is appropriate as written and will not be construed to mean any software other than the software furnished for the Contract in question. The words "and similar design level documentation" have not been added to the words "source code." Source code is a definable commodity but "and similar * * *." is overly vague. REA also feels the definition of the word "Project" is sufficient. If a remote is to be a separate Project, it must be listed as such in Article 1, section 1.

Section 1: One commenter is concerned that the Owner's failure to provide site availability and needed facilities for remotes can unduly hold up Completion of the Project. The commenter proposed adding language to cover that event.

Response: REA feels the definition of "Completion of the Project" is appropriate. The concerns of "Site availability or functionality" not being available in a timely manner is covered under Article II, section 1, Time of Completion of Installation.

Section 2: Two commenters remarked on this section. Their comments are summarized below:

(i) One commenter remarked that this Section still requires that equipment and software support be provided for five or eight years from discontinuing the manufacture of that Equipment. The commenter feels this time period should commence upon Completion of the Contract. It is felt this provision as drafted would penalize Bidders which enhance and manufacture existing equipment and reward Bidders who discontinue manufacture of equipment and develop new and incompatible equipment.

(ii) One commenter wanted to revise the language to change the intent of this paragraph and also add a provision for a one (1) year software warranty.

Response: REA previously responded in the **Federal Register** on March 14, 1991, at 56 FR 10827, that it concludes, based on previous comments, that this new Section strikes a reasonable balance for sellers and buyers.

Section 3: One commenter remarked that its only area of concern arises in a two fold fashion. To begin with, the use of the word "and" following the word "substantially" in the first sentence interferes with the intended meaning of the sentence, and as such, should be deleted. The specific concern arises from the wording of this section 3, Notwithstanding the possibility of authorization by the Administrator, it suggests that such authorization is permissive, not mandatory and that therefore the intent of REA Bulletin 344–3 is not met. The commenter submits that such authorization be mandatory in the event the valuation conditions of the Bulletin are met.

Response: The word "and" following "substantially" in the first sentence is a typographical error and has been changed to "all." In regard to the Administrator's authorization being permissive, the Administrator's authorization is not required when the conditions of Bulletin 344–3 are met. It is only required when the conditions of Bulletin 344–3, paragraph IV.B. or IV.C. are not met.

Section 6: One commenter remarked that the proposed draft has added a new sentence to this section which releases the borrower from its obligation to maintain the confidentiality of the Bidder's proprietary information if the Bidder fails to fulfill its continuing support obligations. The commenter believes the proposed remedy for such a problem is overly broad and is punitive to the Bidder.

Response: REA feels this section offers sufficient protection for the Bidder and the Owner. The only way the Owner can be released from the confidentiality requirement is by the Bidder's failure to meet the obligations of the Form 525 Contract. Article VI, section 6, as proposed, provides some incentive not to violate the obligations of the Contract.

Section 12: One commenter suggested that the Bidder not be required to obtain the consent of its surety for all subcontractors. It is felt that if the surety makes such a requirement on the Bidder, this language adds nothing to the Bidder's obligation to obtain proper protection. On the other hand, if such a condition is not required by the surety, there should be no need to retain this condition.

Response: The only way the REA and the Owner can be assured that the surety allows subcontractors is by written consent. The language in this section remains unchanged.

Section 12: One commenter remarked that either party should be permitted to subcontract the Agreement to an affiliate

without the consent of the other party. A corporate restructuring of a Bidder should not be able to be arbitrarily held up by a single Owner.

Response: REA does not feel that a Bidder should be allowed to arbitrarily subcontract an REA Contract without the proper consent, which will not be unreasonably withheld. This language has worked well in the past and REA feels it will continue to work well in the future.

List of Subjects

7 CFR Part 1753

Communications equipment, Loan programs—communications, Reporting and recordkeeping requirements, Rural areas, Telephone.

7 CFR Part 1755

Loan programs—communications, Reporting and recordkeeping requirements, Rural areas, Telephone.

For the reasons set out in the preamble, chapter XVII of title 7 of the Code of Federal Regulations is amended as follows:

PART 1753—TELECOMMUNICATIONS SYSTEM CONSTRUCTION POLICIES AND PROCEDURES

1. The authority citation for part 1753 continues to read as follows:

Authority: 7 U.S.C. 901 *et seq.*, 1921 *et seq.*

2. In § 1753.39, paragraph (f)(1)(i) is revised to read as follows:

§ 1753.39 Closeout documents.

* * * * *

(f) * * *

(1) * * *

(i) Immediately following completion of the last central office equipment installation, arrange with the contractor's installer, connecting company (where necessary), and the GFR for performance of the acceptance tests of offices not previously tested. The date for testing should be established so that the installer will not be required to return to the site for the sole purpose of assisting in these tests. Acceptance tests shall be performed within 30 days of completion of the installation, unless otherwise requested in writing by the contractor and approved in writing by the borrower.

* * * * *

PART 1755—TELECOMMUNICATIONS STANDARDS AND SPECIFICATIONS FOR MATERIALS, EQUIPMENT AND CONSTRUCTION

1. The authority citation for part 1755 continues to read as follows:

Authority: 7 U.S.C. 901 *et seq.*, 1921 *et seq.*

2. Section 1755.93 is amended by revising the entry for Form 525 in the table and footnote 1 at the end of the table to read as follows:

§ 1755.93 List of standard forms of telecommunications contracts.

* * * * *

REA form No.	Issue date	Title	Purpose	Source of copies
525	July 18, 1994	Central Office Equipment Contract (Including Installation).	Purchase and Installation of central office switching equipment.	REA.[1]

[1] A limited number of copies of the publication will be furnished by REA upon request. As this document is produced by the Federal Government and is, therefore, in the public domain, additional copies may be duplicated locally by any user as desired. Requests for copies should be sent the Director, Administrative Services Division, U.S. Department of Agriculture, Rural Electrification Administration, Washington, DC 20250. The telephone number of the REA Publication Office is (202) 720–8674.

* * * * *

3. Section 1755.525 is added to read as follows:

§ 1755.525 Form 525, central office equipment contract (including installation.)

The REA Form 525, Central Office Equipment Contract (Including Installation), in this section shall be used for all purchases of central office equipment (other than such purchases of special equipment using Form 397) using REA financial assistance when the equipment is supplied and installed by the seller or installed by a firm under contract with the seller as defined in 7 CFR part 1753, subparts E and H. The REA Form 525 Central Office Equipment Contract follows:

Central Office Equipment Contract (Including Installation)

Notice and Instructions to Bidders; Central Office Equipment Project (Including Installation)

1. Sealed Proposals for the engineering, furnishing, delivery, and installation of central office equipment, materials and software for the

_____

_____

(hereinafter called the "Owner") which is to be part of the system known as

_____

_____

to be financed pursuant to a loan contract between the Owner and the United States of America (hereinafter called the "Government") by the Administrator of the Rural Electrification Administration (hereinafter called the "Administrator") will be received by the Owner on or before _____ o'clock, _____.M.,

_____

at _____

_____

at which time and place the Proposals will be publicly opened and read. The Rural Telephone Bank may also be a party to the loan contract.

2. The Bid Documents (composed of plans, specifications and drawings), together with all necessary forms and other documents for Bidders, may be obtained from the Owner or from the Engineer, at the latter's office at

_____

The Specifications may be examined at the office of the Owner or at the office of the Engineer. A copy of the loan contract between the Owner and the Government may be examined at the office of the Owner.

Each set of Bid Documents will have a serial number, assigned by the Engineer, and the number of each set with the name of the Bidder will be recorded by the Engineer. Bids will be accepted only from original Bidders, or from some other qualified Bidder to whom such a set has been transferred by the original Bidder with the approval of the Engineer prior to the pre-bid technical session.

3. A pre-bid technical session will be held with each Bidder during the week of _____, 19_____ at

_____

for the purpose of receiving the Bidder's Technical Proposal, discussing details of the Project(s), and considering suggestions from Bidders. The Owner shall attach to this Notice a list of the information required in the Bidder's Technical Proposal. Each Bidder will be given a specific time period for the pre-bid technical session. At the pre-bid technical session, the Bidder shall fully describe to the Owner any exceptions to the Specifications the Bidder may request. In

addition, the Bidder shall identify all features and capabilities that are not fully developed or do not have a verifiable satisfactory field performance record. If the Owner decides to incorporate any changes into the Specifications, the Owner shall furnish all prospective Bidders a copy of the Specifications containing such revisions (the "Revised Specifications") and all Bids shall be made on the basis of the Revised Specifications. At this session, the Bidder shall identify all documentation and materials that it claims constitute agreed excluded documentation under section (2)(xi) of the Software License. The Bidder shall claim as agreed excluded documentation only those items it may be unable to provide to the Borrower as required by said section (2)(xi). The Engineer shall immediately provide a list of all items so identified to [appropriate REA office]. The Engineer shall inform the Bidder at least _____ days before the scheduled bid opening whether either the Engineer or [REA] will reject the Bid because of items so identified. Licensor agrees that certain Licensed Software cannot be excluded from the requirements of said section (2)(xi), including but not limited to software that would significantly impair the operation of the System, would significantly impair the ability of the Owner to generate revenue, or would pose a risk to REA loan security. If allowed, the agreed excluded documentation shall be individually identified in an attachment to the Bid. No bid shall be accepted from a Bidder who fails to attend the pre-bid technical session or fails to demonstrate to the Owner that its equipment meets the requirements of the Plans and Specifications.

4. Proposals shall be submitted on the forms furnished by the Owner and must be delivered in a sealed envelope addressed to the Owner. The name and address of the Bidder, its license number, if a license is required for bidding on a project by the State, and the date and hour of the opening of bids must appear on the envelope in which the Proposal is submitted. Proposals must be in ink or typewritten. No alterations or interlineations will be permitted, unless made, initialed, and dated before submission.

5. Prior to the submission of the Proposal, the Bidder shall make and shall be deemed to have made a careful examination of the Specifications, forms of Bidder's Proposal and Acceptance, and Contractor's Bond attached hereto, and shall become informed as to the location and characteristics of the proposed central office and remote terminal installations, features and services, the transportation facilities, the kind of facilities required before and during the delivery and installation of the equipment and materials, the general local conditions and all other matters that may affect the cost and the time of completion of the installations. Bidders will be required to comply with all applicable statutes, codes, and regulations, including those pertaining to the licensing of contractors and the "Anti Kick-Back Acts," as amended, (40 U.S.C. 276c; 41 U.S.C. 51 *et seq.*) and regulations issued pursuant thereto, and 18 U.S.C. 287, 874, 1001, as amended.

6. Each Proposal must be accompanied by a Bid Bond, in the form attached, or a certified check on a bank that is a member of the Federal Deposit Insurance Corporation, payable to the order of the Owner, in an amount equal to ten percent (10%) of the maximum possible bid price. The maximum possible bid price is the sum of the total base bid, spare parts, maintenance tools and all positive amounts for alternates. Each Bidder agrees that, if its Proposal is one of the three low Proposals, its Bid Bond or check shall be held by the Owner until a Proposal is accepted and Contractor's Bond, when required, is furnished by the successful Bidder and such acceptance has been approved by the Administrator, or for a period not to exceed ninety (90) days from the date hereinbefore set for the opening of Proposals whichever period shall be the shorter. If such Proposal is not one of the three low Proposals, the Bid Bond or check will be returned to the Bidder within a period of thirty (30) days.

7. The successful Bidder will be required to furnish to the Owner a Contractor's Bond in conformance with the requirements of 7 CFR part 1788, subpart C, Insurance for Contractors, Engineers, and Architects.

8. Should the successful Bidder fail or refuse to furnish a Contractor's Bond within thirty (30) days after written notification of the award of the Contract by the Owner, the Bidder will be considered to have abandoned the Proposal. In such event, the Owner shall be entitled (a) to enforce the Bid Bond in accordance with its terms, or (b) if a certified check has been delivered with the Proposal, to retain from the proceeds of the certified check the difference (not exceeding the amount of the certified check) between the amount of the Proposal and such larger amount for which the Owner may in good faith contract with another party to construct the Project(s). The term "successful Bidder" shall be deemed to include any Bidder whose Proposal is accepted after another Bidder has previously refused or has been unable to execute the Contract or to furnish a Contractor's Bond.

9. If requested by the Owner or the Administrator, the Bidder shall furnish evidence, satisfactory to the Owner and the Administrator, that the Bidder has the necessary facilities, ability, and financial resources to perform the Contract.

10. The Contract, when executed, shall be deemed to include the entire agreement between the parties thereto and neither party shall claim any modification thereof resulting from any representation or promise made at any time by any officer, agent, or employee of the other or by any other person.

11. The Owner reserves the right to waive minor irregularities or minor errors in any Proposal, if it appears to the Owner that such irregularities or errors were made through inadvertence. Any such irregularities or errors so waived must be corrected on the Proposal in which they occur prior to the execution of any Contract which may be awarded thereon. Failure to provide a Bid Bond or check as specified in item six (6) above is not a minor irregularity.

12. The Owner reserves the right to reject any or all Proposals.

13. The equipment to be furnished for all central offices and remote switching terminals included in the Proposal is to be of one and the same basic design. A Proposal submitted on any other basis will not be considered.

14. Equal Opportunity and Employment

(a) The Offeror's or Bidders's attention is called to the "Equal Opportunity Clause" and the "Standard Federal Equal Employment Specifications" set forth herein.

(b) The goals and timetables for minority and female participation, expressed in percentage terms for the Contractor's aggregate workforce in each trade on all construction work in the covered area, are as follows:

Timetables	Goals for minority participation for each trade	Goals for female participation in trade
	(Insert goals for each year)	(Insert goals for each year)

These goals are applicable to all the Contractor's construction work (whether or not it is federal or federally assisted) performed in the covered area. If the Contractor performs construction work in a geographical area located outside of the covered area, it shall apply the goals established for such geographical area where work is actually performed. With regard to this second area, the Contractor also is subject to the goals for both its federally involved and nonfederally involved construction.

The Contractor's compliance with Executive Order 11246 (3 CFR, 1963–1965 Comp., p. 340) and the regulations in 41 CFR part 60–4 shall be based on its implementation of the Equal Opportunity Clause, specific affirmative action obligations required by the specifications set forth in 41 CFR 60–4.3(a), and its efforts to meet the goals. The hours of minority and female employment and training must be substantially uniform throughout the length of the contract, and in each trade, and the Contractor shall make a good faith effort to employ minorities and women evenly on each of its projects. Transfer of minority or female employees or trainees from Contractor to Contractor or from project to project for the sole purpose of meeting the Contractor's goals shall be a violation of the contract, Executive Order 11246 and the regulations in 41 CFR part 60–4. Compliance with the goals will be measured against the total work hours performed.

(c) The Contractor shall provide written notification to the Director of the Office of Federal Contract Compliance Programs within 10 working days of award of any construction subcontract in excess of $10,000 at any tier for construction work under the contract resulting from this solicitation. The notification shall list the name, address and telephone number of the subcontractor; employer identification number of the subcontractor; estimated dollar amount of the subcontract; estimated starting and completion dates of the subcontract; and the geographical area in which the subcontract is to be performed.

(d) As used in this Notice, and in the contract resulting from this solicitation, the "covered area" is

_____

_____

(insert description of the geographical areas where the contract is to be performed giving the state, county and city, if any).

Note: Paragraph 14 is applicable to the extent required by law. If applicable, certain information needs to be inserted at subparagraphs (b) and (d). In determining whether and how this paragraph is applicable, reference should be made to Office of Federal Contract Compliance Programs regulations (41 CFR Chapter 60).

_____

Date

_____

Owner

By _____

Title _____

Bidder's Proposal to Engineer, Furnish, Deliver, and Install Equipment, Materials and Software

(Proposal shall be submitted in ink or typewritten)

To: _____

(Hereinafter called the "Owner")

The undersigned (hereinafter called the "Bidder") hereby proposes to engineer, furnish, deliver, and install the equipment, materials and software for each Project listed under Column 1, "Project," in Article I, section 1, and described in the plans, specifications and drawings (hereinafter called the "Specifications") prepared by the Owner and attached hereto and made a part hereof, financed by a loan to the Owner made or guaranteed by the United States of America, acting through the Administrator of the Rural Electrification Administration (hereinafter called the "Administrator"), or by loans to the Owner by the United States of America and by the Rural Telephone Bank, and designated _____.

The Bidder has become informed as to the location and characteristics of the proposed installations, has become informed as to the kind of facilities required before and during the delivery and installation of the equipment, material, and software and has become acquainted with the labor conditions which would affect the work.

The Bidder agrees that if its bid is accepted the following terms and conditions shall govern.

If, in submitting this Proposal, the Bidder has taken any exception to the form of proposal furnished by the Owner, the Bidder understands that the Owner and the Administrator may evaluate the effect of such change as they see fit and they may exclude the Proposal from consideration in determining the award of the Contract.

ARTICLE I

[Section 1. Bid Price. The Bidder will engineer, furnish, deliver, and install the equipment, materials, and software described in the Specifications for the following sums:]

				Time in calendar days					
Project (see notes 1, 2 and 3)	Materials, equipment, and software	Installation	Base bid	Delivery	Completion of installation	Completion of the project (see note 4)	Spare parts	Item	Maintenance tools
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
	$	$	$				$	a	$
	$	$	$				$	b	$
	$	$	$				$	c	$
	$	$	$				$	d	$
	$	$	$				$	e	$
	$	$	$				$	f	$
	$	$	$				$	g	$
	$	$	$				$	h	$
	$	$	$				$	i	$
	$	$	$				$	j	$
Totals	$	$	XXXXXXX-XXX	XXXXXXX-XXX	XXXXXXX-XXX	XXXXXXX-XXX	$	XXX	$
Total Base Bid			$	XXXXXXX-XXX	XXXXXXX-XXX	XXXXXXX-XXX	XXXXXXX-XXX	XXXXX	XXXXXXX-XXX
Alternate No. 1	$	$	$				$	k	$
Alternate No. 2	$	$	$				$	l	$
Alternate No. 3	$	$	$				$	m	$
Alternate No. 4	$	$	$				$	n	$
Alternate No. 5	$	$	$				$	o	$
Alternate No. 6	$	$	$				$	p	$

Note 1: If a remote switching terminal, so designate and list after host office.
Note 2: All items included in a Project shall have the same completion schedule.
Note 3: Each Project shall be separated by a blank line.
Note 4: Time in calendar days for Completion of the Project shall be 60 days after the time established for Completion of Installation.

Section 2. Acceptable Equipment. Unless otherwise specified by the Owner (and agreed to in advance in writing by REA), the Bidder agrees to furnish under this Proposal only equipment which is currently covered by a letter of acceptance issued by the Chairman, Committee "A" (Telephone). [Note: for convenience of borrowers and others, domestically manufactured products are included in REA Bulletin 17551–100.] The Bidder agrees also to furnish only materials, equipment and software which are new and of most recent issue and manufacture, as of the date of the bid opening, or of near future release for which the Bidder can assure timely delivery.

Section 3. Changes in Project. The Owner, with the approval of the Administrator, may from time to time during the performance of the Contract effected by the acceptance of this Proposal, make reasonable changes, additions to or subtractions from the Specifications which are part of the Proposal as conditions may warrant. However, if substantial changes in the Project shall require an extension of time, a reasonable extension will be granted if the Bidder shall make a written request therefor to the Owner within thirty (30) days after any such change is made. Further, if the cost to the Bidder

shall be increased or decreased by any such change or addition, the Contract price shall be increased or decreased by a reasonable amount in accordance with a contract amendment signed by the Owner and the Bidder and approved by the Administrator. No claim for additional compensation for any such change or addition will be considered unless the Bidder shall have made a written request therefor to the Owner prior to the commencement of work in connection with such change or addition. The Delivery or Completion of Installation times specified under Columns 5, "Delivery", and 6, "Completion of Installation," in Article I, section 1, can only be changed by a Contract amendment approved by the Bidder, the Owner and REA.

Section 4. Taxes. The bid prices herein set forth do not include any amounts payable by the Bidder or the Owner on account of taxes imposed by any taxing authority upon the sale, purchase or use of materials, supplies, equipment or software to be incorporated in the Project(s). If any such tax is applicable to the sale, purchase or use of materials, supplies, equipment or software hereunder, the amount thereof shall be stated separately on all invoices and paid by the Owner.

Article II

Delivery and Installation

Section 1. Time of Completion of Installation. The time of delivery of materials, equipment, and software and of Completion of Installation are of the essence of this Contract. The Bidder shall deliver the materials, equipment, and software required hereunder for each Project upon the time intervals established under Column 5, "Delivery," in Article I, section 1, after the Administrator shall have approved this Contract in writing, and shall prosecute diligently and complete the installation of materials, equipment and software for each Project in accordance with the terms of this Contract and Specifications to the satisfaction of the Owner and the Administrator within the number of calendar days specified under Column 6, "Completion of Installation," in Article I, section 1. The times for such Delivery or such Completion of Installation shall be extended for the period of any reasonable delay due exclusively to causes beyond the control and without the fault of the Bidder, including, but not limited to, acts of God, fires, strikes, floods, changes in the Specifications as herein provided, and acts or omissions of the Owner with respect to matters for which the Owner is solely responsible. However, no such extension of time shall be granted the Bidder unless within thirty (30) days after Bidder becomes aware of the happening of any event relied upon by the Bidder for such an extension of time the Bidder shall have made a request therefor in writing to the Owner. Further, no delay in such time for delivery of materials, equipment and software or Completion of Installation or in the progress of the work shall result in any liability on the part of the Owner, except that the Owner shall be responsible for and shall pay the Bidder on demand all additional, supportable costs and expenses incurred by the Bidder due to delays to the extent such delays are caused by the Owner's failure to perform its obligations under this Contract unless the Owner's failure to perform is caused by forces beyond its control.

Section 2. Sequence of Installation. All Projects shall be completed in the sequence in which they are listed under Column 1, "Project," in Article I, section 1.

Section 3. Supervision and Inspection. The Bidder shall give sufficient supervision to the work at the site of the Project(s), using the Bidder's best skill and attention. The Bidder shall carefully study and compare all drawings, specifications, and other instructions and shall promptly report to the Owner any error, inconsistency or omission which Bidder may discover. The Bidder shall keep on the Project(s) during its progress a competent superintendent (hereinafter called the "Superintendent") and any necessary qualified assistants, all satisfactory to the Owner. The Superintendent shall represent the Bidder and all directions given to the Superintendent by the Owner shall be as binding as if given to the Bidder. When requested by the Bidder, such directions shall be confirmed in writing.

Section 4. Inspection and Tests. The installation of materials, equipment and software hereunder and all materials, equipment and software used therein shall be subject to the inspection, test and approval of the Owner and Administrator, in accordance with the Specifications. The Bidder shall furnish all pertinent information required concerning the nature or source of materials. The Owner and the Administrator shall have the right to inspect pertinent records (other than manufacturing cost information) of the Bidder and of any subcontractor relevant to this Project(s). The Bidder shall provide all reasonable facilities necessary for such inspection and tests, except that the Bidder is not required to provide test equipment for the Owner's tests unless specifically required in the Specifications. Failure of the Owner to make inspections shall not release the Bidder from performance required hereunder.

The Bidder shall notify the Owner in writing upon Completion of Installation of each Project and provide a copy of the results of tests, if any, conducted by the Bidder.

The Owner shall make inspections and tests of each Project for compliance with the Specifications and provide the Bidder the results of such inspections and tests on REA Form 517, Results of Acceptance Tests. If the Owner has not completed its inspections and tests and provided the Bidder the results on REA Form 517 within thirty (30) days after the written notification of Completion of Installation from the Bidder, the Owner shall (1) pay to the Bidder the costs incurred by the Bidder as a result of this delay, and (2) grant an extension of time for the Completion of the Project equal to the number of days from the date of the end of the thirty (30) day period until the date the Owner provides the REA Form 517 to the Bidder.

Within thirty (30) days of receipt of the REA Form 517 from the Owner, the Bidder shall correct all deficiencies, if any, listed on the REA Form 517 and notify the Owner in writing of such corrections and deliver to the Owner the documents set forth in Article III, section 2, at which time a final Owner's inspection and test of each Project shall be conducted. If tests subsequent to this are made necessary by the Bidder's failure to satisfactorily resolve all such deficiencies as previously listed on the REA Form 517, the Bidder shall pay the Owner for the cost incurred by the Owner for all such subsequent tests.

Section 5. Delivery of Possession and Control to the Owner. The Bidder shall deliver to the Owner, and the Owner shall accept, full possession and control of each Project on the date of Completion of the Project or on an earlier date if agreed under Article IV, section 2.

Section 6. Employees. The Owner shall have the right to require the removal of any employee of the Bidder from the Project site if in the judgment of the Owner such removal is necessary in order to protect the interest of the Owner.

Section 7. Defective Workmanship, Materials or Software. Throughout the warranty period defined below the Bidder shall, within thirty (30) days of written notice from the Owner, and without charge to the Owner, at the Bidder's option, either remedy or replace any materials, equipment or software found to be defective in material, workmanship or installation, or not in conformity with the Specification. This is subject to the following definitions and conditions:

(a) The warranty start date for a Project is the date of delivery of possession and control by the Bidder to the Owner of that Project included in the Contract. Refer to Article II, section 5. The warranty period is twelve (12) months from the warranty start date, or six (6) months from Completion of the Project, whichever results in the longer period of coverage.

(b) Without regard to the expiration of the warranty period set forth above, the Bidder warrants to the Owner that any Software furnished under this Contract shall function, for a period of five (5) years from the warranty start date defined in the Contract, in accordance with the specifications and any written or printed technical material provided by the Bidder to explain the operation of the Software and aid in its use. The Bidder shall correct all deficiencies within thirty (30) days from the date of receipt by the Bidder of written notice of such deficiencies from the Owner. An extension of this thirty (30) day period may be allowed only if agreed upon by the Owner. It shall be the Bidder's obligation to insert and thoroughly test, at no charge to the Owner, any software amendment or alteration provided to satisfy the obligations of this Section 7. If a deficiency is detected or a correction made within the final ninety (90) days of the warranty, the warranty shall be extended to a date ninety (90) days after the deficiency has been corrected.

(c) The Owner shall pay the Bidder for any use of the Bidder's technical assistance center except for usage to diagnose defects covered by this warranty.

(d) This warranty is not diminished by the acceptance of workmanship, materials, equipment, or software, or by the issuing of any certificate with respect to Completion of the Project.

(e) This warranty does not cover defects in materials, equipment or software that are caused by modifications to or abuse of materials, equipment or software by the Owner.

(f) The Owner shall bear the cost and risk of shipping defective components to the Bidder's designated repair center. The Bidder shall bear the cost and risk of shipping new or repaired replacement components to the Owner.

Article III

Payments and Releases of Lien

Section 1. Payment to Bidder.

(a) The Owner shall pay the Bidder upon the basis of written estimates of the materials, equipment, and software delivered at the site of the Project, presented by the Bidder, and approved by the Owner, the following percentages of the price of the materials, equipment, and software for each Project set forth under Column 2, "Materials, Equipment, and Software," in Article I, Section 1, as and if revised:

(i) Forty-five percent (45%) when fifty percent (50%) of the materials, equipment, and software for each Project has been delivered at the site of the Project, and

(ii) Ninety percent (90%) when all the materials, equipment, and software required to place each Project into operation has been delivered at the site of the Project.

(b) Upon written notification of the Completion of Installation of each Project, the Owner shall pay the Bidder ninety percent (90%) of the Base Bid plus accepted alternates for that Project.

(c) Upon the Completion of Installation, but prior to the payment to the Bidder of any amount in excess of ninety percent (90%) of the Total Contract Price, the Owner shall inspect the work performed hereunder and if the work shall be found to be in accordance with the Specifications and all provisions hereunder, the Owner shall certify as to that fact and as to the amount of the balance found to be due to the Bidder. No later than thirty (30) days after Completion of the Contract, as defined in Article VII, section 1, "Definitions," the Owner shall submit such final certificate to the Administrator for approval and when such approval has been given, the Owner shall pay to the Bidder all unpaid amounts to which the Bidder shall be entitled hereunder; provided, however, such final payments shall be made not later than sixty (60) days after Completion of the Contract unless approval by the Administrator shall be withheld or delayed due to Bidder's actions or failure to act.

(d) Payment on undisputed invoices submitted by the Bidder shall be due thirty (30) days after receipt. Any amounts of these invoices not paid when due shall accrue interest at a rate one and one-half percent (1½%) higher than the "Prime Rate" published in the Wall Street Journal in its first issue of the month in which payment becomes due and changing each subsequent month with the first issue published in the respective month.

(e) Notwithstanding other provisions of this Article III, the Bidder, shall, at its request in writing, receive payment in full for each Project upon Completion of Installation of such and upon:

(i) Completion of the final acceptance tests of such Project as certified on REA Form 754, Certificate of Completion, Central Office(s) and approved by the Owner.

(ii) Submission to the Owner and Administrator of the releases of lien and Certificate of Contractor referred to in section 2 hereof or in lieu thereof, where the Bidder is the manufacturer, the execution of the Certificate of Contractor and Indemnity Agreement on REA Form 754, all in respect of such Project.

(iii) Approval by the Administrator of the Certificate of Completion, REA Form 754 in respect of such Project.

Ten percent (10%) of the contract price of one central office shall be retained until the Bidder shall have furnished the certificates and releases of lien or indemnity agreement in respect of the Project required by section 2 of this Article III.

(This Section 1(e) is to be used only if (1) the Contract includes at least one central office and (2) the Owner wishes to allow the partial closeout procedure. The Owner shall strike out this Section 1(e) if the partial closeout procedure is not to be allowed)

(f) Acceptance by the Owner of equipment, materials, workmanship or software while the Bidder is in default under any provision of this Contract shall not be construed as a waiver by the Owner of any right hereunder including, without limitation, any right to liquidated damages the Owner may have by virtue of Article V, section 2.

Section 2. Release of Liens. Upon the Completion of Installation by the Bidder, but prior to the payment to the Bidder of any amount in excess of ninety percent (90%) of the Total Contract Price, except as specified in Article III, section 1(e), the Bidder shall deliver to the Owner (a) two original Waiver and Release of Lien in the form attached hereto, from manufacturers, material suppliers and subcontractors who have furnished materials or services for the work, and (b) two original Certificate of Contractor, in the form attached hereto, to the effect that all labor has been paid and that all such releases have been submitted to the Owner; and the Owner shall deliver to the Administrator for approval one of the originals of each such release and certificate.

In lieu of releases of lien where the Bidder is the manufacturer of the equipment, the Bidder may deliver to the Owner, in duplicate in the form attached hereto, a Certificate of Contractor and Indemnity Agreement, stating that all manufacturers, material suppliers and subcontractors who have furnished materials or services for the Project(s) have been paid in full, and agreeing to indemnify the Owner against any liens arising out of the Bidder's performance hereunder which may have been or may be filed against the Owner.

In this Article III "manufacturer" shall mean a Bidder who makes, produces, or manufactures the equipment and whose interest, including non-contracted installation, represent more than fifty percent (50%) of the value of the Total Contract Price.

Article IV

Particular Undertakings of the Bidder

Section 1. Protection to Persons and Property. At all times when equipment and materials are being delivered and installed the Bidder shall exercise reasonable precautions for the safety of employees on the job and of the public and shall comply with all applicable provisions of Federal, State and Municipal safety laws and building and construction codes. All machinery and equipment and other physical hazards shall be guarded in accordance with the "Manual of Accident Prevention in Construction" of the Associated General Contractors of America unless such instructions are incompatible with Federal, State or Municipal laws or regulations. The following provisions shall not limit the generality of the above requirements:

(a) The Bidder shall at all times keep the premises free from accumulations of waste material or rubbish caused by its employees or work, and at the completion of the work the Bidder shall remove all rubbish from and about the Project(s) and all its tools, scaffolding and surplus materials and shall leave its work "broom clean."

(b) The work, from its commencement to completion, or to such earlier date or dates when the Owner may take possession and control, shall be under the charge and control of the Bidder and during such period of control by the Bidder all risks in connection therewith, and in connection with the equipment, materials and software to be used therein, shall be borne by the Bidder. The Bidder shall make good and fully repair all injuries and damages to the equipment, materials and software under the control of the Bidder by reasons of any act of God, or any other casualty or cause whether or not the same shall have occurred by reason of the Bidder's negligence. The Bidder shall hold the Owner harmless from any and all claims for injuries of persons or for damage to property happening by reason of any negligence on the part of the Bidder or any of the Bidder's agents, subcontractors or employees during the control by the Bidder of the Project(s) or any part thereof. The Owner shall promptly notify the Bidder in writing of any such claims received and, except where the Owner is the claimant, shall give to the Bidder full authority and opportunity to settle such claims, and reasonably cooperate with the Bidder in obtaining information relative to such claims.

(c) Monthly reports of all accidents shall be promptly submitted to the Owner by the Bidder giving such data as may be prescribed by the Owner.

Section 2. Termination of Bidder's Risks and Obligations. The Bidder shall deliver to the Owner, and the Owner shall accept, full possession and control of each Project on the date of Completion of the Project. However, at any time after payment by the Owner to the Bidder of ninety percent (90%) of the Total Base Bid plus accepted alternates for that Project, but prior to Completion of the Project, the Owner and the Bidder may agree in writing to an earlier date of delivery of possession and control. Upon such delivery of possession and control of any Project the Bidder's risks and obligations as set forth in Article IV, section 1(b), pertaining to such

Project shall be terminated; provided, however, that nothing herein contained shall relieve the Bidder of its obligation for full performance under the Specifications, or its liability with respect to defective workmanship or materials as specified in Article II, section 7 hereof. The equipment shall not be placed in service until delivery of possession and control to the Owner has been accomplished, as set forth above.

Section 3. Insurance. During the Bidder's performance hereunder, the Bidder shall take out and maintain fully paid insurance providing not less than the minimum coverage required by 7 CFR part 1788, subpart C.

The Owner shall have the right to require public liability insurance and property damage liability insurance in an amount greater than those required in 7 CFR part 1788, subpart C. If this requirement is included in the plans and specifications used for bidding, the added costs shall be included in the bid price. If the requirement is added after the Contract is approved, the additional premium or premiums payable solely as the result of such additional insurance shall be added to the Contract price, by Contract amendment.

Upon request by the Administrator, the Bidder shall furnish to the Administrator a certificate in such form as the Administrator may prescribe evidencing compliance with the foregoing requirements.

Section 4. Purchase of Materials. The Bidder shall purchase all materials and supplies except software outright and not subject to any conditional sales agreements, bailment lease or other agreement reserving unto the seller any right, title or interest therein. Materials and supplies other than software shall become the property of the Owner as the Owner makes payments therefor to the Bidder in accordance with Article III, Section 1(a).

Section 5. Software License. The software licensing agreement, if required, covering the rights, terms and conditions of the use and assignability of all software integral to the operation of the Project(s), shall be in the form of Addendum 1 to this Contract.

Section 6. Assignment of Guarantees. All guarantees of materials, equipment, workmanship and software running in favor of the Bidder shall be transferred and assigned to the Owner upon Completion of the Project and at such time as the Bidder receives final payment. Any such guarantees shall be in addition to the Bidder's warranty defined in Article II, section 7. This provision may be modified with respect to a particular warranty if the Bidder demonstrates to the satisfaction of REA and the Owner that a transfer is not possible.

Section 7. Patent, Copyright, Trademark and Trade Secret Infringement. The Bidder shall hold harmless and indemnify the Owner from any and all claims, suits, and proceedings for the infringement of any patent, copyright, trademark or violation of trade secrets covering any equipment or software used in the work, except for items of the Owner's design or selection. If the Owner's use of equipment or software is enjoined, the Bidder shall promptly, at its own expense, modify or replace the infringing equipment or software so that it no longer infringes but remains functionally equivalent, or obtain for the Owner a license or other right to use. This shall be in addition to any other rights or claims which the Owner may have. The Bidder shall, at its own expense, (and the Owner agrees to permit Bidder to do so,) defend any suits which may be instituted by any party against the Owner for alleged infringement of patents, copyright, trademark or violation of trade secrets relative to the Bidder's performance hereunder. Either party shall notify the other promptly of any such claims, and the Owner shall give to the Bidder full authority and opportunity to settle such claims, and shall reasonably cooperate with the Bidder in obtaining information relative to such claims.

Section 8. Compliance with Statutes and Regulations. The Bidder shall comply with all applicable laws, statutes, ordinances, rules and regulations. The Bidder acknowledges that it is familiar with the Rural Electrification Act of 1936, as amended (7 U.S.C. 901 *et seq.*), the Anti-Kickback Acts, as amended (40 U.S.C. 276c; 41 U.S.C. 51 *et seq.*), and any rules and regulations issued pursuant thereto, and 18 U.S.C. 201, 286, 287, 641, 666, 874, 1001, 1361 and 1366, as amended. The Bidder understands that the obligations of the parties hereunder are subject to the applicable regulations and orders of the Governmental agencies having jurisdiction in the premises.

The Bidder represents that to the extent required by Executive Orders 12549 (3 CFR, 1985–1988 Comp., p. 189) and 12689 (3 CFR, 1989 Comp., p. 235), Debarment and Suspension, and 7 CFR part 3017, it has submitted to the Owner a duly executed certification in the form prescribed in 7 CFR part 3017.

The Bidder represents that, to the extent required, it has complied with the requirements of Public Law 101–121, section 319, 103 Stat. 701, 750–765 (31 U.S.C. 1352), entitled "Limitation on use of appropriated funds to influence certain Federal contracting and financial transactions," and any rules and regulations issued pursuant thereto.

Article V

Remedies

Section 1. Completion on Bidder's Default. If default shall be made by the Bidder in the performance of any of the work hereunder, the Owner, without in any manner limiting its legal and equitable remedies in the circumstances, may serve upon the Bidder and the surety or sureties upon the Bidder's Bond or Bonds a written notice requiring the Bidder to cause such default to be corrected forthwith. Unless within thirty (30) days after the service of such notice upon the Bidder such default shall be corrected or arrangements for the correction thereof, satisfactory to both the Owner and the Administrator, shall have been made by the Bidder or its surety or sureties, the Owner may take over the performance of the Bidder's obligations hereunder and prosecute the same to completion by contract or otherwise for the account and at the expense of the Bidder, and the Bidder and its surety or sureties shall be liable to the Owner for any supportable cost or expense in excess of the bid price occasioned thereby. In such event, the Owner may take possession of and utilize, in completing the Project(s), any tools, supplies, equipment, appliances and plant belonging to the Bidder which may be situated at the site of the Project(s). The Owner, in such contingency, may exercise any rights, claims or demands which the Bidder may have against third persons in connection herewith and for such purpose the Bidder does hereby assign, transfer and set over unto the Owner all such rights, claims and demands.

Section 2. Liquidated Damages. Should the Bidder fail to complete any Project as shown under Column 7, "Completion of the Project," in Article I, Section 1, within the time herein agreed upon, after giving effect to extensions of time, if any, herein provided, then, in that event and in view of the difficulty of estimating with exactness damages caused by such delay, the Owner shall, so long as the subject Project shall not have been placed in service, have the right to deduct from and retain out of such moneys which may be then due, or which may become due and payable to the Bidder, the sum of:

_____

dollars ($_____)

for _____

(Project)

for _____

dollars ($_____)

for _____

(Project)

dollars ($_____

for _____

per day for each and every day that such completion is delayed beyond the scheduled time for Completion of the Project, as liquidated damages and not as a penalty, up to the amount of the respective Base Bid plus accepted alternates for the affected Project: *Provided*, however, that the Owner shall promptly notify the Bidder in writing of the manner in which the amount claimed as liquidated damages was computed. The Bidder shall pay to the Owner the amount necessary to effect such payment in full. Such payment is not to be reduced by the value of any partial performance by the Bidder.

At the technical sessions, each Bidder shall identify all features and capabilities that are not fully developed or do not have a verifiable satisfactory field performance record. If the Owner allows these features to be bid as separate Projects, then they are to be individually listed under Columns 1 through 10, in Article I, section 1. These unproven features and capabilities are to be individually listed in this section 2 also, with liquidated damages amounts determined by the Owner and stated for each. If a Bidder neglects to identify any such feature at the technical session, delay in providing the feature is considered a delay in completing the associated Project and the Owner may assess liquidated damages listed for that Project regardless of whether the Project is placed in service.

Section 3. Consequential Damages. In no event shall the Bidder's liability for

incidental or consequential loss or damage, except for personal injury or tangible property damage, exceed the amount of ten times the total contract price, as amended.

Section 4. Enforcement of Remedies by Administrator. The Administrator may on behalf of the Owner exercise any right or enforce any remedy which the Owner may exercise or enforce hereunder.

Section 5. Cumulative Remedies. Every right or remedy herein conferred upon or reserved to the Owner or the Administrator shall be cumulative and shall be in addition to every right and remedy now or hereafter existing at law or in equity or by statute and the pursuit of any right or remedy shall not be construed as an election. Provided, however, that the provisions of section 2 of this Article V shall be the exclusive measure of damages for failure by the Bidder to have effected the Completion of Project within the time herein agreed upon.

Article VI

Equal Employment

Section 1. The Bidder.

(a) The Bidder represents that:

(1) It has, _____ does not have _____. 100 or more employees, and if it has, that

(2) It has _____, has not _____, furnished the Equal Employment Opportunity Employers Information Report EEO–1, Standard Form 100, required of employers with 100 or more employees pursuant to Executive Order 11246 and Title VII of the Civil Rights Act of 1964.

(b) The Bidder agrees that it will obtain, prior to the award of any subcontract for more than $10,000 hereunder to a subcontractor with 100 or more employees, a statement, signed by the proposed subcontractor, that the proposed subcontractor has filed a current report on Standard Form 100.

(c) The Bidder agrees that if it has 100 or more employees and has not submitted a report on Standard Form 100 for the current reporting year and that if this contract will amount to more than $10,000, the Bidder will file such report, as required by law, and notify the Owner in writing of such filing prior to the Owner's acceptance of this Proposal.

(d) The Bidder certifies that it does not maintain or provide for its employees any segregated facilities at any of its establishments, and that it does not permit its employees to perform their services at any location, under its control, where segregated facilities are maintained. The Bidder certifies further that it will not maintain or provide for its employees any segregated facilities at any of its establishments, and that it will not permit its employees to perform their services at any location, under its control, where segregated facilities are maintained. The Bidder agrees that a breach of this certification is a violation of the Equal Opportunity Clause in this contract. As used in this certification, the term "segregated facilities" means any waiting rooms, work areas, restrooms and washrooms, restaurants and other eating areas, timeclocks, locker rooms and other storage or dressing areas, parking lots, drinking fountains, recreation or entertainment areas, transportation, and housing facilities provided for employees which are segregated by explicit directive or are in fact segregated on the basis of race, color, religion, or national origin, because of habit, local custom, or otherwise. The Bidder agrees that (except where it has obtained identical certifications from proposed subcontractors for specific time periods) it will obtain identical certifications from proposed subcontractors prior to the award of subcontracts exceeding $10,000 which are not exempt from the provisions of the Equal Opportunity Clause, and that it will retain such certifications in its files.

Section 2. During the performance of this contract, the Contractor agrees as follows:

(a) The Contractor will not discriminate against any employee or applicant for employment because of race, color, religion, sex or national origin. The Contractor will take affirmative action to ensure that applicants are employed, and that employees are treated during employment without regard to their race, color, religion, sex or national origin. Such action shall include, but not be limited to, the following: employment, upgrading, demotion or transfer; recruitment or recruitment advertising; layoff or termination; rates of pay or other forms of compensation; and selection for training, including apprenticeship. The Contractor agrees to post in conspicuous places available to employees and applicants for employment, notices to be provided setting forth the provisions of this nondiscrimination clause.

(b) The Contractor will, in all solicitations or advertisements for employees placed by or on behalf of the Contractor, state that all qualified applicants shall receive consideration for employment without regard to race, color, religion, sex or national origin.

(c) The Contractor will send to each labor union or representative of workers with which the Bidder has a collective bargaining agreement or other contract or understanding, a notice to be provided advising the said labor union or workers' representative of the Contractor's commitments under this section, and shall post copies of the notice in conspicuous places available to employees and applicants for employment.

(d) The Contractor will comply with all provisions of Executive Order 11246 of September 24, 1965, and of the rules, regulations and relevant orders of the Secretary of Labor.

(e) The Contractor will furnish all information and reports required by Executive Order 11246 of September 24, 1965, and by rules, regulations and orders of the Secretary of Labor, or pursuant thereto, and will permit access to the Contractor's books, records and accounts by the administering agency and the Secretary of Labor for purposes of investigation to ascertain compliance with such rules, regulations and orders.

(f) In the event of the Contractor's noncompliance with the nondiscrimination clauses of this contract or with any of the said rules, regulations or orders, this contract may be canceled, terminated or suspended in whole or in part and the Contractor may be declared ineligible for further Government contracts or federally assisted construction contracts in accordance with procedures authorized in Executive Order 11246 of September 24, 1965, and such other sanctions as may be imposed and remedies invoked as provided in the said Executive Order 11246 of September 24, 1965, or by rule, regulation or order of the Secretary of Labor, or as otherwise provided by law.

(g) The Contractor will include the portion of the sentence immediately preceding paragraph (a) and the provisions of paragraphs (a) through (g) in every subcontract or purchase order unless exempted by rules, regulations or orders of the Secretary of Labor issued pursuant to Section 204 of Executive Order 11246 of September 24, 1965, so that such provisions will be binding upon each subcontractor or vendor. The Contractor will take such action with respect to any subcontract or purchase order as the administering agency may direct as a means of enforcing such provisions, including actions for noncompliance: *Provided, however,* that in the event a contractor becomes involved in, or is threatened with, litigation with a subcontractor or vendor as a result of such direction by the administering agency, the Contractor may request the United States to enter into such litigation to protect the interests of the United States.

Section 3. Equal Employment Opportunity Specifications.

(a) As used in these specifications:

"Covered area" means the geographical area described in the solicitation from which this contract resulted;

"Director" means Director, Office of Federal Contract Compliance Programs, United States Department of Labor, or any person to whom the Director delegates authority;

"Employer identification number" means the Federal Social Security number used on the Employer's Quarterly Federal Tax Return, U.S. Treasury Department Form 941; and

"Minority" includes:

(i) Black (all persons having origins in any of the Black African racial groups not of Hispanic origin);

(ii) Hispanic (all persons of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish Culture or origin, regardless of race);

(iii) Asian and Pacific Islander (all persons having origins in any of the original peoples of the Far East, Southeast Asia, the Indian Subcontinent, or the Pacific Islands); and

(iv) American Indian or Alaskan Native (all persons having origins in any of the original peoples of North America and maintaining identifiable tribal affiliations through membership and participation or community identification).

(b) Whenever the Contractor, or any Subcontractor at any tier, subcontracts a portion of the work involving any construction trade, it shall physically include in each subcontract in excess of $10,000 the provisions of these specifications and the Notice which contains the applicable goals for minority and female participation and which is set forth in the solicitations from which this contract resulted.

(c) If the Contractor is participating (pursuant to 41 CFR 60–4.5) in a Hometown

Plan approved by the U.S. Department of Labor in the covered area either individually or through an association, its affirmative action obligations on all work in the Plan area (including goals and timetables) shall be in accordance with that Plan for those trades which have unions participating in the Plan. Contractors must be able to demonstrate their participation in and compliance with the provisions of any such Hometown Plan. Each Contractor or Subcontractor participating in an approved Plan is individually required to comply with its obligations under the EEO clause, and to make a good faith effort to achieve each goal under the Plan in each trade in which it has employees. The overall good faith performance by other Contractors or Subcontractors toward a goal in an approved Plan does not excuse any covered Contractor's or Subcontractor's failure to take good faith efforts to achieve the Plan goals and timetables.

(d) The Contractor shall implement the specific affirmative action standards provided in paragraphs (g) (i) through (xvi) of these specifications. The goals set forth in the solicitation from which this contract resulted are expressed as percentages of the total hours of employment and training of minority and female utilization the Contractor should reasonably be able to achieve in each construction trade in which it has employees in the covered area. Covered construction contractors performing construction work in geographical areas where they do not have a federal or federally assisted construction contract shall apply the minority and female goals established for the geographical area where the work is being performed. Goals are published periodically in the **Federal Register** in notice form, and such notices may be obtained from any Office of Federal Contract Compliance Programs office or from Federal procurement contracting officers. The Contractor is expected to make substantially uniform progress in meeting its goals in each craft during the period specified.

(e) Neither the provisions of any collective bargaining agreement, nor the failure by a union with whom the Contractor has a collective bargaining agreement, to refer either minorities or women shall excuse the Contractor's obligations under these specifications, Executive Order 11246, or the regulations promulgated pursuant thereto.

(f) In order for the nonworking training hours of apprentices and trainees to be counted in meeting the goals, such apprentices and trainees must be employed by the Contractor during the training period, and the Contractor must have made a commitment to employ the apprentices and trainees at the completion of their training, subject to the availability of employment opportunities. Trainees must be trained pursuant to training programs approved by the U.S. Department of Labor.

(g) The Contractor shall take specific affirmative actions to ensure equal employment opportunity. The evaluation of the Contractor's compliance with these specifications shall be based upon its effort to achieve maximum results from its actions. The Contractor shall document these efforts fully, and shall implement affirmative action steps at least as extensive as the following:

(i) Ensure and maintain a working environment free of harassment, intimidation, and coercion at all sites, and in all facilities at which the Contractor's employees are assigned to work. The Contractor, where possible, will assign two or more women to each construction project. The Contractor shall specifically ensure that all foremen, superintendents, and other on-site supervisory personnel are aware of and carry out the Contractor's obligation to maintain such a working environment, with specific attention to minority or female individuals working at such sites or in such facilities.

(ii) Establish and maintain a current list of minority and female recruitment sources, provide written notification to minority and female recruitment sources and to community organizations when the Contractor or its unions have employment opportunities available, and maintain a record of the organizations' responses.

(iii) Maintain a current file of the names, addresses and telephone numbers of each minority and female off-the-street applicant and minority or female referral from a union, a recruitment source or community organization and of what action was taken with respect to each such individual. If such individual was sent to the union hiring hall for referral and was not referred back to the Contractor by the union or, if referred, not employed by the Contractor, this shall be documented in the file with the reason therefore, along with whatever additional actions the Contractor may have taken.

(iv) Provide immediate written notification to the Director when the union or unions with which the Contractor has a collective bargaining agreement has not referred to the Contractor a minority person or woman sent by the Contractor, or when the Contractor has other information that the union referral process has impeded the Contractor's efforts to meet its obligations.

(v) Develop on-the-job training opportunities and/or participate in training programs for the area which expressly include minorities and women, including upgrading programs and apprenticeship and trainee programs relevant to the Contractor's employment needs, especially those programs funded or approved by the Department of Labor. The Contractor shall provide notice of these programs to the sources compiled under (g)(ii) above.

(vi) Disseminate the Contractor's EEO policy by providing notice of the policy to unions and training programs and requesting their cooperation in assisting the Contractor in meeting its EEO obligations; by including it in any policy manual and collective bargaining agreement; by publicizing it in the company newspaper, annual report, etc.; by specific review of the policy with all management personnel and with all minority and female employees at least once a year; and by posting the company EEO policy on bulletin boards accessible to all employees at each location where construction work is performed.

(vii) Review, at least annually, the company's EEO policy and affirmative action obligations under these specifications with all employees having any responsibility for hiring, assignment, layoff, termination or other employment decisions including specific review of these items with onsite supervisory personnel such as Superintendents, General Foremen, etc., prior to the initiation of construction work at any job site. A written record shall be made and maintained identifying the time and place of these meetings, persons attending, subject matter discussed, and disposition of the subject matter.

(viii) Disseminate the Contractor's EEO policy externally by including it in any advertising in the news media, specifically including minority and female news media, and providing written notification to and discussing the Contractor's EEO policy with other Contractors and Subcontractors with whom the Contractor does or anticipates doing business.

(ix) Direct its recruitment efforts, both oral and written, to minority, female and community organizations, to schools with minority and female students and to minority and female recruitment and training organizations serving the Contractor's recruitment area and employment needs. Not later than one month prior to the date for the acceptance of applications for apprenticeship or other training by any recruitment source, the Contractor shall send written notification to organizations such as the above, describing the openings, screening procedures, and tests to be used in the selection process.

(x) Encourage present minority and female employees to recruit other minority persons and women and, where reasonable, provide after school, summer and vacation employment to minority and female youth both on the site and in other areas of a Contractor's work force.

(xi) Validate all tests and other selection requirements where there is an obligation to do so under 41 CFR Part 60–3.

(xii) Conduct, at least annually, an inventory and evaluation at least of all minority and female personnel for promotional opportunities and encourage these employees to seek or to prepare for, through appropriate training, etc., such opportunities.

(xiii) Ensure that seniority practices, job classifications, work assignments and other personnel practices, do not have a discriminatory effect by continually monitoring all personnel and employment related activities to ensure that the EEO policy and the Contractor's obligations under these specifications are being carried out.

(xiv) Ensure that all facilities and company activities are nonsegregated except that separate or single-user toilet and necessary changing facilities shall be provided to assure privacy between the sexes.

(xv) Document and maintain a record of all solicitations of offers for subcontracts from minority and female construction contractors and suppliers, including circulation of solicitations to minority and female contractor associations and other business associations.

(xvi) Conduct a review, at least annually, of all supervisors' adherence to and performance under the Contractor's EEO policies and affirmative action obligations.

(h) Contractors are encouraged to participate in voluntary associations which

assist in fulfilling one or more of their affirmative action obligations (g) (i) through (xvi). The efforts of a contractor association, joint contractor-union, contractor-community, or other similar group of which the Contractor is a member and participant, may be asserted as fulfilling any one or more of its obligations under (g) (i) through (xvi) of these specifications provided that the Contractor actively participates in the group, makes every effort to assure that the group has a positive impact on the employment of minorities and women in the industry, ensures that the concrete benefits of the program are reflected in the Contractor's minority and female workforce participation, makes a good faith effort to meet its individual goals and timetables, and can provide access to documentation which demonstrates the effectiveness of actions taken on behalf of the Contractor. The obligation to comply, however, is the Contractor's and failure of such a group to fulfill an obligation shall not be a defense for the Contractor's noncompliance.

(i) A single goal for minorities and a separate single goal for women have been established. The Contractor, however, is required to provide equal employment opportunity and to take affirmative action for all minority groups, both male and female, and all women, both minority and non-minority. Consequently, the Contractor may be in violation of Executive Order 11246 if a particular group is employed in a substantially disparate manner (for example, even though the Contractor has achieved its goals for women generally, the Contractor may be in violation of Executive Order 11246 if a specific minority group of women is underutilized).

(j) The Contractor shall not use the goals and timetables or affirmative action standards to discriminate against any person because of race, color, religion, sex, or national origin.

(k) The Contractor shall not enter into any Subcontract with any person or firm debarred from Government contracts pursuant to Executive Order 11246.

(l) The Contractor shall carry out such sanctions and penalties for violation of these specifications and of the Equal Opportunity Clause, including suspension, termination and cancellation of existing subcontracts as may be imposed or ordered pursuant to Executive Order 11246, as amended, and its implementing regulations, by the Office of Federal Contract Compliance Programs. Any Contractor who fails to carry out such sanctions and penalties shall be in violation of these specifications and Executive Order 11246, as amended.

(m) The Contractor, in fulfilling its obligations under these specifications, shall implement specific affirmative action steps, at least as extensive as those standards prescribed in paragraph (g) of these specifications, so as to achieve maximum results from its efforts to ensure equal employment opportunity. If the Contractor fails to comply with the requirements of Executive Order 11246, the implementing regulations, or these specifications, the Director shall proceed in accordance with 41 CFR 60–4.8.

(n) The Contractor shall designate a responsible official to monitor all employment related activity to ensure that the company EEO policy is being carried out, to submit reports relating to the provisions hereof as may be required by the Government and to keep records. Records shall at least include for each employee the name, address, telephone numbers, construction trade, union affiliation if any, employee identification number when assigned, social security number, race, sex, status (e.g., mechanic, apprentice, trainee, helper, or laborer), dates of changes in status, hours worked per week in the indicated trade, rate of pay, and locations at which the work was performed. Records shall be maintained in an easily understandable and retrievable form; however, to the degree that existing records satisfy this requirement, contractors shall not be required to maintain separate records.

(o) Nothing herein provided shall be construed as a limitation upon the application of other laws which establish different standards of compliance or upon the application of requirements for the hiring of local or other area residents (e.g. those under the Public Works Employment Act of 1977 and the Community Development Block Grant Program).

Section 4. In this Article VI—

(a) The term "Contractor" shall also mean "Bidder" or "Subcontractor" as applicable.

(b) The provisions of sections 2 & 3 are applicable to the extent required by law. In determining whether these Sections are applicable, reference should be made to Office of Federal Contract Compliance Programs regulations (41 CFR part 60).

Article VII

Miscellaneous

Section 1. Definitions.

The term "Completion of the Contract" shall mean accomplishment of Completion of the Project for all central offices (and associated remote switching terminals), features and services listed under Column 1, "Project," in Article I, Section 1, and all alternates accepted by the Owner, on the Owner's Acceptance.

The term "Completion of Installation" shall mean full performance by the Bidder of the Bidder's obligation under the Contract and all amendments and revisions thereof, for a Project, except that it shall not include the acceptance tests nor performance of the Bidder's obligations in respect of (i) releases of lien and Certificate of Contractor under Article III, section 2, hereof and (ii) other final documents. The actual date of Completion of Installation shall be the date the Bidder submits to the Owner written notification that the Project is completed in conformance with the Specifications and ready for the Owner's acceptance inspection and tests as provided for under Article II, section 4.

The term "Completion of the Project" shall mean full performance by the Bidder of the Bidder's obligations herein set out and all amendments and revisions thereof for a central office (and all associated remote switching terminals), feature or service. The scheduled date for Completion of the Project is sixty (60) days after Completion of Installation as specified under Column 7, "Completion of Installation," in Article I, section 1, as amended or adjusted under Article II, section 1, and section 4. The scheduled date for Completion of the Project is the date from which liquidated damages are computed. The actual date of Completion of the Project shall be the date of the receipt by the Owner from the Bidder of (a) all documents listed in Article III, section 2, (b) other final documents, and (c) written notification that all deficiencies listed on the REA Form 517, Results of Acceptance Test, have been corrected; provided, that the final inspection and tests by the Owner finds the deficiencies satisfactorily resolved. If the deficiencies have not been satisfactorily resolved, the actual date of Completion of the Project shall be the date that the deficiencies are fully and satisfactorily resolved as determined by subsequent Owner's tests. The Certificate of Completion approved and signed by the Owner and approved in writing by the Administrator shall be conclusive evidence as to the fact of Completion of the Project and the date thereof. Full compliance with the procedure for "Completion of the Project" and an individual Certificate of Completion is required for each Project listed under Column 1, "Project," in Article I, section 1.

The Contract shall consist of the Notice and Instructions to Bidders, the Bidder's Proposal and the Owner's Acceptance, the Contractor's Bond and the Specifications.

The term "days" shall mean calendar days.

The term "minor errors or irregularities" shall mean a defect or variation in a Bidder's bid that is a matter of form and not of substance. Errors or irregularities are "minor" if they can be corrected or waived without being prejudicial to other Bidders and when they do not affect the price, quantity, quality, or timeliness of construction. Unless otherwise noted, the borrower determines whether an error or irregularity is "minor."

The term "placed in service" shall mean used by the Owner to earn revenue.

The term "Project" shall mean a central office and all associated remote switching terminals (if any), a remote switching terminal if purchased without a supporting central office, a feature (or group of features), or a service (or group of services), which is listed under Column 1, "Project," in Article I, section 1. The only instance in which a remote switching terminal can constitute a separate Project is where such remote switching terminal is purchased with associated modifications to its supporting host switch but no other modifications to the host switch are specified. A Project will have a single completion schedule listed under Column 7, "Completion of Installation," in Article I, section 1, and a single liquidated damages amount shown in Article V, section 2. The Contract may consist of one or more Projects.

The term "Software" shall mean computer programs contained on a tape, disc, semiconductor device or other memory device or system memory consisting of logic instructions and instruction sequences in machine-readable object code, which manipulate data in the central processor.

control and perform input/output operations, perform error diagnostic and recovery routines, control call processing, and perform peripheral control, and administrative and maintenance functions; as well as associated documentation, excluding source code, used to describe, maintain and use the programs provided under the Contract.

The term "Specifications" shall mean the minimum performance requirements of the Owner as contained in the documents listed below, which are either attached or become a part of the Contract by reference, as amended by specific written exceptions contained in the Bidder's proposal and accepted by the Owner and the Administrator:

REA Form _____, dated _____

REA Form _____, dated _____

Section 2. Continuing Equipment Support—Parts, Service, and Software. In addition to warranty repairs and replacement, the Bidder shall offer repair service and repair parts to the Owner in accordance with the Bidder's practices and terms then in effect, for the Bidder's manufactured equipment furnished pursuant to this Agreement. Such repair service or repair parts shall be available for as long as the Bidder is manufacturing or stocking such equipment, or for no less than eight (8) years after the Bidder has ceased manufacturing or offering for sale such equipment. The Bidder shall also offer software support services to the Owner in accordance with the Bidder's practices, terms, and charges then in effect, but in any event for no less than five (5) years after the Bidder has ceased manufacturing or offering for sale such software.

Section 3. Materials and Supplies. The Bidder shall use only such unmanufactured articles, materials and supplies as have been mined or produced in the United States, Mexico or Canada and only such manufactured articles, materials and supplies as have been manufactured in the United States, Mexico or Canada substantially all from articles, materials or supplies mined, produced or manufactured, as the case may be, in the United States, Mexico or Canada; provided that foreign articles, materials or supplies may be used in the event and to the extent that the Administrator shall expressly authorize in writing such use pursuant to the provisions of the Rural Electrification Act of 1938, being Title IV of Public Resolution No. 122, 75th Congress, approved June 21, 1938. The Bidder agrees to submit to the Owner such certificate or certificates, signed by the Bidder and all subcontractors, with respect to compliance with the foregoing provision as the Administrator from time to time may require.

Section 4. Bond. The Bidder shall furnish to the Owner a Contractor's Bond in conformance with the requirements of 7 CFR part 1788, subpart C.

Section 5. Confidentiality. All information supplied by the Bidder to the Owner which bears a legend or notice restricting its use, copying, or dissemination, except insofar as it may be in the public domain through no acts attributable to the Owner, shall be treated by the Owner as confidential information, and the Owner shall not reproduce any such information except for its own internal use and as authorized by this Contract, and shall use any information only for archival backup, in-house training, operating, maintenance and administrative purposes and in conjunction with its use of the equipment, materials and software furnished hereunder. All information supplied to the Bidder by the Owner which bears a legend or notice restricting its use, copying, or dissemination, except insofar as it may be in the public domain through no acts attributable to the Bidder, shall be treated by the Bidder as confidential information, and shall not be used by the Bidder for any purpose adverse to the interests of the Owner, and shall not be reproduced or distributed by the Bidder except for the Bidder's use in its performance under this Contract. The foregoing confidentiality obligations do not apply to information which is independently developed by the receiving party or which is lawfully received by the receiving party free of restriction from another source having a right to so furnish such information, or is already known to the receiving party at the time of disclosure free of restriction. If the Bidder has failed to provide continuing equipment support as described in Article VII, section 2, the Owner is released from this obligation. This provision does not restrict release of information by the United States of America pursuant to the Freedom of Information Act or other legal process.

Section 6. Entire Agreement. The terms and conditions of this Contract as approved by REA supersede all prior oral or written understandings between the parties. There are no understandings or representations, expressed or implied, not expressly set forth herein.

Section 7. Survival of Obligations. The rights and obligations of the parties, which by their nature, would continue beyond the termination, cancellation, or expiration of this Contract, shall survive such termination or expiration.

Section 8. Non-Waiver. No waiver of any terms or conditions of this Contract, or the failure of either party to enforce strictly any such term or condition on one or more occasions, shall be construed as a waiver of the same or of any other terms or conditions of this Contract on any other occasion.

Section 9. Releases Void. Neither party shall require releases or waivers of any personal rights from representatives or employees of the other in connection with visits to its premises, nor shall such parties plead such releases or waivers in any action or proceeding.

Section 10. License. The Bidder shall comply with all applicable construction codes.

(a) The Bidder warrants that it possesses contractor's license number _____ issued to it by the State of _____ in which the project(s) is located, and said license expires on _____, 19____.

(b) The Bidder warrants that no license is required in the state in which the Project(s) is located.

(Bidder shall cross out that subsection that does not apply)

Section 11. Nonassignment of Contract. The Bidder shall not assign the Contract, effected by acceptance of this Proposal, or any part hereof, or enter into any contract with any person, firm or corporation, for the performance of the Bidder's obligations hereunder, or any part hereof, without the approval in writing of the Owner, the Surety, and the Administrator. However, the Bidder may subcontract the whole or any part of the installation work to be performed at the installation site, (as distinguished from furnishing and delivery of equipment and materials), provided that; (a) the Bidder shall remain responsible for the performance thereof and (b) the Bidder shall obtain the consent of the surety to such subcontract. A copy of such consent shall be submitted to the Owner and the Administrator.

Section 12. Choice of Law. The rights and obligations of the parties and all interpretations and performance of this Contract shall be governed in all respects by the laws of the State of _____ except for its rules with respect to the conflict of laws.

Section 13. Approval of the Administrator. The acceptance of this proposal by the Owner shall not create a contract unless such acceptance shall be approved in writing by the Administrator within ninety (90) days after the date hereof:

By _____

(Signature of Bidder)

_____

(Name—Type or Print)

_____

(Title)

_____

(Company Name of Bidder)

_____

_____

(Address of Bidder)

Attest:

_____

(Secretary)

_____

(Date)

The Proposal must be signed with the full name of the Bidder. In the case of a partnership the Proposal must be signed in the firm name by each partner. In the case of a corporation the Proposal must be signed in the corporate name by a duly authorized officer and the Corporate seal affixed and attested by the Secretary of the Corporation.

(If executed by other than the President, a Vice-President, a partner or the individual owner, a power of attorney or other legally acceptable document authorizing execution shall accompany this contract, unless such power of attorney is on file with REA.)

Acceptance

Subject to the approval of the Administrator, the Owner hereby accepts the Proposal of _____

_____

for the Project(s) herein described for the Total Base Bid of

$ _____ and

Alternate For:

Spare Parts, Item(s)	$ _____
Maintenance Tools, Item(s)	$ _____
Alternate No. 1 (add) (deduct)	$ _____
Alternate No. 2 (add) (deduct)	$ _____
Alternate No. 3 (add) (deduct)	$ _____

Alternate No. 4 (add) (deduct) $ _____
Alternate No. 5 (add) (deduct) $ _____
Alternate No. 6 (add) (deduct) $ _____
The total contract price is $ _____

By _____
OWNER
ATTEST: _____
PRESIDENT

SECRETARY

DATE OF ACCEPTANCE
[End of clause]

Dated: June 2, 1994.

Bob J. Nash,

Under Secretary, Small Community and Rural Development.

[FR Doc. 94–14058 Filed 6–16–94; 8:45 am]
BILLING CODE 3410–15–P

EXPORT-IMPORT BANK OF THE UNITED STATES

12 CFR Part 412

Acceptance of Payment From a Non-Federal Source for Travel Expenses

AGENCY: Export-Import Bank of the United States.

ACTION: Final rule.

SUMMARY: This final rule implements the statutory authority of the Export-Import Bank of the United States (Eximbank) to accept from non-Federal sources reimbursement for travel and subsistence expenses incurred by Eximbank employees in connection with official travel to a meeting or similar event. Authorized meetings or similar events under this final rule do not include those described in the Federal Travel Regulations permitting Federal agencies to accept payments from non-Federal sources for travel expenses. This final rule, by effectuating Eximbank's statutory gift acceptance authority, will further the mission of Eximbank by enabling Eximbank to issue more official travel orders for employees to conduct agency business than Eximbank would otherwise be able to issue under its authorized annual travel budget.

EFFECTIVE DATE: June 17, 1994.

FOR FURTHER INFORMATION CONTACT: Mr. Paul W. Boyer, Export-Import Bank of the United States, Office of The General Counsel, telephone (202) 377–7605.

SUPPLEMENTARY INFORMATION:

I. Background

Section 2(a)(1) of the Export-Import Bank Act of 1945, as amended (12 U.S.C. 635(a)), enables Eximbank, subject to regulations issued pursuant to 5 U.S.C. 553, to accept reimbursement for travel and subsistence expenses incurred by a director, officer or employee of Eximbank in accordance with subchapter I of chapter 57 of title 5, United States Code. In order to implement this statutory authority, Eximbank is issuing a regulation that sets forth the parameters for accepting payment from a non-Federal source for an Eximbank employee's travel and subsistence expenses to attend or participate in an event relating to the employee's official duties. The regulation applies to events other than a "meeting or similar function" as defined in 41 CFR 304–1.2(c)(3). The rule enables Eximbank to accept travel expense payments in order to send employees to such functions as meetings, formal gatherings, site visits, negotiation sessions and other similar events in which the employee's participation would further the mission of Eximbank.

In order to avoid any actual impropriety or appearance of impropriety in the acceptance of travel expense payments, the regulation requires that the employee's supervisor and the designated agency ethics official or his/her designee determine that Eximbank's interest in the employee's attendance at the meeting or similar event outweighs concern that acceptance of the payment by Eximbank may cause a reasonable person to question the integrity of Eximbank's programs or operations. As provided in the authorizing statute, the regulation limits payments from a non-Federal source for travel and subsistence payments to the maximum per diem or actual service limitations prescribed in 41 CFR chapter 301.

II. Matters of Regulatory Procedure

Administrative Procedure Act

As General Counsel of Eximbank, I have found good cause pursuant to 5 U.S.C. 553(b) and (d)(3) for waiving, as unnecessary and contrary to the public interest, the general notice of proposed rulemaking and the 30-day delay in effectiveness as to this final rule. The reason for this determination is that this rulemaking is related to Eximbank organization, procedure and practice.

Regulatory Flexibility Act

As General Counsel of Eximbank, I have determined under the Regulatory Flexibility Act (5 U.S.C. chapter 6) that this regulation will not have a significant impact on small business entities.

Paperwork Reduction Act

As General Counsel of Eximbank, I have determined that the Paperwork Reduction Act (44 U.S.C. chapter 35) does not apply because this regulation does not contain any information collection requirements that require the approval of the Office of Management and Budget.

List of Subjects in 12 CFR Part 412

Government employees, Travel and transportation expenses.

Dated: June 13, 1994.

Carol F. Lee,

General Counsel, Export-Import Bank of the United States.

For the reasons set forth in the preamble, the Export-Import Bank of the United States is amending title 12, chapter IV, of the Code of Federal Regulations, by adding a new part 412 to read as follows:

PART 412—ACCEPTANCE OF PAYMENT FROM A NON-FEDERAL SOURCE FOR TRAVEL EXPENSES

Sec.
412.1 Authority.
412.3 General.
412.5 Policy.
412.7 Conditions for acceptance.
412.9 Conflict of interest analysis.
412.11 Payment guidelines.
412.13 Limitations and penalties.

Authority: 5 U.S.C. 5701–5709; 12 U.S.C. 635(2)(a)(1).

§ 412.1 Authority.

This part is issued under the authority of 5 U.S.C. 553, 5 U.S.C. 5701–5709 and 12 U.S.C. 635(2)(a)(1).

§ 412.3 General.

(a) *Applicability.* This part applies to acceptance by the Export-Import Bank of the United States (Eximbank) of payment from a non-Federal source for travel, subsistence, and related expenses with respect to the attendance of an employee in a travel status at any meeting or similar event relating to the official duties of the employee, other than those described in 41 CFR 304–1.2. This part does not authorize acceptance of such payments by an employee in his/her personal capacity.

(b) *Solicitation prohibited.* An employee shall not solicit payment for travel, subsistence and related expenses from a non-Federal source. However, after receipt of an invitation from a non-Federal source to attend a meeting or similar event, Eximbank or the employee may inform the non-Federal source of this authority.

(c) *Definitions.* As used in this part, the following definitions apply:

(1) *Conflicting non-Federal source. Conflicting non-Federal source* means any person who, or entity other than the Government of the United States which, has interests that may be substantially affected by the performance or nonperformance of the employee's duties.

(2) *Employee. Employee* means any director, officer or other employee of Eximbank.

(3) *Meeting or similar event. Meeting or similar event* means a meeting, formal gathering, site visit, negotiation session or similar event that takes place away from the employee's official station and which is directly related to the mission of Eximbank. This term does not include any meeting or similar function described in 41 CFR 304–1.2 or sponsored by Eximbank. A meeting or similar event need not be widely attended for purposes of this definition.

(4) *Non-Federal source. Non-Federal source* means any person or entity other than the Government of the United States. The term includes any individual, private or commercial entity, nonprofit organization or association, state, local, or foreign government, or international or multinational organization.

(5) *Payment. Payment* means funds paid or reimbursed to Eximbank by a non-Federal source for travel, subsistence, and related expenses by check or similar instrument, or payment in kind.

(6) *Payment in kind. Payment in kind* means goods, services or other benefits provided by a non-Federal source for travel, subsistence, and related expenses in lieu of funds paid to Eximbank by check or similar instrument for the same purpose.

(7) *Travel, subsistence and related expenses. Travel, subsistence and related expenses* means the same types of expenses payable under 41 CFR chapter 301.

§ 412.5 Policy.

As provided in this part, Eximbank may accept payment from a non-Federal source (or authorize an employee to receive such payment on its behalf) with respect to attendance of the employee at a meeting or similar event which the employee has been authorized to attend in an official capacity on behalf of Eximbank. The employee's immediate supervisor and Eximbank's designated agency ethics official or his/her designee (DAEO) must approve any offer and acceptance of payment under this part in accordance with the procedures described below. If the employee is a member of Eximbank's Board of Directors, only the DAEO's approval is required. Any employee authorized to travel in accordance with this part is subject to the maximum per diem or actual subsistence expense rates and transportation class of service limitations prescribed in 41 CFR chapter 301

§ 412.7 Conditions for acceptance.

(a) Eximbank may accept payment for employee travel from a non-Federal source when a written authorization to accept payment is issued in advance of the travel following a determination by the employee's supervisor (except in the case of Board members) and the DAEO that the payment is:

(1) For travel relating to an employee's official duties under an official travel authorization issued to the employee;

(2) For attendance at a meeting or similar event as defined in § 412.3(c)(3):

(i) In which the employee's participation is necessary in order to further the mission of Eximbank;

(ii) Which cannot be held at the offices of Eximbank for justifiable business reasons in light of the location and number of participants and the purpose of the meeting or similar event; and

(iii) Which is taking place at a location and for a period of time that is appropriate for the purpose of the meeting or similar event;

(3) From a non-Federal source that is not a conflicting non-Federal source or from a conflicting non-Federal source that has been approved under § 412.9; and

(4) In an amount which does not exceed the maximum per diem or actual subsistence expense rates and transportation class of service limitations prescribed in 41 CFR chapter 301.

(b) An employee requesting approval of payment of travel expenses by a non-Federal source under this part shall submit to the employee's supervisor (except in the case of Board members) and the DAEO a written description of the following: the nature of the meeting or similar event and the reason that it cannot be held at Eximbank, the date(s) and location of the meeting or similar event, the identities of all participants in the meeting or similar event, the name of the non-Federal source offering to make the payment, the amount and method of the proposed payment, and the nature of the expenses.

(c) Payments may be accepted from multiple sources under paragraph (a) of this section.

§ 412.9 Conflict of interest analysis.

Eximbank may accept payment from a conflicting non-Federal source if the conditions of § 412.7 are met and the employee's supervisor (except in the case of Board members) and the DAEO determine that Eximbank's interest in the employee's attendance at or participation in the meeting or similar event outweighs concern that acceptance of the payment by Eximbank may cause a reasonable person to question the integrity of Eximbank's programs and operations. In determining whether to accept payment, Eximbank shall consider all relevant factors, including the purpose of the meeting or similar event, the importance of the travel for Eximbank, the nature and sensitivity of any pending matter affecting the interests of the conflicting non-Federal source, the significance of the employee's role in any such matter, the identity of other expected participants, and the location and duration of the meeting or similar event.

§ 412.11 Payment guidelines.

(a) Payments from a non-Federal source, other than payments in kind, shall be by check or similar instrument made payable to Eximbank. Payments from a non-Federal source, including payments in kind, are subject to the maximum per diem or actual subsistence expense rates and transportation class of service limitations prescribed in 41 CFR chapter 301.

(b) If Eximbank determines in advance of the travel that a payment covers some but not all of the per diem costs to be incurred by the employee, Eximbank shall authorize a reduced per diem rate, in accordance with 41 CFR part 301–7.12.

§ 412.13 Limitations and penalties.

(a) This part is in addition to and not in place of any other authority under which Eximbank may accept payment from a non-Federal source or authorize an employee to accept such payment on behalf of Eximbank. This part shall not be applied in connection with the acceptance by Eximbank of payment for travel, subsistence, and related expenses incurred by an employee to attend a meeting or similar function described in and authorized by 41 CFR part 304–1.

(b) An employee who accepts any payment in violation of this part is subject to the following:

(1) The employee may be required, in addition to any penalty provided by law and applicable regulations, to repay for deposit to the general fund of the Treasury, an amount equal to the amount of the payment so accepted; and

(2) When repayment is required under paragraph (b)(1) of this section, the employee shall not be entitled to any

payment or reimbursement from Eximbank for such expenses.

[FR Doc. 94–14715 Filed 6–16–94; 8:45 am]
BILLING CODE 6690–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 5 and 821

Delegations of Authority and Organization; Center for Devices and Radiological Health

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulations for delegations of authority relating to general redelegations of authority from the Associate Commissioner of Regulatory Affairs to certain FDA officials in the Center for Devices and Radiological Health (CDRH). The redelegation provides these officials with authority to grant or deny certain citizen petitions for exemption or variance from medical device tracking requirements. This action is being taken to facilitate expeditious handling of citizen petitions. FDA is also issuing a conforming amendment to the medical device tracking regulations to make the regulations consistent.

EFFECTIVE DATE: June 17, 1994.

FOR FURTHER INFORMATION CONTACT: Joseph M. Sheehan, Center for Devices and Radiological Health (HFZ–84), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–4765, or Ellen Rawlings, Division of Management Systems and Policy (HFA-340), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4976.

SUPPLEMENTARY INFORMATION: FDA is amending the regulations in § 5.31 *Petitions under part 10* (21 CFR 5.31) by granting the authority to the Director and Deputy Directors, CDRH, and the Director, Office of Compliance (previously known as the Office of Compliance and Surveillance), CDRH, to issue responses to citizen petitions submitted in accordance with §§ 10.30 and 821.2(b) (21 CFR 10.30 and 821.2(b)) requesting an exemption or variance from the provisions of part 821 concerning medical device tracking requirements. FDA is making a conforming amendment to 821.2(b), which currently lists only the Director, Office of Compliance and Surveillance, CDRH, as authorized to issue such responses, to add the Director and Deputy Directors, CDRH.

Further redelegation of the authority delegated is not authorized. Authority delegated to a position by title may be exercised by a person officially designated to serve in such position in an acting capacity or on a temporary basis.

This document is issued as a final rule because the rulemaking requirements in 5 U.S.C. 553 do not apply to rules of agency organization, procedure, or practice.

List of Subjects

21 CFR Part 5

Authority delegations (Government agencies), Imports, Organization and functions (Government agencies).

21 CFR Part 821

Imports, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 5 and 821 are amended as follows:

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

1. The authority citation for 21 CFR part 5 continues to read as follows:

Authority: 5 U.S.C. 504, 552, App. 2; 7 U.S.C. 138a, 2271; 15 U.S.C. 638, 1261–1282, 3701–3711a; secs. 2–12 of the Fair Packaging and Labeling Act (15 U.S.C. 1451–1461); 21 U.S.C. 41–50, 61–63, 141–149, 467f, 679(b), 801–886, 1031–1309; secs. 201–903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321–394); 35 U.S.C. 156; secs. 301, 302, 303, 307, 310, 311, 351, 352, 361, 362, 1701–1706, 2101, 2125, 2127, 2128 of the Public Health Service Act (42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 264, 265, 300u–300u–5, 300aa–1, 300aa–25, 300aa–27, 300aa–28); 42 U.S.C. 1395y, 3246b, 4332, 4831(a), 10007–10008; E.O. 11490, 11921, and 12591; secs. 312, 313, 314 of the National Childhood Vaccine Injury Act of 1986, Pub. L. 99–660 (42 U.S.C. 300aa–1 note).

2. Section 5.31 is amended by adding new paragraph (g) to read as follows:

§ 5.31 Petitions under part 10.

* * * * *

(g) The Director and Deputy Directors, CDRH, and the Director, Office of Compliance, CDRH, are authorized to grant or deny citizen petitions submitted under §§ 10.30 and 821.2(b) of this chapter, requesting an exemption or variance from medical device tracking requirements in part 821 of this chapter.

PART 821—MEDICAL DEVICE TRACKING REQUIREMENTS

3. The authority citation for 21 CFR part 821 continues to read as follows:

Authority: Secs. 301, 501, 502, 510, 515, 518, 519, 701, and 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331, 351, 352, 360, 360e, 360h, 360i, 371, and 374).

4. Section 821.2 is amended by revising the second sentence in introductory text of paragraph (b) to read as follows:

§ 821.2 Exemptions and variances.

* * * * *

(b) * * * The Director or Deputy Directors, CDRH, or the Director, Office of Compliance, CDRH, shall issue responses to requests under this section. * * *

* * * * *

Dated: June 13, 1994.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 94–14855 Filed 6–16–94; 8:45 am]
BILLING CODE 4160–01–F

21 CFR Part 510

Animal Drugs, Feeds, and Related Products; Change of Sponsor Name

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor name from Anaquest, Inc., A Subsidiary of BOC Health Care, Inc., to Ohmeda Pharmaceutical Products Division Inc.

EFFECTIVE DATE: June 17, 1994.

FOR FURTHER INFORMATION CONTACT: Benjamin A. Puyot, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1646.

SUPPLEMENTARY INFORMATION: Anaquest, Inc., A Subsidiary of BOC Health Care, Inc., Liberty Corner, NJ 07938–0804, has informed FDA of a change of sponsor name from Anaquest, Inc., A Subsidiary of BOC Health Care, Inc., to Ohmeda Pharmaceutical Products Division Inc. Accordingly, FDA is amending the regulations in 21 CFR 510.600(c)(1) and (c)(2) to reflect the change of sponsor name.

List of Subjects in 21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 510 is amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 512, 701, 721, of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e).

§ 510.600 [Amended]

2. Section 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended in the table in paragraph (c)(1) by removing the entry for "Anaquest, Inc., A Subsidiary of BOC Health Care, Inc." and by alphabetically adding a new entry for "Ohmeda Pharmaceutical Products Division Inc., Liberty Corner, NJ 07938–0804.....010019"; and in the table in paragraph (c)(2) in the entry for "010019" by removing the sponsor name "Anaquest, Inc., A Subsidiary of BOC Health Care, Inc." and by adding in its place "Ohmeda Pharmaceutical Products Division Inc."

Dated: June 9, 1994.

Robert C. Livingston,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 94–14709 Filed 6–16–94; 8:45 am]

BILLING CODE 4160–01–F

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21 CFR Parts 510 and 522

Animal Drugs, Feeds, and Related Products; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for a new animal drug application (NADA) from Boehringer Ingelheim Animal Health, Inc., to Phoenix Scientific, Inc.

EFFECTIVE DATE: June 17, 1994.

FOR FURTHER INFORMATION CONTACT: Benjamin A. Puyot, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1646.

SUPPLEMENTARY INFORMATION: Boehringer Ingelheim Animal Health, Inc., 2621 North Belth Hwy., St. Joseph, MO 64506–2002, has informed FDA that it has transferred ownership of, and all rights and interests in NADA 99–169 for Oxytocin Injection to Phoenix Scientific, Inc., 3915 South 48th St. Terrace, P.O. Box 6457, St. Joseph, MO, 64506–0457. Accordingly, the agency is amending the regulations in 21 CFR 510.600(c)(1) and (c)(2) and in 21 CFR 522.1680(b) to reflect the change of sponsor.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 522

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510 and 522 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 512, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e).

2. Section 510.600 is amended in the table in paragraph (c)(1) by alphabetically adding a new entry for "Phoenix Scientific, Inc." and in the table in paragraph (c)(2) by numerically adding a new entry for "059130" to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * *	
Phoenix Scientific, Inc. 3915 South 48th St. Terrace, P.O. Box 6457, St. Joseph, MO 64506–0457	059130
* * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * *	
059130	Phoenix Scientific, Inc. 3915 South 48th St. Terrace, P.O. Box 6457, St. Joseph, MO 64506–0457
* * * * *	

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

§ 522.1680 [Amended]

4. Section 522.1680 *Oxytocin injection* is amended in paragraph (b) by removing "000010" and "and 058639" and by adding "058639, and 059130" before the word "in".

Dated: June 9, 1994.

Robert C. Livingston,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 94–14708 Filed 6–16–94; 8:45 am]

BILLING CODE 4160–01–F

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21 CFR Part 529

Certain Other Dosage Form New Animal Drugs; Gentamicin Sulfate Intrauterine Solution

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Fort Dodge Laboratories. The ANADA provides for the use of a generic gentamicin solution for control of bacterial infections of the uterus (metritis) of horses and as an aid in improving conception in mares with uterine infections caused by bacteria sensitive to gentamicin.

EFFECTIVE DATE: June 17, 1994.

FOR FURTHER INFORMATION CONTACT: Larry D. Rollins, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1612.

SUPPLEMENTARY INFORMATION: Fort Dodge Laboratories, Fort Dodge, IA 50501, is the sponsor of ANADA 200–102, which provides for the use of a generic gentamicin solution (100 milligrams/milliliter (mg/mL)) for control of bacterial infections of the uterus (metritis) in horses and as an aid in improving conception in mares with uterine infections caused by bacteria sensitive to gentamicin.

ANADA 200–102 for Fort Dodge Laboratories' gentamicin sulfate solution (100 mg/mL gentamicin) is as a generic copy of Schering's Gentocin Solution (100 mg/mL gentamicin) in

NADA 046–724. The ANADA is approved as of May 19, 1994, and the regulations are amended in 21 CFR 529.1044a to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 529

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 529 is amended as follows:

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 529 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

§ 529.1044a [Amended]

2. Section 529.1044a *Gentamicin sulfate intrauterine solution* is amended in paragraph (b) by removing "000061 and 057561" and adding in its place "000061, 057561, and 000856".

Dated: June 9, 1994.

Richard H. Teske,

Acting Director, Center for Veterinary Medicine.

[FR Doc. 94–14854 Filed 6–16–94; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Housing—Federal Housing Commissioner

24 CFR Parts 207, 213, 221, and 242

[Docket No. R–94–1723; FR–3603–F–01]

RIN 2502–AG19

Disposition of Fire and Hazard Insurance Proceeds

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

ACTION: Final rule.

SUMMARY: This rule revises certain provisions in HUD regulations covering multifamily mortgage insurance which have the effect of requiring prior HUD endorsement before the expenditure of any fire and hazard insurance loss proceeds by mortgagees. Instead of this requirement the regulations would be revised to allow loss proceeds to be expended to restore or repair the property without prior HUD approval. The proceeds may not however, be used for any other purposes without prior HUD approval.

EFFECTIVE DATE: July 18, 1994.

FOR FURTHER INFORMATION CONTACT: James Tahash, Planning and Procedures Division, Office of Multifamily Housing Management, Room 6182, Department of Housing and Urban Development, 451 Seventh Street, SW, Washington, DC 20410, voice (202) 708–3944, TDD (202) 708–4594. (These are not toll-free numbers.)

SUPPLEMENTARY INFORMATION: Under existing HUD regulations (24 CFR 207.260) in the event a loss occurs to the mortgaged property under any policy of fire or other hazard insurance and the mortgagee has received the proceeds therefrom, it shall not exercise its option under the mortgage to use the proceeds of the insurance for the repairing, replacing, or rebuilding of the premises, or apply them to the mortgage indebtedness, or make any other disposition of the proceeds without the prior written approval of the Commissioner. Through cross-referencing this requirement is also made applicable to other FHA multifamily programs *i.e.* Part 213 Cooperative Housing Mortgage Insurance, Part 220 Mortgage Insurance and Insured Improvement Loans for Urban Renewal and Concentrated Development Areas, Part 221 Low Cost and Moderate Income Mortgage Insurance, Part 231 Housing Mortgage Insurance for the Elderly, Part 232 Mortgage Insurance for Nursing Homes, Intermediate Care Facilities, and Board and Care Homes, Part 234 Condominium Ownership Mortgage Insurance, Part 236 Mortgage Insurance and Interest Reduction Payments for Rental Projects, Part 241 Supplementary Financing for Insured Project Mortgages and Part 242 Mortgage Insurance for Hospitals.

This rule revises current regulatory requirements to provide that the mortgagee may exercise its option to use the insurance proceeds for the repairing, replacing or rebuilding of the premises without prior HUD approval. It may not however make any other disposition of insurance proceeds without prior approval.

The Department has found that its Field Office staff resources can be more effectively allocated to tasks other than the endorsing of property insurance loss drafts where the proceeds, in any event, are going to be used to restore or repair the property. We estimate that from $10,000 to $20,000 per year in staff resources could be saved by making this change. Mortgagees could have similar savings (from reduction of paperwork and check cashing steps) of from $5,000 to $10,000 per year. Project owners also could have savings. Approximately 20,000 project owners, their mortgagees and their insurance agents and companies should benefit by eliminating this unnecessary procedural step.

The rule also makes conforming revisions to 24 CFR 207.10, 213.13, 221.521 and 242.43 of HUD regulations to provide that fire and hazard and insurance have attached a standard mortgagee clause making loss payable to the mortgagee, its successors and assigns rather than the current requirement that loss be payable to the mortgagee and the Commissioner as their interests may appear.

Due to the strictly technical nature of this rule, the Department has determined that the notice and public comment procedure under Title 5 of the United States Code is unnecessary and is therefore issuing this document as a final rule.

Procedural Matters

Executive Order 12866—Regulatory Planning and Review

This rule was reviewed by the Office of Management and Budget under Executive Order 12866, Regulatory Planning and Review. Any changes made to the rule as a result of that review are clearly identified in the docket file which is available for public

inspection in the office of the Department's Rules Docket Clerk, room 10276, 451 Seventh Street SW., Washington, DC.

Regulatory Flexibility Act

In accordance with 5 U.S.C. 605(b) (the Regulatory Flexibility Act), the undersigned hereby certifies that this rule does not have a significant economic impact on a substantial number of small entities. This rule is technical in nature. It effects no substantive changes in HUD programs or policies.

Semiannual Agenda

This rule was listed as item 1569 in the Department's Semiannual Agenda of Regulations published on April 25, 1994 (59 FR 20424, 20444) under Executive order 12866 and the Regulatory Flexibility Act.

Executive Order 12612, Federalism

The General Counsel, as the Designated Official under section 6(a) of Executive order 12612, *Federalism*, has determined that the policies contained in this rule do not have Federalism implications and, thus, are not subject to review under the Order. No programmatic or policy changes result from this rule's promulgation which would affect existing relationships between the Federal Government and State and local governments.

Executive Order 12606, The Family

The General Counsel, as the Designated Official under Executive order 12606, *The Family*, has determined that this rule does not have potential for significant impact on family formation, maintenance, and general well-being, and, thus, is not subject to review under the Order. The rule is technical in nature and makes no significant change in existing HUD policies or programs.

Environment

An environmental assessment is unnecessary, since internal administrative procedures whose content do not constitute a development decision affecting the physical condition of specific project areas or building sites is categorically excluded from the Department's National Environmental Policy Act procedures under 24 CFR 50.20(k).

List of Subjects

24 CFR Part 207

Manufactured homes, Mortgage insurance, Reporting and recordkeeping requirements, Solar energy.

24 CFR Part 213

Cooperatives, Mortgage insurance, Reporting and recordkeeping requirements.

24 CFR Part 221

Low and moderate income housing, Mortgage insurance, Reporting and recordkeeping requirements.

24 CFR Part 242

Hospitals, Mortgage insurance, Reporting and recordkeeping requirements.

Accordingly, 24 CFR parts 207, 213, 221, and 242 are amended to read as follows:

PART 207—MULTIFAMILY HOUSING MORTGAGE INSURANCE

1. The authority citation for 24 CFR part 207 continues to read as follows:

Authority: 12 U.S.C. 1713 and 1715b; 42 U.S.C. 3535(d). Sections 207.258 and 207.258b are also issued under 12 U.S.C. 1701z–11(e).

2. Section 207.10 is revised to read as follows:

§ 207.10 Covenant for fire insurance.

The mortgage shall contain a covenant acceptable to the Commissioner binding the mortgagor to keep the property insured by a standard policy or policies against fire and such other hazards as the Commissioner, upon the insurance of the mortgage, may stipulate, in an amount which will comply with the coinsurance clause applicable to the location and character of the property, but not less than 80 percent of the actual cash value of the insurable improvements and equipment of the project. The initial coverage shall be in an amount estimated by the Commissioner at the time of completion of the entire project or units thereof. The policies evidencing such insurance shall have attached thereto a standard mortgagee clause making loss payable to the mortgagee, its successors and assigns.

3. Paragraph (e) of § 207.260 is revised to read as follows:

§ 207.260 Protection of mortgage security.

* * * * *

(e) *Application of insurance proceeds.* (1) In the event a loss has occurred to the mortgaged property under any policy of fire or other hazard insurance and the mortgagee has received the proceeds therefrom, it may exercise its option under the mortgage to use the proceeds of such insurance for the repairing, replacing, or rebuilding of the premises. It may not make other disposition of such proceeds, without the prior written approval of the Commissioner.

(2) If the proceeds are applied to the mortgage with such prior written approval and result in the payment in full of the entire mortgage indebtedness, the contract of mortgage insurance made with the Commissioner shall thereupon terminate.

(3) If the Commissioner shall fail to give his approval to the use or application of such funds within 60 days after written request by the mortgagee, the mortgagee may use or apply such funds for any of the purposes specified in the mortgage without the approval of the Commissioner.

PART 213—COOPERATIVE HOUSING MORTGAGE INSURANCE

4. The authority citation for 24 CFR part 213 continues to read as follows:

Authority: 12 U.S.C. 1715b, 1715e; 42 U.S.C. 3535(d).

5. Section 213.13 is revised to read as follows:

§ 213.13 Covenant for fire insurance.

The mortgage shall contain a covenant acceptable to the Commissioner binding the mortgagor to keep the property insured by a standard policy or policies against fire and such other hazards as the Commissioner, upon the insurance of the mortgage, may stipulate, in an amount which will comply with the coinsurance clause applicable to the location and character of the property, but not less than 80 percent of the actual cash value of the insurable improvements and equipment of the project. The initial coverage shall be in an amount estimated by the Commissioner at the time of completion of the entire project or units thereof. The policies evidencing such insurance shall have attached thereto a standard mortgagee clause making loss payable to the mortgagee, its successors and assigns.

PART 221—LOW COST AND MODERATE INCOME MORTGAGE INSURANCE

6. The authority citation for 24 CFR part 221 is revised to read as follows:

Authority: 12 U.S.C. 1715b and 1715l; 42 U.S.C. 3535(d); sec. 221.544(a)(3) is also issued under 12 U.S.C. 1707(a).

7. Section 221.521 is revised to read as follows:

§ 221.521 Covenant for fire insurance.

The mortgage shall contain a covenant acceptable to the Commissioner binding the mortgagor to keep the property

insured by a standard policy or policies against fire and such other hazards as the Commissioner, upon the insurance of the mortgage, may stipulate, in an amount which will comply with the coinsurance clause applicable to the location and character of the property, but not less than 80 percent of the actual cash value of the insurable improvements and equipment of the project. The initial coverage shall be in an amount estimated by the Commissioner at the time of completion of the entire project or units thereof. The policies evidencing such insurance shall have attached thereto a standard mortgagee clause making loss payable to the mortgagee, its successors and assigns.

PART 242—MORTGAGE INSURANCE FOR HOSPITALS

8. The authority citation for 24 CFR part 242 continues to read as follows:

Authority: 12 U.S.C. 1715b, 1715n(f), 1715z-7; 42 U.S.C. 3535(d).

9. Section 242.43 is revised to read as follows:

§ 242.43 Covenant for fire insurance.

The mortgage shall contain a covenant acceptable to the Commissioner binding the mortgagor to keep the property insured by a standard policy or policies against fire and such other hazards as the Commissioner, upon the insurance of the mortgage, may stipulate, in an amount which will comply with the coinsurance clause applicable to the location and character of the property, but not less than 80 percent of the actual cash value of the insurable improvements and equipment of the project. The initial coverage shall be in an amount estimated by the Commissioner at the time of completion of the entire project or units thereof. The policies evidencing such insurance shall have attached thereto a standard mortgagee clause making loss payable to the mortgagee, its successors and assigns.

Dated: June 9, 1994.

Nicolas P. Retsinas,

Assistant Secretary for Housing-Federal Housing Commissioner.

[FR Doc. 94–14744 Filed 6–16–94; 8:45 am]

BILLING CODE 4210–27–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 515

Cuban Assets Control Regulations; Flight Times; Civil Penalties

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Final rule; amendments.

SUMMARY: This rule amends the Cuban Assets Control Regulations to eliminate the requirement that planes flying between Cuba and the United States arrive and depart during the normal business hours of the U.S. Customs Service. In addition, an interpretive section is removed. The regulatory section on civil penalty authority is expanded to include references to the Cuban Democracy Act, and a regulatory reference is corrected.

EFFECTIVE DATE: June 13, 1994.

FOR FURTHER INFORMATION CONTACT: Steven I. Pinter, Chief of Licensing (tel.: 202/622–2480), or William B. Hoffman, Chief Counsel (tel.: 202/622–2410), Office of Foreign Assets Control, Department of the Treasury, Washington, D.C. 20220.

SUPPLEMENTARY INFORMATION:

Electronic Availability:

This document is available as an electronic file on *The Federal Bulletin Board* the day of the publication in the **Federal Register**. By modem dial 202/512–1387 or call 202/515–1530 for disks or paper copies. This file is available in Postscript, WordPerfect 5.1 and ASCII.

Background

The Office of Foreign Assets Control is amending the Cuban Assets Control Regulations, 31 C.F.R. part 515 (the "Regulations"), to eliminate the requirement that the arrival and departure of planes providing travel between Cuba and the United States occur during the normal business hours of the U.S. Customs Service. This change is being effected to allow greater flexibility in arranging for authorized flights to Cuba. In addition, the Regulations are being amended to add references to the Cuban Democracy Act, 22 U.S.C. 6001–6010, and to correct an error in § 515.701. Section 515.417 is removed.

Because this rule involve a foreign affairs function, Executive Order 12866 and the provisions of the Administrative Procedure Act, 5 U.S.C. 553, requiring notice of proposed rulemaking, opportunity for public participation, and delay in effective date, are inapplicable. Because no notice of proposed rulemaking is required for this rule, the Regulatory Flexibility Act, 5 U.S.C. 601–612, does not apply.

List of Subjects in 31 CFR Part 515

Administrative practice and procedure, Air carriers, Communist countries, Cuba, Currency, Exports, Fines and penalties, Foreign investment in the United States, Foreign trade, Imports, Informational materials, Publications, Reporting and recordkeeping requirments, Securities, Shipping, Travel and transportation expenses, Travel restrictions, Trusts and estates, Vessels

PART 515—CUBAN ASSETS CONTROL REGULATIONS

For the reasons set forth in the preamble, 31 CFR part 515 is amended as set forth below:

1. The authority citation for part 515 is revised to read as follows:

Authority: 50 U.S.C. App. 1–44; 22 U.S.C. 6001–6010; 22 U.S.C. 2370(a); Proc. 3447, 3 CFR, 1959–1963 Comp., p. 157; E.O. 9193, 3 CFR, 1938–1943 Comp., p. 1174; E.O. 9989, 3 CFR, 1943–1948 Comp., p. 748; E.O. 12854, 58 FR 36587, July 7, 1993.

Subpart D—Interpretations

§ 515.417 [Removed]

2. Section 515.417 is removed and reserved.

Subpart E—Licenses, Authorizations, and Statements of Licensing Policy

§ 515.566 [Amended]

3. In § 515.566, paragraph (f) is removed.

Subpart G—Penalties

4. Section 515.701 is amended by revising paragraphs (a)(4) and (5), adding paragraph (a)(6), redesignating paragraph (b) as paragraph (c), and adding paragraph (b) to read as follows:

§ 515.701 Penalties.

(a) * * *

(4) Any property, funds, securities, paper, or other articles or documents, or any vessel, together with its tackle, apparel, furniture, and equipment, that is the subject of a civil penalty issued pursuant to paragraph (a)(3) of this section shall, at the discretion of the Secretary of the Treasury, be forfeited to the United States Government.

(5) The penalties described in paragraphs (a)(3) and (4) of this section may not be imposed for:

(i) newsgathering, research, or the export or import of, or transmission of

information or informational materials; or

(ii) for clearly defined educational or religious activities, or activities of recognized human rights organizations, that are reasonably limited in frequency, duration, and number of participants.

Persons who engage in prohibited transactions related to the activities described in this paragraph may be subject to criminal penalties or other penalties as appropriate.

(6) The penalties provided in the Trading with the Enemy Act are subject to increase pursuant to 18 U.S.C. 3571.

(b) Attention is directed to 22 U.S.C. 6009, which provides that penalties set forth in section 16 of the Trading with the Enemy Act shall apply to violations of the Cuban Democracy Act to the same extent that such penalties apply to violations of the Trading with the Enemy Act.

(c) * * *

5. Section 515.702 is amended by revising paragraph (a) to read as follows:

§ 515.702 Prepenalty Notice.

(a) When required: If the Director of the Office of Foreign Assets Control has reasonable cause to believe that there has occurred a violation of any provision of this part or a violation of the provisions of any license, ruling, regulation, order, direction or instruction issued by or pursuant to the direction or authorization of the Secretary of the Treasury pursuant to this part or otherwise under the Trading with the Enemy Act or the Cuban Democracy Act, and the Director determines that further proceedings are warranted, he shall issue to the person concerned a notice of his intent to impose a monetary penalty and/or forfeiture. The prepenalty notice shall be issued whether or not another agency has taken any action with respect to this matter.

* * * * *

Dated: May 31, 1994

Steven I. Pinter,

Acting Director, Office of Foreign Assets Control.

Approved: June 3, 1994

R. Richard Newcomb,

Acting Deputy Assistant Secretary (Law Enforcement).

[FR Doc. 94-14727 Filed 6-13-94; 4:33 pm]

BILLING CODE 4810-25-F

Office of Foreign Assets Control

31 CFR Part 550

Libyan Sanctions Regulations; Definition of "Government of Libya"

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Final rule; amendment.

SUMMARY: This rule amends the Libyan Sanctions Regulations to remove from the definition of "Government of Libya" a provision stating that an entity will not be deemed a part of that government solely because it is located in, organized under the laws of, or has its principal place of business in, Libya, and to make an additional change to the definition.

EFFECTIVE DATE: June 17, 1994.

FOR FURTHER INFORMATION CONTACT: Steven I. Pinter, Chief of Licensing, tel.: 202/622-2480, or William B. Hoffman, Chief Counsel, tel.: 202/622-2410, Office of Foreign Assets Control, Department of the Treasury, Washington, D.C. 20220.

SUPPLEMENTARY INFORMATION:

Electronic Availability

This document is available as an electronic file on *The Federal Bulletin Board* the day of publication in the **Federal Register**. By modem dial 202/512-1387 or call 202/512-1530 for disks or paper copies. This file is available in Postscript, WordPerfect 5.1 and ASCII.

Background

This rule amends the Libyan Sanctions Regulations, 31 CFR part 550 (the "Regulations"), to remove paragraph (b) from § 550.304, the definition of the term "Government of Libya." Paragraph (b) of § 550.304 provided that a partnership, association, corporation, or other organization shall not be deemed to be within the term "Government of Libya" solely by reason of being located in, organized under the laws of, or having its principal place of business in, Libya.

In addition, former paragraph (a)(2) is revised to remove the word "substantially," which was used to describe the extent of Libyan government control of an entity required to qualify that entity as a part of the Government of Libya, and to add the words "directly or indirectly" to describe the nature of the governmental control.

Because the Regulations involve a foreign affairs function, Executive Order 12866 and the provisions of the Administrative Procedure Act, 5 U.S.C. 553, requiring notice of proposed rulemaking, opportunity for public participation, and delay in effective date, are inapplicable. Because no notice of proposed rulemaking is required for this rule, the Regulatory Flexibility Act, 5 U.S.C. 601-612, does not apply.

List of Subjects in 31 CFR Part 550

Adminstrative practice and procedure, Banks, Banking, Blocking of assets, Exports, Foreign investment, Foreign trade, Government of Libya, Imports, Libya, Loans, Penalties, Reporting and recordkeeping requirements, Securities, Services, Specially designated nationals, Travel restrictions.

For the reasons set forth in the preamble, 31 CFR part 550 is amended as set forth below:

PART 550—LIBYAN SANCTIONS REGULATIONS

1. The authority citation for part 550 continues to read as follows:

Authority: 50 U.S.C. 1701-1706; 50 U.S.C. 1601-1651; 22 U.S.C. 287c; 49 U.S.C. App. 1514; 22 U.S.C. 2349aa-8 and 2349aa-9; 3 U.S.C. 301; E.O. 12543, 3 CFR, 1986 Comp., p. 181; E.O. 12544, 3 CFR, 1986 Comp., p. 183; E.O. 12801, 3 CFR, 1992 Comp., p. 294.

Subpart C—Definitions

2. Section 550.304 is revised to read as follows:

§ 550.304 Government of Libya.

The term *Government of Libya* includes:

(a) The state and the Government of Libya, as well as any political subdivision, agency, or instrumentality thereof, including the Central Bank of Libya;

(b) Any partnership, association, corporation, or other organization owned or controlled directly or indirectly by the foregoing;

(c) Any person to the extent that such person is, or has been, or to the extent that there is reasonable cause to believe that such person is, or has been, since the effective date, acting or purporting to act directly or indirectly on behalf of any of the foregoing;

(d) Any other person or organization determined by the Secretary of the Treasury to be included within this section.

Dated: May 31, 1994

Steven I. Pinter,

Acting Director, Office of Foreign Assets Control.

Approved: June 3, 1994

R. Richard Newcomb,

Acting Deputy Assistant Secretary (Law Enforcement).

[FR Doc. 94–14726 Filed 6–13–94; 4:33 pm]

BILLING CODE 4810–25–F

DEPARTMENT OF DEFENSE

Department of the Army

32 CFR Part 552

Prohibited Personnel Practices on the Installation of Fort Jackson, SC

AGENCY: Department of the Army, DOD.

ACTION: Final rule.

SUMMARY: This action establishes 32 CFR part 552, subpart L, Personnel—Prohibited Practices and authenticates Fort Jackson Regulation 600–3, printed in the **Federal Register** as a proposed rule on 29 July 1993 (58 FR 40611). This subpart establishes prohibited practices on the installation of Fort Jackson, South Carolina. These prohibited practices apply to all persons as signed to, attached to, or present on the installation of Fort Jackson, South Carolina. Prohibited practices listed in this part are not all inclusive.

EFFECTIVE DATE: This final rule is effective June 17, 1994.

ADDRESSES: Commander, U.S. Army Training Center and Fort Jackson, Office of the Staff Judge Advocate, Fort Jackson, SC 29207–5000.

FOR FURTHER INFORMATION CONTACT: CPT Thomas M. Gagne, Trial Counsel, telephone: (803) 751–6848.

SUPPLEMENTARY INFORMATION: This part does not list all activities or practices prohibited on the installation of Fort Jackson, South Carolina. Various other Army and Fort Jackson regulations specifically prohibit other activities or practices. See Appendix A to this subpart.

Executive Order 12291

This rule is not affected by Executive Order 12291.

Regulatory Flexibility Act

The Regulatory Flexibility Act has no bearing on this rule.

Paperwork Reduction Act

This rule does not contain reporting or recordkeeping requirements subject to the Paperwork Reduction Act.

List of Subjects in 32 CFR Part 552

Military personnel, government employees.

Accordingly, 32 CFR part 552, subpart L is added to read as follows:

PART 552—SUBPART L—PROHIBITED PERSONNEL PRACTICES ON THE INSTALLATION OF FORT JACKSON, SOUTH CAROLINA

Sec.

Authority: 10 U.S. Code, Ch. 47, 21 U.S. Code 801, *et seq.*

Subpart L—Prohibited Personnel Practices on the Installation of Fort Jackson, SC

§ 552.150 Purpose.

This part is punitive in nature and applies to all persons assigned to, attached to, or present on the installation of Fort Jackson, South Carolina. A violation of, attempted violation of, or solicitation or conspiracy to violate any provision of this part provides the basis for criminal prosecution under the Uniform Code of Military Justice, applicable Federal Law, other regulations, and/or adverse administrative action. Civilian visitors may be barred from the installation of Fort Jackson and prosecuted under appropriate Federal laws. The enumeration of prohibited activities in this part is not intended to preclude prosecution under other provisions of law or regulation.

§ 552.151 Scope.

This part does not list all activities or practices prohibited on the installation of Fort Jackson, South Carolina. Various other Army and Fort Jackson regulations specifically prohibit other activities or practices. See Appendix A to this subpart.

§ 552.152 Prohibited practices.

The following activities are prohibited:

(a) The possession, delivery, sale, transfer, or introduction into the installation of Fort Jackson of any device, instrument or paraphernalia designed or reasonably intended for use in introducing into the human body a controlled substance, as defined in the Controlled Substances Act, 21 U.S.C. 801, *et seq.*, is prohibited.

(b) Unless an exception is approved by the Chief of Staff or a Major Subordinate Commander for a special occasion, consumption of alcoholic beverages, or the possession of an open container thereof, is prohibited under the circumstances listed in this section. For the purpose of this part, an "alcoholic beverage" is any liquid beverage containing any amount of ethyl alcohol, including wines, malt beverages and distilled spirits.

(1) By military personnel in uniform during duty hours (0730–1630).

(2) By military personnel during their assigned duty hours when different than those in paragraph (b)(1) of this section.

(3) By civilian employees during their assigned duty hours. Lunch time is not considered duty time for civilian employees.

(4) By civilian or military personnel in places of duty.

(5) By any person in a public place, except: in the Twin Lakes and Weston Lake Recreational Areas, in the immediate vicinity of Oyster Point (Officers' Club), at installation club facilities governed by section II of AR 215–2, and at Army/Air Force Exchange Service (AAFES) eating establishments which serve alcoholic beverages for on-premises consumption.

(6) By any person in any Fort Jackson parking lot or parking area, to include the Burger King parking lot and all parking lots of AAFES facilities and installation club facilities.

(c) The presence of any person in a training area or of any permanent party soldier or civilian employee in a trainee/receptee billeting area while impaired by alcoholic beverages or illegal drugs is prohibited. For the purpose of this part, "Impaired by alcoholic beverages" for military personnel is defined as having a blood alcohol level of .05 percent (.05 is equivalent to 55 milligrams of alcohol per 100 milliliters of blood) or more.

(d) Privately Owned Firearms and Ammunition. For the purpose of this part, a "firearm" means any device which is designed to or readily may be converted to expel a projectile by the action of an explosive. Air/pellet guns, BB guns and bows are subject to all of the provisions of this paragraph except paragraph (d)(1) of this section.

(1) It is prohibited for persons residing on the installation to fail to register privately owned firearms with their unit commander.

(2) Storage of privately owned firearms in the barracks is prohibited. For the purposes of this part, "barracks" does not include BOQs or SBEQs.

(3) It is prohibited to store privately owned firearms in BOQs, SBEQs, or family quarters unless the firearm is unloaded, ammunition is stored

separately from the firearm in a locked container, and one of the following methods for firearms storage is employed: by using a trigger locking device, by storing the firearm in a locked container, by removing the firing pin from the firearm and storing the firing pin in a locked container, or by disassembling the firearm and storing the disassembled parts in separate places. For the purposes of this part a "locked container" and a "locking device" mean locked containers and locking devices the keys to which are stored in a place not assessable to persons under 18 years of age.

(4) It is prohibited to carry on one's person any privately owned firearm in a public place on the installation of Fort Jackson unless participating in an authorized sporting activity or hunting in accordance with applicable regulations.

(5) In addition to the requirements of paragraph (d)(4) of this section, a person under 18 years of age is prohibited from carrying on his or her person a firearm outside the presence of a responsible adult.

(6) Carrying a concealed firearm on one's person, except by military, state and Federal law enforcement authorities in the performance of their duties, is prohibited.

(7) It is prohibited to transport in a vehicle any privately owned firearm except in a manner prescribed by the laws of South Carolina.

(8) It is prohibited to carry on one's person or transport in a vehicle any privately owned firearm within the Weston Lakes and Twin Lakes Recreation areas.

(e) Weapons Other Than Privately Owned Firearms. The possession of the following privately owned weapons or devices is prohibited:

(1) Any knife having a switchblade or automatic blade.

(2) Brass knuckles or similar devices.

(3) Blackjacks, saps, nunchaku and similar devices. As exceptions, nunchucks may be possessed for bona fide educational instruction or competition in a recognized martial arts program and may be carried and transported directly to and from educational and competitive martial arts events.

(4) When carried on one's person in an unconcealed manner, knives with blades in excess of three inches in length except while engaged in authorized hunting, fishing, camping or other outdoor recreational activities, or when required by duty purposes.

(5) When carried on one's person in a concealed manner, knives with blades in excess of three inches, razors and ice picks.

(f) The charging of a usurious interest rate, defined as a rate exceeding thirty-six (36) percent per annum or three (3) percent per month, for the loan of money or for the extension of credit, is prohibited.

(g) Sexual intercourse or any indecent, lewd or lascivious act in any office, barracks, training area, duty location, parking lot, public recreation area or public place is prohibited.

(h) Relationships between service members of different rank or sex which involve or reasonably give the appearance of partiality, preferential treatment, the improper use of rank or position for any personal gain, or which can otherwise be reasonably expected to undermine discipline, authority or morale, are prohibited.

(i) Being present in any "off-limits" or "limited access" areas, except as authorized in Fort Jackson Regulation 190–3, is prohibited (See Appendix A to this subpart).

(j) Use of a metal detector for other than official purposes is prohibited.

(k) When directed to do so by the Military Police, failure to relinquish possession or control to the Military Police of abandoned property found on the installation is prohibited.

(l) Scavenging in or removal of waste items or recyclable materials from dumpsters, garbage cans, outdoor trash receptacles, recycling collection points, or landfill areas is prohibited, except for official purposes. This part does not prohibit persons from collecting and disposing of scattered litter, including aluminum cans, from roadsides, parking lots and recreation areas.

(m) It is prohibited for military personnel to engage in outside employment of any nature, including ownership or operation of a private business, without the prior written approval of their commander. Soldiers reassigned or reattached from one Fort Jackson unit to another Fort Jackson unit must obtain approval for continued employment from the gaining commander within 30 days of reassignment.

(n) Except as authorized by the Installation Commander, Chief of Staff or a Major Subordinate Commander, the use of radios, stereos, tape players, compact disk players or any other similar electronic sound generating or amplification source, including equipment installed or located in motor vehicles, in a manner that can be heard more than 125 feet from the source, is prohibited. This paragraph does not apply to law enforcement or emergency vehicles, or safety warning devices.

(o) Loitering in any public place on Fort Jackson, to include all parking lots, is prohibited. Loitering is defined as remaining idle in essentially one location, spending time idly, loafing, or walking around without a purpose in a public place in such a manner as to create a disturbance or annoyance to the comfort of any person, create a danger of a breach of the peace, obstruct or interfere with any person lawfully in any public place, or obstruct or hinder the free passage of vehicles or pedestrians. Any person loitering as defined above in any public place may be ordered by a law enforcement officer to leave that place or the Fort Jackson military reservation.

§ 552.153 Dissemination.

(a) Unit commanders and supervisors shall ensure that newly assigned or attached military and civilian personnel are informed of the prohibitions contained in this regulation. Soldiers-in-training will be informed of the provisions of this regulation at the beginning of each training cycle.

(b) All permanent party personnel and civilian employees will be reminded annually of their duty to comply with this part.

Appendix A to Subpart L—Partial List of Other Publications Applicable on Fort Jackson Which List Prohibited Practices

These publications are available for inspection at the Office of the Staff Judge Advocate, Fort Jackson, SC 29207–5000.

1. Distribution of Written Materials on the Installation—Fort Jackson Supplement 1 to AR 210–10.

2. Demonstrations, Pickets, Sit-ins, etc.—Fort Jackson Supplement 1 to AR 210–10.

3. Standards of Ethical Conduct for Employees of the Executive Branch, 5 Code of Federal Regulations, Part 2635.

4. Improper Associations—Fort Jackson Regulation 600–5.

5. Mistreatment of Soldiers-in-Training—Fort Jackson Regulation 350–1.

6. Participation in Military Labor Unions—Army Regulation 600–20.

7. Traffic Violations—Fort Jackson Regulation 190–5.

8. Areas of Access—Fort Jackson Regulation 190–3.

Kenneth L. Denton,

Army Federal Register Liaison Officer.

[FR Doc. 94–13947 Filed 6–16–94; 8:45am]

BILLING CODE 3710–08–M

Corps of Engineers

33 CFR Part 209

Administrative Procedure—Shipping Safety Fairways and Anchorage Areas, Gulf of Mexico; Guidelines for the Industry Capability Program

AGENCY: U.S. Army Corps of Engineers, DoD.

ACTION: Final rule.

SUMMARY: The Corps is revoking the regulations in 33 CFR 209.135 and 209.147. The regulations in § 209.135 prohibit structures within shipping safety fairways in the Gulf of Mexico and prescribe certain conditions for nationwide permits issued by the Corps for temporary anchors and chains for floating or semisubmersible drilling rigs. Similar rules were promulgated in 33 CFR 322.5 and through an oversight, the rules of Section 209.135 were not revoked at that time. Section 209.147 which establish the Guidelines for the Industry Capability Program is no longer needed and these guidelines are removed.

EFFECTIVE DATE: June 17, 1994.

ADDRESSES: HQUSACE, CECW–OR, Washington, DC 20314–1000.

FOR FURTHER INFORMATION CONTACT: Mr. Ralph T. Eppard at (202) 272–1783.

SUPPLEMENTARY INFORMATION: The Corps published rules pertaining to shipping safety fairways in 33 CFR 322.5(1) on November 13, 1986, (51 FR 41206–41260) to consolidate all permit matters under the same section. These rules replaced the rules in 33 CFR 209.135 and the Corps intended to subsequently revoke the rules in § 209.135. The rules in § 209.135 are duplicative and unnecessary. Pursuant to its general authorities to operate and maintain Federal navigation projects, the Corps conducted a study to determine the capability of the dredging industry to accomplish the Government's dredging work at reasonable costs and in a timely manner. The Guidelines in 33 CFR 209.147 provided uniform procedures to evaluate Corps/Industry roles over a four-year period. That study has been completed and accordingly, these Guidelines are no longer needed.

The Corps has determined that notice of proposed rulemaking and public procedures thereto are unnecessary and impractical in this instance since this action will only remove obsolete materials from the CFR.

Economic Assessment and Certification

Regulatory Flexibility Act

Pursuant to the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 et seq.), it is certified that the removal of these regulations will not have a significant economic impact on a substantial number of small entities. The removal of these two regulations will not have any effect on the public, any private enterprise or any Government agency. This action will result in the removal of two obsolete regulations from the CFR.

Executive Order 12866: This document does not meet the criteria for a significant regulatory action as specified in E.O. 12866.

List of Subjects in 33 CFR Part 209

Electric power, Navigation (water), Water pollution control, Waterway.

In consideration of the above, 33 CFR Part 209 is amended as set forth below.

PART 209—ADMINISTRATIVE PROCEDURE

1. The authority citation for Part 209 continues to read as follows:

Authority: 5 U.S.C. 301; 33 U.S.C. 1; 10 U.S.C. 3012

§ 209.135 [Removed]

2. Section 209.135 is removed.

§ 209.147 [Removed]

3. Section 209.147 is removed]

Dated: June 9, 1994.

Approved:

Stanley G. Genega,

Major General, U.S. Army, Director of Civil Works.

[FR Doc. 94–14763 Filed 6–16–94; 8:45 am]

BILLING CODE 3710–92–M

DEPARTMENT OF AGRICULTURE

Forest Service

36 CFR Parts 261 and 290

RIN 0596–AA02

Cave Resources Management

AGENCY: Forest Service, USDA.

ACTION: Final rule.

SUMMARY: This final rule establishes procedures for nominating, evaluating, and designating significant caves on lands administered as part of the National Forest System. The rule also establishes procedures for releasing information about the location of caves and establishes general prohibitions to protect cave resources from abuse and degradation. The intended effect is to fully implement the Federal Cave Resources Protection Act of 1988 on National Forest System lands and to ensure that National Forest System lands are managed in a manner to protect and maintain, to the extent practicable, significant caves. These regulations have been developed in close consultation with the Department of the Interior to ensure uniformity and consistency in approach to the extent that statutory authority permits.

EFFECTIVE DATE: This rule is effective June 17, 1994.

FOR FURTHER INFORMATION CONTACT: Brent Botts, Recreation, Cultural Resources and Wilderness Management Staff, Forest Service, USDA, P.O. Box 96090, Washington, DC 20090–6090, (202) 205–1313.

SUPPLEMENTARY INFORMATION:

Background

The Federal Cave Resources Protection Act of 1988 (16 U.S.C. 4301–4309; 102 Stat. 4546), hereafter referred to as the "Act", seeks to secure, protect, and preserve significant caves on Federal lands for the perpetual use, enjoyment, and benefit of all people. The Act also seeks to foster increased cooperation and exchange of information between governmental authorities and those who utilize caves located on Federal lands for scientific, educational, or recreational purposes. The Act requires the Secretary of Agriculture to issue such regulations as he deems necessary to achieve the purposes of the Act on National Forest System lands. The regulations are required to include, but need not be limited to, criteria for the identification of significant caves.

On March 3, 1989, the Forest Service published an advance notice of proposed rulemaking in the **Federal Register** inviting comments on what should be included in a proposed rule, and particularly requesting suggestions as to criteria for identifying a significant cave. A total of nine comments were received in response to that notice: 4 from agencies of State government, 2 from business entities, 2 from individuals, and 1 from a Federal agency.

Subsequently, a proposed rule was published on December 23, 1991 (56 FR 66388). The proposed rule described the process the Forest Service would use in designating significant caves, provided for public nomination of caves, specified six criteria by which a cave would be evaluated to determine whether it is significant, and identified the authorized officer as the authority for designating and documenting a significant cave. The proposed rule also specified how cave information and locations would be released. Lastly, the proposed rule revised certain

prohibitions specific to caves and cave resources. Seventy-six letters were received during the 90-day comment period in response to the proposed rule: 30 from individuals, 18 from cave-related organizations, 16 from Federal agencies, 5 from natural resource organizations, 4 from business entities, and 3 from State agencies.

All comments received are available for review in the Office of the Director, Recreation, Cultural Resources, and Wilderness Management Staff, Auditors Building, 4th Floor, 201 14th Street, S.W. at Independence Ave., SW., Washington, DC, during regular business hours (8 a.m. to 5 p.m.) Monday through Friday.

Analysis of Public Comment

Overall, almost all respondents were pleased that the Forest Service was promulgating regulations. Many offered valuable suggestions for improving or clarifying specific sections. Some of these suggestions were group efforts, using similar or identical language to identify and describe their interests, concerns, and recommended modifications to the proposed rule. A few letters endorsed other respondents' statements.

The majority of comments centered on four major issues in the proposed 261 and 290 rules: scope of the rule, including the definition and manner of determining the significance of a cave; confidentiality of cave information; public participation; and differences with the proposed rule (57 FR 1344) published by Department of the Interior on January 13, 1992.

Several comments also referred to information contained in a document entitled "Proposed Procedure for Listing Significant Caves," which was circulated at the same time as the proposed rule but was not intended for codification in the regulations. This document described a proposed implementation process in greater detail. These comments also were considered as part of the rulemaking record to the extent that they were relevant to the provisions of the rulemaking.

General Comments on 36 CFR Part 290

Under the proposed rule, cave protection regulations would be set out in title 36, part 290, of the Code of Federal Regulations. The following summarizes general comments received on the proposed rule and the Department's response to them.

1. Cooperation and Consultation With the Department of Interior

Many respondents noted disparities between the Forest Service proposed rule and the proposed rule issued at the same time by the U.S. Department of the Interior (USDI). Most respondents recommended that the final rule of both agencies be as similar as possible.

Response. Throughout the rulemaking process, the Forest Service and USDI land managing agencies have been participating in an interagency committee to agree on cave resource standards and procedures. The goal has been to adopt rules as similar as possible. However, each agency has a different statutory background and mission which result in some procedural differences such as in integrating cave resource protection into planning processes, delegations of authority, and information requirements. In these instances, the language may differ to reflect the specific authorities of the agencies involved.

2. Public Participation

The majority of respondents felt the proposed rule completely ignored Section 2(b)(2) of the Act which states that one purpose of the Act is "to foster increased cooperation and exchange of information between governmental authorities and those who utilize caves for scientific, education, or recreational purposes." Respondents believed the proposed rule denied the caving community access to cave information thus discouraging the exchange of information. Many respondents recommended that public interaction occur through establishment of an advisory committee and the development of volunteer agreements. Some respondents felt that these two actions were required by the Act in Sections 4(b)(3) and 4(b)(4).

Response. Under § 290.3 of the proposed rule, the agency intended that the public be given the opportunity to nominate significant caves. Additionally, proposed § 290.4 provided a process by which information on caves and their location could be disclosed to bona fide educational or research organizations although not to the general cave recreationing community. Additionally, under the proposed rule, the agency envisioned addressing cave resource protection standards in forest plans pursuant to National Forest Management Act and implementing regulations. Forest plans are developed with full public participation; however, in response to comments on the proposed rule, the final rule does strengthen and encourage greater cooperation and exchange of information in the nomination and evaluation process as well as in a new provision permitting the disclosure of cave information to groups who assist the Federal land managing agencies with cave management. These changes are discussed in the section-by-section discussion of comments which follows.

The suggestion to form an advisory committee has not been adopted. It is not at all clear that such advisory groups are needed either nationally or locally. Whether local advisory groups are needed is a decision best left to the local land manager. Should the Forest Supervisor determine that an advisory committee would be helpful in achieving the purposes of the Cave Resources Protection Act, the Department has ample authority and procedures in place to establish such advisory committees.

3. Scope and Detail of the Regulations

Many respondents felt that the proposed rule should have provided more details on how to manage and protect significant caves. Most of these respondents understood that significant caves would be managed "to the extent practical" using current management plans, but wanted the final rule to incorporate or further clarify portions of the proposed rule. Respondents asked questions such as: how will significant cave listings and significant cave management concerns be integrated into forest plans; how will specific management concerns about significant caves be identified; how will ecosystem considerations, including protection of karst features and hydrological recharge areas, be made; and how will the Forest Service address proposed projects that potentially impact caves.

Another respondent requested that goals and standards for cave resource protection and management be described in the rule and that language be added emphasizing that land management decisions should balance consideration of cave resource protection with consideration of human activity.

Response. Through section 4(c)(1) of the Act, Congress made clear that caves should be managed through the agency's land and resource management planning process, and not through the significant cave designation process. Section 4(c)(1) states that significant caves are to be ". . . considered in the preparation of any land management plan if the preparation or revision of the plan began after the enactment of this Act." Forest land and resource management planning is a continuous,

dynamic process which is dependent on monitoring and evaluation of actions taken under the plan. The agency keeps plans current and updated through amendment or revision and maintains ongoing and meaningful communication with the public and other government entities. New data such as an inventory of significant caves is new information that Forest Supervisors consider as forest plans are implemented to determine if forest plan direction needs to be changed. Designating caves as significant will not automatically trigger the need to amend or revise forest plans. Upon development of the initial listing of significant caves on National Forest System lands, the Forest Supervisor will review the forest plan and determine if it is adequate to ensure protection of significant cave resources. If not, the Supervisor would initiate amendment or revision of the plan to address the protection of significant cave resources on the forest. The public must be involved in amendment or revision. Thus, any special management concerns for significant caves, including connected ecosystem considerations, can and should be identified by the public so that the comments can be analyzed and considered through the forest planning process. The forest planning process is already adequately regulated by the provisions of 36 CFR part 219; therefore, no additional change to this rule was made.

Where a proposed project might impact a significant cave or cave yet to be evaluated for significance, the effects of the project would be analyzed in compliance with the National Environmental Policy Act (NEPA) implementing regulations. Public input is solicited to identify environmental issues relevant to a proposed action (project).

Agency policy and procedures under the NEPA in Forest Service Handbook 1909.15 require that decision documents (Decision Memo, Decision Notice, Record of Decision) contain "Findings required by other laws." If a decision affects a significant cave, a finding will be disclosed describing how the decision considered this cave.

Section-by-Section Comments on 36 CFR Part 290

Section 290.1 Purpose and Scope

In considering the general comments on the scope and detail of the regulations addressed in the preceding section of this preamble, the Department concludes that the proposed rule was confusing in specifying that the initial determination of significant caves would be made by a special process and that subsequent significant cave determinations would be made through the forest plan amendment or revision process. The final rule clarifies this concern by: (1) stating that significant cave resources will be managed pursuant to direction contained in individual forest plans and in accordance with the policies contained in the Forest Service Directive System and (2) by eliminating any reference to forest planning in the initial and subsequent listings. This change acknowledges that forest plans provide direction to manage significant caves but do not contain a list of these caves.

Section 290.2 Definitions

Authorized Officer

Several respondents expressed concern over the range of potentially designated authorized officers listed in the proposed rule. One respondent felt that the authorizing officer should be the Regional Forester while another felt this authority should not be delegated below the Forest Supervisor level. Another felt the final decision for determining significant caves should be at a senior management level. Further, some respondents indicated that the authorized officer should have qualifications and duties related to caves and/or cave resources.

The comments received on this definition reflect a lack of understanding of how authority is delegated through the Forest Service. Authority flows from the Chief through Regional Foresters to Forest Supervisors and District Rangers. These line officers have responsibility for managing all resources, including caves, and will be legally responsible for complying with this rule and the Act. The agency will delegate that responsibility through the issuance of internal agency directives and the delegation of authority will vary depending on the significance of the action being assigned. In general, the authorized officer will refer to the Forest Supervisor who must carry out the evaluations and documentations required by the rule in the context of forest planning. To avoid confusion, the definition in the final rule does not include the list of all potential authorized officers.

Cave

The agency received a range of opinions on this definition. Some respondents felt the definition was too narrow; others believed it was too broad. Some respondents, stating that a vug is one resource the Act is intended to protect, were concerned with the exclusion of vugs from the definition. Individual respondents suggested modifying the definition to include qualifiers such as: a dark zone; a minimum horizontal or vertical length; absence or presence of an entrance at any specific time period, and a naturally formed subterranean open area. A couple of respondents were concerned about the requirement that an individual be able to enter. One felt this precluded passages accessible for small cave biota. Another felt this requirement may allow for enlarging small openings to make them accessible as caves. One respondent was concerned that the definition would not protect the "unnatural" portion of caves from destruction or restrict the location of such from the general public.

The Department has concluded that the definition in the proposed rule was confusing because it described both the components of a cave and the features that do not comprise a cave. Accordingly, in the final rule, this definition has been revised to focus on what a cave is, rather than what it is not. "Feature" was replaced with "opening" since it was felt the intent is to include small air passages that extend from the cave itself and that are integral parts of the cave. This definition encompasses any entranceways, including excavated passage; therefore, the location and passage associated with the excavated portion is considered under purposes of this Act. While the suggested qualifiers further define features associated with caves, they were not added because they extend beyond the scope of the cave definition listed in the Act.

Cave Resources

Some respondents suggested that historical resources be separated from the rest of the resources listed as naturally occurring. A few respondents noted that speleogens and speleothems should be defined since these terms are not commonly found in dictionaries.

The term "naturally" was removed as suggested since cultural materials do not occur naturally in caves. Speleogens and speleothems are not included in the definition in the final rule since they are but a couple of the features that comprise geologic and mineralogic materials or substances.

National Forest System Lands

Several respondents were confused over which lands the Act applied to: non-federal lands on which the agency has planned projects, private lands with caves affected by agency projects on Federal lands, lands owned in fee title, and/or National Forest System lands.

A definition for "National Forest System lands" has been added. This

rule applies only to lands managed by and under the legal jurisdiction of the Forest Service. The Act contains no language extending agency authority to private property.

Significant Cave

Several respondents noted that this definition should correspond to the criteria listed in proposed section 290.3(b).

This definition was revised to include the criteria now in § 290.3 (c) and (d).

Vug

Respondents overlapped their comments on "vug" with the "cave" definition. A couple of respondents suggested clarifications to the definition including: Add a size definition other than "small" and make clear that a vug is only a stand-alone cavity presumable intersected by a man-made passage.

Since the only reference to a vug was in the definition of a cave and this reference has now been removed, the separate definition of a vug is no longer necessary.

Section 290.3 Determining Significant Caves

Comments are presented by major paragraph of this section of the proposed rule.

Paragraph (a) Nominations for Initial and Subsequent Listings

Proposed paragraph (a) provided that the Secretary of Agriculture shall cooperate and consult with the Secretary of Interior to devise a similar nomination process for initial listing of significant caves and give public notice of the nomination process. In addition, subsequent determinations of significant caves would be made through the forest planning process. Many respondents felt that the review of nominations and the determination by the authorized officer should be conducted in consultation and cooperation with an advisory committee, team, acknowledged experts in the field of speleology, or appropriate private sector interests, including cavers. A few respondents felt an appeal process was needed for those caves determined not to be significant.

This paragraph was revised to focus more narrowly on the nomination process, and a new paragraph (b) was added to describe the evaluation process. The reference in the proposed rule to subsequent determination of significant caves through the forest planning process has been removed. Determination of significant caves can be made at any time by the authorized officer. Reference to consultation between the Secretaries of Agriculture and Interior was removed since this coordination has occurred in the writing of the entire rule and through a separate effort to develop a Proposed Procedure for Listing Significant Caves. Both paragraphs emphasize public and agency input and consultation. Notice of the nomination procedures for the initial listing must be published in the Federal Register. Notice of future listings is not required as the rule provides that the public and government agencies are to submit such nominations to the Forest Supervisor where the cave is located.

Paragraph (c) Criteria for Significant Caves

Many respondents stated that the criteria were too broad; others felt the criteria were too restrictive. Those respondents who felt the criteria are too broad suggested that criteria be developed at the State-level, be eliminated, or be modified with a strong emphasis on the cave having an important value. The majority of respondents felt that these criteria would eliminate the majority of caves from listing as significant. Most requested that criteria be based only on a cave processing "one or more of the following features, characteristics, or values." Some recommended that the criteria focus on identifying insignificant caves; thus, managing all others as significant. Individual respondents identified the need to add new criteria categories for caves of undetermined status, caves with abnormal dangers, caves with other values, and caves within a special management area which was designated wholly or in part due to the cave resources found there.

Additionally, two business entities felt that the criteria for selection of significant caves are too broad and that the proposed rule neglected to consider the impacts that such a designation would have on oil and gas production. They felt that the designation of significant caves needed to be based on caves having an "important value", especially when considering other uses of the land. They recommended that significant cave values be weighed against the economic values of mineral development.

The Act in section 4(a) requires that the Secretary issue criteria for the identification of significant caves in regulations. Thus, criteria focusing on insignificant caves or criteria developed at the State level do not address the Act's mandate. To focus the criteria on an inventory procedure that can be interpreted and more consistently applied across the agency, the qualifier "* * * which are deemed by the authorized officer to be unusual, significant, or otherwise meriting special management" has not been adopted on the final rule. This phrase confused respondents since it added another level of evaluation and review to the six stated criteria. There is nothing in the Act or its legislative history that indicates that a cave has to have a value more important than, or be weighed against, other uses of public lands before being designated significant. The criteria for designating significant caves are identical to those adopted in the Department of the Interior's final rule.

(1) *Biota.* All respondents commenting on this paragraph requested modifications to make the criteria less restrictive. They recommended the removal of qualifiers such as "cave dependent," "that occur in large numbers or variety," and "disturbance."

"Cave dependent" was replaced with "seasonal or yearlong" to better describe the conditions under which biota use a cave. The qualifier "* * * occur in large numbers or variety * * *" was removed because caves typically contain small populations and variety of flora and fauna by the very nature of the cave environment.

(2) *Cultural.* All respondents commenting on this paragraph felt the criterion was too restrictive to include potentially eligible sites, religious sites for native Americans, caves mined for saltpeter, and sites with ethnographic or historic associations with events or persons considered important to local communities or social groups. A few suggested eliminating the requirement that the site be eligible for or listed on the National Register or Historic Places.

This paragraph was clarified to address and refer to the terms "historic or prehistoric" that are already defined through other laws and regulations. These terms encompass "cultural" resources better than historical properties and archaeological resources. The paragraph also was expanded to better describe the types of resources that could be included or eligible for inclusion on the National Register of Historic Places based on the cave itself or the contents contained within. The paragraph as revised encompasses religious sites for native Americans, caves mined for saltpeter, and other sites with ethnographic or historic associations. Allowing for a site to be eligible for or listed on the National Register of Historic Places consistently ties to the agency management of cultural resources.

(3) *Geologic/Mineralogic/Paleontologic.* Respondents felt that the terms "outstanding" and "important" were too restrictive. Most recommended that "outstanding" be replaced with "other interesting" or that it and "important" be deleted completely. Several respondents felt these criteria would allow every cave to be determined significant. One recommended that this paragraph be completely eliminated; another recommended tying the criteria to only "fragile or outstanding" examples.

In the final rule the qualifiers "outstanding", "useful" and "important" have been eliminated and replaced with more tangible terms. However, while some restrictive qualifiers have been expanded, there are still qualifiers that could appropriately eliminate caves from listing under this criteria.

(4) *Hydrologic.* One respondent felt this criterion should be limited to waters that are necessary to maintain municipal water supplies and maintain scientifically important biota or cave features.

The Department disagrees. This criterion is adopted without change from the proposed rule since it addresses hydrological resources associated with caves and cave resources.

(5) *Recreational.* Most respondents requested that "challenge" be replaced and values such as wilderness, sporting, natural, aesthetic, exploration, educational, and scientific be substituted. One respondent felt that this section should be completely removed. Another noted that scenic values and challenge must have an important value.

This criterion responds to the Act which recognizes caves for their perpetual use, enjoyment, and benefit for all people and further notes that people utilize caves for recreational purposes. The qualifier "by virtue of challenge" has been eliminated since it does not describe a type of recreational opportunity that can be measured. In the final rule, this paragraph is written broadly enough to incorporate the suggested values of wilderness, sporting, aesthetic, and exploration if they tie to recreational and scenic opportunities.

(6) *Educational or scientific.* One respondent noted that any new cave discoveries would automatically qualify as significant under this proposed criterion. Several other respondents felt that qualifiers should be deleted to make the criteria less restrictive. One suggested adding wilderness and uniqueness to this category. Other felt that these criteria must either note an important value or it should be removed.

Changes to this paragraph in the final rule are minor. "Contemporary" is inserted before "human disturbance" to ensure that cultural resources are considered rather than recent acts of vandalism. New cave discoveries could be designated significant if they lack evidence of contemporary human disturbance or impact. This acknowledges that a pristine cave offers potential values from a scientific, educational, and recreational standpoint.

A new paragraph (d), *Specially designated areas,* has been added to recognize that some management decisions have already been made wholly or in part due to caves. Where special management designations are already associated with protecting caves, it is efficient to designate them as significant without re-evaluating them under the requirements of paragraph (c).

Paragraph (e) Designation and Documentation

Several respondents felt clarification was needed for the authorized officer's designation of significant caves. They felt that designation should be tied to the authorized officer confirming that a cave met one of the criteria rather than evaluating the criteria itself. Another respondent requested that the rule be specific as to what information must be provided.

The wording of this paragraph in the final rule clarifies that the authorized officer will confirm whether or not a cave meets one of the criteria listed in § 290.3(c). This clearly defines the role of authorized officer as a decisionmaker not a reviewer of the criteria. The paragraph also specifies the minimum documentation to be retained for each cave designated as significant.

A new paragraph (f), *Undiscovered passages,* has been added to clearly recognize that once a cave has been listed, the designation applies to the entire cave on federal land, regardless of agency jurisdiction or extent of exploration.

A decision to place a cave on the significant cave list is an inventory type decision, and as such, is not appropriately subject to administrative appeal. Accordingly, new paragraph (g), *Decision final,* has been added to clearly state that this determination is not subject to appeal. However, paragraph (a) of this section of the final rule contains a new sentence that makes explicit that a nomination may be resubmitted for listing, thus acknowledging that a decision not to list a cave may be changed when better or new information accompanies the nomination.

Section 290.4 Confidentiality of Cave Information

The majority of respondents focused on three concerns:

(1) That the confidentiality language of the proposed rule went beyond the intent of the Act. They specifically noted that the provisions were to apply only to cave locations, not other cave information. Further, they felt that these provisions would inhibit exchange of information between the caving community and the Federal agencies.

(2) That caves not designated significant have their locations protected under confidentiality provisions. Otherwise, all information about that cave would become public.

(3) That denial of cave location information be subject to appeal. A couple of respondents noted that the requirements for requesting information differed between the FS proposed rule and the USDI proposed rule. Two others expressed the concern that without knowing the exact location of a cave, it is impossible for a mineral lessee to know whether the cave will affect his lease.

Paragraph (a) has been revised to indicate that only location information will be held confidential, but other specific information could be withheld if, in the judgment of the authorized officer, it would reveal the location of a cave. Locational information for all caves will be protected until the designation decision is made. This protection will continue for caves listed as significant. The information submitted for caves that are not listed will be returned to the person or organization submitting the nomination. Consequently, the responsibility for maintaining the confidentiality of unlisted caves will rest with the originator of the information and not with the agency.

Paragraph (b) of this section has procedures to request confidential information, and has been rewritten to be identical to the language adopted by the USDI in its final rule for uniformity.

Paragraph (c), which states the decision regarding access to information is not appealable, has been retained. The Act provides specific exemption from the requirements of the Freedom of Information Act. It is the Department's determination that the appeal process would not further public interest in protecting cave information. A procedure exists to permit the release of cave locations. The authorized officer will release cave location information

based on a written request and a determination that the request would further the purposes of the Act and would not create a substantial risk of harm, theft, or destruction of such cave.

General Comments on 36 CFR Part 261

Implementation of Proposed Prohibitions

One respondent was confused by the prohibitions. Concern was expressed that some additional action must occur for the prohibition to take effect.

Prohibitions applying to National Forest System lands are separated into three Subparts: General Prohibitions; Prohibitions in Areas Designated by Order; and Prohibitions in Regions. General Prohibitions are enforced on all National Forest System lands and do not require any formal posting. Prohibitions in Areas Designated by Order require an additional action to inform a forest visitor. The order must be posted in accordance with 261.51 of this chapter.

Criminal and Civil Penalties

Several respondents noted that existing penalties do not correspond to the penalties described in Sections 7 and 8 of the Act.

The primary purpose of the current rulemaking was to establish the criteria for significant caves. Where it was expedient to make minor adjustments to existing prohibitions in order to help protect significant cave resources, this was also done. If experience with administering significant cave resources shows additional regulations and penalties are needed, subsequent rulemaking specific to those management concerns will be undertaken.

Collection and Removal From Federal Caves

Several respondents noted that the rule is unclear on how collecting permits will be issued or regulated.

The Forest Service has an established procedure for issuing special use permits, which is regulated through rules of subpart B of part 251, title 36. All permits for significant caves must be in accordance with this regulation.

Section-by-Section Comments on 36 CFR Part 261

Section 261.2 Definitions

All respondents commenting on definitions of caves and cave resources under 290 2, repeated their comments here. Several respondents noted that these definitions should be identical to those defined in section 290.2.

This suggestion was adopted and identical definitions are provided in §§ 290.2 and 261.2.

Section 261.8 Fish and Wildlife

Respondents were concerned that this prohibition would not allow a gate to be installed if it was needed to protect a species, including those listed as threatened or endangered.

The paragraph was modified to address this concern by adding ". . . except as authorized to protect a cave resource." A gate was not specifically cited since there may be other types of installations that could curtail the movement of cave life to protect a cave resource.

Section 261.9(j) Property

Two respondents were confused by the intent of this paragraph. One asked whether enlarging a naturally occurring cave passage or entrance would require a special use authorization. Another requested clarification stating that a special use authorization cannot permit damage to, or excavation of, a significant cave. One respondent suggested adding a new prohibition to address section 7(a)(2) of the Act dealing with possessing, consuming, selling, bartering, or exchanging any cave resource without authorization.

Section 7(a)(1) of the Act states that activities that may lead to destroying altering, or removing of cave resources or interfering with free movement of plant or animal life may only be permitted with prior authorization. Thus, any excavation of a cave passage or entrance would have to be approved by a special use authorization. A special use authorization permitting excavation in a cave is site-specific, thus, this provision does not encourage nor allow blanket approval for this type of activity for all caves on a given forest. A clause has been added prohibiting the removal of any cave resource for commercial purposes.

Section 261.10(d) Occupancy and Use

One respondent requested the wording in this section include the cave entrance area. Another requested that the discharge of fireworks be prohibited.

The proposed wording has been retained. The cave entrance area is protected by the existing wording in paragraphs (d)(1) and (d)(2).

A new paragraph (n) was added to specifically address the discharge of fireworks. No existing prohibition addressed this human safety concern.

Section 261.58(ee) Occupancy and Use

Most respondents requested that "litter" be incorporated into this clause. A couple of respondents felt that additional wording was needed to allow cavers to bring and remove their own receptacles. Another respondent recommended that fluid wastes be considered on a cave by cave basis.

Paragraph 11(b) of this section already prohibits "Possessing or leaving . . . litter in an exposed or unsanitary condition." Current wording does not specify who must provide the receptacles; therefore, it can be interpreted that cavers may bring in and remove their own receptacles. Since this prohibition is applicable to a specific area designated through an order by the Forest Supervisor, there is the flexibility to add an exception for a particular cave to only prohibit solid wastes.

Regulatory Impact

This final rule has been reviewed under USDA procedures and Executive Order 12866 on Regulatory Planning and Review. It has been determined that this is not a significant rule. This rule will not have an annual effect of $100 million or more on the economy nor adversely affect productivity, competition, jobs, the environment, public health or safety, nor State or local governments. This rule will not interfere with an action taken or planned by another agency nor raise new legal or policy issues. Finally, this action will not alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients of such programs.

Moreover, this final rule has been considered in light of the Regulatory Flexibility Act (5 U.S.C. 601 et. seq.), and it has been determined that this action will not have a significant economic impact on a substantial number of small entities as defined by that Act. To the extent that small entities engaged in resource extraction activities may have to site operations to protect significant caves, these requirements are the minimum necessary to protect the public interest, and are well within the capability of small entities to perform.

Environmental Impact

Based on both experience and environmental analysis, this final rule (or final policy) will have no significant effect on the human environment, individually or cumulatively. Therefore, it is categorically excluded from documentation in an environmental assessment or an environmental impact statement (40 CFR 1508.4).

Controlling Paperwork Burdens on the Public

The information required by this rule constitutes new information collection requirements as defined in 5 CFR part 1320, Controlling Paperwork Burdens on the Public. In accordance with those rules and the Paperwork Reduction Act of 1980 (44 U.S.C. 3507), the Forest Service received approval from the Office of Management and Budget to collect cave nomination information and confidential cave information. The agency estimates that each person will spend an average of three hours per response for a cave nomination and one-half hour per response for the confidential cave information request.

No Taking Implications

This rule has been analyzed in accordance with the principles and criteria contained in Executive Order 12630, and it has been determined that the rule does not pose the risk of a taking of Constitutionally-protected private property.

List of Subjects

36 CFR Part 261

Prohibitions, National forests.

36 CFR Part 290

Cave resources management, National forests.

Therefore, for the reasons set out in the preamble, title 36 of the Code of Federal Regulations is amended by amending part 261 and adding a new part 290 as set forth below.

PART 261—PROHIBITIONS

1. Revise the authority citation for part 261 to read as follows:

Authority: 16 U.S.C. 551; 16 U.S.C. 472; 7 U.S.C. 1011(f); 16 U.S.C. 1246(i); 16 U.S.C. 1133(c)–(d)(1); 16 U.S.C. 4306, 4307.

Subpart A—General Prohibitions

2. Amend § 261.2 by adding definitions for the terms "cave" and "cave resources" in alphabetical order to read as follows:

§ 261.2 Definitions.

* * * * *

Cave means any naturally occurring void, cavity, recess, or system of interconnected passages beneath the surface of the earth or within a cliff or ledge and which is large enough to permit a person to enter, whether the entrance is excavated or naturally formed. Such term shall include any natural pit, sinkhole, or other opening which is an extensive of a cave entrance or which is an integral part of the cave.

Cave resources mean any materials or substances occurring in caves including, but not limited to, biotic, cultural, mineralogic, paleontologic, geologic, and hydrologic resources.

* * * * *

3. Amend § 261.8 by adding a new paragraph (e) to read as follows:

§ 261.8 Fish and wildlife.

* * * * *

(e) Curtail the free movement of any animal or plant life into or out of a cave, except as authorized to protect a cave resource.

4. Amend § 261.9 by adding a new paragraph (j) to read as follows:

§ 261.9 Property.

* * * * *

(j) Excavating, damaging, or removing any cave resource from a cave without a special use authorization, or removing any cave resource for commercial purposes.

5. Amend § 261.10 by revising paragraph (d) introductory text and adding new paragraphs (d)(3) and (n) to read as follows:

§ 261.10 Occupancy and use.

* * * * *

(d) Discharging a firearm or any other implement capable of taking human life, causing injury, or damaging property as follows:

(1) * * *

(2) * * *

(3) into or within any cave.

* * * * *

(n) Discharging or igniting a firecracker, rocket or other firework, or explosive into or within any cave.

Subpart B—Prohibitions in Areas Designated by Order

6. Amend § 261.58 by adding a new paragraph (ee) to read as follows:

§ 261.58 Occupancy and use.

* * * * *

(ee) Depositing any body waste in caves except into receptacles provided for that purpose.

7. Add a new part 290 to read as follows:

PART 290—CAVE RESOURCES MANAGEMENT

Sec.

290.1 Purpose and scope.
290.2 Definitions.
290.3 Nomination, evaluation, and designation of significant caves.
290.4 Confidentiality of cave location information.
290.5 Collection of information.

Authority: 16 U.S.C. 4301–4309; 102 Stat. 4546.

§ 290.1 Purpose and scope.

The rules of this part implement the requirements of the Federal Cave Resources Protection Act (16 U.S.C. 4301–4309), hereafter referred to as the "Act". The rules apply to cave management on National Forest System lands. These rules, in conjunction with rules in part 261 of this chapter, provide the basis for identifying and managing significant caves on National Forest System lands in accordance with the Act. National Forest System lands will be managed in a manner which, to the extent practical, protects and maintains significant cave resources in accordance with the policies outlined in the Forest Service Directive System and the management direction contained in the individual forest plans.

§ 290.2 Definitions.

For the purposes of this part, the terms listed in this section have the following meaning:

Authorized officer means the Forest Service employee delegated the authority to perform the duties described in this part.

Cave means any naturally occurring void, cavity, recess, or system of interconnected passages beneath the surface of the earth or within a cliff or ledge and which is large enough to permit a person to enter, whether the entrance is excavated or naturally formed. Such term shall include any natural pit, sinkhole, or other opening which is an extension of a cave entrance or which is an integral part of the cave.

Cave resources mean any materials or substances occurring in caves including, but not limited to, biotic, cultural, mineralogic, paleontologic, geologic, and hydrologic resources.

National Forest System lands means all national forest lands reserved or withdrawn from the public domain, acquired through purchase, exchange, or donation, national grasslands and land utilization projects, and other lands, waters, or interests administered by the Forest Service.

Secretary means the Secretary of Agriculture.

Significant cave means a cave located on National Forest System lands that has been determined to meet the criteria in § 290.3 (c) or (d) and has been designated in accordance with § 290.3(e).

§ 290.3 Nomination, evaluation, and designation of significant caves.

(a) *Nominations for initial and subsequent listings.* The authorized officer will give governmental agencies and the public, including those who utilize caves for scientific, educational,

or recreational purposes, the opportunity to nominate caves. The authorized officer shall give public notice, including a notice published in the **Federal Register**, calling for nominations for the initial listing and setting forth the procedures for preparing and submitting the nominations. Nominations for subsequent listings will be accepted from governmental agencies and the public by the Forest Supervisor where the cave is located as new cave discoveries are made. Caves nominated but not approved for designation may be renominated as additional documentation or new information becomes available.

(b) *Evaluation for initial and subsequent listings.* The evaluation of the nominations for significant caves will be carried out in consultation with individuals and organizations interested in the management and use of caves and cave resources, within the limits imposed by the confidentiality provisions of § 290.4. Nominations shall be evaluated using the criteria in § 290.3 (c) and (d).

(c) *Criteria for significant caves.* A significant cave on National Forest System lands shall possess one or more of the following features, characteristics, or values.

(1) *Biota.* The cave provides seasonal or yearlong habitat for organisms or animals, or contains species or subspecies of flora or fauna native to caves, or are sensitive to disturbance, or are found on State or Federal sensitive, threatened, or endangered species lists.

(2) *Cultural.* The cave contains historic properties or archeological resources (as defined in Parts 800.2 and 296.3 of this chapter respectively, or in 16 U.S.C. 470, *et seq.*), or other features included in or eligible for inclusion on the National Register of Historic Places because of their research importance for history or prehistory, historical associations, or other historical or traditional significance.

(3) *Geologic/Mineralogic/ Paleontologic.* The cave possesses one or more of the following features:

(i) Geologic or mineralogic features that are fragile, represent formation processes that are of scientific interest, or that are otherwise useful for study.

(ii) Deposits of sediments or features useful for evaluating past events.

(iii) Paleontologic resources with potential to contribute useful educational or scientific information.

(4) *Hydrologic.* The cave is a part of a hydrologic system or contains water which is important to humans, biota, or development of cave resources.

(5) *Recreational.* The cave provides or could provide recreational opportunities or scenic values.

(6) *Educational or scientific.* The cave offers opportunities for educational or scientific use; or, the cave is virtually in a pristine state, lacking evidence of contemporary human disturbance or impact; or, the length, volume, total depth, pit depth, height, or similar measurements are notable.

(d) *Specially designated areas.* All caves located within special management areas, such as Special Geologic Areas, Research Natural Areas, or National Monuments, that are designated wholly or in part due to the cave resources found therein are determined to be significant.

(e) *Designation and documentation.* If the authorized officer determines that a cave nominated and evaluated under paragraphs (a) and (b) of this section meets one or more of the criteria in paragraph (c) of this section, the authorized officer shall designate the cave as significant. The authorized officer will notify the nominating party of the results of the evaluation and designation. Each forest will retain appropriate documentation for all significant caves located within its administrative boundaries. At a minimum, this documentation shall include a statement of finding signed and dated by the authorized officer and the information used to make the determination. This documentation will be retained as a permanent record in accordance with the confidentiality provision in § 290.4.

(f) *Undiscovered passages.* If a cave is determined to be significant, its entire extent on federal land, including passages not mapped or discovered at the time of the determination, is deemed significant. This includes caves that extend from lands managed by any other Federal agency into National Forest System lands, as well as caves initially believed to be separate for which interconnecting passages are discovered after significance is determined.

(g) *Decision final.* The decision to designate or not designate a cave as significant is made at the sole discretion of the authorized officer based upon the criteria in paragraphs (c) and (d) of this section and is not subject to further administrative review of appeal under Parts 217 or 251.82 of this chapter.

§ 290.4 Confidentiality of cave location information.

(a) *Information disclosure.* No Forest Service employee shall disclose any information that could be used to determine the location of a significant cave or a cave nominated for designation, unless the authorized officer determines that disclosure will further the purposes of the Act and will not create a substantial risk of harm, theft, or destruction to cave resources.

(b) *Requesting confidential information.* Notwithstanding paragraph (a) of this section, the authorized officer may make confidential cave information available to Federal or State governmental agencies, bona fide educational or research institutes, or individuals or organizations assisting the land management agencies with cave management activities. To request confidential cave information, such entities shall make a written request to the authorized officer which includes the following:

(1) Name, address, and telephone number of the individual responsible for the security of the information received;

(2) A legal description of the area for which the information is sought;

(3) A statement of the purpose for which the information is sought; and,

(4) Written assurances that the requesting party will maintain the confidentiality of the information and protect the cave and its resources.

(c) *Decision final.* The decision to permit or deny access to confidential cave information is made at the sole discretion of the authorized officer and is not subject to further administrative review or appeal under 5 U.S.C. 552 or parts 217 or 251.82 of this chapter.

§ 290.5 Collection of information.

The collection of information contained in this rule represents new information requirements as defined in 5 CFR part 1320, Controlling Paperwork Burdens on the Public. In accordance with those rules and the Paperwork Reduction Act of 1980 as amended (44 U.S.C. 3507), the Forest Service has received approval by the Office of Management and Budget to collect cave nomination information under clearance number 0596–0123 and confidential information under 0596–0122. The information provided for the cave nominations will be used to determine which caves will be listed as "significant" and the information in the requests to obtain confidential cave information will be used to decide whether to grant access to this information. Response to the call for cave nominations is voluntary. No action may be taken against a person for refusing to supply the information requested. Response to the information requirements for obtaining confidential cave information is required to obtain a benefit in accordance with section 5 of

the Federal Cave Resources Protection Act of 1988 (16 U.S.C. 4304).

Dated: May 17, 1994.

James R. Lyons,

Assistant Secretary, Natural Resources and Environment.

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BILLING CODE 3410–11–M

POSTAL SERVICE

39 CFR Part 233

Removal of Provision Providing 10-Day Maximum Period for Giving Inventory of Property Seized for Forfeiture to Party Whose Property Was Seized

AGENCY: Postal Service.

ACTION: Final rule.

SUMMARY: This final rule amends Postal Service regulations on forfeiture procedures by removing the provision requiring the agency to provide a receipt of the inventory of the property seized for forfeiture to the party whose property was seized within 10 days of the seizure. This amendment is intended to make the inventory notice precedure of the Postal Service consistent with other federal agencies and to eliminate an unnecessary burden on the agency.

EFFECTIVE DATE: June 17, 1994.

FOR FURTHER INFORMATION CONTACT: Postal Inspector-Attorney Frederick I. Rosenberg, (202) 268–5477.

SUPPLEMENTARY INFORMATION: Postal Service regulations concerning inventory procedures for property seized for forfeiture are published in title 39 of the Code of Federal Regulations (CFR) as § 233.7(c). The last sentence of that section establishes a 10-day maximum period for the agency to give a written receipt of the inventory of the property seized for forfeiture and the identity of the Postal Inspector who conducted the seizure to the party from whom the property was seized. Section 233.7(c) is amended to remove the 10-day limit to make the inventory notice procedure of the Postal Service consistent with other federal agencies and to eliminate an unnecessary burden on the agency when the party whose property was seized cannot be readily identified.

List of Subjects in 39 CFR Part 233

Crime, Law enforcement, Postal Service, Seizures and forfeitures.

Accordingly, 39 CFR 233 is amended as set forth below.

PART 233—INSPECTION SERVICE/ INSPECTOR GENERAL AUTHORITY

1. The authority citation for part 233 continues to read as follows:

Authority: 39 U.S.C. 101, 401, 402, 403, 404, 406, 410, 411, 3005(e)(1); 12 U.S.C. 3401–3422; 18 U.S.C. 981, 1956, 1957, 2254, 3061; 21 U.S.C. 881; Inspector General Act of 1978, as amended (Pub. L. No. 95–4542, as amended), 5 U.S.C. App. 3.

2. Section 233.7(c) is amended by revising the last sentence to read as follows:

§ 233.7 Forfeiture authority and procedures.

* * * * *

(c) * * * A written receipt containing such information and identifying the Postal Inspector who conducted the seizure must be provided to the party from whom the property was seized, or the party's agent or representative, at the time of the seizure or as soon thereafter as is practicable.

* * * * *

Stanley F. Mires,

Chief Counsel, Legislative Division.

[FR Doc. 94–14719 Filed 6–16–94; 8:45 am]

BILLING CODE 7710–12–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[ME–8–1–6282; A–1–FRL–4854–8]

Approval and Promulgation of Air Quality Implementation Plans; Maine; VOC RACT Catch-ups

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is approving a State Implementation Plan (SIP) revision submitted by the Maine Department of Environmental Protection (DEP) on January 8, 1993. This SIP revision contains regulations which require the implementation of reasonably available control technology (RACT) for various types of volatile organic compound (VOC) sources. The EPA has evaluated this SIP revision and is approving it under the Clean Air Act, as amended in 1990.

EFFECTIVE DATE: This final rule will become effective on July 18, 1994.

ADDRESSES: Copies of the documents relevant to this action are available for public inspection during normal business hours, by appointment at the Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region I, One Congress Street, 10th floor, Boston, MA; Air Docket 6102, U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460; and the Bureau of Air Quality Control, Department of Environmental Protection, 71 Hospital Street, Augusta, ME 04333.

FOR FURTHER INFORMATION CONTACT: Anne E. Arnold, (617) 565–3166.

SUPPLEMENTARY INFORMATION: On December 1, 1993 (58 FR 63316), EPA published a notice of proposed rulemaking (NPR) for the State of Maine. The NPR proposed approval of several regulations adopted by the State of Maine which require the implementation of RACT for various types of VOC sources. No public comments were received on the NPR.

Background

Under the pre-amended Clean Air Act, ozone nonattainment areas were required to adopt RACT rules for sources of VOC emissions. EPA issued three sets of control technique guidelines (CTGs) documents, establishing a "presumptive norm" for RACT for various categories of VOC sources. The three sets of CTGs were: (1) Group I—issued before January 1978 (15 CTGs); (2) Group II—issued in 1978 (9 CTGs); and (3) Group III—issued in the early 1980's (5 CTGs). Those sources not covered by a CTG were called non-CTG sources. EPA determined that the area's SIP-approved attainment date established which RACT rules the area needed to adopt and implement. Under section 172(a)(1), ozone nonattainment areas were generally required to attain the ozone standard by December 31, 1982. Those areas that submitted an attainment demonstration projecting attainment by that date were required to adopt RACT for sources covered by the Group I and II CTGs. Those areas that sought an extension of the attainment date under section 172(a)(2) to as late as December 31, 1987 were required to adopt RACT for all CTG sources and for all major (i.e., 100 ton per year or more of VOC emissions) non-CTG sources.

Under the pre-amended Clean Air Act, Maine was designated as rural nonattainment and, therefore, was required to adopt regulations pursuant to the Group I and Group II CTGs for major sources. Based on monitored ozone exceedances in Maine, EPA notified the Governor of Maine on May 25, 1988 and November 8, 1988 that portions of the SIP were inadequate to attain and maintain the ozone standard and requested that deficiencies in the existing SIP be corrected (EPA's SIP-Call). On November 15, 1990,

amendments to the 1977 CAA were enacted. Public Law 101–549, 104 Stat. 2399, codified at 42 U.S.C. 7401–7671q. In amended Section 182(a)(2)(A) of the CAA, Congress statutorily adopted the requirement that pre-enactment ozone nonattainment areas that retained their designation of nonattainment and were classified as marginal or above fix their deficient RACT rules for ozone by May 15, 1991. Pursuant to the amended CAA, two counties in Maine were classified as marginal (these two counties constitute one marginal ozone nonattainment area) and seven counties in Maine were classified as moderate (these seven counties constitute three moderate ozone nonattainment areas). 56 FR 56694 (Nov. 6, 1991). The State submitted revisions to meet the RACT fix-up requirement and EPA approved these revisions to the Maine SIP on February 3, 1992 and March 22, 1993 (57 FR 3946 and 58 FR 15281).

Section 182(b)(2) of the amended Act requires States to adopt RACT rules for all areas designated nonattainment for ozone and classified as moderate or above. There are three parts to the section 182(b)(2) RACT requirement: (1) RACT for sources covered by an existing CTG—i.e., a CTG issued prior to the enactment of the CAAA of 1990; (2) RACT for sources covered by a post-enactment CTG; and (3) all major sources not covered by a CTG, i.e., non-CTG sources. This RACT requirement which applies to nonattainment areas that previously were exempt from certain RACT requirements requires areas to "catch up" to those nonattainment areas that became subject to those requirements during an earlier period. In addition, it requires newly designated ozone nonattainment areas to adopt RACT rules consistent with those for previously designated nonattainment areas. As previously mentioned, the State of Maine contains three moderate ozone nonattainment areas. These areas are thus subject to the section 182(b)(2) RACT catch-up requirement.

Also, the State of Maine is located in the Northeast Ozone Transport Region (OTR). The entire State is, therefore, subject to section 184(b) of the amended CAA. Section 184(b) requires that RACT be implemented for all VOC sources covered by a CTG issued before or after the enactment of the CAAA of 1990 and for all major VOC sources (defined as 50 tons per year or greater for sources in the OTR).

Since Maine had previously submitted regulations for bulk gasoline terminals, fixed roof petroleum tanks, and paper coating sources pursuant to the RACT fix-up requirement, in order to meet the RACT catch-up requirement, the State must, therefore, adopt regulations (or affirm that no sources exist) for the remaining 26 CTG categories as well as adopt rules for all major non-CTG sources. (Rules for non-CTG sources are not part of this SIP revision and will not be further discussed in this document).

EPA's Evaluation of Maine's Submittal

In response to the RACT catch-up requirement, on May 14, 1992 and June 12, 1992, Maine submitted negative declarations for the CTG categories listed below.

1. Surface coating of coils.
2. Surface coating of magnet wire.
3. Surface coating of large appliances.
4. Surface coating of automobiles and light duty trucks.
5. Manufacturing of synthesized pharmaceuticals.
6. Manufacturing of pneumatic rubber tires.
7. Manufacturing of vegetable oil.
8. Air oxidation processes in synthetic organic chemical manufacturing industry.
9. Manufacturing of high density polyethylene, polypropylene and polystyrene resins.
10. Leaks from synthetic organic chemical and polymer manufacturing.
11. Petroleum liquid storage in external floating roof tanks.
12. Equipment leaks from natural gas/gasoline processing plants.
13. Petroleum refinery processes.
14. Leaks from petroleum refinery equipment.
15. Large petroleum dry cleaners.

Through the negative declaration, the State of Maine is asserting that there are no sources within the State that would be subject to a rule for that source category. EPA is approving this negative declaration submittal as meeting the section 182(b)(2) and section 184(b) RACT requirements for the source categories listed.

After submitting the above negative declarations, Maine then proceeded with the process of adopting regulations to control the remaining CTG categories which include surface coating processes, solvent metal cleaning, graphic arts operations, the use of cutback asphalt, and gasoline marketing operations. Maine's gasoline marketing RACT catch-up regulations are not a part of this SIP revision, and will not be further discussed in this notice.

The VOC regulations that are included in Maine's January 13, 1993 SIP submittal are briefly summarized below.

Chapter 100: Definitions Regulation

This regulation was amended to include the following 19 newly adopted definitions: as applied, capture system, carbon adsorber, condensate, condenser, continuous emission monitor, control system, double block-and-bleed system, exempt VOC compounds, gaseous excess emissions, leak, maximum true vapor pressure, open-ended valve or line, organic compound, overall VOC emission reduction efficiency, pressure release, solvent, standard atmospheric conditions, and VOC incinerator.

Chapter 129: Surface Coating Facilities

This regulation contains requirements for limiting the VOC emissions from the surface coating of cans, fabric, vinyl, metal furniture, flatwood paneling, and miscellaneous metal parts and products. Surface coating facilities may comply with this regulation through the use of low VOC coatings, daily-weighted averaging, and/or add-on control equipment.

Chapter 130: Solvent Degreasers

This regulation contains equipment and operation standards for solvent degreasing operations. These requirements apply to cold cleaners, open-top vapor degreasers and conveyorized degreasers.

Chapter 131: Cutback and Emulsified Asphalt

This regulation contains prohibitions regarding the mixing, storage, use, and application of cutback and emulsified asphalts.

Chapter 132: Graphic Arts-Rotogravure and Flexography

This regulation contains requirements to limit the emissions from rotogravure and flexographic printing operations. Graphic arts facilities may comply with these requirements through the use of low VOC coatings, daily-weighted averaging, and/or add-on control equipment.

EPA has evaluated Maine's VOC regulations and has found that they are consistent with EPA model regulations and the applicable CTG documents. As such, EPA believes that the submitted rules constitute RACT for the applicable sources. By this action, EPA is approving Maine's submittal as meeting the requirements of sections 182(b)(2) and 184(b)(1)(B) for the applicable VOC sources. Maine's regulations and EPA's evaluation are detailed in a memorandum, dated July 16, 1993, entitled "Technical Support Document—Maine—VOC RACT Catch-ups." Copies of that document are available, upon request, from the EPA

Regional Office listed in the ADDRESSES section of this document.

Final Action

EPA is approving Maine's Chapter 100 "Definitions Regulation," Chapter 129 "Surface Coating Facilities," Chapter 130 "Solvent Degreasers," Chapter 131 "Cutback and Emulsified Asphalt," and Chapter 132 "Graphic Arts-Rotogravure and Flexography" as meeting the requirements of sections 182(b)(2) and 184(b) of the CAA for the following categories of VOC sources: the surface coating of cans, fabric, vinyl, metal furniture, flatwood paneling, and miscellaneous metal parts and products; solvent metal cleaning; the use of cutback asphalt; and rotogravure and flexographic printing operations. EPA is also approving the negative declarations submitted by the State of Maine as meeting the requirements of sections 182(b)(2) and 184(b) of the CAA for the 15 source categories for which negative declarations were submitted.

Under the Regulatory Flexibility Act, 5 U.S.C. 600 *et seq.*, EPA must prepare a regulatory flexibility analysis assessing the impact of any proposed or final rule on small entities. 5 U.S.C. 603 and 604. Alternatively, EPA may certify that the rule will not have a significant impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and government entities with jurisdiction over populations of less than 50,000.

As noted elsewhere in this action, EPA received no adverse public comment on the proposed action. As a direct result, the Regional Administrator has reclassified this action from Table 2 to Table 3 under the procedures published in the **Federal Register** on January 19, 1989 (54 FR 2214–2225). On January 6, 1989, the Office of Management and Budget (OMB) waived Table 2 and Table 3 SIP revisions from the requirement of section 3 of Executive Order 12291 for a period of two years. The EPA has submitted a request for a permanent waiver for Table 2 and Table 3 SIP revisions. The OMB has agreed to continue the waiver until such time as it rules on EPA's request. This request continues in effect under Executive Order 12866 which superseded Executive Order 12291 on September 30, 1993.

SIP approvals under section 110 and subchapter I, part D of the CAA do not create any new requirements, but simply approve requirements that the State is already imposing. Therefore, because the federal SIP-approval does not impose any new requirements, I certify that it does not have a significant impact on any small entities affected. Moreover, due to the nature of the federal-state relationship under the CAA, preparation of a regulatory flexibility analysis would constitute federal inquiry into the economic reasonableness of state action. The CAA forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co. v. U.S. E.P.A.*, 427 U.S. 246, 256–66 (S.Ct. 1976); 42 U.S.C. 7410 (a)(2).

Nothing in this action should be construed as permitting or allowing or establishing a precedent for any future request for revision to any State implementation plan. Each request for revision to the State implementation plan shall be considered separately in light of specific technical, economic, and environmental factors and in relation to relevant statutory and regulatory requirements.

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by August 16, 1994. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Hydrocarbons, Incorporation by reference, Ozone.

Note: Incorporation by reference of the State Implementation Plan for the State of Maine was approved by the Director of the **Federal Register** on July 1, 1982.

Editorial Note: This document was received by the Office of the Federal Register June 13, 1994.

Dated: February 18, 1994.

Patricia L. Meaney,

Acting Regional Administrator, Region I.

Part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401–7671q.

Subpart U—Maine

2. Section 52.1020 is amended by adding paragraph (c)(33) to read as follows:

§ 52.1020 Identification of plan.

* * * * *

(c) * * *

(33) Revisions to the State Implementation Plan submitted by the Maine Department of Environmental Protection on January 8, 1993.

(i) Incorporation by reference.

(A) Letter from the Maine Department of Environmental Protection dated January 8, 1993 submitting a revision to the Maine State Implementation Plan.

(B) Revised Chapter 100 of the Maine Department of Environmental Protection Regulations, "Definitions" effective in the State of Maine on February 10, 1993.

(C) Chapter 129 of the Maine Department of Environmental Protection Regulations, "Surface Coating Facilities" effective in the State of Maine on February 10, 1993.

(D) Chapter 130 of the Maine Department of Environmental Protection Regulations, "Solvent Degreasers" effective in the State of Maine on February 10, 1993.

(E) Chapter 131 of the Maine Department of Environmental Protection Regulations, "Cutback and Emulsified Asphalt" effective in the State of Maine on February 10, 1993.

(F) Chapter 132 of the Maine Department of Environmental Protection Regulations, "Graphic Arts—Rotogravure and Flexography" effective in the State of Maine on February 10, 1993.

(G) Appendix A "Volatile Organic Compounds Test Methods and Compliance Procedures" incorporated into Chapters 129 and 132 of the Maine Department of Environmental Protection Regulations, effective in the State of Maine on February 10, 1993.

(ii) Additional materials.

(A) Nonregulatory portions of the submittal.

§ 52.1031 [Amended]

3. In § 52.1031, Table 52.1031 is amended by adding a new entry to existing state citation "Chapter 100" and by adding new state citations "Chapter 129," "Chapter 130," "Chapter 131," and "Chapter 132" to read as follows:

TABLE 52.1031.—EPA-APPROVED RULES AND REGULATIONS

State citation	Title/Subject	Date adopted by State	Date approved by EPA	Federal Register citation	52.1020	
•	•	•	•	•	•	•
Chapter:						
100	Definitions	01/06/93	[Insert date of publication].	[Insert *FR* citation from published date].	(c)(33)	Revised to add definitions associated with VOC RACT rules
•	•	•	•	•	•	•
129	Surface coating Facilities.	01/06/93	[Insert date of publication].	[Insert *FR* citation from published date].	(c)(33)	Includes surface coating of: cans, fabric, vinyl, metal furniture, flatwood paneling, and miscellaneous metal parts and products
130	Solvent Degreasers ..	01/06/93	[Insert date of publication].	[Insert *FR* citation from published date].	(c)(33)	
131	Cutback and Emulsified Asphalt.	01/06/93	[Insert date of publication].	[Insert *FR* citation from published date].	(c)(33)	
132	Graphic Arts: Rotogravure and Flexography.	01/06/93	[Insert date of publication].	[Insert *FR* citation from published date].	(c)(33)	

[FR Doc. 94–14723 Filed 6–16–94; 8:45 am]
BILLING CODE 6560–60–P

40 CFR Part 61

[FRL–4893–5]

Interpretive Rule for Roof Removal Operations Under the Asbestos NESHAP

AGENCY: Environmental Protection Agency.

ACTION: Interpretive rule.

SUMMARY: The Environmental Protection Agency ("EPA") is today publishing an interpretive rule regarding roof removal operations under the National Emission Standards for Hazardous Air Pollutants for Asbestos ("Asbestos NESHAP"). The purpose of the interpretive rule is to clarify the Asbestos NESHAP as it affects roof removal operations by: specifying which roof removal operations EPA construes the NESHAP to cover; and specifying roof removal work practices that EPA deems to be in compliance with the NESHAP in roofing operations where the NESHAP applies.

EFFECTIVE DATE: June 17, 1994.

FOR FURTHER INFORMATION CONTACT: Mr. Thomas Ripp at (703) 308–8727 at U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards, Stationary Source Compliance Division. For copies, contact Mr. Larry Tessier at 1–800–368–5888 or at (703) 305–5938.

SUPPLEMENTARY INFORMATION: On November 20, 1990, EPA published in the **Federal Register** (55 FR 48406) revisions to the Asbestos NESHAP, which is codified at 40 CFR part 61, subpart M. Members of the roofing industry have expressed confusion regarding the asbestos NESHAP and have requested clarification from EPA with regard to how compliance with the NESHAP can be achieved for roof removal operations.

EPA is today publishing, as a new appendix A to subpart M of 40 CFR part 61, the interpretive rule that is set forth below. The purpose of the interpretive rule is to clarify the Asbestos NESHAP as it affects roof removal operations by: (i) Specifying which roof removal operations EPA construes the NESHAP to cover; and (ii) specifying roof removal work practices that EPA deems to be in compliance with the NESHAP in roofing operations where the NESHAP applies.

The new appendix A to the Asbestos NESHAP does not supersede, alter or replace the Asbestos NESHAP; nor does it change the scope or stringency of the NESHAP. Rather appendix A interprets the NESHAP as it applies to roof removal operations, in order to provide particularized guidance which, if followed, would promote compliance with, and more effective and consistent enforcement of, the NESHAP in such operations. This interpretive rule is intended as guidance to the roofing industry and the public and does not constitute an action which is subject to judicial review under section 307(b)(1) of the Clean Air Act, 42 U.S.C. 7607(b)(1), or under the Administrative Procedure Act, 5 U.S.C. 704. In addition, because the rule prescribed in this notice is an interpretive rule and does not promulgate or revise a standard or regulation listed in section 307(d)(1) of the Clean Air Act (42 U.S.C. 7607(d)(1)), the procedural requirements for rulemaking under the Clean Air Act and the Administrative Procedure Act do not apply to this action. See 42 U.S.C. 7607(d); 5 U.S.C. 553(b).

It is the present intent of EPA that if this interpretive rule is revoked or withdrawn before new regulations regarding asbestos emissions or work practices for handling of asbestos containing materials during roof removal operations under the Clean Air Act are promulgated by EPA, then EPA shall replace the interpretive rule with another interpretation or guidance document that would address how the NESHAP applies to roof removal in renovation and demolition operations. It is also the present intent of EPA that prior to replacing or substantially revising this interpretive rule, EPA would consult with the public regarding such action.

List of Subjects in 40 CFR Part 61

Air pollution control Asbestos.

Dated: May 31, 1994.

Mary D. Nichols,

Assistant Administrator, Office of Air and Radiation.

40 CFR part 61 is amended as follows:

1. The authority citation for part 61 continues to read as follows:

Authority: Secs. 101, 112, 114, 116, 301, Clean Air Act as amended (42 U.S.C. 7401, 7412, 7414, 7416, 7601).

Subpart M—[Amended]

2. Appendix A is added to subpart M to read as follows:

Appendix A to Subpart M—Interpretive Rule Governing Roof Removal Operations

I. Applicability of the Asbestos NESHAP

1.1. Asbestos-containing material (ACM) is material containing more than one percent asbestos as determined using the methods specified in appendix A, subpart F, 40 CFR part 763, section 1, Polarized Light Microscopy. The NESHAP classifies ACM as either "friable" or "nonfriable". Friable ACM is ACM that, when dry, can be crumbled, pulverized or reduced to powder by hand pressure. Nonfriable ACM is ACM that, when dry, cannot be crumbled, pulverized or reduced to powder by hand pressure.

1.2. Nonfriable ACM is further classified as either Category I ACM or Category II ACM. Category I ACM and Category II ACM are distinguished from each other by their potential to release fibers when damaged. Category I ACM includes asbestos-containing gaskets, packings, resilient floor coverings, resilient floor covering mastic, and asphalt roofing products containing more than one percent asbestos. Asphalt roofing products which may contain asbestos include built-up roofing; asphalt-containing single ply membrane systems; asphalt shingles; asphalt-containing underlayment felts; asphalt-containing roof coatings and mastics; and asphalt-containing base flashings. ACM roofing products that use other bituminous or resinous binders (such as coal tars or pitches) are also considered to be Category I ACM. Category II ACM includes all other nonfriable ACM, for example, asbestos-cement (A/C) shingles, A/C tiles, and transite boards or panels containing more than one percent asbestos. Generally speaking, Category II ACM is more likely to become friable when damaged than is Category I ACM. The applicability of the NESHAP to Category I and II ACM depends on: (1) the condition of the material at the time of demolition or renovation, (2) the nature of the operation to which the material will be subjected, (3) the amount of ACM involved.

1.3. Asbestos-containing material regulated under the NESHAP is referred to as "regulated asbestos-containing material" (RACM). RACM is defined in § 61.141 of the NESHAP and includes: (1) friable asbestos-containing material; (2) Category I nonfriable ACM that has become friable; (3) Category I nonfriable ACM that has been or will be sanded, ground, cut, or abraded; or (4) Category II nonfriable ACM that has already been or is likely to become crumbled, pulverized, or reduced to powder. If the coverage threshold for RACM is met or exceeded in a renovation or demolition operation, then all friable ACM in the operation, and in certain situations, nonfriable ACM in the operation, are subject to the NESHAP.

A. Threshold Amounts of Asbestos-Containing Roofing Material

1.A.1. The NESHAP does not cover roofing projects on single family homes or on residential buildings containing four or fewer dwelling units. 40 CFR 61.141. For other roofing renovation projects, if the total asbestos-containing roof area undergoing renovation is less than 160 ft^2, the NESHAP does not apply, regardless of the removal method to be used, the type of material (Category I or II), or its condition (friable versus nonfriable). 40 CFR 61.145(a)(4). However, EPA would recommend the use of methods that damage asbestos-containing roofing material as little as possible. EPA has determined that where a rotating blade (RB) roof cutter or equipment that similarly damages the roofing material is used to remove Category I nonfriable asbestos-containing roofing material, the removal of 5580 ft^2 of that material will create 160 ft^2 of RACM. For the purposes of this interpretive rule, "RB roof cutter" means an engine-powered roof cutting machine with one or more rotating cutting blades the edges of which are blunt. (Equipment with blades having sharp or tapered edges, and/or which does not use a rotating blade, is used for "slicing" rather than "cutting" the roofing material; such equipment is not included in the term "RB roof cutter".) Therefore, it is EPA's interpretation that when an RB roof cutter or equipment that similarly damages the roofing material is used to remove Category I nonfriable asbestos-containing roofing material, any project that is 5580 ft^2 or greater is subject to the NESHAP; conversely, it is EPA's interpretation that when an RB roof cutter or equipment that similarly damages the roofing material is used to remove Category I nonfriable asbestos-containing roofing material in a roof removal project that is less than 5580 ft^2, the project is not subject to the NESHAP, except that notification is always required for demolitions. EPA further construes the NESHAP to mean that if slicing or other methods that do not sand, grind, cut or abrade will be used on Category I nonfriable ACM, the NESHAP does not apply, regardless of the area of roof to be removed.

1.A.2. For asbestos cement (A/C) shingles (or other Category II roofing material), if the area of the roofing material to be removed is at least 160 ft^2 and the removal methods will crumble, pulverize, reduce to powder, or contaminate with RACM (from other ACM that has been crumbled, pulverized or reduced to powder) 160 ft^2 or more of such roofing material, the removal is subject to the NESHAP. Conversely, if the area of the A/C shingles (or other Category II roofing materials) to be removed is less than 160 ft^2, the removal is not subject to the NESHAP regardless of the removal method used, except that notification is always required for demolitions. 40 CFR 61.145(a). However, EPA would recommend the use of methods that damage asbestos-containing roofing material as little as possible. If A/C shingles (or other Category II roofing materials) are removed without 160 ft^2 or more of such roofing material being crumbled, pulverized, reduced to powder, or contaminated with RACM (from other ACM that has been crumbled, pulverized or reduced to powder), the operation is not subject to the NESHAP, even where the total area of the roofing material to be removed exceeds 160 ft^2; provided, however, that if the renovation includes other operations involving RACM, the roof removal operation is covered if the total area of RACM from all renovation activities exceeds 160 ft^2. *See* the definition of regulated asbestos-containing material (RACM), 40 CFR 61.141.

1.A.3. Only roofing material that meets the definition of ACM can qualify as RACM subject to the NESHAP. Therefore, to determine if a removal operation that meets or exceeds the coverage threshold is subject to the NESHAP, any suspect roofing material (*i.e.* roofing material that may be ACM) should be tested for asbestos. If any such roofing material contains more than one percent asbestos and if the removal operation is covered by the NESHAP, then EPA must be notified and the work practices in § 61.145(c) must be followed. In EPA's view, if a removal operation involves at least the threshold level of suspect material, a roofing contractor may choose not to test for asbestos if the contractor follows the notification and work practice requirements of the NESHAP.

B. A/C Shingle Removal (Category II ACM Removal)

1.B.1. A/C shingles, which are Category II nonfriable ACM, become regulated ACM if the material has a high probability of becoming or has become crumbled, pulverized or reduced to powder by the forces expected to act on the material in the course of demolition or renovation operations. 40 CFR 61.141. However, merely breaking an A/C shingle (or any other category II ACM) that is not friable may not necessarily cause the material to become RACM. A/C shingles are typically nailed to buildings on which they are attached. EPA believes that the extent of breakage that will normally result from carefully removing A/C shingles and lowering the shingles to the ground will not result in crumbling, pulverizing or reducing the shingles to powder. Conversely, the extent of breakage that will normally occur if the A/C shingles are dropped from a building or scraped off of a building with heavy machinery would cause the shingles to become RACM. EPA therefore construes the NESHAP to mean that the removal of A/C shingles that are not friable, using methods that do not crumble, pulverize, or reduce the A/C shingles to powder (such as pry bars, spud bars and shovels to carefully pry the material), is not subject to the NESHAP provided that the A/C shingles are properly handled during and after removal, as discussed in this paragraph and the asbestos NESHAP. This interpretation also applies to other Category II nonfriable asbestos-containing roofing materials.

C. Cutting vs. Slicing and Manual Methods for Removal of Category I ACM

1.C.1. Because of damage to the roofing material, and the potential for fiber release, roof removal operations using rotating blade (RB) roof cutters or other equipment that sand, grind, cut or abrade the roof material are subject to the NESHAP. As EPA interprets the NESHAP, the use of certain manual methods (using equipment such as axes, hatchets, or knives, spud bars, pry bars, and shovels, but not saws) or methods that slice, shear, or punch (using equipment such as a power slicer or power plow) does not constitute "cutting, sanding, grinding or abrading." This is because these methods do not destroy the structural matrix or integrity of the material such that the material is crumbled, pulverized or reduced to powder. Hence, it is EPA's interpretation that when such methods are used, assuming the roof material is not friable, the removal operation is not subject to the regulation.

1.C.2. Power removers or power tear-off machines are typically used to pry the roofing material up from the deck after the roof membrane has been cut. It is EPA's interpretation that when these machines are used to pry roofing material up, their use is not regulated by the NESHAP.

1.C.3. As noted previously, the NESHAP only applies to the removal of asbestos-containing roofing materials. Thus, the NESHAP does not apply to the use of RB cutters to remove non-asbestos built up roofing (BUR). On roofs containing some asbestos-containing and some non-asbestos containing materials, coverage under the NESHAP depends on the methods used to remove each type of material in addition to other coverage thresholds specified above. For example, it is not uncommon for existing roofs to be made of non-asbestos BUR and base flashings that do contain asbestos. In that situation, EPA construes the NESHAP to be inapplicable to the removal of the non-asbestos BUR using an RB cutter so long as the RB cutter is not used to cut 5580 ft² or more of the asbestos-containing base flashing or other asbestos-containing material into sections. In addition, the use of methods that slice, shear, punch or pry could then be used to remove the asbestos flashings and not trigger coverage under the NESHAP.

II. Notification

2.1. Notification for a demolition is always required under the NESHAP. However, EPA believes that few roof removal jobs constitute "demolitions" as defined in the NESHAP (§ 61.141). In particular, it is EPA's view that the removal of roofing systems (i.e., the roof membrane, insulation, surfacing, coatings, flashings, mastic, shingles, and felt underlayment), when such removal is not a part of a demolition project, constitutes a "renovation" under the NESHAP. If the operation is a renovation, and Category I roofing material is being removed using either manual methods or slicing, notification is not required by the NESHAP. If Category II material is not friable and will be removed without crumbling, pulverizing, or reducing it to powder, no notification is required. Also, if the renovation involves less than the threshold area for applicability as discussed above, then no notification is required. However, if a roof removal meets the applicability and threshold requirements under the NESHAP, then EPA (or the delegated agency) must be notified in advance of the removal in accordance with the requirements of § 61.145(b), as follows:

- Notification must be given in writing at least 10 working days in advance and must include the information in § 61.145(b)(4), except for emergency renovations as discussed below.
- The notice must be updated as necessary, including, for example, when the amount of asbestos-containing roofing material reported changes by 20 percent or more.
- EPA must be notified if the start date of the roof removal changes. If the start date of a roof removal project is changed to an earlier date, EPA must be provided with a written notice of the new start date at least 10 working days in advance. If the start date changes to a later date, EPA must be notified by telephone as soon as possible before the original start date and a written notice must be sent as soon as possible.
- For emergency renovations (as defined in § 61.141), where work must begin immediately to avoid safety or public health hazards, equipment damage, or unreasonable financial burden, the notification must be postmarked or delivered to EPA as soon as possible, but no later than the following work day.

III. Emission Control Practices

A. Requirements to Adequately Wet and Discharge No Visible Emission

3.A.1. The principal controls contained in the NESHAP for removal operations include requirements that the affected material be adequately wetted, and that asbestos waste be handled, collected, and disposed of properly. The requirements for disposal of waste materials are discussed separately in section IV below. The emission control requirements discussed in this section III apply only to roof removal operations that are covered by the NESHAP as set forth in Section I above.

3.A.2. For any operation subject to the NESHAP, the regulation (§§ 61.145(c)(2)(i), (3), (6)(i)) requires that RACM be adequately wet (as defined in § 61.141) during the operation that damages or disturbs the asbestos material until collected for disposal.

3.A.3. When using an RB roof cutter (or any other method that sands, grinds, cuts or abrades the roofing material) to remove Category I asbestos-containing roofing material, the emission control requirements of § 61.145(c) apply as discussed in Section I above. EPA will consider a roof removal project to be in compliance with the "adequately wet" and "discharge no visible emission" requirements of the NESHAP if the RB roof cutter is equipped and operated with the following: (1) a blade guard that completely encloses the blade and extends down close to the roof surface; and (2) a device for spraying a fine mist of water inside the blade guard, and which device is in operation during the cutting of the roof.

B. Exemptions From Wetting Requirements

3.B.1. The NESHAP provides that, in certain instances, wetting may not be required during the cutting of Category I asbestos roofing material with an RB roof cutter. If EPA determines in accordance with § 61.145(c)(3)(i), that wetting will unavoidably damage the building, equipment inside the building, or will present a safety hazard while stripping the ACM from a facility component that remains in place, the roof removal operation will be exempted from the requirement to wet during cutting. EPA must have sufficient written information on which to base such a decision. Before proceeding with a dry removal, the contractor must have received EPA's written approval. Such exemptions will be made on a case-by-case basis.

3.B.2. It is EPA's view that, in most instances, exemptions from the wetting requirements are not necessary. Where EPA grants an exemption from wetting because of the potential for damage to the building, damage to equipment within the building or a safety hazard, the NESHAP specifies alternative control methods (§ 61.145(c)(3)(i)(B)). Alternative control methods include (a) the use of local exhaust ventilation systems that capture the dust, and do not produce visible emissions, or (b) methods that are designed and operated in accordance with the requirements of § 61.152, or (c) other methods that have received the written approval of EPA. EPA will consider an alternative emission control method in compliance with the NESHAP if the method has received written approval from EPA and the method is being implemented consistent with the approved procedures (§ 61.145(c)(3)(ii) or § 61.152(b)(3)).

3.B.3. An exemption from wetting is also allowed when the air or roof surface temperature at the point of wetting is below freezing, as specified in § 61.145(c)(7). If freezing temperatures are indicated as the reason for not wetting, records must be kept of the temperature at the beginning, middle and end of the day on which wetting is not performed and the records of temperature must be retained for at least 2 years. 42 CFR § 61.145(c)(7)(iii). It is EPA's interpretation that in such cases, no written application to, or written approval by the Administrator is needed for using emission control methods listed in § 61.145(c)(3)(i)(B), or alternative emission control methods that have been previously approved by the Administrator. However, such written application or approval is required for alternative emission control methods that have not been previously approved. Any dust and debris collected from cutting must still be kept wet and placed in containers. All of the other requirements for notification and waste disposal would continue to apply as described elsewhere in this notice and the Asbestos NESHAP.

C. Waste Collection and Handling

3.C.1. It is EPA's interpretation that waste resulting from slicing and other methods that do not cut, grind, sand or abrade Category I nonfriable asbestos-containing roofing material is not subject to the NESHAP and can be disposed of as nonasbestos waste. EPA further construes the NESHAP to provide that if Category II roofing material (such as A/C shingles) is removed and disposed of

without crumbling, pulverizing, or reducing it to powder, the waste from the removal is not subject to the NESHAP waste disposal requirements. EPA also interprets the NESHAP to be inapplicable to waste resulting from roof removal operations that do not meet or exceed the coverage thresholds described in section I above. Of course, other State, local, or Federal regulations may apply.

3.C.2. It is EPA's interpretation that when an RB roof cutter, or other method that similarly damages the roofing material, is used to cut Category I asbestos containing roofing material, the damaged material from the cut (the sawdust or debris) is considered asbestos containing waste subject to § 61.150 of the NESHAP, provided the coverage thresholds discussed above in section 1 are met or exceeded. This sawdust or debris must be disposed of at a disposal site operated in accordance with the NESHAP. It is also EPA's interpretation of the NESHAP that if the remainder of the roof is free of the sawdust and debris generated by the cutting, or if such sawdust or debris is collected as discussed below in paragraphs 3.C.3, 3.C.4, 3.C.5 and 3.C.6, the remainder of the roof can be disposed of as nonasbestos waste because it is considered to be Category I nonfriable material (as long as the remainder of the roof is in fact nonasbestos material or if it is Category I asbestos material and the removal methods do not further sand, grind, cut or abrade the roof material). EPA further believes that if the roof is not cleaned of such sawdust or debris, *i.e.*, it is contaminated, then it must be treated as asbestos-containing waste material and be handled in accordance with § 61.150.

3.C.3. In order to be in compliance with the NESHAP while using an RB roof cutter (or device that similarly damages the roofing material) to cut Category I asbestos containing roofing material, the dust and debris resulting from the cutting of the roof should be collected as soon as possible after the cutting operation, and kept wet until collected and placed in leak-tight containers. EPA believes that where the blade guard completely encloses the blade and extends down close to the roof surface and is equipped with a device for spraying a fine mist of water inside the blade guard, and the spraying device is in operation during the cutting, most of the dust and debris from cutting will be confined along the cut. The most efficient methods to collect the dust and debris from cutting are to immediately collect or vacuum up the damaged material where it lies along the cut using a filtered vacuum cleaner or debris collector that meets the requirements of 40 CFR 61.152 to clean up as much of the debris as possible, or to gently sweep up the bulk of the debris, and then use a filtered vacuum cleaner that meets the requirements of 40 CFR 61.152 to clean up as much of the remainder of the debris as possible. On smooth surfaced roofs (nonaggregate roofs), sweeping up the debris and then wet wiping the surface may be done in place of using a filtered vacuum cleaner. It is EPA's view that if these decontamination procedures are followed, the remaining roofing material does not have to be collected and disposed of as asbestos waste. Additionally, it is EPA's view that where such decontamination procedures are followed, if the remaining portions of the roof are non-asbestos or Category I nonfriable asbestos material, and if the remaining portions are removed using removal methods that slice, shear, punch or pry, as discussed in section 1.C above, then the remaining portions do not have to be collected and disposed of as asbestos waste and the NESHAP's no visible emissions and adequately wet requirements are not applicable to the removal of the remaining portions. In EPA's interpretation, the failure of a filtered vacuum cleaner or debris collector to collect larger chunks or pieces of damaged roofing material created by the RB roof cutter does not require the remaining roofing material to be handled and disposed of as asbestos waste, provided that such visible chunks or pieces of roofing material are collected (e.g. by gentle sweeping) and disposed of as asbestos waste. Other methods of decontamination may not be adequate, and should be approved by the local delegated agency.

3.C.4. In EPA's interpretation, if the debris from the cutting is not collected immediately, it will be necessary to lightly mist the dust or debris, until it is collected, as discussed above, and placed in containers. The dust or debris should be lightly misted frequently enough to prevent the material from drying, and to prevent airborne emissions, prior to collection as described above. It is EPA's interpretation of the NESHAP that if these procedures are followed, the remaining roofing material does not have to be collected and disposed of as asbestos waste, as long as the remaining roof material is in fact nonasbestos material or if it is Category I asbestos material and the removal methods do not further sand, grind, cut or abrade the roof material.

3.C.5. It is EPA's interpretation that, provided the roofing material is not friable prior to the cutting operation, and provided the roofing material has not been made friable by the cutting operation, the appearance of rough, jagged or damaged edges on the remaining roofing material, due to the use of an RB roof cutter, does not require that such remaining roofing material be handled and disposed of as asbestos waste. In addition, it is also EPA's interpretation that if the sawdust or debris generated by the use of an RB roof cutter has been collected as discussed in paragraphs 3.C.3, 3.C.4 and 3.C.6, the presence of dust along the edge of the remaining roof material does not render such material "friable" for purposes of this interpretive rule or the NESHAP, provided the roofing material is not friable prior to the cutting operation, and provided that the remaining roofing material near the cutline has not been made friable by the cutting operation. Where roofing material near the cutline has been made friable by the use of the RB cutter (*i.e.* where such remaining roofing material near the cutline can be crumbled, pulverized or reduced to powder using hand pressure), it is EPA's interpretation that the use of an encapsulant will ensure that such friable material need not be treated or disposed of as asbestos containing waste material. The encapsulant may be applied to the friable material after the roofing material has been collected into stacks for subsequent disposal as nonasbestos waste. It is EPA's view that if the encapsulation procedure set forth in this paragraph is followed in operations where roofing material near the cutline has been rendered friable by the use of an RB roof cutter, and if the decontamination procedures set forth in paragraph 3.C.3 have been followed, the NESHAP's no visible emissions and adequately wet requirements would be met for the removal, handling and disposal of the remaining roofing material.

3.C.6. As one way to comply with the NESHAP, the dust and debris from cutting can be placed in leak-tight containers, such as plastic bags, and the containers labeled using warning labels required by OSHA (29 CFR 1926.58). In addition, the containers must have labels that identify the waste generator (such as the name of the roofing contractor, abatement contractor, and/or building owner or operator) and the location of the site at which the waste was generated.

IV. Waste Disposal

A. Disposal Requirements

4.A.1. Section 61.150(b) requires that, as soon as is practical, all collected dust and debris from cutting as well as any contaminated roofing squares, must be taken to a landfill that is operated in accordance with § 61.154 or to an EPA-approved site that converts asbestos waste to nonasbestos material in accordance with § 61.155. During the loading and unloading of affected waste, asbestos warning signs must be affixed to the vehicles.

B. Waste Shipment Record

4.B.1. For each load of asbestos waste that is regulated under the NESHAP, a waste shipment record (WSR) must be maintained in accordance with § 61.150(d). Information that must be maintained for each waste load includes the following:

- Name, address, and telephone number of the waste generator
- Name and address of the local, State, or EPA regional office responsible for administering the asbestos NESHAP program
- Quantity of waste in cubic meters (or cubic yards)
- Name and telephone number of the disposal site operator
- Name and physical site location of the disposal site
- Date transported
- Name, address, and telephone number of the transporter(s)
- Certification that the contents meet all government regulations for transport by highways.

4.B.2. The waste generator is responsible for ensuring that a copy of the WSR is delivered to the disposal site along with the waste shipment. If a copy of the WSR signed by the disposal site operator is not returned to the waste generator within 35 days, the waste generator must contact the transporter and/or the disposal site to determine the status of the waste shipment. 40 CFR 61.150(d)(3). If the signed WSR is not received within 45 days, the waste generator must report, in writing, to the responsible

NESHAP program agency and send along a copy of the WSR. 40 CFR 61.150(d)(4). Copies of WSRs, including those signed by the disposal site operator, must be retained for at least 2 years. 40 CFR 61.150(d)(5).

V. Training

5.1. For those roof removals that are subject to the NESHAP, at least one on-site supervisor trained in the provisions of the NESHAP must be present during the removal of the asbestos roofing material. 40 CFR 61.145(c)(8). In EPA's view, this person can be a job foreman, a hired consultant, or someone who can represent the building owner or contractor responsible for the removal. In addition to the initial training requirement, a refresher training course is required every 2 years. The NESHAP training requirements became effective on November 20, 1991.

5.2. Asbestos training courses developed specifically to address compliance with the NESHAP in roofing work, as well as courses developed for other purposes can satisfy this requirement of the NESHAP, as long as the course covers the areas specified in the regulation. EPA believes that Asbestos Hazard Emergency Response Act (AHERA) training courses will, for example, satisfy the NESHAP training requirements. However, nothing in this interpretive rule or in the NESHAP shall be deemed to require that roofing contractors or roofing workers performing operations covered by the NESHAP must be trained or accredited under AHERA, as amended by the Asbestos School Hazard Abatement Reauthorization Act (ASHARA). Likewise, state or local authorities may independently impose additional training, licensing, or accreditation requirements on roofing contractors performing operations covered by the NESHAP, but such additional training, licensing or accreditation is not called for by this interpretive rule or the federal NESHAP.

5.3. For removal of Category I asbestos containing roofing material where RB roof cutters or equipment that similarly damages the asbestos-containing roofing material are used, the NESHAP training requirements (§ 61.145(c)(8)) apply as discussed in Section I above. It is EPA's intention that removal of Category I asbestos-containing roofing material using hatchets, axes, knives, and/or the use of spud bars, pry bars and shovels to lift the roofing material, or similar removal methods that slice, punch, or shear the roof membrane are not subject to the training requirements, since these methods do not cause the roof removal to be subject to the NESHAP. Likewise, it is EPA's intention that roof removal operations involving Category II nonfriable ACM are not subject to the training requirements where such operations are not subject to the NESHAP as discussed in section I above.

[FR Doc. 94–14815 Filed 6–16–94; 8:45 am]

BILLING CODE 6560–50–P3

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 94–5; RM–8420]

Radio Broadcasting Services; Sauk Rapids and Olivia, MN

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document substitutes Channel 269C2 for Channel 269A at Sauk Rapids, Minnesota, and modifies the license for Station WHMH(FM) to specify operation on the higher class channel in response to a petition filed by Tri-County Broadcasting, Inc. See 59 FR 8163, February 18, 1994. The coordinates for Channel 269C2 at Sauk Rapids are 45–32–00 and 94–17–00. To accommodate the upgrade at Sauk Rapids, we shall substitute Channel 261A for Channel 269A at Olivia, Minnesota, and modify the license for Station KOLV to specify operation on Channel 261A. The coordinates for Channel 261A are 44–45–51 and 94–55–45. With this action, this proceeding is terminated.

EFFECTIVE DATE: July 25, 1994.

FOR FURTHER INFORMATION CONTACT: Kathleen Scheuerle, Mass Media Bureau, (202) 634–6530.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Report and Order, MM Docket No. 94–5, adopted June 1, 1994, and released June 10, 1994. The full text of this Commission decision is available for inspection and copying during normal business hours in the Commission's Reference Center (room 239), 1919 M Street NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Services, Inc., 2100 M Street NW., suite 140, Washington, DC 20037, (202) 857–3800.

List of Subjects in 47 CFR Part 73

Radio Broadcasting.

Part 73 of Title 47 of the Code of Federal Regulations is amended as follows:

PART 73—[AMENDED]

1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Minnesota, is amended by removing Channel 269A and adding Channel 269C2 at Sauk Rapids and by removing Channel 269A and adding Channel 261A at Olivia.

Federal Communications Commission.

John A. Karousos,

Acting Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 94–14772 Filed 6–16–94; 8:45 am]

BILLING CODE 6712–01–M

47 CFR Part 73

[MM Docket No. 93–309; RM–8393]

Radio Broadcasting Services; Buhl, MN

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document allots Channel *223C2 to Buhl, Minnesota, and reserves the channel for noncommercial educational use in response to a petition filed by Minnesota Public Radio. See 59 FR 42, January 3, 1994. Canadian concurrence has been obtained for this allotment at coordinates 47–29–37 and 92–46–40. With this action, this proceeding is terminated.

EFFECTIVE DATE: July 25, 1994.

FOR FURTHER INFORMATION CONTACT: Kathleen Scheuerle, Mass Media Bureau, (202) 634–6530.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Report and Order, MM Docket No. 93–309, adopted May 25, 1994, and released June 10, 1994. The full text of this Commission decision is available for inspection and copying during normal business hours in the Commission's Reference Center (Room 239), 1919 M Street, NW, Washington, D.C. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Services, Inc., 2100 M Street, NW., suite 140, Washington, D.C. 20037, (202) 857–3800.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Part 73 of title 47 of the Code of Federal Regulations is amended as follows:

PART 73—[AMENDED]

1. The authority citation for Part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Minnesota, is amended by adding Buhl, Channel *223C2.

Federal Communications Commission.

John A. Karouses,

Acting Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 94–14644 Filed 6–16–94; 8:45 am]

BILLING CODE 6712–01–M

47 CFR Part 73

[MM Docket No. 94–7; RM–8425]

Television Broadcasting Services; Eagle River, WI

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document allots UHF Television Channel 34 to Eagle River, Wisconsin, as that community's first local television service, in response to a petition filed by Lyle Robert Evans d/b/a Eagle River Television Company. See 59 FR 7966, February 17, 1994. Canadian concurrence has been obtained for this allotment at coordinates 45–55–00 and 89–14–42. With this action, this proceeding is terminated.

EFFECTIVE DATE: July 25, 1994.

FOR FURTHER INFORMATION CONTACT: Kathleen Scheuerle, Mass Media Bureau, (202) 634–6530.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Report and Order, MM Docket No. 94–7, adopted May 25, 1994, and released June 10, 1994. The full text of this Commission decision is available for inspection and copying during normal business hours in the Commission's Reference Center (Room 239), 1919 M Street NW, Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Services, Inc., 2100 M Street NW, Suite 140, Washington, DC 20037, (202) 857–3800.

List of Subjects in 47 CFR Part 73

Television broadcasting.

Part 73 of Title 47 of the Code of Federal Regulations is amended as follows:

PART 73—[AMENDED]

1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303.

§ 73.606 [Amended]

2. Section 73.606(b), the Table of TV Allotments under Wisconsin, is amended by adding [Eagle River,] Channel 34.

Federal Communications Commission.

John A. Karouses,

Acting Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 94–14645 Filed 6–16–94; 8:45 am]

BILLING CODE 6712–01–M

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 541

[Docket No. T84–01; Notice 35]

RIN 2127–AF34

Final Listing of High Theft Lines for 1995 Model Year; Motor Vehicle Theft Prevention Standard

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Final rule.

SUMMARY: This final rule reports the results of NHTSA's determinations of high-theft car lines that are subject to the parts-making requirements of the motor vehicle theft prevention standard, and high-theft car lines that are exempted from parts marking, for Model Year 1995. This action is pursuant to the Motor Vehicle Information and Cost Savings Act, which provides that NHTSA select high-theft lines, with the agreement of the manufacturer, if possible. This final listing is intended to inform the public, particularly law enforcement groups, of the car lines that are subject to the parts-marking requirements of the theft prevention standard for Model Year 1995.

EFFECTIVE DATE: The amendment made by this final rule is effective July 18, 1994.

FOR FURTHER INFORMATION CONTACT: Ms. Barbara A. Gray, Office of Market Incentives, NHTSA, 400 Seventh Street, SW., Washington, DC 20590. Ms. Gray's telephone number is (202) 366–1740.

SUPPLEMENTARY INFORMATION: The Federal Motor Vehicle Theft Prevention Standard, 49 CFR part 541, sets forth requirements for inscribing or affixing identification numbers onto covered original equipment major parts, and the replacement parts for those original equipment parts, on all vehicles in lines selected as high-theft lines.

Section 603(a)(2) of the Motor Vehicle Information and Cost Savings Act (15 U.S.C. 2023(a)(2)) (hereinafter "the Cost Savings Act") specifies that NHTSA shall select the high-theft lines, with the agreement of the manufacturer, if possible. Section 603(d) of the Cost Savings Act (15 U.S.C. 2023(d)) provides that once a line has been designated as a high-theft line, it remains subject to the theft prevention standard unless that line is exempted under section 605 of the Cost Savings Act (15 U.S.C. 2025). Section 605 provides that a manufacturer may petition to have a high theft line exempted from the requirements of section 602, if the line is equipped with an antitheft device as standard equipment. The exemption is granted if NHTSA determines that the antitheft device is likely to be as effective as compliance with the theft prevention standard in reducing and deterring motor vehicle thefts.

The agency annually publishes the names of the lines which were previously listed as high-theft lines and of the lines which are being listed for the first time and will be subject to the theft prevention standard beginning with Model Year 1995. It also identifies those car lines that are exempted from the theft prevention standard for the 1995 model year because of standard equipment antitheft devices.

For Model Year 1995, two car lines, the General Motors Oldsmobile Toronado and the Mazda Amati 800 were renamed as the Oldsmobile Aurora and the Mazda Millenia, respectively. Also, the Plymouth Sundance and Dodge Shadow have been renamed the Plymouth and Dodge Neon car lines. These two lines were listed in the MY 1994 Final Listing of High Theft Lines. Unfortunately, Chrysler did not inform the agency of the new nameplates for these lines until after the publication of the **Federal Register** (58 FR 63296), announcing the high-theft lines. This name change became effective beginning with the 1994 model year. The updated list reflects these name changes. Additionally, for Model Year 1995, the agency selected seven new car lines, in accordance with the procedures published in 49 CFR part 542, as likely to be high-theft lines. The newly selected lines are: The Chrysler Cirrus, Chrysler Sebring, Dodge Avenger, Dodge Stratus, Honda Acura (nameplate to be announced), Subaru Legacy, which was erroneously listed in the **Federal Register** (58 FR 63298) as a new car line for MY 1994, and the Toyota Avalon. In addition to these seven lines, the list of high-theft lines includes all those lines that were selected as high-theft lines and listed for prior model years.

The list of exempted lines includes five high-theft lines exempted by the Agency, beginning with Model Year 1995, from the parts-marking requirements of part 541. The five car lines exempted in full are the Buick Riviera, Oldsmobile Aurora, Mazda

Millenia, Volkswagen Cabriolet, and Volkswagen Corrado. Additionally, Toyota requested that the agency lists its Lexus car lines without its 3-digit engine identifier. Therefore, the updated list reflects this request.

Notice and Comment; Effective Date

The car lines listed as being subject to the parts-marking standard have previously been selected as high-theft lines in accordance with the procedures of 49 CFR part 542 and section 603 of the Cost Savings Act. Under these procedures, manufacturers evaluate new car lines to conclude whether those new lines are likely to be high-theft lines. Manufacturers submit these evaluations and conclusions to the agency, which makes an independent evaluation, and, on a preliminary basis, determines whether the new line should be subject to parts marking. NHTSA informs the manufacturer in writing of its evaluations and determinations, together with the factual information considered by the agency in making them. The manufacturer may request the agency to reconsider these preliminary determinations. Within 60 days of the receipt of the request, NHTSA makes its final determination. NHTSA informs the manufacturer by letter of these determinations and its response to the request for reconsideration. If there is no request for reconsideration, the agency's determination becomes final 45 days after sending the letter with the preliminary determination. Each of the new car lines on the high-theft list is the subject of a prior final determination.

Similarly, the car lines listed as being exempt from the standard have previously been exempted in accordance with the procedures of 49 CFR part 543 and section 605 of the Cost Savings Act.

Therefore, NHTSA finds for good cause that notice and opportunity for comment on these listings are unnecessary. Further, public comment on the listings of selections and exemptions is not contemplated by Title VI, and is unnecessary since the selections and exemptions have previously been made in accordance with the statutory criteria and procedure.

For the same reasons, since this revised listing only informs the public of previous agency actions and does not impose any additional obligations on any party, NHTSA finds for good cause that the amendment made by this notice should be effective as soon as it is published in the **Federal Register**.

Regulatory Impacts

1. Costs and Other Impacts

NHTSA has analyzed this rule and determined that is not "significant" within the meaning of the Department of Transportation's regulatory policies and procedures. The agency has also considered this notice under Executive Order 12866. As already noted, the selections in this final rule have previously been made in accordance with the provisions of the Cost Savings Act, and the manufacturers of the selected lines have already been informed that those lines are subject to the requirements of part 541 for Model Year 1995. Further, this listing does not actually exempt lines from the requirements of part 541; it only informs the general public of all such previously granted exemptions. Since the only purpose of this final listing is to inform the public of prior action for Model Year 1995, a full regulatory evaluation has not been prepared.

2. Regulatory Flexibility Act

The agency has also considered the effects of this listing under the Regulatory Flexibility Act. I hereby certify that this rule will not have a significant economic impact on a substantial number of small entities. As noted above, the effect of this final rule is simply to inform the public of those lines that are subject to the requirements of part 541 for Model Year 1995. The agency believes that listing of this information will not have any economic impact on small entities.

3. Environmental Impacts

In accordance with the National Environmental Policy Act of 1969, the agency has considered the environmental impacts of this rule, and determined that it will not have any significant impact on the quality of the human environment.

4. Federalism

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 12612, and it has been determined that this final rule does not have sufficient Federalism implications to warrant the preparation of a Federalism Assessment.

5. Civil Justice Reform

This final rule does not have a retroactive effect and it does not preempt any state law. Section 613 of the Motor Vehicle Information and Cost Savings Act (15 U.S.C. 2030) provides that judicial review of this rule may be obtained pursuant to section 504 of the Cost Savings Act (15 U.S.C. 2004). The Cost Savings Act does not require submission of a petition for reconsideration or other administrative proceedings before parties may file suit in court.

List of Subjects in 49 CFR Part 541

Administrative practice and procedure, Labeling, Motor vehicles, Reporting and recordkeeping requirements.

PART 541—[AMENDED]

In consideration of the foregoing, 49 CFR part 541 is amended as follows:

1. The authority citation for part 541 continues to read as follows:

Authority: 15 U.S.C. 2021–2024 and 2026; delegation of authority at 49 CFR 1.50.

2. In part 541, Appendix A, Appendix A–I, and Appendix A–II are revised to read as follows:

APPENDIX A—LINES SUBJECT TO THE REQUIREMENTS OF THIS STANDARD

Manufacturer	Subject lines
Alfa Romeo	Milano 161.
	Fiat 164.
BMW	3 Car Line.
	5 Car Line.
	6 Car Line.
Chrysler	Chrysler Cirrus.[1]
	Chrysler Executive Sedan/Limousine.
	Chrysler Fifth Avenue/Newport.
	Chrysler Laser.
	Chrysler LeBaron/Town & Country.
	Chrysler LeBaron GTS.
	Chrysler's TC.
	Chrysler New Yorker Fifth Avenue.
	Chrysler Sebring.[1]
	Dodge 600.
	Dodge Aries.
	Dodge Avenger.[1]
	Dodge Colt.
	Dodge Daytona.
	Dodge Diplomat.
	Dodge Lancer.
	Dodge Neon.[2]
	Dodge Stealth.
	Dodge Stratus.[1]
	Eagle Summit.
	Eagle Talon.
	Plymouth Caravelle.
	Plymouth Colt.
	Plymouth Laser.
	Plymouth Gran Fury.
	Plymouth Neon.[2]
	Plymouth Reliant.
Consulier	Consulier GTP.
Ferrari	Mondial 8.
	308.
	328.
Ford	Ford Mustang.
	Ford Thunderbird.
	Ford Probe.

APPENDIX A—LINES SUBJECT TO THE REQUIREMENTS OF THIS STANDARD—Continued

Manufacturer	Subject lines
	Mercury Capri.
	Mercury Cougar.
	Lincoln Continental.
	Lincoln Mark.
	Lincoln Town Car.
	Merkur Scorpio.
	Merkur XR4Ti.
General Motors	Buick Electra.
	Buick Reatta.
	Buick Regal.
	Chevrolet Nova.
	Chevrolet Lumina.
	Chevrolet Monte Carlo.
	Oldsmobile Cutlass Supreme.
	Pontiac Fiero.
	Pontiac Grand Prix.
	Geo Prizm.
	Geo Storm.
	Saturn Sports Coupe.
Honda	Acura (nameplate to be announced).[1]
Isuzu	Impulse.
	Stylus.
Jaguar	XJ.
	XJ–6.
	XJ–40.
Lotus	Elan.
Maserati	Biturbo.
	Quattroporte.
	228.
Mazda	GLC.
	626.
	MX–6.
	MX–5 Miata.
	MX–3.
Mercedes-Benz	190 D.
	190 E.
	250 D–T.
	260 E.
	300 SE.
	300 TD.
	300 SDL.
	300 SEC/500 SEC.
	300 SEL/500 SEL.
	420 SEL.
	560 SEL.
	560 SEC.
	560 SL.
Mitsubishi	Cordia.
	Eclipse.
	Mirage.
	Tredia.
	3000GT.
Peugeot	405.
Porsche	924S.
Subaru	XT.
	SVX.
	Legacy.[1]
Toyota	Avalon.[1]
	Camry.
	Celica.
	Corolla/Corolla Sport.
	MR2.
	Starlet.

APPENDIX A—LINES SUBJECT TO THE REQUIREMENTS OF THIS STANDARD—Continued

Manufacturer	Subject lines
Volkswagen	Audi Quattro.
	Rabbit.
	Scirocco.

[1] Car lines added for Model Year 1995.
[2] The Dodge and Plymouth Neon car lines replaced the Dodge Shadow and Plymouth Sundance car lines beginning with MY 1994.

APPENDIX A–I—HIGH-THEFT LINES WITH ANTITHEFT DEVICES WHICH ARE EXEMPTED FROM THE PARTS-MARKING REQUIREMENTS OF THIS STANDARD PURSUANT TO 49 CFR PART 543

Manufacturer	Subject lines
Austin Rover	Sterling.
BMW	7 Car Line.
	8 Car Line.
Chrysler	Chrysler Conquest.
	Imperial.
General Motors	Buick Riviera.[1]
	Cadillac Allante.
	Chevrolet Corvette.
	Oldsmobile Aurora.[1 2]
	Oldsmobile Toronado (MYs 1987–1994).
Honda	Acura NS–X.
	Acura Legend.
	Acura Vigor.
Isuzu	Impulse (MYs 1987–1991).
Mazda	929.
	RX–7
	Amati 1000.
	Millenia.[2]
Mercedes-Benz	124 Carline (the models within this line are):
	300D.
	300E.
	300CE.
	300TE.
	400E.
	500E.
	129 Carline (the models within this line are):
	300SL.
	500SL.
	600SL.
Mitsubishi	Galant.
	Starion.
	Diamante.
Nissan	Maxima.
	300 ZX.
	Infiniti M30.
	Infiniti Q45.
	Infiniti J30.
Porsche	911.
	928.
	968.
Saab	900.
	9000.
Toyota	Cressida.
	Supra.
	Lexus ES.

APPENDIX A–I—HIGH-THEFT LINES WITH ANTITHEFT DEVICES WHICH ARE EXEMPTED FROM THE PARTS-MARKING REQUIREMENTS OF THIS STANDARD PURSUANT TO 49 CFR PART 543—Continued

Manufacturer	Subject lines
	Lexus GS.
	Lexus LS.
	Lexus SC.
Volkswagen	Audi 5000S.
	Audi 100.
	Audi 200.
	Cabriolet.[1]
	Corrado.[1]
	Jetta III.

[1] Lines exempted in full from the requirements of Part 541 pursuant to 49 CFR Part 543, beginning from MY 1995.
[2] The Oldsmobile Toronado was renamed the Oldsmobile Auroia, and the Mazda Amati 800 was renamed the Mazda Millenia beginning with the 1995 model year.

APPENDIX A–II—HIGH-THEFT LINES WITH ANTITHEFT DEVICES WHICH ARE EXEMPTED IN PART FROM THE PARTS-MARKING REQUIREMENTS OF THIS STANDARD PURSUANT TO 49 CFR PART 543

Manufacturer	Subject lines	Parts to be marked
General Motors.	Chevrolet Camaro.	Engine, Transmission.
	Pontiac Firebird ..	Engine, Transmission.
	Cadillac Deville ..	Engine, Transmission.
	Cadillac Eldorado	Engine, Transmission.
	Cadillac Seville ..	Engine, Transmission.
	Cadillac Sixty Special.	Engine, Transmission.
	Oldsmobile 98	Engine, Transmission.
	Buick Park Avenue.	Engine, Transmission.
	Pontiac Bonneville.	Engine, Transmission.
	Buick LeSabre ...	Engine, Transmission.
	Oldsmobile 88 Royale.	Engine, Transmission.

Issued on: June 9, 1994.

Christopher A. Hart,

Deputy Administrator.

[FR Doc. 94–14382 Filed 6–16–94; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Parts 216 and 229

[Docket No. 950542–4142; I.D. 050394B]

Interim Exemption for Commercial Fisheries

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final rule.

SUMMARY: NMFS issues this final rule to reinstate the regulations implementing the interim exemption from the general prohibition on taking marine mammals in the Marine Mammal Protection Act (MMPA) for certain incidental takings of marine mammals by commercial fishermen until September 1, 1995, or until superseded by regulations prescribed under section 118 of the MMPA. This reinstatement is required by section 114 of the MMPA, as amended by section 15 of the MMPA Amendments of 1994.

EFFECTIVE DATE: This rule is effective on June 17, 1994 through September 1, 1995.

ADDRESSES: Office of Protected Resources, National Marine Fisheries Service, 1335 East-West Highway, Silver Spring, MD 20910.

FOR FURTHER INFORMATION CONTACT: Thomas C. Eagle, 301–713–2319 or Patricia A. Montanio, 301–713–2322.

SUPPLEMENTARY INFORMATION: The 1988 amendments to the MMPA directed the Secretary of Commerce to implement an interim exemption from the general prohibition on taking marine mammals in the MMPA for certain incidental takings by commercial fishermen during the period November 23, 1988, through October 1, 1993, while a permanent regime to govern interactions between marine mammals and commercial fishing operations was developed. Congress subsequently extended the interim exemption until May 1, 1994. For background on this issue, refer to earlier regulatory actions (56 FR 23958, May 24, 1991; 57 FR 59832, December 16, 1992; 58 FR 51788, October 5, 1993; and 59 FR 17048, April 11, 1994).

The MMPA Amendments of 1994, Public Law 103–238, among other things, amended the MMPA by adding a new section 118 to establish a permanent regime to govern interactions between marine mammals and commercial fishing operations. Section 15 of the MMPA Amendments of 1994 amended section 114(a) of the MMPA to extend the interim exemption through September 1, 1995, or until superseded by regulations prescribed under new section 118 implementing the new regime, whichever is earlier.

Due to an administrative delay, 50 CFR part 229, the regulations implementing the interim exemption, expired on May 1, 1994, and now must be reissued. This final rule reinstates those regulations until September 1, 1995, unless they are superseded earlier by regulations implementing new section 118. The reissued regulations are identical to those that expired except for changes in the addresses of the Southwest and Southeast Regions, NMFS. This reinstatement is required by section 114 of the MMPA, as amended by section 15 of the MMPA Amendments of 1994. This rule also amends a note in 50 CFR part 216 to conform to a cross reference from part 50 CFR part 229.

Classification

This rule is not significant for purposes of E.O. 12866. Under section 114 of the MMPA, as amended by Public Law 103–238, the interim extension was extended until September 1, 1995, or until superseded by regulations prescribed under new section 118, whichever is earlier. This rule merely reinstates the regulations which, through administrative delay, were allowed to lapse. The lapsed regulations were subject to full notice and opportunity-for-public-comment procedures and no useful purpose would be served by delaying their reinstatement to provide notice and opportunity for public comment. Full notice and opportunity for public comments will be provided for the section 118 regulations presently being developed. Further, to delay reinstatement of the interim exemption regulations would be inconsistent with section 114 whose clear intent was to have the exemption and its implementing regulations continue to avoid any disruption to our commercial fisheries. Accordingly, the Assistant Administrator for Fisheries, under section 553(b)(B) of the Administrative Procedure Act (APA), 5 U.S.C. 553(b)(B), finds, for good cause, that providing notice and opportunity for public comment is unnecessary and would be contrary to the public interest. Because reinstatement of the regulations relieves a restriction of commercial fisheries, under section 553(d)(1) of the APA, 5 U.S.C. 553(d)(1), this rule is not subject to a 30-day delay in effective date.

List of Subjects

50 CFR Part 216

Administrative practice and procedure, Imports, Indians, Marine mammals, Penalties, Reporting and recordkeeping requirements, Transportation.

50 CFR Part 229

Administrative practice and procedure, Confidential business information, Fisheries, Marine mammals, Reporting and recordkeeping requirements.

Dated: June 7, 1994.

Charles Karnella,

Acting Program Management Officer, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR parts 216 and 229 are amended as follows:

PART 216—REGULATIONS GOVERNING THE TAKING AND IMPORTING OF MARINE MAMMALS

1. The authority for part 216 continues to read as follows:

Authority: 16 U.S.C. 1361 *et seq.*, unless otherwise noted.

§ 216.24 [Amended]

2. Section 216.24 is amended in the note by revising the phrase "November 23, 1988, through October 1, 1993." to read "June 17, 1994 through September 1, 1995."

3. Part 229 is added to read as follows:

Subpart A—General Provisions

Sec.

Subpart B—Emergency and Special Regulations [Reserved]

Authority: 16 U.S.C. 1361 *et seq.*, unless otherwise noted.

Subpart A—General Provisions

§ 229.1 Purpose and scope.

(a) The regulations in this part implement section 114 of the Marine Mammal Protection Act of 1972, as amended, 16 U.S.C. 1384, Public Law 100–711, which provides for a 5-year exemption from the Act's prohibition on the taking of marine mammals incidental to certain commercial fishing operations.

(b) The provisions of section 114 of the Marine Mammal Protection Act of 1972, rather than sections 101, 103 and 104, will govern the incidental taking of marine mammals in the course of commercial fishing operations by persons using vessels of the United States, other than vessels used in the eastern tropical Pacific tuna purse seine fishery, and vessels which have valid fishing permits issued in accordance with section 204(b) of the Magnuson Fishery Conservation and Management Act (16 U.S.C. 1824(b)) for the period from November 23, 1988, through September 1, 1995, or until superseded by regulations prescribed under section 118, whichever is earlier. Therefore, the regulations in this part supersede until September 1, 1995, or until superseded by regulations prescribed under section 118, whichever is earlier, the other provisions for granting incidental take authority to these commercial fishermen, including regulations at § 216.24 of this chapter and guidelines on the taking of small numbers of marine mammals incidental to commercial fishing operations. (See § 216.24 of this chapter).

§ 229.2 Definitions.

In addition to the definitions contained in the Act and unless the context otherwise requires, in this part 229:

(a) *Act* means the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*).

(b) *Assistant Administrator* means the Assistant Administrator for Fisheries, National Marine Fisheries Service, National Oceanic and Atmospheric Administration, or authorized representative.

(c) *Category I fishery* means a commercial fishery determined by the Assistant Administrator to have a frequent incidental taking of marine mammals and identified as such in the List of Fisheries.

(d) *Category II fishery* means a commercial fishery determined by the Assistant Administrator to have an occasional incidental taking of marine mammals and identified as such in the List of Fisheries.

(e) *Category III fishery* means a commercial fishery determined by the Assistant Administrator to have a remote likelihood of, or no known incidental taking of, marine mammals and identified as such in the List of Fisheries. Eligible commercial fisheries not specifically identified as Category I or II fisheries are deemed to be Category III fisheries.

(f) *Certificate* or *Exemption Certificate* means a document issued by the Assistant Administrator under the authority of section 114 of the Act that authorizes the incidental taking of marine mammals and that specifies the terms and conditions of the authorized incidental taking, including any document that modifies the Exemption Certificate.

(g) *Commercial fishing operation* means the catching, taking or harvesting of fish from the marine environment (or other areas where marine mammals occur) as part of an ongoing for-profit business enterprise. The term includes licensed commercial passenger fishing vessel (as defined in § 216.3 of this chapter) activities.

(h) *Depleted species* means any species or population which has been determined to be depleted under the Act and is listed in § 216.15 of this chapter or part 18, subpart E of this title or any endangered or threatened species of marine mammal.

(i) *Endangered or threatened species* means any species, subspecies or population that has been listed under section 4 of the Endangered Species Act of 1973. A list of endangered and threatened species is found in §§ 17.11 through 17.12 of this title.

(j)(1) *Fishing vessel* or "vessel" means any vessel, boat, ship, or other craft which is used for, equipped to be used for, or of a type which is normally used for:

(i) Fishing; or

(ii) Aiding or assisting one or more vessels at sea in the performance of any activity relating to fishing, including, but not limited to, preparation, supply, storage, refrigeration, transportation, or processing.

(2) Fishing vessel or vessel refers only to vessels of the United States, other than vessels used in the eastern tropical Pacific yellowfin tuna purse seine fishery, and vessels which have valid fishing permits issued in accordance with section 204(b) of the Magnuson Fishery Conservation and Management Act.

(k) *Incidental take* means the accidental or intentional taking of a marine mammal in the course of commercial fishing operations.

(l) *List of Fisheries* means the most recent final list of commercial fisheries published in the **Federal Register** by the Assistant Administrator, categorized according to the frequency of incidental taking of marine mammals, in accordance with the criteria in § 229.3 of this chapter.

(m) *Marine mammal* means any mammal which:

(1) Is morphologically adapted to the marine environment, including sea otters and members of the orders Cetacea (whales and dolphins), Sirenia (dugongs and manatees) and suborder Pinnipedia (seals, sea lions and walrus); or

(2) Primarily inhabits the marine environment (such as the polar bear).

(n) *Non-vessel fishery* means a commercial fishing operation that uses fixed or other gear without a vessel, such as gear used in set gillnet, trap, beach seine, weir, ranch and pen fisheries.

(o) *Observer* means a qualified individual designated by the National Marine Fisheries Service to record the incidence of marine mammal interaction and other scientific data during commercial fishing activities.

(p) *Vessel owner* means the owner of:

(1) A fishing vessel which is engaged in a commercial fishing operation; or

(2) Fixed or other commercial fishing gear that is used in a non-vessel fishery.

§ 229.3 Criteria for categorizing fisheries.

(a) *Publication.* (1) The Assistant Administrator will publish in the **Federal Register** notice of a proposed revised List of Fisheries on or about July 1, 1990, 1991 and 1992, for the purpose of receiving public comment. On or about October 1, 1990, 1991, and 1992, the Assistant Administrator will publish a final revised List of Fisheries which will become effective January 1 of the next calendar year.

(2) The proposed and final revised List of Fisheries will:

(i) Categorize each commercial fishery according to the criteria set forth in paragraph (b) of this section; and

(ii) List the marine mammals and the estimated number of vessels or persons involved in each commercial fishery.

(3) The Assistant Administrator may publish a revised List of Fisheries at other times, after notice and opportunity for public comment. The revised final List of Fisheries will become effective no sooner than 30 days after publication in the **Federal Register**.

(b) *Categories.* The List of Fisheries will be revised and commercial fisheries will be categorized into Category I, Category II or Category III according to the following criteria. In evaluating incidental takes for purposes of categorizing fisheries, the Assistant Administrator will consider the definition of take in section 3 of the Act, the language of section 114 of the Act and the legislative history of the 1988 amendments.

(1) *Category I.* (i)(A) There is documented information indicating a "frequent" incidental taking of marine mammals in the fishery; or

(B) Congress intended that the fishery should be placed in Category I and there

is no documented information indicating that it should be placed in another Category.

(ii) "Frequent" means that it is highly likely that more than one marine mammal will be incidentally taken by a randomly selected vessel in the fishery during a 20-day period.

(2) *Category II.* (i)(A) There is documented information indicating an "occasional" incidental taking of marine mammals in the fishery; or

(B) In the absence of information indicating the frequency of incidental taking of marine mammals, other factors such as fishing techniques, gear used, methods used to deter marine mammals, target species, seasons and areas fished, and species and distribution of marine mammals in the area suggest there is a likelihood of at least an "occasional" incidental taking in the fishery.

(ii) "Occasional" means that there is some likelihood that one marine mammal will be incidentally taken by a randomly selected vessel in the fishery during a 20-day period, but that there is little likelihood that more than one marine mammal will be incidentally taken.

(3) *Category III.* (i)(A) There is information indicating no more than a "remote likelihood" of an incidental taking of a marine mammal in the fishery;

(B) In the absence of information indicating the frequency of incidental taking of marine mammals, other factors such as fishing techniques, gear used, methods used to deter marine mammals, target species, seasons and areas fished, and species and distribution of marine mammals in the area suggest there is no more than a remote likelihood of an incidental take in the fishery; or

(C) Congress intended that the fishery should be placed in Category III and there is not documented information indicating that it should be placed in another Category.

(ii) "Remote likelihood" means that it is highly unlikely that any marine mammal will be incidentally taken by a randomly selected vessel in the fishery during a 20-day period.

§ 229.4 Prohibitions.

(a) *Prohibited activities.* (1) It is unlawful for a commercial fishing vessel, a vessel owner, or a master or operator of a vessel to engage in a Category I or II fishery unless the vessel owner or authorized representative has complied with the requirements pertaining to registration, Exemption Certificates, decals and reports as contained in this part 229.

(2) It is unlawful to assault, harm, oppose, impede, intimidate, impair or in any way interfere with an observer or the observations being carried out.

(b) *Prohibited taking.* (1) Except as otherwise provided in part 17 of this title, part 216 of this chapter or this part 229, it is unlawful to take any marine mammal incidental to commercial fishing operations.

(2) Under this part 229, it is unlawful to:

(i)(A) Take any southern (California) sea otter; or

(B) Intentionally lethally take any Steller sea lion, any Alaskan sea otter, any cetacean, any depleted species (including the Pribilof Island population of North Pacific fur seal), or any endangered or threatened marine mammal.

(ii) If the use of firearms or other means to deter marine mammals results in an injury or mortality of a marine mammal, the taking is presumed to be an intentional lethal taking.

(3) Exemptions under this part 229 apply only to prohibitions under the Marine Mammal Protection Act and do not apply to prohibitions under the Endangered Species Act of 1973. To be exempt from the taking prohibitions under the Endangered Species Act, specific authority under that Act is required.

(c) *Other prohibitions.* It is unlawful to violate any other provision of these regulations or the terms and conditions of Exemption Certificates.

§ 229.5 Registrations for Category I and II fisheries.

(a) *Registrations.* To engage lawfully in a Category I or II fishery after July 21, 1989, the vessel owner or authorized representative of the vessel owner must register for and receive an Exemption Certificate or annual renewal. Registrations should be submitted at least 30 days prior to the vessel engaging in a Category I or II fishery. The following information is required to register:

(1) Name, address, and phone number of vessel owner;

(2) Name and address of operator, if different from owner;

(3) Vessel name, length and home port; state commercial vessel license number, Coast Guard documentation number, state registration number, and/or Tribal plaque number, where appropriate;

(4) A list of all Category I and II fisheries that the vessel is expected to participate in during the calendar year (or during 1989 and 1990, if the registration is made during 1989), and the estimated number of trips from port for each fishery; and

(5) A certification, signed and dated by the vessel owner or authorized representative, as follows: "I hereby certify under penalty of perjury that I am the owner of the vessel or that I am authorized to register for this exemption on behalf of the owner, that I have reviewed all information contained on this document, and that it is true and complete to the best of my knowledge."

(b) *Fee.* A check or money order made payable to NOAA, National Marine Fisheries Service, in the amount of $30.00 must accompany each registration or renewal. For good cause, the Assistant Administrator may waive the fee requirement.

(c) *Address.* Registrations and requests for registration forms should be sent to the Director, Office of Protected Resources, National Marine Fisheries Service, National Oceanic and Atmospheric Administration, 1335 East West Highway, Silver Spring, MD 20910; telephone: 301–713–2319; or one of the following Regional Offices:

(1) Director, Alaska Region, National Marine Fisheries Service, P.O. Box 21668, 709 West 9th Street, Juneau, AK 99802; telephone: 907–586–7233;

(2) Director, Northwest Region, National Marine Fisheries Service, 7600 Sand Point Way NE., Seattle, WA 98115–0070; telephone: 206–526–6110;

(3) Director, Southwest Region, National Marine Fisheries Service, 501 West Ocean Blvd., Suite 4200, Long Beach, CA 90802–4213; telephone: 310–980–4001;

(4) Director, Northeast Region, National Marine Fisheries Service, 1 Blackburn Drive, Gloucester, MA 01930; telephone: 508–281–9328; or

(5) Director, Southeast Region, National Marine Fisheries Service, 9721 Executive Center Drive, St. Petersburg, FL 33702; telephone: 813–893–3141.

§ 229.6 Issuance of Exemption Certificates.

(a) *Criteria.* After receipt of a completed initial registration and required fee, an Exemption Certificate and decal will be issued to the vessel owner. If the Certificate and decal are issued in 1989, a 1990 annual sticker for the decal will be automatically issued upon receipt of required report(s) for 1989. The Exemption Certificate will be renewed and an annual sticker issued after receipt of an updated registration, required fee and required report(s) covering all registered Category I and II fisheries. An interim report should be submitted with the renewal request if fishing under the current Exemption Certificate will not be completed by December 31.

(b) *Possession of Certificates and decals.* (1) The decal and, after 1989, a current annual sticker must be attached

to the vessel port side on the cabin or, in the absence of a cabin, port side forward on the hull, and must be free of obstruction and in good condition. A decal is not required for non-vessel fisheries.

(2) The Exemption Certificate or valid copy must be on board the vessel while it is operating in a Category I or II fishery, or, in the case of non-vessel fisheries, the Certificate or valid copy must be in the possession of the person in charge of the fishing operation. The Certificate or valid copy must be made available upon request to any state or Federal enforcement agent authorized to enforce the Act or to any designated agent of the National Marine Fisheries Service.

(c) *Terms and conditions.* (1) Certificates will expire at the end of the calendar year, except that Certificates issued in 1989 will expire at the end of 1990. After 1989, a current annual sticker is required for a decal to be valid.

(2) *Reports.* (i) All Exemption Certificate holders must ensure that a daily log of fishing effort and incidental takes of marine mammals is accurately maintained on board the fishing vessel in such form as prescribed by the Assistant Administrator for Fisheries. Fishermen must complete an entry on the report/log form each day they fish. Marine mammal report/log forms require information on: The fishery, fishing effort, gear type and fish species involved; the marine mammal species (or description of the animal(s), if species is not known), number, date, and location of marine mammal incidental takes; type of interaction and any injury to the marine mammal; a description of any intentional takes (i.e., efforts to deter animals to protect gear, catch, or human life by non-lethal or lethal means); and any loss of fish or gear caused by marine mammals. With prior approval by the Assistant Administrator for Fisheries, National Marine Fisheries Service, alternate report/log forms, such as forms issued by individual states, Fishery Management Councils, or Indian Governments, which collect the same information required by the National Marine Fisheries Service, are acceptable.

(ii) A current report/log must be kept on board and must be made available for inspection upon request by any state or Federal enforcement agent authorized to enforce the Act or any designated agent of the National Marine Fisheries Service.

(iii) An annual report, consisting of a copy of the required log, must be submitted to the National Marine Fisheries Service no later than December 31 of each year covering all Categories I and II fisheries for which the Exemption Certificate holder is registered. This log shall include information for all Categories I and II fisheries for which each Exemption Certificate holder is registered, whether or not any marine mammals were taken. If a fishing vessel was not used in a Category I or Category II fishery during an exemption period for which it was registered, a report to that effect must be submitted.

(3) *Observer requirements.* (i) If requested by the National Marine Fisheries Service, a Certificate holder engaged in a Category I fishery must take on board an observer to accompany the vessel on any or all fishing trips in a fishing season.

(ii) After being notified by the National Marine Fisheries Service that the vessel is required to carry an observer, the Certificate holder must comply with the notification by providing the specified information within the specified time on scheduled or anticipated fishing trips to facilitate observer placement.

(iii) The National Marine Fisheries Service may waive the observer requirement based on a finding that the facilities for housing the observer or for carrying out observer functions are so inadequate or unsafe that the health or safety of the observer or the safe operation of the vessel would be jeopardized.

(iv) The Certificate holder, master and crew must cooperate with the observer in the performance of the observer's duties including:

(A) Providing adequate accommodations;

(B) Allowing for the embarking and debarking of the observer as specified by the National Marine Fisheries Service. The operator of a vessel must ensure that transfers of observers at sea are accomplished in a safe manner, via small boat or raft, during daylight hours as weather and sea conditions allow, and with the agreement of the observer involved;

(C) Allowing the observer access to all areas of the vessel necessary to conduct observer duties;

(D) Allowing the observer access to communications equipment and navigation equipment as necessary to perform observer duties;

(E) Providing true vessel locations by latitude and longitude or loran coordinates, upon request by the observer;

(F) Providing marine mammal specimens, as requested;

(G) Notifying the observer in a timely fashion of when commercial fishing operations are to begin and end; and

(H) Complying with other guidelines, regulations or conditions in Certificates that the National Marine Fisheries Service may develop to ensure the effective deployment and use of observers.

(v) Marine mammals killed during fishing operations which are readily accessible to crew members must be brought aboard the vessel for biological processing, if feasible and if requested by the observer. Marine mammals designated as biological specimens by the observer must be retained in cold storage aboard the vessel, if feasible, until retrieved by authorized personnel of the National Marine Fisheries Service.

(vi) Observers may not bring a civil action against the vessel or vessel owner under any law of the United States for any illness, disability, injury or death from service as an observer, except in cases of the vessel owner's willful misconduct or if the observer is engaged by the owner, master or individual in charge of a vessel to perform any duties in service to the vessel.

(vii) The National Marine Fisheries Service will provide for the payment of all reasonable costs directly related to housing and maintaining observers on board vessels and related to maintaining biological specimens as requested by the observer or required in Exemption Certificates.

(4) Any marine mammal incidentally taken must be immediately returned to the sea with a minimum of further injury and may be retained only if authorized by an observer, by a condition of the Exemption Certificate, or by a scientific research permit that is in the possession of the operator.

(5) A Certificate holder or a crew member may intentionally take marine mammals to protect catch, gear or person during the course of the commercial fishing operation by a means and in a manner not expected to cause death or injury to a marine mammal.

(6) If the infliction of the damage to catch, gear or person is substantial and immediate and only after all non-injurious means authorized by paragraph (c)(5) of this section have been taken, a Certificate holder or crew member may intentionally injure or kill a marine mammal to protect gear, catch or person; except that it is prohibited for a Certificate holder or crew member to intentionally lethally take any Steller sea lion, any Alaskan sea otter, any cetacean, any depleted species (including the Pribilof Island population

of North Pacific fur seal), or any endangered or threatened marine mammal.

(7) No fishing gear, in whole or in part, may be willfully discarded.

(8) A Certificate holder must notify the Assistant Administrator in writing:

(i) If the vessel will engage in any Category I or II fishery not listed on the registration at least 30 days prior to engaging in that fishery; and

(ii) Of any changes in mailing address or vessel ownership within 30 days of such change.

(9) Certificates and decals are not transferable. In the event of the sale or change in ownership of the vessel, the Certificate is void and the new owner must register for an Exemption Certificate and decal.

(10) The Assistant Administrator may establish other terms and conditions on Exemption Certificates, including terms and conditions for specific fisheries necessary to minimize adverse impacts to a marine mammal population in accordance with the procedures in § 229.8(b) of this chapter or to comply with the Endangered Species Act of 1973.

(d) *Suspension, revocation or denial of Certificates.* (1)(i) The Assistant Administrator may suspend or revoke an Exemption Certificate or deny a Certificate renewal in accordance with the provisions in 15 CFR part 904 if the Certificate holder:

(A) Fails to submit reports as required;

(B) Fails to take on board an observer in a Category I fishery, if requested by the National Marine Fisheries Service; or

(C) Fails to comply with other terms and conditions, including special conditions, of the Exemption Certificate or with these regulations.

(ii) Except that the suspension, revocation or denial specified in paragraph (d)(1)(i) of this section may be without prior notice or opportunity for hearing.

(2) A suspended Certificate may be reinstated at any time at the discretion of the Assistant Administrator.

§ 229.7 Requirements for Category III fisheries.

(a) Vessel owners engaged only in Category III fisheries are not required to register for or receive an Exemption Certificate. Vessel owners and crew members of such vessels may incidentally take marine mammals subject to these provisions.

(b) Vessel owners must report all lethal incidental takes of marine mammals by contacting the nearest National Marine Fisheries Service office, in person, by phone, or by letter, within 10 days of return from the fishing trip during which the incidental take occurred. The report must include information on: The fishery, fishing effort, gear type and fish species involved; the marine mammal species (or description of the animal(s), if species is not known), number, date, and location of all lethal incidental takes of marine mammals; a description of any incidental lethal takes (i.e., efforts to deter animals to protect gear, catch, or human life); and any loss of fish or gear caused by marine mammals.

(c) Any marine mammal incidentally taken must be immediately returned to the sea with a minimum of further injury and may be retained only if authorized by an observer, by the Assistant Administrator, or by a scientific research permit that is in the possession of the operator.

(d) Vessel owners and crew members may intentionally take marine mammals to protect catch, gear or person during the course of commercial fishing operations, by a means and in a manner not expected to cause death or injury to a marine mammal.

(e) If the infliction of the damage to gear, catch or person is substantial and immediate and only after all non-injurious methods authorized by paragraph (d) of this section have been taken, a vessel owner or crew member may intentionally injure or kill a marine mammal to protect gear, catch or person; except that it is prohibited for a vessel owner or crew member to intentionally lethally take any Steller sea lion, any Alaskan sea otter, any cetacean, any depleted species (including the Pribilof Island population of North Pacific fur seal), or any endangered or threatened marine mammal.

(f) The willful discard of any fishing gear, in whole or in part, is prohibited.

§ 229.8 Emergency and special regulations.

(a) *Emergency regulations.* If the Assistant Administrator finds that the incidental taking of marine mammals in a fishery is having an immediate and significant adverse impact on a marine mammal population, or in the case of Steller sea lions and North Pacific fur seals, that more than 1,350 and 50, respectively, will be incidentally killed during a calendar year in all fisheries combined, the Assistant Administrator will issue emergency regulations to prevent, to the maximum extent practicable, any further taking. Any such regulations:

(1) Will be issued only after consultation with Regional Fishery Management Councils, state fishery agencies and treaty Indian tribal governments, where appropriate, and will, to the maximum extent practicable, avoid interfering with existing Regional, state or tribal fishery management plans;

(2) Will take into account the economics of the fishery and the availability of existing technology to minimize incidental taking to the extent that elimination of the adverse effects on the marine mammal population will allow;

(3) May take effect immediately upon publication in the **Federal Register** and will remain in effect for no more than 180 days or until the end of the fishing season, whichever is earlier; and

(4) Will be terminated by notice in the **Federal Register** at an earlier date if the Assistant Administrator determines that the reasons for the emergency regulations no longer exist.

(b) *Special regulations or conditions.* (1) If the Assistant Administrator finds that the incidental taking of marine mammals in a fishery is not having an immediate and significant adverse impact on a marine mammal population, but that it will likely have a significant adverse impact over a period of time longer than one year, the Assistant Administrator will request Regional Fishery Management Councils, state fisheries agencies or treaty Indian tribal governments, where appropriate, to initiate or take action to minimize such impact.

(2) If the Councils, states or tribes do not take appropriate action in a reasonable period of time, the Assistant Administrator will issue special regulations or impose special conditions on Exemption Certificates to mitigate the adverse impacts.

(3) Any such regulations or conditions will be issued only if, after notice and opportunity for public comment, the Assistant Administrator determines such action is necessary to further the purposes of section 114 of the MMPA.

§ 229.9 Penalties.

(a) Except as otherwise provided, all violations of these regulations are subject to NOAA's civil procedures contained in 15 CFR part 904.

(b) Notwithstanding any other provision in these or other NOAA regulations, a person or vessel will not be subject to penalties for unknowing violations based on failure to register occurring before January 1, 1990. An unknowing violation is one where the violator can establish that he or she has not received actual prior notice of the registration requirements and has not had the opportunity to receive actual notice. Actual notice is presumed where

a person has received a MMPA Exemption Registration form or any other publication published by National Marine Fisheries Service for the purpose of informing the public of the registration requirements contained in these regulations.

§ 229.10 Confidential fisheries data.

(a) Proprietary or confidential information includes information, the unauthorized disclosure of which could be prejudicial or harmful, such as information or data that are identifiable with an individual fisherman. Proprietary or confidential information obtained under this part 229 must not be disclosed except:

(1) To Federal employees whose duties require access to such information;

(2) To state employees under an agreement with the Assistant Administrator that prevents public disclosure of the identity or business of any person;

(3) When required by court order; or

(4) In the case of scientific information involving fisheries, to employees of Regional Fishery Management Councils who are responsible for fishery management plan development and monitoring.

(b) Information will be made public in aggregate, summary, or other such form that does not disclose the identity or business of any person in accordance with NOAA Directive 88–30. Aggregate or summary form means data or information submitted by three or more persons that have been summed or assembled in such a way that the summation or assembly does not reveal the identity or business of any person.

Subpart B—Emergency and Special Regulations [Reserved]

[FR Doc. 94–14248 Filed 6–16–94; 8:45 am]
BILLING CODE 3510–22–P

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50 CFR Part 661

[Docket No. 940422–4122; I.D. 060994F]

Ocean Salmon Fisheries Off the Coasts of Washington, Oregon, and California

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Closure.

SUMMARY: NMFS announces that the recreational salmon fishery in the area from Humbug Mountain, OR, to Horse Mountain, CA, was closed at 12 midnight, June 7, 1994. The Director, Northwest Region, NMFS (Regional Director), has determined that the recreational quota of 10,300 chinook salmon for the area has been reached. This action is necessary to conform to the preseason announcement of the 1994 management measures and is intended to ensure conservation of chinook salmon.

DATES: Effective at 2400 hours local time, June 7, 1994. Comments must be received by July 1, 1994.

ADDRESSES: Comments may be mailed to J. Gary Smith, Acting Director, Northwest Region, NMFS, 7600 Sand Point Way NE., BIN C15700–Bldg. 1, Seattle, WA 98115–0070; or Rodney R. McInnis, Acting Director, Southwest Region, NMNS, 501 W. Ocean Boulevard, Suite 4200, Long Beach, CA 90802–4213. Information relevant to this document has been compiled in aggregate form and is available for public review during business hours at the Office of the NMFS Northwest Regional Director.

FOR FURTHER INFORMATION CONTACT: William L. Robinson at (206) 526–6140, or Rodney R. McInnis at (310) 980–4030.

SUPPLEMENTARY INFORMATION: Regulations governing the ocean salmon fisheries at 50 CFR 661.21(a)(1) state that:

> When a quota for the commercial or the recreational fishery, or both, for any salmon species in any portion of the fishery management area is projected by the Regional Director to be reached on or by a certain date, the Secretary will, by notice issued under § 661.23, close the commercial or recreational fishery, or both, for all salmon species in the portion of the fishery management area to which the quota applies as of the date the quota is projected to be reached.

In the annual management measures for ocean salmon fisheries (59 FR 22999, May 4, 1994), NMFS announced that the 1994 recreational fishery in the area between Humbug Mountain, OR, and Horse Mountain, CA, would be open May 1 through June 30, 1994, or attainment of the 10,300 chinook salmon quota, whichever occurs first.

The best available information on June 6, 1994, indicated that recreational catches in the area totaled 10,570 chinook salmon through June 5, 1994. To provide public notice of at least 24 hours, the determination was made to close the fishery at 12 midnight, June 7, 1994.

The Regional Director consulted with representatives of the Pacific Fishery Management Council, the Oregon Department of Fish and Wildlife, and the California Department of Fish and Game regarding this closure. The States of Oregon and California will manage the recreational fishery in state waters adjacent to this area of the exclusive economic zone in accordance with this Federal action. In accordance with the inseason notice procedures of 50 CFR 661.23, actual notice to fishermen of this action was given prior to 2400 hours local time, June 7, 1994, by telephone hotline number (206) 526–6667 or (800) 662–9825 and by U.S. Coast Guard Notice to Mariners broadcasts on channel 16 VHF-FM and 2182 kHz. Because of the need for immediate action, the Secretary of Commerce has determined that good cause exists for this document to be issued without affording a prior opportunity for public comment.

Classification

This action is authorized by 50 CFR 661.21 and 661.23 and has been determined to be exempt from OMB review under E.O. 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: June 13, 1994.

David S. Crestin,

Acting Director, Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 94–14787 Filed 6–16–94; 8:45 am]
BILLING CODE 3510–22–F

Proposed Rules

Federal Register
Vol. 59, No. 116
Friday, June 17, 1994

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Parts 870, 871, 872, 873, 874, and 890

RIN 3206–AF94

Federal Employees' Group Life Insurance and Federal Employees Health Benefits Programs; Reconsideration of Employing Office Enrollment Decisions

AGENCY: Office of Personnel Management.

ACTION: Proposed regulations with request for comments.

SUMMARY: In keeping with the Administration's initiative to reinvent Government, the Office of Personnel Management (OPM) is issuing proposed regulations to improve the administrative process used by the Federal Employees' Group Life Insurance (FEGLI) and Federal Employees Health Benefits (FEHB) programs in resolving disputes between Federal employees and agencies over coverage and enrollment issues. The purpose of the proposed regulations is to improve the performance of the Government by delegating to Federal agencies the authority to reconsider disputes over coverage and enrollment issues in these two programs and to make retroactive as well as prospective corrections of errors. The proposed regulations would result in more efficient Government operations and improved service to individuals seeking benefits under the programs.

DATES: Comments must be received on or before August 16, 1994.

ADDRESSES: Written comments may be sent to Lucretia F. Myers, Assistant Director for Insurance Programs, Retirement and Insurance Group, Office of Personnel Management, P.O. Box 57, Washington, DC 20044, or delivered to OPM, Room 3415, 1900 E Street, NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Margaret Sears, (202) 606–0191.

SUPPLEMENTARY INFORMATION: Under the FEGLI law, eligible employees are automatically insured under Basic Life insurance (generally equal to their annual pay, rounded to the next thousand, plus $2,000), unless they waive coverage. In addition, employees with Basic Life coverage may elect coverage under one or more of the 3 types of optional insurance available. (Standard Optional offers an additional $10,000 of insurance. Additional Optional offers insurance in an amount of one, two, three, four, or five times annual pay rounded to the next thousand. Family Optional offers $5,000 insurance for the spouse and $2,500 for each child.) OPM's regulations prescribe the circumstances under which employees cancel waivers of Basic Life, elect optional coverage, increase optional coverage, or drop coverage.

Under the FEHB Program, eligible employees may enroll in FEHB when they are first hired. They may enroll or change enrollment during open season, when their family status changes, or at other times prescribed by OPM's regulations. The FEHB law also provides for enrollment by certain former employees, former spouses, and children when they lose regular FEHB coverage because of separation from service or loss of family member status. The specific conditions of their enrollment and opportunities to change enrollment are controlled by OPM's regulations.

Employees (and family members who are eligible to enroll in FEHB) make changes in their life insurance coverage and health benefits enrollment through the employee's personnel office. These administrative actions are normally conducted entirely between the agency and the individual, based on FEGLI and FEHB law and regulations. However, occasions arise when individuals challenge the agency's denial of their request for coverage, to change their FEHB enrollment or FEGLI coverage, or to change their FEGB enrollment or FEGLI optional coverage retroactively. (Because Basic Life insurance coverage is mandatory under FEGLI law unless the employee waives it, an agency that erroneously denies Basic Life to an employee must restore it retroactively when the error is discovered.) Under OPM's regulations, elections of optional life insurance coverage and FEHB enrollment or enrollment changes are generally effective prospectively unless a specific statutory or regulatory provision requires or allows the agency to make a retroactive change. Errors that consist of allowing an employee to elect life insurance coverage under circumstances not prescribed by law or regulation are corrected retroactively, including errors that are not discovered until after the death of an insured employee.) The current process used to resolve disputes between individuals and agencies over coverage or enrollment determinations is described in 5 CFR §§ 870.205, 871.206, 872.206, 873.206, 874.305, and 890.104.

Under these current procedures, employees, children, or former spouses who are denied coverage or enrollment, the opportunity to change coverage or enrollment, or, in most cases, to have a change made retroactively by a Federal agency must write to the Office of Personnel Management within 30 days after the agency's written denial if they believe the agency's decision was incorrect and want to have it reviewed. OPM reviews the agency's denial to determine if it complies with the applicable law and regulations. Since agencies currently do not have the regulatory authority to make retroactive changes in most cases, they must deny most such requests. Therefore, most requests for a retroactive change must come to OPM for review before the retroactive change can be made. (Basic life insurance is an exception. Under the FEGLI law, employees are automatically covered for Basic Life insurance; therefore, agencies must correct failures to withhold retroactively.) In addition, OPM has the authority, by regulation, to order corrections of errors, mistakes, or omissions based on its determination that it would be against equity and good conscience not to do so.

In 1992, OPM received 283 requests for reconsideration and upheld the agency's decision in 39 percent of the cases. OPM overturned 38 percent of agency decisions and returned 23 percent to the agency because the individual failed to follow proper administrative procedures. As of August 30, 1993, there has been a 50 percent increase in requests for reconsideration over the 1992 figures.

In many of these cases, the issue was (or included) a request that the coverage or change in coverage be made retroactive to some earlier date. Out of

94 requests from employees involving retroactive coverage, we allowed 70 and denied 24. Although an agency has all the necessary information at its disposal and knows whether a retroactive correction is appropriate, it lacks the authority under current regulations to make corrections retroactively. It can accept the employee's request to enroll or change enrollment, but only on a prospective basis. The agency must deny the employee's request for a retroactive change. Therefore, the employees write to OPM to have the decision reviewed. If appropriate, OPM can then order the agency to make the retroactive correction.

As part of OPM's ongoing efforts to improve efficiency, and in keeping with the Administration's initiative to streamline Government operations, OPM is issuing proposed regulations that would delegate to Federal agencies the authority to correct coverage and enrollment errors retroactively. In addition, the proposed regulations would transfer the reconsideration (review) process for the FEGLI and FEHB programs from OPM to the agencies. Under the proposed regulations, Federal agencies (or retirement systems, if applicable) would make the initial decisions at the employing office level and would provide for reconsideration at a higher, or otherwise independent, level of review. The reconsideration could, at each agency's discretion, be made at a higher level within the employing office or at the same level elsewhere in the agency. The proposed regulations set forth only the most basic elements necessary to meet due process requirements. For the most part, agencies would be free to use existing administrative review procedures that include these basic elements or to create administrative procedures specific to this purpose. The agency's decision based on its reconsideration of the initial decision would be final. (FEGLI and FEHB decisions are not appealable to the Merit Systems Protection Board.)

Current regulations regarding employee withholdings and Government contributions would continue to apply. That is, when agencies make retroactive changes, the agency must pay into the respective trust fund an amount equal to any withholdings and contributions due from the effective date of the change. The agency may collect the amount of the withholdings due from the employee or may waive collection under existing law and regulations.

With the authority to make retroactive changes conferred by the proposed regulations, the agencies could correct errors promptly, review initial decisions on request, and give the individual a thorough, written explanation of the final decision. Thus, we believe that the Government would operate more efficiently and employees, their children, and their former spouses would be better served under these regulations.

Regulatory Flexibility Act

I certify that this regulation will not have a significant economic impact on a substantial number of small entities because it merely amends administrative procedures currently performed by OPM and Federal agencies.

List of Subjects

5 CFR Part 870

Administrative practice and procedure, Government employees, Hostages, Iraq, Kuwait, Lebanon, Life insurance, Retirement.

5 CFR Parts 871, 872, and 873

Administrative practice and procedure, Government employees, Life insurance, Retirement.

5 CFR Part 874

Government employees, Life insurance, Retirement.

5 CFR Part 890

Administrative practice and procedure, Government employees, Health facilities, Health insurance, Health professions, Hostages, Iraq, Kuwait, Lebanon, Reports and recordkeeping requirements, Retirement.

U.S. Office of Personnel Management.

James B. King,

Director.

Accordingly, OPM proposes to amend 5 CFR parts 870, 871, 872, 873, 874, and 890 as follows:

PART 870—FEDERAL EMPLOYEES' GROUP LIFE INSURANCE PROGRAM

1. The authority citation for part 870 continues to read as follows:

Authority: 5 U.S.C. 8716; § 870.202(c) also issued under 5 U.S.C. 7701(b)(2); subpart J is also issued under section 599C of Pub. L. 101–513, 104 Stat. 2064, as amended.

2. In subpart A, § 870.102 is revised, § 870.103 is redesignated as § 870.104, a new § 870.103 is added, and newly redesignated § 870.104 is amended by revising the introductory test of the definition of *Employing Office* and by adding paragraph (d) to the definition of *Employee Office* to read as follows:

§ 870.102 Correction of errors.

(a) The employing office may make corrections of administrative errors as to coverage or changes in coverage any time. Retroactive corrections of coverage are subject to the provisions of § 870.401(h).

(b) OPM may order correction of an error upon a showing satisfactory to OPM that it would be against equity and good conscience not to do so.

§ 870.103 Initial decision and reconsideration.

(a) *Who may file.* (1) An employee may request his or her agency to reconsider an employing office's initial decision denying insurance coverage or the opportunity to change coverage.

(2) An annuitant may request his or her retirement system to reconsider its initial decision affecting insurance coverage.

(3) A judge may request his or her agency, or retirement system if applicable, to reconsider an employing office's initial decision that denies an entitlement related to assignments under 5 U.S.C. 8706(e) of this chapter.

(b) *Initial employing office decision.* An employing office's decision is considered an initial decision as used in paragraph (a) of this section when rendered by the employing office in writing and stating the right to an independent level of review (reconsideration) by the appropriate agency or retirement system. However, an initial decision rendered at the highest level of review available within OPM is not subject to reconsideration.

(c) *Reconsideration.* (1) A request for reconsideration must be made in writing, must include the claimant's name, address, date of birth, Social Security number, reasons for the request, and, if applicable, retirement claim number.

(2) The reconsideration review must be made at or above the level at which the initial decision was rendered.

(d) *Time limit.* A request for reconsideration of an initial decision must be filed within 30 calendar days from the date of the written decision stating the right to a reconsideration. The time limit on filing may be extended when the individual shows that he or she was not notified of the time limit and was not otherwise aware of it, or that he or she was prevented by circumstances beyond his or her control from making the request within the time limit. An agency or retirement system decision in response to a request for reconsideration of an employing office's decision is a final decision as described in paragraph (e) of this section.

(e) *Final decision.* After reconsideration, the agency or retirement system must issue a final decision, which must be in writing and must fully set forth the findings and conclusions.

§ 870.104 Definitions.

* * * * *

Employing office means the office of the agency or retirement system to which jurisdiction and responsibility for life insurance actions have been delegated.

* * * * *

(d) For judges of the United States Court of Veterans Appeals, the employing office is the United States Court of Veterans Appeals.

* * * * *

3. In supart B, § 870.205 is moved.

PART 871—STANDARD OPTIONAL LIFE INSURANCE

1. The authority citation for part 871 continues to read as follows:

Authority: 5 U.S.C. 8716.

2. In subpart A, § 871.103 is revised to reads as follows:

§ 871.103 Correction of errors; initial decision and reconsideration.

The rules and procedures under §§ 870.102 and 870.103 are applicable in this part, subject to the provisions of § 870.401(h) of this part.

871.104 [Amended]

3. In § 871.104 the reference to "§ 870.103" is removed and "§ 870.104" is added in its place.

§ 871.206 [Removed]

4. In subpart B, § 871.206 is removed.

PART 872—ADDITIONAL OPTIONAL LIFE INSURANCE

1. The authority citation for part 872 continues to read as follows:

Authority: 5 U.S.C. 8716.

2. In subpart A, § 872.103 is revised to read as follows:

§ 872.103 Correction of errors; initial decision and reconsideration.

The rules and procedures under §§ 870.102 and 870.103 are applicable in this part, subject to the provisions of § 870.401(h) of this part.

§ 872.104 [Amended]

3. In § 872.104 the reference to "§ 870.103" is removed and "§ 870.104" is added in its place.

§ 872.206 [Removed]

4. In subpart B, § 872.206 is removed.

PART 873—FAMILY OPTIONAL LIFE INSURANCE

1. The authority citation for part 873 continues to read as follows:

Authority: 5 U.S.C. 8716.

2. In subpart A, § 871.103 is revised to reads as follows:

§ 873.103 Corrections of errors; initial decision and reconsideration.

The rules and procedures under §§ 870.102 and 870.103 are applicable in this part, subject to the provisions of § 870.401(e) of this part.

§ 873.104 [Amended]

3. In § 873.104 the reference to "§ 870.103" is removed and "§ 870.104" is added in its place.

§ 873.206 [Removed]

4. In subpart B, § 873.206 is removed.

PART 874—ASSIGNMENT OF LIFE INSURANCE

1. The authority citation for part 874 continues to read as follows:

Authority: 5 U.S.C. 8716.

§ 874.101 [Amended]

2. In subpart A, § 874.101, the reference to "§ 870.103" is removed and "§ 870.104" is added in its place.

3. In subpart C, § 874.305 is revised to read as follows:

§ 874.305 Correction of errors, initial decision and reconsideration.

The rules and procedures under §§ 870.102 and 870.103 are applicable in this part, subject to the provisions of § 874.502 of this part.

PART 890—FEDERAL EMPLOYEES HEALTH BENEFITS PROGRAM

1. The authority citation for part 890 continues to read as follows:

Authority: 5 U.S.C. 8913; § 890.803 also issued under 50 U.S.C. 403p, 22 U.S.C. 4069c and 4069c–1; subpart L also issued under sec. 599C of Pub. L. 101–513, 104 Stat. 2064, as amended.

2. In § 890.103, paragraphs (a) and (b) are revised to read as follows:

§ 890.103 Correction of errors.

(a) The employing office may make prospective and retroactive correction of administrative errors as to enrollment at any time. Retroactive corrections are subject to withholdings and contributions under the provisions of § 890.502 of this part.

(b) OPM may order correction of an error upon a showing satisfactory to OPM that it would be against equity and good conscience not to do so.

* * * * * *

3. Section 890.104 is revised to read as follows:

§ 890.104 Initial decision and reconsideration on enrollment.

(a) *Who may file.* Except as provided under § 890.1112, an individual may request an agency or retirement system to reconsider an initial decision of its employing office denying coverage or change of enrollment.

(b) *Initial employing office decision.* An employing office's decision for an individual is considered an initial decision as used in paragraph (a) of this section when rendered by the employing office in writing and stating the right to an independent level of review (reconsideration) by the agency or retirement system. However, an initial decision rendered at the highest level of review available within OPM is not subject to reconsideration.

(c) *Reconsideration.* (1) A request for reconsideration must be made in writing, must include the claimant's name, address, date of birth, Social Security number, name of carrier, reasons for the request, and, if applicable, retirement claim number.

(2) The reconsideration review must be designated at or above the level at which the initial decision was rendered.

(d) *Time limit.* A request for reconsideration of an initial decision must be filed within 30 calendar days from the date of the written decision stating the right to a reconsideration. The time limit on filing may be extended when the individual shows that he or she was not notified of the time limit and was not otherwise aware of it, or that he or she was prevented by circumstances beyond his or her control from making the request within the time limit. An agency or retirement system decision in response to a request for reconsideration of an employing office's decision is a final decision as described in paragraph (e) of this section.

(e) *Final decision.* After reconsideration, the agency or retirement system must issue a final decision, which must be in writing and must fully set forth the findings and conclusions.

[FR Doc. 94–14820 Filed 6–16–94; 8:45 am]

BILLING CODE 6325–01–M

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 1250

RIN 0581–AB32

[Docket No. PY–94–002]

Amendment to Egg Research and Promotion Order To Increase the Rate of Assessment

AGENCY: Agricultural Marketing Service.

ACTION: Proposed Rule.

SUMMARY: This proposed rule would amend the Egg Research and Promotion Order to increase the assessment rate from 5 cents to 10 cents per 30-dozen case of commercial eggs. The increase is authorized by amendments to the Egg Research and Consumer Information Act must be approved by egg producers voting in a referendum. This proposal would also make a conforming amendment to regulations.

DATES: Comments must be received on or before August 16, 1994.

ADDRESSES: Written comments are to be mailed to Janice L. Lockard, Chief, Standardization Branch, Poultry Division, AMS, USDA, Room 3944-South, P.O. Box 96456, Washington, DC. 20090–6456. Comments received may be inspected at this location between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. State that your comments refer to Docket No. PY–94–002.

FOR FURTHER INFORMATION CONTACT: Janice L. Lockard, 202–720–3506.

SUPPLEMENTARY INFORMATION:

Executive Orders 12866 and 12778

This rule has been determined not-significant for purposes of Executive Order 12866, and has been reviewed by the Office of Management and Budget.

This proposed rule has been reviewed under Executive Order 12778, Civil Justice Reform. It is not intended to have retroactive effect. This rule would not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 14 of the Act, a person subject to an order may file a petition with the Secretary stating that such order, any provisions of such order or any obligations imposed in connection with such order are not in accordance with law; and requesting a modification of the order or an exemption therefrom. Such person is afforded the opportunity for a hearing on the petition. After a hearing, the Secretary would rule on the petition. The Act provides that the district court of the United States in any district in which such person is an inhabitant, or has his principal place of business, has jurisdiction to review the Secretary's ruling on the petition, if a complaint is filed within 20 days after date of the entry of the ruling.

Effect on Small Entities

The Administrator of the Agricultural Marketing Service has determined that this proposed rule will not have a significant economic impact on a substantial number of small entities, as defined by the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

Currently, 618 egg producers pay assessments to the American Egg Board (AEB). A proposed rule to increase the exemption level from 30,000 to 75,000 laying hens was published in the **Federal Register** on March 22, 1994 (59 FR 13460). The increased exemption level would exempt 253 small egg producers who represent 41 percent of the egg producers currently paying assessments, but only 4 percent of AEB's total assessment income. It is anticipated that the 75,000-hen exemption level would be in place before the referendum on the assessment rate increase. Therefore, a change in the assessment rate would affect only egg producers owning more than 75,000 laying hens.

There are an estimated 365 producers who own more than 75,000 hens. Currently, egg producers must pay a mandatory assessment of 5 cents per 30-dozen case of eggs marketed to fund the research and promotion activities authorized by the Act. The present 5-cent assessment is equivalent to approximately 0.231 percent of the wholesale price of a 1-dozen carton of Large eggs. An assessment rate of 10 cents per 30-dozen case would be equivalent to approximately 0.463 percent of the wholesale price of a1-dozen carton of Large eggs. This is based on the Economic Research Service's 3-year average wholesale price for New York City Grade A Large cartoned eggs (1991–93) of 72 cents per dozen. AEB collects approximately $7.5 million annually from the 5-cent assessment, and it is estimated that it would collect $14 million for a 10-cent assessment. It is estimated that any additional costs would be offset by the benefits to be derived from strengthened research and promotion programs.

Paperwork Reduction

Information collection requirements and recordkeeping provisions contained in 7 CFR Part 1250 have been previously approved by the Office of Management and Budget and assigned OMB Control No. 0581–0093 under the Paperwork Reduction Act of 1980.

No additional recordkeeping requirements would be imposed as a result of this proposed rule.

Background and Proposed Changes

On December 14, 1993, the Egg Research and Consumer Information Act (7 U.S.C. 2711) was amended (Pub. L. 103–188) to increase the maximum rate of assessment, raise the exemption level, and provide for research project funding.

Under the amended section 8 of the Act, the maximum rate of assessment was raised from 10 cents to 20 cents per case of commercial eggs. The actual assessment rate is prescribed by the Egg Research and Promotion Order and is currently 5 cents per case. Producers owning 30,000 or fewer laying hens are exempt from paying assessments and other provisions of the Act. Section 12 of the Act was amended to increase the exemption level to 75,000 or fewer hens. A proposed rule to raise the exemption level in the Order was published in the **Federal Register** on March 22, 1994. The new exemption level will become effective after publication of the final rule.

The Act amendments provide that AEB may recommend an increase in the assessment rate to the Secretary. The recommendation must be based on a scientific study, marketing analysis, or other evidence demonstrating a need for the increase. Consequently, AEB conducted a marketing analysis and evaluated the advertising and nutrition research programs.

Advertising

AEB began its first advertising campaign in 1977. For the next 3 years, media expenditures averaged $3.5 million annually. In 1980, the American Association of Advertising Agencies noted that, during that 3-year period, per capita consumption of eggs had increased and consumer attitudes toward eggs had improved.

Considering inflation, an estimated $9 million would be required for AEB to conduct a media program in 1994 comparable to that in 1977. Further, because consumers have grown more concerned with a variety of issues affecting egg consumption, an even greater level of funding would be needed to achieve the same results today.

AEB's analysis establishes that egg consumption has been steadily declining over many years. In fact, USDA statistics show that per capita consumption dropped from 402 in 1945 to 234 in 1993. In general, the decline is attributed to fewer egg-consuming households and less frequent egg consumption.

Eggs face certain barriers in the marketplace which have contributed to the declining consumption. Considered by consumers to be primarily a breakfast food, eggs must compete with a variety of breakfast alternatives: cold cereal; pancakes and waffles; rolls, muffins, and toast; and hot cereal. The total measured media spending for the breakfast food category was $937 million in 1993. Egg industry advertising-including that funded by AEB, State and regional associations, and companies promoting name brands-represents only 0.7 percent of that amount.

In addition, consumer concerns with fat and cholesterol have significantly affected consumer eating habits. The judgment that eggs are high in cholesterol has further contributed to consumers using fewer eggs. Overcoming negative consumer attitudes is even more difficult when other breakfast foods are more heavily promoted.

AEB's current advertising strategy is three-fold: (1) Educate consumers about eggs and cholesterol by providing facts on egg cholesterol in a healthy diet; (2) remind consumers how much they love the great taste of eggs; and (3) connect eggs with the rich, pleasurable associations people have with eggs and egg-eating occasions.

The current "I Love Eggs" advertising campaign based on this strategy proved effective in consumer testing. Prior to being exposed to the advertising, 43 percent of consumers tested had extremely positive or very positive attitudes about eggs. This number increased by 13 percent after consumers were exposed to the advertising. Further, almost half of the consumers tested reported an increased likelihood of eating and serving eggs more often.

With current funding, AEB has earmarked about $2.8 million for this campaign in 1995. This budget supports 15-second television commercials and 30-second radio spots. A 5-cent increase in the assessment rate would allow for an advertising budget of $7.5 million. This budget would enable the use of more effective 30-second television spots; allow advertising to be aired almost every other week, as opposed to the 10 weeks per year now; and provide for over 1,000 additional commercial announcements. Most significantly, an additional one million target households would be reached by AEB advertising each week.

Nutrition Research

The nutrition portion of AEB's budget encompasses two programs of importance both for the egg industry and the consuming public-nutrition research and nutrition education.

In recent years, an increased amount of the AEB budget has been used for research to evaluate the effects of dietary cholesterol on plasma lipids. Since 1991, $1.3 million has funded research projects at various universities, all of which have focused on this issue. For example, a recently completed study was published in the April issue of the American Heart Association's "Arteriosclerosis and Thrombosis" journal. The results of this study found that blood cholesterol levels in young healthy men did not significantly increase when they were fed 1 or 2 eggs per day. Additional funding would allow the egg industry to study the same effects across other population groups.

Increased funding also would allow AEB to expand its contacts with scientists, health professionals, and the media in developing nutrition materials, sponsoring scientific symposiums and related forums, and compiling research data.

AEB Recommendation

At the March 17, 1994, Board meeting in Chicago, Illinois, AEB members voted unanimously to recommend that the assessment rate be increased from 5 cents to 10 cents per 30-dozen case of commercial eggs. Their decision was based on the marketing analysis as well as an overall sense from producers nationwide that more funds are necessary to help improve the position of the industry's products in the marketplace through strengthened advertising and research programs. AEB further requested that a referendum on this increase be held as soon as possible.

Referendum

After an opportunity for public comment, a referendum will be held among egg producers not exempt from the Act. Producers engaged in the production of commercial eggs during a representative period determined by the Secretary will be eligible to vote on the assessment rate change proposed by AEB.

All known eligible egg producers will receive information in the mail regarding the referendum. It is anticipated that the 75,000-hen exemption level will be in place before the referendum.

The increase in the assessment rate shall become effective if the change is approved or favored by not less than two-thirds of the producers voting in the referendum, or a majority of such producers if they represent not less than two-thirds of the commercial eggs produced by those voting.

List of Subjects in 7 CFR Part 1250

Administrative practice and procedure, Advertising, Agricultural research, Eggs and egg products, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble 7 CFR Part 1250 is proposed to be amended as follows:

PART 1250—EGG RESEARCH AND PROMOTION

1. The authority citation of Part 1250 is revised to read as follows:

Authority: 7 U.S.C. 2701–2718.

2. Section 1250.347 is revised to read as follows:

§ 1250.347 Assessments.

Each handler designated in § 1250.349 and pursuant to regulations issued by the Board shall collect from each producer, except for those producers specifically exempted in § 1250.348, and shall pay to the Board at such times and in such manner as prescribed by regulations issued by the Board an assessment at a rate of not to exceed 10 cents per 30-dozen case of eggs, or the equivalent thereof, for such expenses and expenditures, including provisions for a reasonable reserve and those administrative costs incurred by the Department of Agriculture after this subpart is effective, as the Secretary finds are reasonable and likely to be incurred by the Board and the Secretary under this subpart, except that no more than one such assessment shall be made on any case of eggs.

3. In section 1250.514, the first sentence is revised to read as follows:

§ 1250.514 Levy of assessments.

An assessment rate of 10 cents per case of commercial eggs is levied on each case of commercial eggs handled for the account of each producer. * * *

Dated: June 9, 1994.

L. P. Massaro,

Acting Administrator, Agricultural Marketing Service.

[FR Doc. 94–14741 Filed 6–16–94; 8:45 am]

BILLING CODE 3410–02–P

FEDERAL TRADE COMMISSION

16 CFR Part 600

Statement of General Policy or Interpretation; Commentary on the Fair Credit Reporting Act

AGENCY: Federal Trade Commission.

ACTION: Proposed amendment to commentary.

SUMMARY: The Commission is seeking public comment on a proposed amendment to its Commentary on the Fair Credit Reporting Act ("FCRA"), 16 CFR Part 600. The proposed amendment clarifies the Commission's interpretation that the FCRA requires the disclosure of "risk scores" to consumers by consumer reporting agencies. This action responds to widespread interest in this issue, and various inquiries the Commission and its staff have received about it.

DATES: Comments must be received on or before August 16, 1994. This comment period will not be extended absent compelling circumstances.

ADDRESSES: Comments should be addressed to: Clarke Brinckerhoff, Attorney, Division of Credit Practices, Federal Trade Commission, Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Clarke Brinckerhoff, Attorney, Division of Credit Practices, Federal Trade Commission, Washington, DC 20580, 202–326–3208.

SUPPLEMENTARY INFORMATION:

Background

During the late 1980s, the credit reporting industry developed a product, called the "risk score," to evaluate a consumer's credit history for its clients. A risk score assesses the likelihood of a particular adverse event, such as default or bankruptcy, based on various factors in a consumer report. The result of this evaluation is communicated by means of a numerical score.

Section 609 of the FCRA requires a consumer reporting agency, upon receiving a request and proper identification from a consumer, to "clearly and accurately disclose to the consumer . . . [t]he nature and substance of all information (except medical information) in its files on the consumer at the time of the request." A consumer reporting agency also must disclose, in most instances, the sources of the information in the consumer's file, as well as the recipients of any consumer report on the consumer which the reporting agency has furnished six months preceding the consumer's request (or two years, if the report is for employment purposes).

On February 11, 1992, the Commission amended its FCRA Commentary to state that, pursuant to section 609 of the FCRA, "a risk score (or other numerical evaluation, however named) that is reported by a consumer reporting agency to a client to assist in evaluating a consumer's eligibility for credit (or other permissible purposes) must be disclosed (along with an explanation of the risk score)" to a consumer requesting disclosure of his or her credit file from the consumer reporting agency. 57 FR 4935–36 (Feb. 11, 1992). It noted that Congresswoman Leonor Sullivan, when introducing the conference report on the bill that ultimately enacted the FCRA, had stated:

> (The House conferees) stressed that the consumer should have access to all information *in any form which would be relayed to a prospective employer, insurer or creditor in making a judgment as to the worthiness of the individual's application for such benefits.* * * It is not intended that the credit reporting firm should have a free hand in excluding from the consumer's access information other than medical information it just does not want to give him, but will give to a client-user.*

116 Cong Rec. 36572 (October 12, 1970) (emphasis added)

After the Commission amended the FCRA Commentary, several industry representatives requested clarification of the revision. As part of this process, some of these parties (as well as consumer representatives and other interested parties) submitted informal statements of their positions that appear on the Commission's public record. Commissioners and Bureau of Consumer Protection staff have discussed these issues with industry, consumer and state representatives. During these discussions, the following three principal issues arose concerning the applicability of the FCRA to risk scores: (1) When a consumer reporting agency must disclose a risk score; (2) what score(s) must be disclosed; and (3) what type of explanation of the score, if any, must be provided as part of the disclosure.

In response to these inquiries, the Commission proposes to expand the discussion of risk scores in the FCRA Commentary as set forth below.

Proposed Revision

The Commission proposes to delete the single sentence that discusses "risk scores" in comment 7 to section 609 of the FCRA Commentary, and to add a separate comment 12 to read as follows:

> 12. Risk scores. A consumer reporting agency must disclose to a consumer in response to a consumer's disclosure request: (a) risk scores (or other numerical evaluations, however named), calculated at the time of the consumer's request; and (b) a brief statement that explains what the risk score predicts, how the score may be applied by its user, and how the consumer ranks against other consumers under the scoring model. The agency must disclose this information for each type of score, regardless of who developed the score, that the agency has reported to its clients within the six months preceding the date of the consumer's disclosure request (or within two years, if for employment purposes).

Questions for Public Comment

The Commission requests public comment on this proposed revision to the FCRA Commentary, and is particularly interested in receiving comments on the questions that follow. Legal and policy analysis of these questions would be particularly useful. The Commission specifically requests comments based on reasoned analysis of provisions of the FCRA that discuss the impact of the proposal on consumers and the marketplace.

(1) What type of risk score disclosure is mandated under section 609 of the FCRA?

(2) Consumer reporting agencies generally calculate risk scores only when they receive a request for such a score from a client. Is a consumer entitled to a risk score disclosure if the consumer reporting agency has never reported a score on that individual? Assuming some prior risk score report is necessary to trigger the disclosure requirement, does a risk score provided by a consumer reporting agency only in the context of "prescreening" provide an appropriate trigger?

(3) If provision of a risk score to a client is an appropriate trigger for the disclosure requirement, in what time frame, if any, must that score have been provided? Are each of the proposed time frames, which are based on sections 609(a)(3) and 611(d) of the FCRA, proper and sensible? Are they unduly burdensome on credit bureaus or insufficient to provide adequate disclosure to consumers?

(4) Risk scoring systems can be created by or for consumer reporting agencies themselves ("generic models"), or they can be created by or for one or more of the agency's clients ("custom models"). Should the disclosure requirement for risk scores based on generic models and custom models be the same?

(5) Credit files are constantly changing. New items are added while older items become statutorily obsolete

and are dropped. Because of the dynamic nature of consumer reports, the risk score that is reported to a creditor at any given time may differ from the score that would be assigned to that report at a time shortly thereafter. Should "historical" risk scores (those actually provided to the agency's clients) or "current" risk scores (calculated at the time of the disclosure) be disclosed to consumers?

(6) A consumer reporting agency may produce a variety of different risk scores, such as a bankruptcy risk score, a default risk score, or other types of scores. Should the consumer reporting agency be required to disclose to consumers each type of risk score it offers its clients the option of purchasing, or only those scores that have actually been provided about that consumer to one or more clients?

(7) What explanation, if any, should a consumer reporting agency provide consumers about their risk scores? Should agencies discuss how the score may be used by their clients? Should agencies specify how the individual consumer ranks in regard to others? If so, should the ranking be done by percentile or other technique? Should the Commentary specify the precise form of explanation, or contain expanded requirements as to the details of the explanation? Is the proposal to require an explanation of the risk score too narrow or too broad? If so, in what way should it be expanded or contracted?

(8) Is there some approach other than disclosure of actual risk scores that would better inform consumers of the information about them being reported by consumer reporting agencies? For example, might it be more useful for a consumer reporting agency to provide a single score to all consumers designed to show the likelihood of obtaining credit? Would it be more helpful for the consumer to receive a list of the elements on which the calculation of such a "score" is based, rather than the actual score and explanation required by the proposal?

List of Subjects in 16 CFR Part 600

Credit, Trade practices.

For the reasons set out in the preamble, the Commission proposes to amend title 16, chapter I, part 600 of the Code of Federal Regulations as follows:

PART 600—STATEMENT OF GENERAL POLICY OR INTERPRETATIONS

1. The authority citation for part 600 continues to read as follows:

Authority: 15 U.S.C. 1681s and 16 CFR 1.73.

2. In the appendix to part 600, the Commission proposes to amend section 609 by revising comment 7 and adding a new comment 12, to read as follows:

Appendix—Commentary on the Fair Credit Reporting Act

* * * * *

Section 609—Disclosures to Consumers

* * * * *

7. Ancillary Information

A consumer reporting agency is not required to disclose information consisting of an audit trail of changes it makes in the consumer's file, billing records, or the contents of a consumer relations folder, if the information is not from consumer reports and will not be used in preparing future consumer reports. Such data is not included in the term "information in the files" which must be disclosed to the consumer pursuant to this section. A consumer reporting agency must disclose claims report information only if it has appeared in consumer reports.

* * * * *

12. Risk Scores

A consumer reporting agency must disclose to a consumer in response to a consumer's disclosure request: (a) Risk scores (or other numerical evaluations, however named), calculated at the time of the consumer's request; and (b) a brief statement that explains what the risk score predicts, how the score may be applied by its user, and how the consumer ranks against other consumers under the scoring model. The agency must disclose this information for each type of score, regardless of who developed the score, that the agency has reported to its clients within the six months preceding the date of the consumer's disclosure request (or within two years, if for employment purposes).

* * * * *

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 94–14780 Filed 6–16–94; 8:45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Part 191

Drawback; Application for Exporter's Summary Procedure; Withdrawal

AGENCY: U. S. Customs Service, Department of the Treasury.

ACTION: Proposed rule; withdrawal.

SUMMARY: This document withdraws the proposed amendment to the Customs Regulations, which would have permitted drawback claimants to file only one application for use of the exporter's summary procedure, instead of filing separate applications for the use of the procedure for each Customs region or district in which they file drawback claims. Customs has determined that any amendment of the exporter's summary procedure, including any necessary provisions to ensure uniformity in approving or revoking the use of this procedure, would more appropriately be considered in concert with the broad-based review and revision of the drawback regulations necessitated by, and which will shortly be undertaken pursuant to, the Customs modernization portion of the North American Free Trade Agreement Implementation Act.

DATES: The withdrawal is effective on June 17, 1994.

FOR FURTHER INFORMATION CONTACT: Bruce Friedman, Office of Trade Operations, (202–927–0260).

SUPPLEMENTARY INFORMATION:

Background

Drawback is a refund or remission, in whole or in part, of a Customs duty, internal revenue tax, or fee. There are a number of different kinds of drawback authorized under law. In order to qualify for drawback, there must be an exportation or a destruction under Customs supervision. The statute providing for specific types of drawback is 19 U.S.C. 1313. The Customs Regulations implementing the statute are contained in 19 CFR part 191.

The requirements for establishing the exportation of goods subject to drawback are set forth in subpart E of part 191. This subpart authorizes the use of several alternative procedures to establish exportation. One of these is the exporter's summary procedure, which is provided for in § 191.53.

Under the exporter's summary procedure, the claimant is allowed to establish exportation for drawback simply by summarizing his exports in chronological order, along with certain associated data, using a format acceptable to the appropriate regional commissioner or district director.

A drawback claimant wishing to use the exporter's summary procedure must first make application with each regional commissioner, or, if applicable, with each district director, in whose region or district drawback will be sought. The regional commissioner or the district director, if applicable, would approve the request, if it is determined that the use of the procedure would contribute to administrative efficiency, and the claimant is not otherwise delinquent or remiss in transactions with Customs. This can result in excessive paperwork.

Accordingly, by a document published in the **Federal Register** on

September 10, 1992 (57 FR 41446), Customs proposed to amend paragraph (c) of § 191.53 so that drawback claimants would not have to file separate applications to use the exporter's summary procedure in each region or district where they file drawback claims. Approval, denial, or revocation of a claimant's use of the procedure in one region or district would govern the claimant's eligibility in all regions and districts.

While three commenters responded to the notice of proposed rulemaking, all generally favoring adoption of the proposal, the concern was expressed that there was a lack of uniformity among the various regions and districts in processing applications to use the exporter's summary procedure. This problem was not resolved or addressed by the regulation in question.

Withdrawal of Proposal

In consideration of the foregoing, and, moreover, in view of the extensive drawback regulation changes necessitated by the Customs modernization portion of the North American Free Trade Agreement (NAFTA) Implementation Act (Pub. L. 103–182, § 632), Customs has now determined that any amendment of the exporter's summary procedure, including any necessary provisions to ensure 4 uniformity in approving or revoking the use of this procedure, would more properly be considered in concert with the broad-based review and revision of the drawback regulations which will be shortly undertaken pursuant to the Customs modernization portion of the NAFTA Implementation Act.

Drafting Information

The principal author of this document was Russell Berger, Regulations Branch, U.S. Customs Service. However, personnel from other offices participated in its development.

Approved: June 4, 1994.

Samuel H. Banks,

Acting Commissioner of Customs.

John P. Simpson,

Deputy Assistant Secretary of the Treasury.

[FR Doc. 94–14705 Filed 6–16–94; 8:45 am]

BILLING CODE 4820–02–P

POSTAL SERVICE

39 CFR Chapter I

Invoicing Procedures for Freight Carriers

AGENCY: Postal Service

ACTION: Request for comments.

SUMMARY: The Postal Service is considering changes to its payment system to permit the implementation of new software applications. The Postal Service seeks comments from interested parties, because these changes would affect invoicing procedures for freight transportation carriers.

DATES: Comments must be received on or before July 18, 1994.

ADDRESSES: Written comments should be mailed or delivered to: Manager, Materiel Distribution, U.S. Postal Service, room 1141, 475 L'Enfant Plaza SW., Washington, DC 20260–6225. Copies of all written comments will be available for inspection and photocopying between 9 a.m. and 4 p.m., Monday through Friday, at the above address.

FOR FURTHER INFORMATION CONTACT: Dr. Frank Scheer, (202) 268–2120.

SUPPLEMENTARY INFORMATION: Under 39 U.S.C. 401(4), the Postal Service has the general power to determine and keep its own system of accounts and the forms and contents of its contracts and other business documents. In the past, for freight invoicing purposes, the Postal Service has generally used Government Bills of Lading, Standard Form 1103 (SF 1103), in accordance with the procedures set forth in 41 CFR 101–41.000, et seq. The Postal Service is considering changes to its payment system that would affect invoicing procedures for all freight transportation carriers currently handling shipments on Government Bills of Lading. Shipments of U.S. Mail, household goods, or other personal property not handled on SF 1103 would not be covered by the new payment system.

This change would permit the Postal Service to implement new software applications for freight traffic management. The principal feature of the new system would be to permit freight carriers to submit billings either electronically, or by paper invoices using the Public Voucher, Standard Form 1113 (SF 1113), along with the required supporting documentation.

New billing procedures would be drafted to provide guidance both for electronic and paper billing. These procedures would include information about the Electronic Data Interchange (EDI) approval process, Trading Partner Agreements, submission of electronic invoices, testing rejection and resubmission of valid invoices, payments, and suspension of EDI operations. Information about waivers, payee codes, and other payment processes would also be included.

The Postal Service believes that freight carriers electing to conduct business electronically should be required to use the EDI Standards X12, developed by the Accredited Standards Committee (ASC) of the American National Standards Institute (ANSI). The Postal Service would obtain commercial EDI Value-Added Network (VAN) services to send and receive EDI shipping and billing data. Carriers would be required to use the VAN selected by the Postal Service to transfer data electronically for these transactions.

Although existing procedures for issuing and paying Government Bills of Lading for Postal Service shipments will continue, one change would be required to be consistent with electronic practices, if they are implemented. Any carrier submitting paper billings would be required to include its Tax Identification Number (TIN) on the SF 1113. A TIN for a parent company would also be required if the carrier is a subsidiary of a parent company. The carrier TIN would be used for vendor identification during payment processing; the Postal Service would not assign its own vendor supplier code for this purpose.

In view of the foregoing, the Postal Service requests comments and proposals from interested parties on the following matters:

1. The level of carrier interest in electronic communications to replace hardcopy bills of lading and freight bills.
2. The procedures carriers would prefer to see used for handling these transactions.
3. The impact upon carriers of adding the carrier's TIN to SF 1113.

Comments regarding these matters are requested within 30 days of the date of publication of this notice. The Postal Service will take these comments under consideration as it formulates possible changes in its payment system.

Stanley F. Mires,

Chief Counsel, Legislative Division.

[FR Doc. 94–14718 Filed 6–16–94; 8:45 am]

BILLING CODE 7710–12–P

39 CFR Part 111

Revisions to Standards Concerning Physical Mailpiece Dimensions, Addressing, and Address Placement

AGENCY: Postal Service.

ACTION: Proposed rule.

SUMMARY: The Postal Service proposes changes to several Domestic Mail Manual (DMM) standards defining a

mailpiece's length, height, and thickness, and relating these dimensions to processing category and other criteria. The Postal Service also proposes changes to other DMM standards concerning the content and placement of delivery and return addresses, including placement standards for delivery addresses on flat-size mailpieces not prepared in a full enclosure, and letter- and flat-size pieces prepared in an unattached sleeve or partial wrapper; the location of, and the use of a ZIP Code or ZIP+4 code in, the return address on certain mail; terms related to post office boxes and standards for their use in addressing mail; and the prohibition of dual addresses on certain types of mail.

DATES: Comments must be received on or before August 1, 1994.

ADDRESSES: Written comments should be mailed or delivered to Manager, Mailing Standards, USPS Headquarters, 475 L'Enfant Plaza SW., Washington, DC 20260–2419. Copies of all written comments will be available for inspection and photocopying between 9 a.m. and 4 p.m., Monday through Friday, in room 5610 at the above address.

FOR FURTHER INFORMATION CONTACT: Leo F. Raymond, (202) 268–5199.

SUPPLEMENTARY INFORMATION: These proposed changes to Domestic Mail Manual (DMM) standards arise from suggestions presented during the 1993 DMM redesign project.

Revisions Concerning Physical Mailpiece Dimensions and Address Placement

The proposed revisions to C010 and C050 (with lesser changes to A010, A200, and E312) concern how the physical characteristics of a mailpiece are used in determining which dimensions are its length, height, and thickness. This information is used to determine correct address placement and the mailpiece's mailability, susceptibility to a nonstandard surcharge, processing category, and rate eligibility. This proposal will apply a consistent definition of length, height, and thickness to all mail, except for pieces eligible for and claimed at a Barcoded rate for flats.

Although this proposal affects all addressed mail, its impact will be on address placement on letter-size pieces (including, for purposes of these standards, cards), which are subject to standards for address placement and orientation and rate eligibility based on those characteristics. The Postal Service proposes to make the following specific changes to the DMM:

1. A010.1.0 is amended to standardize address placement on all letter-size mail claimed at other than a single-piece rate (or, for pieces within a small dimensional range, at the Barcoded rate for flats) to require that the address be oriented parallel to the length of the piece (as defined in revised C010.1.1). Letter-size mail, which represents the majority of postal volume, is processed in a mostly automated or mechanized mailstream. An increasing proportion of letter-size mail (already subject to strict physical standards) moves through automated equipment, and most of the remainder is handled by letter-sorting machines. Manual processing—the slowest and most costly handling—is used for mail having physical or address characteristics that are incompatible with automated or mechanized processing.

Although the Postal Service recognizes that some mail may never be compatible with its equipment, it believes that such compatibility is a reasonable condition for mail being claimed at a discounted rate. Whether to render a mailpiece compatible with automation (as under existing standards), mechanization, or human handling, the benefit of the proposed rule is clear. Certain necessary, basic assumptions about how mail is oriented when its address is to be read underlie how equipment is designed to receive and move mail and how employees are trained to read, sort, and carry it. Most letter-size mail has address and dimensional characteristics that are compatible with these assumptions, but the absence of effective standards allows incompatible mail to enjoy discounts that are incongruous with how it must be processed. (Nonstandard surcharges do not apply to all such mail.)

For the sake of creativity, some customers currently generate mail at bulk or presort rates that must be held vertically ("portrait" style) rather than horizontally ("landscape" style) to read the delivery address. Such mailpieces must be processed manually because they are incompatible with Postal Service automation and mechanized letter-sorting machines. These pieces cause problems even for the letter carrier, who must turn them to sort and again to deliver. The Postal Service acknowledges that this proposal will inhibit such mailpiece design practices. However, the benefit of facilitating efficient processing—for cost and for service—outweighs the minor loss of creative latitude that will result if the proposed rule is adopted. (Mailers to whom this creative latitude is truly significant will have the option of mailing pieces at single-piece rates.) However, given the relative proportion of the mailstream represented by incompatible bulk or presort rate letter-size mail, compared with the volume that is compatible, the Postal Service believes that few mailers will be impacted by the effects on mailpiece design of the proposed rule.

2. A010.1.0 and A200.1.3 are revised to add mandatory address placement standards for other-than-single-piece rate flat-size mail prepared in an unattached sleeve or partial wrapper, or otherwise not prepared in an envelope, polybag, or similar enclosure. The types of mail affected by this standard are relatively difficult and costly to process and sort; the second type has the added potential to come apart in the mail, resulting in its failure to reach the addressee. None of these circumstances benefits the mailer, the Postal Service, or the addressee. The proposed change will further Postal Service efforts to provide efficient and timely service.

The first of these mandatory placement standards affects flat-size mailpieces not prepared in a full enclosure and that may have an open edge presented either forward (as the piece travels through mechanization) or to the right (as the piece is held for manual sortation, casing, or delivery). The proposed revisions would require that such mail be addressed so that, when oriented to read the address, the mailpiece is positioned for more efficient processing, i.e., with its bound or final-folded edge to the right, and that pieces in partial wrappers or sleeves would have to have the open ends at the top and bottom of the mailpiece. The Postal Service, which has traditionally recommended that such mail be addressed in the manner described in the proposed rule (see existing Exhibit A200.1.3), has received only limited cooperation from mailers and, consequently, has been unable to improve the efficiency with which that mail can be handled. Some mailers (and some postal employees) have said that they were uncertain about whether the proposed placement was previously required.

In proposing this standard, the Postal Service seeks to balance the needs of the mailing community with its own operational need to curtail undesirable addressing practices that raise postal costs. Further, the Postal Service realizes that, if adopted as a final rule, the operational effect of this proposal on some mailers would require considerable lead time before actual implementation. Therefore, commenters who are concerned about the effect this proposal would have on their operations

are asked to provide specific information and suggestions:

- How could the problems associated with handling the affected mail be overcome by measures other than the proposed rule as written?
- What are commenters prepared to do to make that mail more efficient to handle?
- If the proposed rule is adopted, how much lead time would be needed to make the necessary internal operational changes?
- Would a short-term general implementation date be acceptable if the Postal Service worked with individual customers and allowed specific exceptions for delayed implementation?

The second mandatory address placement standard requires that flat-size mailpieces prepared in an unattached sleeve or partial wrapper must bear a delivery address on the item being mailed itself, by addressing just the item (provided that the address remains visible when the item is mailed), by addressing both the item and the wrapper, or by using an address label to firmly attach the item and its wrapper. (Flat-size pieces would also have to meet the standard proposed above.) The Postal Service has no preference for the method chosen, instead focusing on the objective: Ensuring that separation of the item and its wrapper do not result in the item becoming undeliverable. Some customers have complained that existing addressing methods sometimes cause them not to get this type of mail or to receive only the wrapper, pointing out that the Postal Service's tolerance of the underlying addressing practice is contrary to the best interests of the addressee. Recognizing the validity of these complaints, the Postal Service proposes to require those mailers who generate flat-size mailpieces prepared in an unattached sleeve or partial wrapper to move to an addressing method that corrects the problem just described. Commenters who object to this proposal are asked to provide constructive responses to the same questions asked for in the proposed revision discussed above.

For consistency, A200.1.3 would be revised to incorporate a reference to the foregoing sections. Other organizational changes are proposed to A010.1.0 that do not affect the substance of the standards.

3. C010.1.0 is amended to reduce the role of address placement in the determination of which of a mailpiece's physical dimensions are its length, height, and thickness. Existing standards are inconsistent in associating these basic physical dimensions to the delivery address. The proposed rule would remedy this by establishing consistent definitions, based on the physical characteristics of the mailpiece. For the typical letter-size piece, the proposed rule always defines its length (horizontal dimension) as the longest dimension; the mailpiece's height (vertical dimension) is the next longest dimension, and the thickness is the remaining dimension. Variations on this rule are proposed for pieces that do not have three unequal dimensions. While the Postal Service realizes that this change may affect a small volume of customer mail, as discussed above, the benefits of the consistent definitions contained in the changes proposed below, and of the processing efficiencies of the mail these proposals would produce, far outweigh any loss of creative latitude.

4. C050.1.0 is amended for consistency. By the revised wording, assignment of most mailpieces to a processing category depends solely on their dimensions as determined by C010.1.0. Existing standards base processing category on physical dimensions, without regard to address placement, so that the proposed rule, in effect, makes only minor changes to ensure that this section is harmonious with those discussed above.

5. C050.5.0 is amended to make it clear that merchandise samples are not by definition always irregular parcels, and may be categorized as letter- or flat-size pieces based on the usual criteria.

Other Revisions Concerning Addressing

1. These proposed changes to Domestic Mail Manual (DMM) standards relate to the content and placement of delivery and return addresses. The proposed revisions are intended to serve two general purposes: making existing standards more consistent and improving the address quality of mail.

2. Revisions to the standards in A010.4.3 and 4.5 are proposed to mandate the use of a ZIP Code or ZIP+4 code in the return address on certain mail. (The standard for required use of a return address is not changed by these proposals.) Specifically, by the proposed revision to A010.4.3, the correct ZIP Code or ZIP+4 code would be required in the return address on any mail where a return address is itself required under existing standards. Further, by the proposed change to A010.4.5, the existing placement standard for the return address on mail claimed at a ZIP+4 rate is both made more specific and extended to all mail on which a return address is required. Under the proposed rule, the return address must be placed in the top left corner of the address side, area, or label of the mailpiece, parallel to the delivery address. On ZIP+4 rate cards and letter-size mailpieces that do not bear a delivery point barcode, the return address would have to be outside the OCR read area (a current requirement applied broadly to all ZIP+4 rate mail).

The proposed revisions should facilitate the accurate and efficient return of mail by making complete return address information available in a readily identifiable location. Because mailers know their own ZIP Codes, the Postal Service believes that the proposed standards do not represent either a significant new burden on customers or one that customers will have serious problems in implementing. Customers who believe that deferred implementation will be necessary are asked to indicate this in their comments, with an explanation of why they require deferral and how long an adjustment period they require, and should propose appropriate terms for excepting those mailers/mailings while the necessary operational adjustments are made.

3. A010.5.3 is added to clarify the meaning and appropriate use of the terms "post office box," "P. O. Box," "PO Box," "POB," "P. O. B.," and similar combinations. These terms are sometimes incorrectly used to denote destinations other than post office box or caller service, such as a rural or highway contract route box, a college or business mailroom box, or a private commercial mail receiving agent. As a result, the imprecise use of terms conveys incorrect information or causes misinterpretation, either of which sometimes impedes the Postal Service in providing the desired service—delivering the mail where the sender intends. The potential for misdelivery has increased in today's automated mail processing environment: Optical character readers scan and "read" addresses to determine the correct delivery point barcode to assign to the mailpiece. Once this barcode is applied, the mailpiece is processed with minimal human intervention so that ambiguous address information applied by the mailer may result in a misdirected mailpiece.

To avoid these potential delivery problems, the proposed standard defines the terms "post office box," "P. O. Box," "PO Box," "POB," "P. O. B.," and similar combinations as referring exclusively to the delivery services provided by the Postal Service under D910 and D920 (Post Office Box Service and Caller Service, respectively). The proposed standard states that those

terms are always included in the correct address of mail destined for post office box or caller service addresses, that they are incorrect for mail intended for other addresses, and that the Postal Service cannot ensure accurate delivery of incorrectly addressed mail. (Correct addressing practices are described in detail in Publication 28, Postal Addressing Standards, available from postal business centers and larger post offices.)

This proposed rule will not have an adverse affect on customers because it merely clarifies the correct use of these terms. Moreover, many large mailers have already taken measures to improve the quality of their address lists, and may have already standardized such lists in conformance with the proposed rule.

4. A010.3.2c is also revised for organizational consistency.

5. Proposed changes to A010.5.1 should minimize the problems associated with dual addresses. Dual addresses, which typically include both a street address and a post office box, can lead to confusion for USPS employees identifying to which location the Postal Service is expected to make delivery despite the existing standards that the address immediately above the city-state-ZIP Code line takes precedence. Dual addressing can result in a potential for misdelivery (to the unintended address) as well as the potential for confusion and dissatisfaction on the part of the sender, addressee, or both. (Under the proposed rule, for those ZIP Code areas having no delivery service other than by post office box service, the correct address will be to the intended recipient's post office box address.)

Accurate delivery to the intended addressee is always important, but more so when the item has been identified by the sender as having exceptional value through the level of service selected (e.g., Express Mail or Priority Mail, or registered, certified, restricted delivery, or special delivery mail). Therefore, under the proposed rule, dual addresses are prohibited in the delivery and return addresses on those types of mail. Although this change may cause occasional inconvenience for some customers, the Postal Service believes that any inconvenience is more than offset by elimination of the ambiguity and delay potentially associated with dual addressing. This benefit is particularly true because the sender has invested a relatively large sum to ensure safe and accurate delivery.

The proposed rule also prohibits dual addresses on any mail claimed at a bulk or presort rate. Because of the problems described above, allowing dual addressing on this mail would be inconsistent with the Postal Service's ongoing efforts to improve address quality in volume mailings. Whereas this prohibition may have the appearance of a sweeping new requirement, its net affect should be minimal. Most mailers who use bulk or presort rates have enough awareness of addressing standards to know why dual addresses are not advisable and, therefore, seldom use them. The majority of those same mailers are already involved in ongoing address management to improve the quality of their addressing practices.

Mail sent at single-piece First-, third-, or fourth-class rates, without the special services mentioned earlier, is not subject to the proposed rule's prohibitions though mailers are advised not to use dual addresses on this mail to ensure delivery to the intended address.

Miscellaneous organizational and technical revisions are also being proposed for clarity and consistency.

Although exempt from the notice and comment requirements of the Administrative Procedure Act (5 U.S.C. 553(b), (c)) regarding proposed rulemaking by 39 U.S.C. 410(a), the Postal Service invites comments on the following proposed revisions of the DMM, incorporated by reference in the Code of Federal Regulations. See 39 CFR Part 111.

List of Subjects in 39 CFR Part 111

Postal Service.

PART 111—[AMENDED]

1. The authority citation for 39 CFR part 111 continues to read as follows:

Authority: 5 U.S.C. 552(a); 39 U.S.C. 101, 401, 403, 404, 3001–3011, 3201–3219, 3403–3406, 3621, 5001.

2. Revise the following units of the Domestic Mail Manual as follows:

A010 General Information

1.0 Address Content and Placement

* * * * *

1.2 Address Elements

* * * * *

d. ZIP Code (5-digit or ZIP+4) where required. A ZIP Code or ZIP+4 code is required on Presorted First-Class Mail; mail claimed at an automation rate; postal cards and postcards mailed under specific First-Class standards; second-class mail; bulk third-class mail; fourth-class mail; business reply mail; mail sent using merchandise return service; mail sent to military addresses within the United States; penalty mail; and personalized envelopes.

1.3 Placement

Specific conditions apply to certain types of mail; for purposes of these standards, letter-size mailpieces include cards; flat-size mailpieces include letter-size pieces eligible for and claimed at a Barcoded rate for flats:

a. The delivery address must parallel the length of a letter-size mailpiece unless that piece is paid at a single-piece rate. Letter-size mailpieces bearing an address oriented otherwise are not eligible for any presort or automation-based discount and may be nonmailable or subject to a nonstandard surcharge. First-Class card-rate pieces and all mail claimed at an automation rate are subject to additional standards.

b. If flat-size mail is not prepared in an envelope, polybag, or similar complete enclosure, the delivery address must be placed so that when the mailpiece is held to read the address, the bound edge or (if applicable) final-folded edge of the mailpiece is to the right, the address is at the top of the mailpiece parallel with the top edge, and, for mailpieces prepared in a sleeve or partial wrapper, the open ends of the sleeve or partial wrapper are at the top and bottom of the mailpiece.

c. If flat-size mail is prepared in an unattached sleeve or partial wrapper, the address must be placed on the enclosed material so that it can be read without moving the wrapper, or on both the wrapper and the enclosed matter, unless the address label is used to attach the wrapper to the enclosed matter.

d. If mail including an attachment does not bear the name and address of both the sender and intended recipient on both the host and the attachment, the sender's name and address must be placed on the host piece or the delivery address label (which may also show the return address) must be used to affix the attachment securely to the host. Combination containers that have inseparable parts or compartments (e.g., cartons with letter-size envelopes completely and securely attached to one side) are mailable with the names and addresses on only one.

* * * * *

1.5 Basic Addressing

Basic addressing standards for First-, third-, and fourth-class mail and for Express Mail are in E100, E300, E400, and E500, respectively. The detailed addressing standards for second-class mail are in A200. Additional standards apply to overseas military mail, Department of State mail, mail in window envelopes, international mail,

and mail claimed at any automation rate.

[Delete existing 1.6 and 1.7.]

* * * * *

3.0 Complete Addresses

* * * * *

3.2 Elements

* * * * *

c. Street number and name (including predirectional, suffix, and postdirectional as shown in USPS ZIP+4 file for the delivery address or rural route and box number (RR5 BOX 10), highway contract route and box number (HC4 BOX 45), or post office box number (PO BOX 458) (see 5.3), as shown in USPS ZIP+4 file for the delivery address).

* * * * *

4.0 Return Address

* * * * *

4.3 Required Use

Except as provided in 4.1, the sender's actual return address (including the correct ZIP Code or ZIP+4 code) must appear legibly on:

* * * * *

4.5 Placement

On any mail on which a return address is required, and on non-delivery point barcoded mail claimed at any ZIP+4 rate, the return address must be on the same side as, and parallel to, the delivery address, in the top left corner of the address side, area, or label of the mailpiece. Also, on non-delivery point barcoded ZIP+4 rate mailpieces, the return address must not be in the OCR read area, and must not extend farther than one-half the length of the mailpiece to the right edge, and no lower than one-third the height of the mailpiece from the top (see Exhibit 4.5).

5.0 Restrictions

5.1 Dual Address

A dual address is one that contains two delivery points, e.g., a street address and a post office box number (see Exhibit 5.1), and is subject to these restrictions:

a. A dual address is prohibited in the delivery and return addresses on Express Mail, Priority Mail, special delivery mail, registered mail, certified mail, restricted delivery mail, and any mail claimed at a bulk or presort rate.

b. Other mail bearing a dual address is delivered (or returned, as applicable) to the address immediately above the city and state (or to the post office box if both the street address and post office box are on the same line). If a ZIP+4 code or 5-digit ZIP Code is used in any dual address, it must correspond to the address element immediately above the city and state (or with the post office box number in the address if both the street address and post office box are on the same line).

* * * * *

5.3 Post Office Box Mail

The terms "post office box," "P. O. Box," "PO Box," "P. O. B.," "POB," and other similar combinations refer exclusively to the delivery services provided by the USPS under D910 and D920, and the correct address for those services always includes one of these terms. These terms are not correctly used on mail intended for delivery through a private box system or to other types of addresses (e.g., rural route boxes). The USPS cannot ensure accurate delivery of incorrectly addressed mail.

* * * * *

A200 Second-Class Mail

1.0 Basic Standards

* * * * *

1.3 Address Placement

Addresses and address labels must be visible. Subject to the general standards in A010, addresses or address labels may be placed on wrappers (on a flat side, not on the fold); label carriers; subscription order, renewal, gift, or request forms or receipts; incidental First-Class attachments; or supplements, but only if those items and the host second-class publication are enclosed within a plastic wrapper (polybag). The delivery address must parallel the length of a letter-size mailpiece, as defined in C010.

[Revise the title of Exhibit 1.3 to read "Address Placement—Other Than Letter-Size Pieces."]

* * * * *

C010 General Mailability Standards

1.0 Minimum and Maximum Dimensions

1.1 Determining Length and Height

Except as provided by 1.6, mailpiece length and height are determined as follows:

a. For pieces having three different dimensions, the longest dimension of a mailpiece is its length (horizontal dimension); the next longest, its height (vertical dimension); the shortest, its thickness.

b. For pieces having two equal dimensions:

(1) If the third dimension is longer than the equal dimensions, it is the mailpiece's length (horizontal dimension); the remaining dimensions are its height and thickness.

(2) If the third dimension is shorter than the equal dimensions, it is the mailpiece's thickness; of the remaining dimensions, the length is the dimension parallel to the address as read; the height is the remaining dimension.

c. For pieces having three equal dimensions, or having an irregular shape, or requiring a specific orientation because of the contents, the location and orientation of the address on the mailpiece establish which dimensions are its height and length. The length is the dimension parallel to the address as read; the height is perpendicular to the length on the address side of the piece.

* * * * *

1.4 Maximum

No single addressed mailpiece may exceed 70 pounds or 108 inches in length and girth combined. Girth is the total distance around the mailpiece, measured at its thickest part, perpendicular to its length.

1.5 Nonmailable

Except for keys and identification devices, all pieces not meeting the minimum size standards above are nonmailable.

1.6 Other Standards

Mailpieces to be claimed at the Barcoded rate for flats are subject to the definitions of length and height in C820 (rather than 1.1). The standards for specific classes or rates may prescribe higher minimum and/or lower maximum size and weight limits than those stated above.

* * * * *

1.8 Top and Bottom

For single-piece rate mail and pieces eligible for and claimed at the Barcoded or third-class carrier route rate for flats, the top and bottom of a letter- or flat-size mailpiece are its upper and lower edges, respectively, when the delivery address is oriented to be read. For other mail, the top and bottom of a letter- or flat-size mailpiece are its upper and lower edges, respectively, when the mailpiece is positioned with the length horizontal.

* * * * *

C050 Mail Processing Categories

1.0 Basic Information

All mail is assigned to one of the mail processing categories listed below based on the method for determining a mailpiece's length, height, and thickness prescribed in C010. Unless permitted by standard, any mailing at other than a single-piece rate may not

contain pieces from more than one processing category.

[Delete existing 1.2.]

* * * * *

5.0 Irregular Parcels

[After the phrase "merchandise samples that are not individually addressed," add the phrase "and that are neither letter-size nor flat-size."]

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E310 Basic Standards

* * * * *

E312 Additional Standards Applicable to Bulk Third-Class Mail

* * * * *

2.0 Standards for Rates, Fees, and Postage

2.1 Minimum Per-Piece Rates

[Delete the last sentence.]

* * * * *

An appropriate amendment to 39 CFR 111.3 to reflect these changes will be published if the proposal is adopted.

Stanley F. Mires,

Chief Counsel, Legislative.

[FR Doc. 94–14717 Filed 6–16–94; 8:45 am]

BILLING CODE 7710–12–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 70

[AD-FRL–5000–2]

Clean Air Act Disapproval of Operating Permits Program; Commonwealth of Virginia

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed disapproval.

SUMMARY: EPA is proposing to disapprove the Operating Permits Program submitted by the Commonwealth of Virginia for the purpose of complying with Federal requirements which mandate that States develop, and submit to EPA, programs for issuing operating permits to all major stationary sources, and to certain other sources. The reasons for proposing disapproval are as follows: Virginia's program does not contain the necessary legal authority to afford judicial review to persons who have participated in the public comment process, and it also does not contain the necessary legal authority to prevent default issuance of a permit. The submitted regulations have an expiration date of June 28, 1994 and cannot be applied or enforced after that date. Also, the regulatory portion of the program does not include the proper universe of sources required to be subject to a state operating permit program or ensure that permits contain all applicable requirements, or correctly delineating provisions enforceable only by the Commonwealth. In addition, there are other deficiencies in Virginia's submitted program, as specified in the Technical Support Document, which must be corrected before EPA can grant full approval to Virginia's operating permits program.

DATES: Comments on this proposed action must be received in writing by July 18, 1994.

ADDRESSES: Comments should be mailed to Thomas J. Maslany, Director, Air, Radiation & Toxics Division at the Region III address.

A copy of Virginia's submittal and other supporting information used in developing the proposal are contained in the docket and available for inspection during normal business hours at the following location: EPA Region III, Air, Radiation & Toxics Division, 841 Chestnut Building, Philadelphia, PA 19107.

FOR FURTHER INFORMATION CONTACT: Lisa M. Donahue, Environmental Scientist, at the Region III address, or call 215–597–9781.

SUPPLEMENTARY INFORMATION:

I. Background

A. Introduction

As required under title V of the Clean Air Act ("CAA"), EPA has promulgated rules which define the minimum elements of an approvable state operating permits program and the corresponding standards and procedures by which the EPA will approve, oversee, and withdraw approval of State operating permits programs (see 57 FR 32250 (July 21, 1992)). These rules are codified at 40 CFR part 70. Title V requires States to develop, and submit to EPA, programs for issuing these operating permits to all major stationary sources and to certain other sources.

The CAA requires that states develop and submit these programs to EPA by November 15, 1993, and that EPA take actions to approve or disapprove each program within 1 year after receiving the submittal. The EPA's program review occurs pursuant to section 502 of the CAA and 40 CFR part 70, which together outline criteria for approval or disapproval. Where a program substantially, but not fully, meets the requirements of 40 CFR part 70, EPA may grant the program interim approval for a period of up to 2 years. If EPA has not fully approved a program by November 15, 1995, or by the end of an interim program period, it must establish and implement a Federal operating permits program.

On November 12, 1993, Virginia submitted an operating permits program for review by EPA. It was received by EPA on November 19, 1994. The submittal was supplemented by a letter dated January 14, 1994, and was found to be administratively complete pursuant to 40 CFR 70.4(e)(1). The submittal contains a program description, a legal opinion from the Virginia Attorney General, confirmation of regulatory authority, program and fee regulations, relevant portions of Virginia statutes, guidance and forms, a description of enforcement provisions, a resource and fee demonstration, and a transition plan.

B. Federal Oversight and Sanctions

Sanctions must be imposed 18 months after EPA disapproves a state submittal, unless prior to expiration of the 18-month period the state submits a revised program that EPA approves. If a state has not submitted a revised program that EPA approves within 6 months after EPA applies the first sanction, a second sanction is required. In addition, discretionary sanctions may be applied any time during the 18-month period following the date required for program submittal or the date of program disapproval. If the Commonwealth does not have an approved program by November 15, 1995, EPA must promulgate, administer, and enforce a Federal operating permits program for the Commonwealth.

II. Summary and Analysis of State Submission

The analysis contained in this document focuses on the major portions of Virginia's submittal and particularly portions which must be corrected to meet the minimum requirements of 40 CFR part 70. The full program submittal, the Technical Support Document, and other relevant materials are available for detailed information as part of the public docket. The docket may be viewed during regular business hours at the address listed above.

A. Statutory Authority

1. Standing for Judicial Review

The Attorney General of the Commonwealth, in his opinion dated November 5, 1993, states that "the laws of the Commonwealth provide adequate authority to carry out all aspects of the Commonwealth's program for Federal operating permits." The Attorney General cites Va. Code section 10.1–

1318(B) as providing an opportunity for judicial review to any person who is aggrieved by a final decision of the State Air Pollution Control Board and who meets certain criteria, including having an immediate, pecuniary, and substantial interest. The requirement for standing for judicial review, as specifically required by section 502(b)(6) of the CAA and 40 CFR 70.4(b)(3)(x), must provide standing for any person who has participated in the public comment process and any other person who could obtain judicial review of that action under applicable law. EPA interprets section 502(b)(6) of the CAA as requiring that title V permits programs must provide judicial review to any party who participated on the public comment process and who at a minimum meets the threshold standing requirements of Article III of the U.S. Constitution.

In comparison, Section 10.1–1318(B) of the Code of Virginia extends the right to seek judicial review only to persons who have suffered an "actual, threatened, or imminent injury..." where "such injury is an invasions of an immediate, legally protected, pecuniary and substantial interest which is concrete and particularized..." The Virginia statute, as well Virginia case law does not enable a party who meets the minimum threshold standing requirements of Article III of the U.S. Constitution access to the Commonwealth's court system. The Commonwealth's Attorney General's opinion submitted with Virginia's program states that "the inclusion of the word 'pecuniary' in the amended Virginia law means the requirement for standing to obtain judicial review may be more stringent than Article III standing requirements, as the EPA interprets them under the United States Supreme Court decision in *Lujan* v. *Defenders of Wildlife*, 112 S.Ct. 2130, 2136 (1992) and related cases."

The limitations on judicial review in Virginia do not meet the minimum threshold standing requirements of Article III of the U.S. Constitution and thus do not meet the minimum program approval criteria under title V. Therefore, EPA is proposing to disapprove Virginia's program because it does not meet the minimum requirement for standing for judicial review. Va. Code section 10.1–1318(B) must be amended.

2. Default Issuance of Permits

Va. Code section 9–6.14:3 provides that the purpose of Virginia's Administrative Process Act is to supplement present and future basic laws. Although Regulations sections 120–08–0525 C and E provide for EPA veto and affected states review, these regulations may be superseded by the Administrative Process Act. Sections 9–6.14:11 and 9–6.14:12 of the Administrative Process Act provide that a party may provide written notice to the agency that a decision on a permit is due, and that the decision is deemed in favor of the named party if no decision is reached within 30 days. This provision prevents the Commonwealth from meeting the requirement of section 505(b)(3) of the CAA that no permit be issued unless it is revised to meet the objection of EPA, if EPA objects to the permit within 45 days after receiving a copy of the proposed permit. This provision also prevents the Commonwealth from meeting § 70.8(e), which requires the Attorney General to certify that no provision of state law requires that a permit be issued after a certain time if the permitting authority has failed to take action on the application. Virginia must ensure that no permit will be issued by default through this process until affected states and EPA have had a chance to review the proposed permit as required by 40 CFR 70.8. In addition Virginia must ensure that no permit will be issued through this process if EPA has objected within 45 days. EPA is proposing to disapprove Virginia's program because it does not ensure that EPA and affected states are given an adequate opportunity for review of proposed permits and that no permit will be issued if EPA objects.

B. Regulations and Program Implementation

1. Effectiveness and Enforceability of Rules

The Virginia operating permit program Regulations for the Control and Abatement of Air Pollution (Regulations) Emergency Rule 8–5, Federal Operating Permits for Stationary Sources, and Emergency Rule 8–6, Permit Program Fees, do not meet the requirements of 40 CFR part 70. Although the rules are currently effective, they expire on June 28, 1994 and cannot be implemented or enforced beyond that date. EPA is proposing to disapprove Virginia's program because its regulations expire on June 28, 1994.

2. Applicability Under the Operating Permits Program

a. Definitions and Exemptions. The requirements of § § 70.2 and 70.3 for applicability have not been met. Primarily, Virginia's regulations at section 120–08–0502 and section 120–08–0602 do not correctly define major source or stationary source. Virginia's definitions, and the exemptions of insignificant activities and affected sources found in section 120–08–0501 of Virginia's regulations limit the universe of sources that are applicable to Rule 8–5 by exempting or deferring sources that are required by 40 CFR part 70 to obtain an operating permit. EPA is proposing to disapprove Virginia's program because the regulations do not apply to the proper universe of sources. Further discussion of these deficiencies is contained in the Technical Support Document.

b. Variances. Virginia has the authority to issue a variance from requirements imposed by Virginia law. The variance provision at Va. Code section 10.1–1307.C. empowers the Air Pollution Control Board, after a public hearing, to grant a local variance from any regulation adopted by the board. EPA regards this provision as wholly external to the program submitted for approval under 40 CFR part 70, and consequently is proposing to take no action on this provision of Virginia law. EPA has no authority to approve provisions of state law, such as the variance provision referred to, which are inconsistent with the CAA. EPA does not recognize the ability of a permitting authority to grant relief from the duty to comply with a federally enforceable permit, except where such relief is granted through procedures allowed by 40 CFR part 70. EPA reserves the right to enforce the terms of the permit where the permitting authority purports to grant relief from the duty to comply with a permit in a manner inconsistent with 40 CFR part 70 procedures.

3. Applicable Federal Requirements and Federally Enforceable Provisions

Virginia's submittal does not ensure the Commonwealth's ability to issue permits which include all applicable Federal requirements and which correctly delineate requirements that are enforceable only by Virginia. The Commonwealth also cites Virginia's regulations rather than Federal regulations (in the form of federally promulgated regulations or state regulations that have been approved into the State Implementation Plan) in the definitions in section 120–08–0502. In section 120–08–0507, Federal enforceability is incorrectly extended to portions of Virginia's regulations that have been submitted, but not yet approved, into the State Implementation Plan.

EPA is proposing to disapprove Virginia's program because it explicitly purports to extend Federal enforceability to provisions which are

not enforceable by the administrator and also does not include certain provisions which must be considered federally enforceable (and thus applicable) requirements.

4. Public Participation and Affected State Review

Virginia uses the term "locality particularly affected" in determining the geographic scope of notification to the public of a public comment period on a draft permit. This scope is too narrow and it does not fully meet the requirements of 40 CFR 70.7(h) for public participation. For full approval, Virginia must ensure that any locality that could potentially be affected by a permit would be notified of the opportunity for public comment on that permit. In addition, Virginia incorrectly exempts minor permit modifications from the requirement under § 70.8(b)(2) for affected state review of those modifications. Virginia must also correct this deficiency before EPA can grant full approval to Virginia's program.

C. Permit Fees and Demonstration

Va. Code section 10.1–1322.1 and Rule 8–6 allow for a fee rate of up to $25 per ton, as adjusted by the consumer price index (CPI), of emissions to be charged to a source. The fee is set by the Air Pollution Control Board and can be adjusted annually, without exceeding the statutory cap, to meet the costs of implementation of the program. Virginia's fee revenue projections are based on revenues from a $25 per ton fee, using 1990 as a base year, and adjusted annually by the CPI, as set out in Section 502 of the CAA. However, no specific fee schedule was included in the submittal and the cap on the fee amount limits the Board's flexibility in ensuring that revenues are sufficient to cover the direct and indirect costs of the program. (CAA section 502(b)(3)(A) and Va. Code section 10.1–1322. B.) Va. Code section 10.1–1322. B. precludes the Commonwealth from collecting title V fees to cover the indirect costs charged and collected by the Commonwealth's Department of Accounts. This provision violates 40 CFR 70.9(b).

The fee amounts projected by Virginia in the "Total Fee Revenue Projections" table, although sufficient to cover the estimated costs of the program (as set out in the resource demonstration), do not accurately reflect the mandate of Va. Code section 10.1–1322.1 to adjust fees using the CPI calculation method stipulated in CAA section 502. Also, it is unclear whether or not the estimated emissions used in the "Total Fee Revenue Projections" table include emissions from acid rain sources, which Virginia exempts from fees in the years 1995 to 1999 (section 120–08–0601 C.5.) or includes Hazardous Air Pollutants.

In order for EPA to grant full approval to Virginia's program, the Commonwealth must remove the statutory impediment to using permit fees to fund certain indirect costs of its program and ensure that the Commonwealth's fee provision comply with 40 CFR part 70.

D. Provisions Implementing the Requirements of Other Titles of the CAA

1. Authority and Commitments for Section 112 Implementation

In Va. Code section 10.1–1322.A. and Rule 8–5, Virginia has demonstrated broad legal authority to incorporate into permits and enforce all applicable CAA section 112 requirements. However, Virginia also indicated that additional authority may be necessary to conduct specific section 112 activities, and did not commit to implementing CAA section 112(r) for prevention of accidental release. Virginia supplemented its broad legal authority with a commitment to "develop the state regulatory provisions as necessary to carry out these programs and the responsibilities under the delegation after approval of the operating permit program and EPA has issued the prerequisite guidance for development of these title III programs." Also, Virginia has the authority under section 120–08–0505 K to require that an applicant state that the source has complied with CAA section 112(r) or state in the compliance plan that the source intends to comply and has set a schedule to do so. In the case of CAA section 112(g) requirements, EPA notes that Virginia must begin to implement this program upon approval of an operating permits program.

2. Authority and Commitments for Implementation of Acid Rain Requirements

Virginia has committed to adopting regulations to meet the requirements of the Acid Rain program by January 1, 1995. The Attorney General, in his November 5, 1993 opinion, committed to including a statutory and regulatory analysis of the acid rain portions of the operating permits program in the January 1, 1995 submittal. Virginia has begun its regulatory development process to adopt regulations for the acid rain portion of the Virginia Operating Permits Program.

III. Request for Public Comments

EPA is soliciting public comments on the issues discussed in this document or on other relevant matters. These comments will be considered before taking final action. Interested parties may participate in this Federal rulemaking action by submitting written comments to the EPA Regional office listed in the **ADDRESSES** section of this document. EPA has received a petition from the Environmental Defense Fund, dated December 23, 1993, to disapprove Virginia's operating permits program. This petition will be included in the docket and will be considered in EPA's final action.

Proposed Action

EPA is proposing to disapprove the operating permits program submitted by the Commonwealth on November 12, 1993. If promulgated, this disapproval will constitute a disapproval under section 502(d) of the CAA (see generally 57 FR 32253–32254). As provided under section 502(d)(1) of the CAA, the Commonwealth will have up to 180 days from the date of EPA's notification of disapproval for the Governor of Virginia to revise and resubmit the program. EPA is proposing to disapprove this program on the basis that Virginia has not met the following five requirements:

1. Pursuant to section 502(b)(6) of the CAA and 40 CFR 70.4(b)(3)(x) and 70.7(h), adequate provisions for public participation in the permit process, including statutory authority that meets the minimum threshold for judicial standing.
2. Pursuant to section 505(b)(3) of the CAA and 40 CFR 70.8(e), authority to prevent default issuance of permits.
3. Regulations that expire on June 28, 1994.
4. Issuance of permits to the proper universe of sources required by 40 CFR part 70 to be included in the Commonwealth's operating permit program.
5. Regulations that meet the requirements of 40 CFR part 70 ensuring issuance of permits that contain all applicable Federal requirements and correctly delineate provisions only enforceable by the Commonwealth.

Virginia must amend its program to correct the deficiencies and resubmit all relevant portions of the program, including a revised Attorney General's opinion. The Technical Support Document discusses Virginia's submittal in detail, and contains specific references to revisions and modifications necessary to obtain full approval. Submittal of revised portions of Virginia's operating permit program, including revised statutes and regulations, will undergo additional notice and comment in the **Federal**

Register before EPA takes final action on the program submittal, if those revised portions are received before November 19, 1994. November 19, 1994 is one year from the date of receipt of the submittal and the date by which EPA is required under 40 CFR 70.4(e) to take final action on the current submittal.

The Commonwealth of Virginia must submit a corrected program within 180 days following final EPA disapproval of the program. If Virginia fails to submit a fully approvable whole part 70 program, or a required revision thereto, in conformance with the provision of 40 CFR 70.4, EPA may, at any time, apply one of the sanctions specified in section 179(b) of the Act. Sanctions must be imposed 18 months after EPA disapproves a state's submittal.

The Office of Management and Budget (OMB) has exempted this action from Executive Order 12866 review.

Under the Regulatory Flexibility Act, 5 U.S.C. 600 *et seq.*, EPA must prepare a regulatory flexibility analysisassessing the impact of any proposed or final rule on small entities. 5 U.S.C. 603 and 604. Alternatively, EPA may certify that the rule will not have a significant impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and government entities with jurisdiction over populations of less than 50,000.

EPA's disapproval of the State request under section 502 of the CAA does not affect any existing requirements applicable to small entities. Any pre-existing Federal requirements remain in place after this disapproval. Federal disapproval of the State submittal does not affect its state-enforceability. Moreover, EPA's disapproval of the submittal does not impose any new Federal requirements. Therefore, EPA certifies that this disapproval action does not have a significant impact on a substantial number of small entities because it does not impose any new Federal requirements.

The Regional Administrator's decision to approve or disapprove Virginia's operating permits program will be based on whether it meets the requirements of title V of the Clean Air Act, as amended, and EPA regulations in 40 CFR part 70.

Authority: 42 U.S.C. 7401–76719.

Dated: May 5, 1994.

Stanley L. Laskowski,

Acting Regional Administrator.

[FR Doc. 94–14816 Filed 6–16–94; 8:45 am]

BILLING CODE 6560–50–F

40 CFR Part 435

[FRL–5000–9]

Public Meeting on Planned Effluent Guidelines for the Coastal Oil and Gas Subcategory

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of public meeting.

SUMMARY: The Environmental Protection Agency is announcing a public meeting prior to proposing effluent guidelines and standards for the Coastal Oil and Gas subcategory of the Oil and Gas Extraction category. EPA intends to propose a rule in January 1995, and this is the only public meeting that the Agency plans to sponsor prior to proposal. The meeting is intended to be a forum in which EPA can report on the status of regulatory development and in which interested parties can provide information and ideas to the Agency on key technical, scientific, and other issues.

DATES: The meeting will be held on July 19, 1994 from 9:00 a.m. to 2:00 p.m.

ADDRESSES: The meeting will be held in Conference Room 111 at the Minerals Management Service (MMS), Gulf of Mexico/Outer Continental Shelf Regional Office, 1201 Elmwood Park Blvd., New Orleans, LA. Seating will be available for approximately 100 attendees.

MMS is located approximately five miles from New Orleans International Airport. To reach MMS, go East on U.S. Route 61 (Airline Highway). Turn right on Clearview Parkway and go over the overpass. There will be a shopping center on the right. Turn right at the light marking the entrance to the shopping center. MMS is in the Elmwood Towers Building adjacent to the K-Mart. Parking is available at the front and rear of the building. For additional directions please call Cheryl Rauch of MMS at 504–736–2949.

FOR FURTHER INFORMATION CONTACT: Allison Wiedeman, Engineering and Analysis Division, Office of Science and Technology/Office of Water, Mail Code 4303, US EPA, 401 M Street, SW, Washington, DC 20460. Telephone (202) 260–7179, fax (202) 260–7185.

SUPPLEMENTARY INFORMATION: EPA is developing effluent limitations guidelines and standards for the Coastal Oil and Gas subcategory under authority of the Clean Water Act (33 U.S.C. 1251 et seq.). The Coastal subcategory includes operations involved in drilling for and production of oil and gas in the coastal areas of the United States. Such coastal areas include states bordering the Gulf of Mexico, the coast of California, and both the North Slope and Cook Inlet in Alaska.

The public meeting will include discussions of the effluent guidelines regulatory development process, applicability of the forthcoming rule, regulatory approach (i.e. treatment technologies considered for effluent limits and their costs), affected population estimates, and general coastal oil and gas issues. The meeting will not be recorded by a reporter or transcribed for inclusion in the record for the Coastal Oil and Gas industry rule.

Documents relating to the topics mentioned above and a more detailed agenda will be available at the meeting.

Tudor T. Davies,

Director, Office of Science and Technology.

[FR Doc. 94–14818 Filed 6–16–94; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 22

[CC Docket No. 92–115; FCC 94–102]

Public Mobile Services

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The Federal Communications Commission proposes further revisions to its rules governing the Public Mobile Services. The proposed further revisions are necessary to update these rules. The intent of this proposal is to eliminate unnecessary information collection requirements, streamline licensing procedures, reduce the processing and review burden on the Commission's staff, and ensure that licensees in the public mobile services are fully qualified to provide service to the public as expeditiously as possible.

DATES: Comments must be submitted on or before June 20, 1994. Reply comments must be submitted on or before July 5, 1994.

ADDRESSES: Address written comments to: Federal Communications Commission, 1919 M Street, NW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Leila Brown, 202–632–6450 or Dan Abeyta, 202–632–6450.

SUPPLEMENTARY INFORMATION:

Summary of the Further Notice of Proposed Rulemaking

The following is a summary of the Commission's further notice of

proposed rulemaking in CC Docket No. 92–115, adopted April 20, 1994 and released May 20, 1994. The full texts of all Commission decisions are available for inspection and copying during normal business hours in the FCC Docket Branch (room 230), 1919 M Street, NW., Washington, DC. The complete text of this decision may be purchased from the Commission's copy contractor, International Transcription Services, (202) 857–3800, 2100 M Street, NW., suite 140, Washington, DC 20037.

1. In this Further Notice, the Federal Communications Commission proposes further revisions to 47 CFR part 22. The rules in part 22 govern the Public Mobile Services. These revisions are proposed in order to eliminate unnecessary information collection requirements, streamline licensing procedures, reduce the processing and review burden on the Commission's staff, and ensure that licensees in the public mobile services are fully qualified to provide service to the public as expeditiously as possible.

2. On May 14, 1992, the Commission adopted a Notice of Proposed Rulemaking in the docket 57 FR 29260, July 1, 1992 proposing comprehensive revisions to part 22. Prior to adoption of a Report and Order in this proceeding, Congress enacted the Omnibus Budget Reconciliation Act of 1993 (Budget Act) which amends section 3(n) and section 332 of the Communications Act. The Budget Act creates a comprehensive regulatory framework for all mobile radio services, including existing part 22 common carrier mobile services, private land mobile services, and future services. Because of the broad statutory changes that affect the regulation of mobile services, action on the part 22 revision was deferred. The proposals adopted in the further notice augment those proposals adopted in the notice.

3. We propose to require licensees notifying the Commission of minor modifications to their systems on FCC Form 489, which include Service Area Boundary (SAB) extensions into the adjacent market, to specify whether the 5 year fill-in period for the market has expired and, if so, to state that the SAB extension does not cover any unserved area. Current rules allow a cellular licensee to expand its SAB into an adjacent cellular service territory pursuant to a written agreement with the latter licensee. A licensee is permitted to expand its SAB into an adjacent cellular geographic service area (CGSA) at any time and may extend into an adjacent metropolitan service area or a rural service area provided the 5 year fill-in period has not expired. Many of the contracts included with FCC Forms 489 that notify the Commission of such minor modifications simply acknowledge a licensee's permission to allow a SAB extension into its market, even when the 5 year fill-in period has expired. In these cases, the staff must devote a significant amount of time to determine if the SAB extension covers any unserved area, because licensees may apply to serve such area only by filing a separate application with the Commission.

4. We propose to revise the scale of the maps required to be filed by the Commission's rules from 1:250,000 to 1:500,000. We believe that reducing the map scale would serve the public interest by reducing both filing burdens on applicants as well as review burdens on the staff.

5. We propose to modify the rules to allow cellular licensees to make minor changes to their facilities and to add transmitters within the contours of authorized stations without seeking prior approval or notifying the Commission of such changes. If we adopt this proposal, we plan to eliminate the listing of internal cell sites on our authorizations for existing licensees. However, we intend to maintain accurate, current information regarding the cell sites that constitute a system's CGSA boundary—i.e., the external cell sites. Therefore, we propose to require all cellular licenses to submit the following information for each of their external cell sites: (1) The geographic coordinates and cell site location description as required in Item 27 on Schedule B of FCC Form 401 and (2) the operating and technical parameters for the cell site which is currently required in Table MOB 2 and Table MOB 3 of FCC Form 401. This is a one time filing that would assist the staff in updating the Commission's database systems.

6. We propose to modify the information that licensees must submit pursuant to rule § 22.925 of the Commission's rules. First, consistent with the proposal to revise the map scale, we propose to revise the scale of the full-size map to a scale of 1:500,000. Second, we propose to require that all maps submitted pursuant to this rule show only the exterior cell sites and their respective service area boundaries that make up the CGSA. Third, we propose to require licensees to include an exhibit providing the coordinates for each exterior cell site and the information currently required in the MOB 3 Table of FCC Form 401. Fourth, we propose to eliminate the requirement that licensees submit a frequency utilization plan or chart. Fifth, we propose to require licensees to label all System Information Update maps with specific language explaining which carrier is filing the map and for which market.

7. We propose that for all 931 MHz paging applications, applicants must specify the frequency for which they seek authorization. The frequency requested must be available at the time the application is filed. Applications that are acceptable for filing will be placed on public notice. Mutually exclusive applications received within 30 days after the public notice will be considered one processing group. Mutually exclusive applicants for specific frequencies that are accepted for filing after July 26, 1993 would be subject to the competitive bidding process. We also propose that applicants for 931 MHz paging frequencies with applications pending when final rules become effective be given 60 days from the effective date of a final order in this proceeding to amend their applications to specify frequencies for which they seek authorization. Failure to amend a pending application to specify a frequency will result in dismissal of that application. All pending amended applications and newly filed applications that are mutually exclusive and received within 60 days of the effective date of this Order will be considered together as a processing group this one time only. We propose that the amended applications be subject to the competitive bidding process. However, we seek comment on whether we should instead use lotteries for these applications.

8. We propose to consider the following to be an initial 931 MHz paging application: (1) an application anywhere on a new frequency and (2) a proposal to locate a new facility more than two kilometers (1.6 miles) from any existing facility operating on the same frequency. A 931 MHz paging application would be considered a modification of an existing system only if: (1) It proposes a new location two kilometers or less from a previously authorized and fully operational base station licensed to the same licensee operating on the same frequency; or (2) the application is for a change of location within two kilometers of an existing station licensed to the same licensee; or (3) the application proposes a technical change that would not increase the service contour. We tentatively conclude that we will use first come, first served procedures to process 931 MHz paging modification licenses in cases in which we conclude, as a result of our examination of the issue in this rulemaking proceeding, that the use of competitive bidding

procedures would not be legally permissible or otherwise appropriate. Under the first come, first served procedure, only manually exclusive modification applications received on the same day would, consistent with the Budget Act, be designated for comparative hearing to determine which modification application should be granted.

9. We welcome comment on any and all of the proposed further revisions to 47 CFR part 22. We also invite suggestions for any other proposals or refinements to the proposals that we have made in this proceeding.

10. This is a non-restricted notice and comment rulemaking proceeding. *Ex parte* presentations are permitted except during the Sunshine Agenda period, provided they are disclosed as provided in Commission rules. See generally 47 CFR 1.1202, 1.1203 and 1.1206(a).

11. Pursuant to applicable procedures in 47 CFR 1.415 and 1.419, interested parties may file comments on or before June 20, 1994 and reply comments on or before July 5, 1994. All relevant and timely comments will be considered by the Commission before final action is taken in this proceeding. To file formally in this proceeding, participants must file an original and four copies of all comments, reply comments and supporting comments. If participants want each Commissioner to receive a personal copy of their comments, an original plus nine copies must be filed. Comments and reply comments should be sent to Office of the Secretary, Federal Communications Commission, Washington, DC 20554. Comments and reply comments will be available for public inspection during regular business hours in the Dockets Reference Room (room 239) of the Federal Communications Commission, 1919 M Street NW., Washington, DC 20554.

12. Accordingly, it is ordered that, pursuant to section 4(i) and 303(r) of the Communications Act of 1934, as amended, 47 U.S.C. 154(i) and 303(r), this further notice of proposed Rulemaking is issued. It is further ordered, That the Secretary shall cause a copy of this further notice to be sent to the Chief Counsel for advocacy of the Small Business Administration.

Paperwork Reduction Act

The following collections of information contained in this proposed rule have been submitted to the Office of Management and Budget for review under section 3504(h) of the Paperwork Reduction Act (44 U.S.C. 3504(h)). Copies of this submission may be purchased from the Commission's copy contractor, International Transcription Service, Inc., (202) 857–3800, 2100 M Street NW., suite 140, Washington, DC 20037. Persons wishing to comment on this collection of information should direct their comments to Timothy Fain, (202) 395–3561, Office of Management and Budget, room 3235, NEOB, Washington, DC 20503. A copy of any comments file with the Office of Management and Budget should also be sent to the following address at the Commission: Federal Communications Commission, Records Management Division, room 234, Paperwork Reduction Project, Washington, DC 20554. For further information contact Judy Boley, (202) 632–7513.

Title: Revision of part 22 of the Commission's Rules Governing the Public Mobile Services, CC Docket No. 92–115, FNPRM.

OMB Number: 3060–0508.

Action: Proposed new and revised collections.

Respondents: Businesses or other for profit, including small businesses.

Frequency of Response: On occasion.

Public Burden For the Collections Is Estimated As Follows:

Proposed requirements	Estimated average hours per response	Estimated annual burden
Service Area Boundary	.....	3200
Extensions	2	1700
Cell Sites Report	1	1700
System Information Update	1	4000
931 MHz Applications	1	.....
Total Annual Hours	.....	10,600

Needs and Uses: The further notice of proposed rulemaking solicits public comment to revise part 22 of FCC's rules governing the Public Mobile Services. The revisions are proposed in order to make the rules easier to understand, eliminate outdated rules and unnecessary information collection requirements, streamline licensing procedures, and allow licensees greater flexibility in providing service to the public. Generally, the collected information is used to determine the legal and technical qualifications of the respondents.

Regulatory Flexibility

Pursuant to the Regulatory Flexibility Act of 1980, the Commission's initial regulatory flexibility analysis follows:

Reason for Action and Objective

The Commission is proposing to revise title 47, part 22 of the Code of Federal Regulations to eliminate unnecessary information collection requirements and, whenever possible, provide greater flexibility to carriers while at the same time promoting the public interest. The objective of this proposal is to provide effective and adaptive regulation for communications.

Legal Basis

Authority for this further notice is contained in sections 4(i) and 303(r) of the Communications Act of 1934, 47 U.S.C. 154(i) and 303(r).

Reporting, Recordkeeping and Other Compliance Requirements

The proposed rules would not significantly change the existing reporting, recordkeeping and other compliance requirements. In the case of required map filings, for example, the proposal merely changes the scale of the map filed. Several new requirements are proposed. For example, one of the proposed new rules would require that cellular licensees submit information for each of their external cell sites. Another proposed rule would require that applicants for 931 MHz paging service request specific frequencies in their applications.

Federal Rules That Overlap, Duplicate or Conflict With These Rules

None.

Description, Potential Impact and Number of Small Entities Affected

There are approximately 8,600 licensees subject to the rules in part 22. A substantial portion of these are small entities. There are also a number of small entities whose business is consulting or providing other services in connection with part 22. The proposed further notice would not significantly impact these small entities.

Significant Alternatives Minimizing Impact on Small Entities and Consistent With States Objectives

The proposals contained in this Further Notice are meant to simplify and ease the regulatory burden on all Public Mobile Services applicants and licensees consistent with the Commission's established public interest objectives.

The Chief Counsel for Advocacy of the Small Business Administration will be served with a copy of this Further Notice of Proposed Rule Making in accordance with section 603(a) of the Regulatory Flexibility Act, 5 U.S.C. 603(a).

List of Subjects in 47 CFR Part 22

Public mobile services, Radio.

Federal Communications Commission.
William F. Caton,
Acting Secretary.
[FR Doc. 94–14455 Filed 6–16–94; 8:45 am]
BILLING CODE 6712–01–M

DEPARTMENT OF DEFENSE

48 CFR Part 215

Defense Federal Acquisition Regulation Supplement; Overhead Should-Cost Reviews

AGENCY: Department of Defense (DoD). Q02
ACTION: Proposed rule with request for public comments.

SUMMARY: The Department of Defense is proposing changes to the Defense Federal Acquisition Regulation Supplement (DFARS) to provide criteria for when DoD activities should consider performing should-cost reviews.

DATES: Comments on the proposed DFARS rule should be submitted in writing to the address shown below on or before August 16, 1994 to be considered in the formulation of a final rule.

ADDRESSES: Interested parties should submit written comments to Defense Acquisition Regulations Directorate, Attn: IMD 3D139, PDUSD(A&T), 3062 Defense Pentagon, Washington, DC 20301–3062. Telefax number (703) 604–5971. Please cite DFARS Case 92–D010 in all correspondence related to this issue.

FOR FURTHER INFORMATION CONTACT: Mrs. Alyce Sullivan, (703) 604–5929.

SUPPLEMENTARY INFORMATION:

A. Background

This proposed rule originated based on a recommendation in the General Accounting Office (GAO) report dated October 30, 1991, entitled "Economy and Efficiency Audits Can Help Reduce Overhead Costs," which recommends that regulations be revised to provide guidance for the use of overhead should-cost reviews. The proposed rule modifies DFARS 215.810 to supplement the FAR rule published for public comment on April 6, 1994 (59 FR 16388). It provides specific criteria for when DoD activities should consider performing should-cost reviews.

B. Regulatory Flexibility Act

The proposed rule is not expected to have significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, because contracts awarded to small entities normally are not subject to program or overhead should-cost reviews. An initial regulatory flexibility analysis has, therefore, not been performed. Comments are invited from small businesses and other interested parties. Comments from small entities concerning the affected DFARS sections will also be considered in accordance with section 610 of the Act. Such comments must be submitted separately and cite DFARS Case 94–610 in correspondence.

C. Paperwork Reduction Act

The proposed rule does not impose any additional reporting or recordkeeping requirements which require the approval of OMB under 44 U.S.C. 3501, *et seq.*

List of Subjects in 48 CFR Part 215

Government procurement.

Claudia L. Naugle,
Deputy Director, Defense Acquisition Regulations Council.

Therefore, it is proposed that 48 CFR part 215 be amended as follows:

1. The authority citation for 48 CFR part 215 continues to read as follows:

Authority: 41 U.S.C. 421 and 48 CFR part 1.

PART 215—CONTRACTING BY NEGOTIATION

2. Section 215.810 is revised to read as follows:

215.810 Should-cost review.

3. Section 215.810–2 is added to read as follows:

215.810–2 Program should-cost review.

(b) DoD contracting activities should consider performing a program should-cost review before award of a definitive major systems contract exceeding $100 million.

4. Section 215.810–3 is added to read as follows:

215.810–3 Overhead should-cost review.

(b)(i) The Defense Contract Management Command/Defense Logistics Agency (DCMC/DLA), or the military department responsible for performing contract administration functions (e.g., Navy SUPSHIP), should consider performing an overhead should-cost review of a contractor business unit (as defined in FAR 31.001) when all the following conditions exist—

(A) Projected annual sales to DoD exceed $1 billion;

(B) Projected DoD vs. total business exceeds 30 percent;

(C) High level of sole-source DoD contracts;

(D) Significant volume of proposal activity anticipated; and

(E) Production or development of major weapon system or program anticipated.

(ii) The head of the contracting activity may request an overhead should-cost review for a business unit which does not meet the criteria in paragraph (b)(i) of this subsection.

(iii) Overhead should-cost reviews are labor intensive and require participation by the buying activities, contract administration, and contract audit elements. The extent of availability of military department, contract administration, and contract audit resources to support DCMC/DLA-led teams should be considered when determining whether a review will be conducted. Overhead should-cost reviews generally shall not be conducted at a contractor business segment more frequently than every three years.

[FR Doc. 94–14320 Filed 6–16–94; 8:45 am]
BILLING CODE 5000–04–M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 676

[I.D. 060994B]

Limited Access Management of Federal Fisheries in and Off of Alaska

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.
ACTION: Notice of availability of amendments to Fishery Management Plans and request for comments.

SUMMARY: NMFS announces that the North Pacific Fishery Management Council (Council) has submitted Amendment 31 to the Fishery Management Plan (FMP) for the Groundfish Fishery of the Bering Sea and Aleutian Islands Area (BSAI) and Amendment 35 to the FMP for Groundfish of the Gulf of Alaska (GOA) for Secretarial review and is requesting comments from the public. These amendments would implement the Modified Block proposal, an action intended to discourage excessive consolidation in the Pacific halibut and sablefish individual fishing quota (IFQ) program.

DATES: Comments on the FMP amendments should be submitted by August 12, 1994.

ADDRESSES: Comments on the FMP amendments should be submitted to Ronald J. Berg, Chief, Fisheries Management Division, Alaska Region, NMFS, 709 W. 9th, Room 453, Juneau, AK 99801 or P.O. Box 21668, Juneau, AK 99802, Attention: Lori J. Gravel. Copies of the amendments and the environmental assessment/regulatory impact review/initial regulatory flexibility analysis prepared for the amendments are available from the Council, P.O. Box 103136, Anchorage, AK 99510.

FOR FURTHER INFORMATION CONTACT: John Lepore, 907–586–7228.

SUPPLEMENTARY INFORMATION: The Magnuson Fishery Conservation and Management Act (Magnuson Act) requires that each Regional Fishery Management Council submit any fishery management plan or plan amendment it prepares to the Secretary of Commerce (Secretary) for review and approval, disapproval, or partial disapproval. The Magnuson Act also requires that the Secretary, upon reviewing the plan or amendment, must immediately publish a notice that the plan or amendment is available for public review and comment. The Secretary will consider the public comments received during the comment period in determining whether to approve the plan or amendment.

Amendments 31 and 35 to the respective FMPs would implement the Modified Block proposal to the Pacific halibut and sablefish IFQ program. These amendments would authorize the issuance of quota share (QS) blocks for QS that would have resulted in less than 20,000 lb (9 mt) of IFQ based on the 1994 total allowable catch for fixed gear in the halibut and sablefish fisheries, allow the combination of QS blocks that are less than 1,000 lb (0.5 mt) of IFQ for halibut and less than 3,000 lb (1.4 mt) for sablefish, and restrict the amount of blocks that may be held in any one IFQ regulatory area. These amendments are intended to prevent excessive consolidation of the Pacific halibut and sablefish fisheries off Alaska, and are consistent with the management objectives of the Magnuson Act and the Northern Pacific Halibut Act.

Dated: June 13, 1994.

David S. Crestin,

Acting Director, Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 94–14724 Filed 6–13–94; 4:36 pm]

BILLING CODE 3510–22–F

Notices

Federal Register
Vol. 59, No. 116
Friday, June 17, 1994

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Forest Service

Florida National Scenic Trail Advisory Council

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: This notice announces the schedule and proposed agenda of a meeting of the Florida National Scenic Trail Advisory Council.

DATES: The meeting is scheduled Friday, July 22, 7:30 p.m. through Sunday, July 24, 1994, noon. Anyone wishing to make an oral statement must contact the Florida National Scenic Trails Coordinator by July 15, 1994.

ADDRESSES: The meeting will be held at the Pensacola Grand Hotel, 200 East Gregory Street, Pensacola, Florida 32501. Written statements can be sent to the National Forests in Florida, Woodcrest Office Park, 325 John Knox Road, suite F–100, Tallahassee, Florida 32303.

FOR FURTHER INFORMATION CONTACT: Debbie Allen, Florida National Scenic Trail Coordinator, (904) 942–9300.

SUPPLEMENTARY INFORMATION: The meeting will be open to the public. Interested persons may make oral comments during a public comment session. Anyone wishing to make an oral statement at the meeting must contact the Florida National Scenic Trail Coordinator by July 15, 1994.

Subjects to be covered at the meeting are the discussion of a trail sign plan, the route in the Panhandle for the Florida National Scenic Trail, and future direction for the Council.

Dated: June 13, 1994.

Lyle Laverty,

Acting Deputy Chief.

[FR Doc. 94–14789 Filed 6–16–94; 8:45 am]

BILLING CODE 3410–11–M

Nomination of Significant Caves

AGENCY: Forest Service, USDA.

ACTION: Notice and call for nominations.

SUMMARY: The Secretary of Agriculture is requesting nominations for the listing of significant caves on National Forest System lands administered by the Forest Service. This call for nominations is in response to provisions in the Federal Cave Resources Protection Act of 1988 which directs the Secretary of Agriculture to prepare and maintain a listing of significant caves.

DATES: Nominations to be considered for the initial listing of significant caves must be received by December 14, 1994. Nominations received after this date will be considered in subsequent listings.

ADDRESSES: Send written nominations to Cave Nominations Clearinghouse, P.O. Box 10, Three Rivers, CA 93271.

FOR FURTHER INFORMATION CONTACT: Brent Botts, USDA, Forest Service, P.O. Box 96090, Washington, DC 20090–6090, 202–205–1313.

SUPPLEMENTARY INFORMATION: The criteria for selection of significant caves is found in part 290 of title 36 Code of Federal Regulations. Federal caves considered for nomination must meet one or more of the criteria listed in 36 CFR part 290.3(c). Any person or organization may submit a nomination.

Nominations must follow a prescribed format as outlined in an information packet which is available from a forest or regional office of the Forest Service. Copies of the information packet can also be obtained by writing Brent Botts, Cave Coordinator, P.O. Box 96090, Washington, DC 20090–6090.

Dated: May 31, 1994.

David A. Harcharik,

Acting Chief, Forest Service.

[FR Doc. 94–14790 Filed 6–16–94; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF THE INTERIOR

Office of the Secretary

Notice of Availability of the Draft Environmental Impact Statement for the Exxon Valdez Oil Spill Restoration Plan

AGENCY: Forest Service, Department of Agriculture, and the Office of the Secretary, Department of the Interior. National Marine Fisheries Service, Department of Commerce is a cooperating agency.

ACTION: Notice of availability of the draft environmental impact statement for the Exxon Valdez restoration plan.

SUMMARY: On behalf of the Exxon Valdez Trustee Council, the Department of Agriculture, Forest Service announces the availability of the Draft Environmental Impact Statement (DEIS) for the Exxon Valdez Oil Spill Restoration Plan. This notice announces the locations and dates of public meetings to solicit comments on the DEIS. The responsible official for the preparation of the DEIS is the Regional Forester, Phil Janik. The Restoration Plan will establish management direction and guide all natural resource restoration activities covered by the civil settlement to the Exxon Valdez oil spill.

DATES: Comments concerning the DEIS should be received within 45 days of the publication of the Notice of Availability by the Environmental Protection Agency in the **Federal Register**.

ADDRESSES: Send written comments to or for copies of a Summary of the DEIS or for copies of the DEIS itself, contact the Oil Spill Public Information Office, 645 G. Street, Anchorage, Alaska, 99501. Phone number 907 278–8008 or within Alaska 800 478–7745, outside Alaska 800 283–7745. Copies also will be sent to public libraries in Anchorage, Juneau, Fairbanks, Valdez, Cordova, Kodiak, Homer, and Seward, Alaska for review.

SUPPLEMENTARY INFORMATION:

A. Introduction

On October 8, 1991, a federal court approved settlement between the State and Federal governments and Exxon under which Exxon will pay $1 billion in criminal restitution and civil damages to the governments. The State and Federal Trustees will receive $900 million in civil damages from Exxon over the 10 years. The funds are to be used to restore to their pre-spill condition the natural resources and the services they provide, that were injured by the Exxon Valdez oil spill. This includes the restoration of any natural resource injured, lost or destroyed and the services provided by that resource or which replaces or substitutes for the injured, lost or destroyed resource and affected services. Restoration includes

all phases of injury assessment, restoration, replacement, and enhancement of natural resources, and acquisition of equivalent resources and services.

All decisions about restoration and uses of restoration funds are determined by six natural resources Trustees, three Federal and three State. The three Federal Trustees are: The Administrator for the National Oceanic and Atmospheric Administration, U.S. Department of Commerce, and the Secretaries of the Department of Agriculture and of the Interior. The three State Trustees are: The Commissioners of Fish and Game and Environmental Conservation, and the Attorney General. A Trustee Council, located in Alaska, which is made up of the three State Trustees and designees of the three Federal Trustees, is responsible for decisions relating to the assessment of injuries, uses of the restoration funds, and all restoration activities including the preparation of a Restoration Plan.

On April 10, 1992 (57 FR 12473–12475) on behalf of the Exxon Valdez Trustee Council, the Forest Service published a Notice of Intent to prepare an EIS on the Restoration Plan. This was later revised on January 14, 1994 (59 FR 2352–2353). Since then the Trustee Council developed a draft Restoration Plan which has become the proposed action for the analysis conducted in the DEIS.

B. Draft Restoration Plan

The proposed action (Draft Restoration Plan) consists of nine policy statements, a discussion of categories of restoration actions and broad objectives for injured resources. The policies for identifying and conducting restoration actions are:

1. The restoration program will take an ecosystem approach.
2. Restoration activities may be considered for any injured resource or service.
3. Most restoration activities will occur within the spill area. However, restoration activities outside the spill are, but within Alaska, may be considered when the most effective restoration actions for an injured migratory population are in a part of its range outside the spill area or when the information acquired from research and monitoring activities outside the spill area will be important for restoration or understanding injuries within the spill area.
4. Restoration activities will emphasize resources and services that have not recovered. Resources and services will be enhanced, as appropriate, to promote restoration. Restoration projects should not adversely affect the ecosystem.
5. Projects designed to restore or enhance an injured service must have a sufficient relationship to an injured resource; must benefit the same user group that was injured; and, should be compatible with the character and public uses of the area.
6. Competitive proposals for restoration projects will be encouraged.
7. Restoration projects will be subject to independent scientific review before Trustee Council approval.
8. Meaningful public participation in restoration decisions will be actively solicited.
9. Government agencies will be funded only for restoration work that they do not normally conduct.

Four types of restoration actions are identified and discussed in the Draft Restoration Plan: General restoration, habitat protection and acquisition, monitoring and research, and public information and administration. Alternatives to the proposed action place different emphases on each of these categories of restoration actions.

General Restoration consists of activities that fall within manipulation of the environment, management of human use for reduction of marine pollution. Decisions about conducting general restoration projects would look at the following factors: Extent of natural recovery, the value of an injured resource to the ecosystem and to the public, the duration of benefits, the technical feasibility of the project, the likelihood of success, the relationship of costs to expected benefits, potential for harmful side effects, benefits to more than one resource, effects on health and human safety, consistency with applicable laws, and policies, and duplication with other actions.

Habitat Protection and Acquisition is a category that includes purchase of private land or interests in land such as conservation easements, mineral rights, or timber rights. It also includes recommendations for changing public agency management practices. Specific policies that relate to habitat protection and acquisition are proposed. These policies deal with ranking potential lands to determine potential benefits, the need for a willing seller, purchasing at fair market value, post acquisition management of the acquired lands and involving the public in the prioritization process.

Monitoring and Research consists of recovery monitoring, restoration monitoring and ecological monitoring and research. Specific policies governing the selecting and performance of monitoring activities are discussed in the Draft Restoration Plan.

Public Information and Administration is the last category of restoration actions. It consists of all necessary administrative actions that are not attributable to a particular project. The Draft Restoration Plan goal for this category is for administrative costs to average no more than 5% of overall restoration expenditures for the remainder of the settlement period.

General restoration objectives have been developed for resources that are recovering, resources not recovering, resources where the recovery is unknown, resources such as archaeological resources and wilderness, and services. These broad objectives will guide in the development of annual work plans.

Further information regarding the proposed action and possible restoration alternatives is included in the Draft Exxon Valdez Oil Spill Restoration Plan, Summary of Alternatives for Public Comment, April 1993; the Supplement to Draft Exxon Valdez Oil spill Restoration Plan, Summary of Alternatives for Public Comment, June 1993; the Summary of Public Comment on Alternatives of the Draft Exxon Valdez Oil Spill Restoration Plan, September 1993; and the Draft Exxon Valdez Oil Spill Restoration Plan, November 1993. Copies of these documents may be requested from the Oil Spill Public Information Office, 645 G. Street, Anchorage, Alaska, 99501. Phone number 907 278–8008 or within Alaska 800 478–7745, outside Alaska 800 283–7745.

C. Public Meetings

During the comment period for the DEIS public meetings will be held on the following dates at the locations shown:

June 27, 1994—EVOS Trustee Council Restoration Office, 645 G. Street, suite 100, Anchorage, AK

June 29, 1994—Kenai Fjords National Park Visitor's Center, 1212 4th Avenue, Small Boat Harbor, Seward, AK

July 1, 1994—City Council Chambers, 491 E Pioneer Avenue, Homer, AK

July 5, 1994—Alaska Dept. of Fish and Game Conference Room, 211 Mission Road, Kodiak, AK

July 7, 1994—U.S. Forest Service Third Floor Conference Room, 612 Second Street, Cordova, AK

July 19, 1994—City Council Chambers, 212 Chenega Avenue, Valdez, AK

D. Comments

The comment period on the DEIS will be 45 days from the date the Environmental Protection Agency's notice of availability appears in the **Federal Register.** It is very important that those interested in this proposed action participate at this time. To be most helpful, comments on the DEIS statement should be as specific as possible, and may address the adequacy of the statement or the merits of the alternatives discussed. (See the Council on Environmental Quality Regulations for implementing the procedural provisions of the National Environmental Policy Act at 40 CFR 1503.3).

In addition, Federal court decisions have established that reviewers of DEIS statements must structure their participation in the environmental review of the proposal so that it is meaningful and alerts an agency to the reviewer's position and concerns. Vermont Yankee Nuclear Power Corp. v. NRDC. 435 U.S. 519, 553 (1978). Environmental objections that could have been raised at the draft stage may be waived if not raised until after completion of the final EIS. Wisconsin Heritage, Inc. v. Harris, 490 F. Supp. 1334, 1338 (E.D. Wis. 1980). The reason for this is to ensure that substantive comments and objections are made available to the Forest Service at a time when it can meaningfully consider them and respond to them in the final.

Dated: June 9, 1994.

Phil Janik,

Regional Forester, Alaska Region Forest Service, Department of Agriculture.

Dated: June 13, 1994.

Robert P. Davison,

Deputy Assistant Secretary for Fish and Wildlife and Parks, Department of the Interior.

[FR Doc. 94–14716 Filed 6–16–94; 8:45 am]

BILLING CODE 3410–11–M

Packers and Stockyards Administration

Amendment to Certification of Central Filing System—Oklahoma

The Statewide central filing system of Oklahoma has been previously certified, pursuant to Section 1324 of the Food Security Act of 1985, on the basis of information submitted by the Oklahoma Secretary of State, for farm products produced in that State (52 FR 49056, December 29, 1987).

The certification is hereby amended on the basis of information submitted by Glo Henley, Secretary of State, for an additional farm product produced in that State as follows:

goat embryos

This is issued pursuant to authority delegated by the Secretary of Agriculture.

Authority: Sec. 1324(c) (2), Pub. L. 99–198, 99 Stat. 1535, 7 U.S.C. 1631(c) (2); 7CFR §§ 2.18(e) (3), 2.56(a) (3), 55 F.R. 22795.

Dated: June 13, 1994.

Calvin W. Watkins,

Acting Administrator, Packers and Stockyards Administration.

[FR Doc. 94–14743 Filed 6–16–94; 8:45 am]

BILLING CODE 3410–KD–P

Rural Electrification Administration

Dickson Electric System; Finding of No Significant Impact

AGENCY: Rural Electrification Administration, USDA.

ACTION: Notice of finding of no significant impact.

SUMMARY: Notice is hereby given that the Rural Electrification Administration (REA) has made a finding of no significant impact (FONSI) with respect to the potential environmental impacts resulting from a proposal by Dickson Electric System to construct a new headquarters, operations center, and warehouse in Dickson, Dickson County, Tennessee. The FONSI is based on a Borrower's Environmental Report submitted to REA by Dickson Electric System. REA conducted an independent evaluation of the report and concurs with its scope and content. In accordance with REA Environmental Policies and Procedures, 7 CFR 1794.61, REA has adopted the borrower's environmental report as its environmental assessment for the proposed facility.

FOR FURTHER INFORMATION CONTACT: Lawrence R. Wolfe, Chief, Environmental Compliance Branch, Electric Staff Division, REA, South Agriculture Building, Washington, DC 20250, telephone (202) 720–1784.

SUPPLEMENTARY INFORMATION: The proposed facility is to be located on Cowan Road 0.75 mile south of downtown Dickson on the south edge of the developed commercial and light industrial area of the city. The facility will require approximately 13 acres of clearing on a 28.75 acre tract of land.

The proposed facility will include the following:

A 15,800-square foot headquarters building,
A 15,000-square foot warehouse,
A 5-bay vehicle maintenance building with covered islands for gasoline and diesel fuel pumps,
A small PCB testing building with an outdoor concrete transformer storage pad approximately 20 foot by 120 foot,
A 3-acre pole storage yard,
Paved public and employee parking spaces, and
A 180-foot radio tower.

Alternatives considered to the project as proposed were no action and constructing the new facility adjacent to Dickson Electric System's existing warehouse.

Copies of the environmental assessment and FONSI are available for review at, or can be obtained from, REA at the address provided herein or Mr. E.R. Brown, Manager, Dickson Electric System, P.O. Box 627, Dickson, Tennessee 37056, telephone (615) 446–9051.

Date: June 8, 1994.

Adam M. Golodner,

Deputy Administrator Program Operations.

[FR Doc. 94–14796 Filed 6–16–94; 8:45 am]

BILLING CODE 3410–15–P

DEPARTMENT OF COMMERCE

Bureau of Export Administration

Computer Systems Technical Advisory Committee; Partially Closed Meeting

A meeting of the Computer Systems Technical Advisory Committee will be held July 11 & 12, 1994, in the Western Regional Office, Bureau of Export Administration, U.S. Department of Commerce, 5201 Great America Parkway, Suite 333, Santa Clara, California. The Committee advises the Office of Technology and Policy Analysis with respect to technical questions that affect the level of export controls applicable to computer systems/peripherals or technology.

Agenda

Executive Session July 11—9:00 a.m.–12:00 p.m.

1. Discussion of matters properly classified under Executive Order 12356, dealing with the U.S. and COCOM control program and strategic criteria related thereto.

General Session July 11—1:00 p.m.–5:00 p.m.

2. Opening remarks by the Chairmen.
3. Presentation of papers or comments by the public.
4. Presentation of Cray Research, Inc. on computer controls.
5. Discussion on rules of aggregation according to the Composite Theoretical Performance (CTP) formula.

General Session July 12—9:00 a.m.–4:00 p.m.

6. Discussion on graphics performance measurement and control thresholds.
7. Review of software controls in Category 4, Part D.
8. Discussion on expansion of foreign policy controls in Category 4.
9. Discussion on the role of CSTAC in the post-COCOM era.
10. Preview of work plan for the coming year.

Executive Session July 12—4:00 p.m.–5:00 p.m.

11. Discussion of matters properly classified under Executive Order 12356, dealing with the U.S. and COCOM control program and strategic criteria related thereto.

The General Session of the meeting will be open to the public and a limited number of seats will be available. To the extend that time permits, members of the public may present oral statements to the Committee. Written statements may be submitted at any time before or after the meeting. However, to facilitate distribution of public presentation materials to the Committee members, the Committee suggests that presenters forward the public presentation materials two weeks prior to the meeting date to the following address: Ms. Lee Ann Carpenter, TAC Unit/OAS/EA Room 3886C, Bureau of Export Administration, U.S. Department of Commerce, Washington, D.C. 20230.

The Assistant Secretary for Administration, with the concurrence of the General Counsel, formally determined on January 6, 1994, pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, that the series of meetings of the Committee and of any Subcommittee thereof, dealing with the classified materials listed in 5 U.S.C., 552b(c)(1) shall be exempt from the provisions relating to public meetings found in section 10 (a)(1) and (a)(3), of the Federal Advisory Committee Act. The remaining series of meetings or portions thereof will be open to the public.

A copy of the Notice of Determination to close meetings or portions of meetings of the Committee is available for public inspection and copying in the Central Reference and Records Inspection Facility, room 6020, U.S. Department of Commerce, Washington, D.C. 20230. For further information or copies of the minutes, contact Lee Ann Carpenter on (202) 482–2583.

Dated: June 14, 1994.

Betty Ferrell,

Director, Technical Advisory Committee Unit.

[FR Doc. 94–14843 Filed 6–16–94; 8:45 am]

BILLING CODE 3510–DT–M

International Trade Administration

[A–351–824]

Notice of Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination: Silicomanganese from Brazil

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: June 17, 1994.

FOR FURTHER INFORMATION CONTACT: Lori Way or Stephen Alley, Office of

Antidumping Investigations, Import Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone (202) 482–0656 or 482–5288, respectively.

Preliminary Determination:

We preliminarily determine that silicomanganese from Brazil is being, or is likely to be, sold in the United States at less than fair value, as provided in section 733 of the Tariff Act of 1930, as amended (the Act). The estimated margins are shown in the "Suspension of Liquidation" section of this notice.

Case History

Since the initiation of this investigation on December 2, 1993 (58 FR 64553, December 8, 1993), the following events have occurred.

On December 27, 1993, the U.S. International Trade Commission (ITC) issued an affirmative preliminary determination in this case (see USITC Publication 2714, December, 1993).

We issued the antidumping questionnaire on January 18, 1994, to Companhia Paulista de Ferro-Ligas and Sibra-Eletrosideŕurgica Brasileira S/A (collectively, "Paulista"). On January 24, 1994, representatives of the Department of Commerce (the Department) met with Paulista officials in Brazil to provide further explanation of the antidumping questionnaire and to answer outstanding technical and procedural questions.

Responses to the questionnaire were received on February 4, 1994, and March 7, 1994. Petitioners in this investigation, Elkem Metals Company and the Oil, Chemical & Atomic Workers, Local 3–639, submitted comments regarding deficiencies in Paulista's questionnaire responses on March 17 and 18, 1994. A supplemental questionnaire was issued on March 28, 1994. Paulista submitted responses to this questionnaire in April and May, 1994.

On February 2 and 8, 1994, Paulista asked the Department to amend the product matching criteria included in Appendix V of its questionnaire. Petitioners submitted comments on Paulista's request on February 7 and 9, 1994. On February 10, 1994, we amended Appendix V with respect to the silicon content and sieve size categories (see letter from Gary Taverman to Dorsey & Whitney, dated February 10, 1994, on file in Room B–099 of the main building of the Department of Commerce).

At the request of petitioners, on March 30, 1994, the Department postponed its preliminary determination until no later than June 10, 1994 (59 FR 16177, April 6, 1994).

On May 13, 1994, based on petitioners' March 14, 1994, allegation of sales below cost of production (COP), the Department initiated a COP investigation (*see* decision memorandum from Richard Moreland to Barbara Stafford, dated May 13, 1994) and issued a COP questionnaire. However, because of the deadline established for Paulista's COP questionnaire response, this information could not be considered for the preliminary determination. It will be considered for the final determination.

Postponement of Final Determination

Pursuant to section 735(a)(2)(A) of the Act, on April 26, 1994, Paulista requested that, in the event of an affirmative preliminary determination in this investigation, the Department postpone its final determination to 135 days after the date of publication of an affirmative preliminary determination. Pursuant to 19 CFR 353.20(b), if our preliminary determination is affirmative, and the Department receives a request from producers or resellers who account for a significant portion of the exports under investigation, we will, absent compelling reasons for denial, grant the request. Because Paulista represents a significant portion of the exports under investigation and there are no compelling reasons to deny the request, we are postponing the final determination until the 135th day after the date of publication of this notice in the Federal Register.

Scope of Investigation

The merchandise covered by this investigation is silicomanganese. Silicomanganese, which is sometimes called ferrosilicon manganese, is a ferroalloy composed principally of manganese, silicon, and iron, and normally containing much smaller proportions of minor elements, such as carbon, phosphorous and sulfur. Silicomanganese generally contains by weight not less than 4% iron, more than 30% manganese, more than 8% silicon and not more than 3% phosphorous. All compositions, forms and sizes of silicomanganese are included within the scope of this investigation, including silicomanganese slag, fines and briquettes. Silicomanganese is used primarily in steel production as a source of both silicon and manganese. This investigation covers all silicomanganese, regardless of its tariff classification. Most silicomanganese is currently classifiable under subheading 7202.30.0900 of the Harmonized Tariff Schedule of the United States (HTS). Some silicomanganese may also be classifiable under HTS subheading 7202.99.5040. Although the HTS subheading is provided for convenience and customs purposes, our written description of the scope of this proceeding is dispositive.

Period of Investigation

The period of investigation (POI) is June 1, 1993, through November 30, 1993.

Such or Similar Comparisons

We have determined that the class or kind of merchandise subject to this investigation constitutes two such or similar categories: silicomanganese lumps and silicomanganese fines. In making our fair value comparisons, in accordance with the Department's standard methodology, we first compared identical merchandise. Where there were no sales of identical merchandise in the home market to compare to U.S. sales, we made similar merchandise comparisons on the basis of the criteria defined in Appendix V to the antidumping duty questionnaire. In accordance with 19 CFR 353.58, the Department normally attempts to compare U.S. sales to home market sales made at the same level of trade, where possible. Because Paulista did not make sales at the same level of trade in Brazil and the United States, we made comparisons without regard to level of trade.

Fair Value Comparisons

To determine whether Paulista's sales of silicomanganese from Brazil to the United States were made at less than fair value, we compared the United States price (USP) to the foreign market value (FMV), as specified in the "United States Price" and "Foreign Market Value" sections of this notice.

United States Price

In accordance with section 772(b) of the Act, we based USP for Paulista on purchase price because all sales were made to unrelated parties prior to importation into the United States.

We calculated purchase price sales based on prices to unrelated customers in the United States. We made deductions, where appropriate, for foreign brokerage, handling and foreign inland freight in order to adjust these prices to an ex-factory basis. We did not add an amount for interest revenue because Paulista failed to place adequate information on the record to support this adjustment (see concurrence memorandum, dated June 3, 1994). We will, however, examine

this issue further at verification, and consider it for the final determination.

On October 7, 1993, the Court of International Trade (CIT), in *Federal-Mogul Corp. and The Torrington Co.* v. *United States*, Slip Op. 93–194 (CIT, October 7, 1993), rejected the Department's methodology for calculating an addition to USP under section 772(d)(1)(C) of the Act to account for taxes that the exporting country would have assessed on the merchandise had it been sold in the home market. The CIT held that the addition to USP under section 772(d)(1)(C) of the Act should be the result of applying the foreign market tax rate to the price of the United States merchandise at the same point in the chain of commerce that the foreign market tax was applied to foreign market sales. *Federal- Mogul*, Slip Op. 93–194 at 12.

In accordance with the Federal-Mogul decision, we have added to USP the product of the home market tax rate and the price of the United States merchandise at the same point in the chain of commerce that the home market tax was applied to foreign market sales. We have also deducted from the USP and the FMV those portions of the home market tax and the USP tax adjustments attributable to expenses included in the home market and United States bases of the tax if those expenses are later deducted to calculate FMV and USP. These adjustments to the home market tax and the USP tax adjustment are necessary to prevent the methodology for calculating the USP tax adjustment from creating antidumping duty margins where no margins would exist if no taxes were levied upon foreign market sales.

This margin creation effect is due to the fact that the basis for calculating both the amount of tax included in the price of the foreign market merchandise and the amount of the USP tax adjustment include many expenses that are later deducted when calculating USP and FMV. After these deductions are made, the tax included in FMV and the USP tax adjustment still reflect the inclusion of these expenses in the bases. Thus, a margin may be created that is not dependent upon a difference between adjusted USP and FMV, but is the result of differences between the expenses in the United States and the home market that were deducted through adjustments.

This adjustment to avoid the margin creation effect is in accordance with court decisions. The United States Court of Appeals has held that the application of the USP tax adjustment under section 772(d)(1)(C) of the Act should not create an antidumping duty margin if pre-tax FMV does not exceed USP. *Zenith Electronics Corp.* v. *United States*, 988 F.2d 1573, 1581 (Fed. Cir. 1993). In addition, the CIT has specifically held that an adjustment should be made to mitigate the impact of expenses that are deducted from FMV and USP upon the USP tax adjustment and the amount of tax included in FMV. *Daewoo Electronics Co., Ltd.* v. *United States*, 760 F. Supp. 200, 208 (CIT, 1991). However, the mechanics of the Department's adjustments to the USP tax adjustment and the foreign market tax amount as described above are not identical to those suggested in *Daewoo*.

In this investigation, we added to USP an amount for value added tax that would have been paid had the U.S. sale not been exported. In Brazil, there are four different taxes levied on sales of the subject merchandise in the home market which are not levied on export sales:

(1) Imposto sobre a Circulacão de Mercadorias e Servicos (ICMS), a regional tax with a rate that varies depending upon the state in which the purchase originates;

(2) Imposto sobre Produtos Industrializados (IPI), the Federal value-added tax which is levied at a rate of four percent;

(3) Programa de Integracão Social (PIS), a social integration program tax which is levied at a rate of 0.65 percent; and

(4) Contribuicao do Fim Social (CONFINS), a social investment fund tax which is levied at a rate of 2.0 percent.

Foreign Market Value

In order to determine whether there was a sufficient volume of sales in the home market to serve as a viable basis for calculating FMV, we compared the volume of home market sales of subject merchandise to the volume of third country sales of subject merchandise, in accordance with section 773(a)(1)(B) of the Act. Since the total volume of merchandise sold by Paulista in Brazil during the POI was greater than five percent of the aggregate volume of third country sales for each such or similar category, we determined that the home market was viable. Therefore, we based FMV on home market sales for both silicomanganese lumps and silicomanganese fines, in accordance with 19 CFR 353.48(a). We excluded from our analysis sales to a related customer that were not claimed by Paulista to be at arm's length.

We calculated FMV based on prices to unrelated customers. In light of the Court of Appeals for the Federal Circuit's (CAFC) decision in *Ad Hoc Committee of AZ–NM–TX–FL Producers of Gray Portland Cement* v. *United States*, Slip Op. 93–1239 (Fed. Cir., January 5, 1994), the Department no longer deducts home market movement charges from FMV pursuant to its inherent authority to fill in gaps in the antidumping statute. We instead adjust for those expenses under the circumstance of sale provision of 19 CFR 353.56 and the exporter's sales price offset provision of 19 CFR 353.56(b) (1) and (2), as appropriate.

Accordingly, in the present case, we made circumstance of sale adjustments for certain post-sale home market movement charges under 19 CFR 353.56. Also pursuant to 19 CFR 353.56(a)(2), we made circumstance of sale adjustments, where appropriate, for differences in credit expenses, warehousing, sampling-weighing-testing expenses, and bank fees. In accordance with 19 CFR 353.56(b), we added commissions paid on U.S. sales and deducted indirect selling expenses incurred on sales in Brazil up to the amount of the U.S. commission.

Under our past practice, if the Department determines that a country is hyperinflationary, we calculate FMVs on a monthly basis to eliminate the distortive effects of inflation (see, Final Determination of Sales at Less Than Fair Value and Amended Antidumping Duty Order, Tubeless Steel Disc Wheels from Brazil, 53 FR 34566, September 7, 1988). An economy is deemed to be hyperinflationary if its monthly inflation rate is greater than 5 percent or if its annual inflation rate is greater than 60 percent. We determined that Brazil's economy was hyper-inflationary during the POI. Brazil's inflation rate was over 60 percent during 1993.

We included in FMV the amount of the VAT collected in the home market (*i.e.*, the sum of the actual IPI, PIS and CONFINS tax rates plus the weighted-average ICMS rate). However, we calculated the amount of tax that was due solely to the inclusion of price deductions in the original tax base (*i.e.*, the sum of any adjustments, expenses, and charges that were deducted from the tax base). *See* the "United States Price" section of this notice, above. This amount was deducted from the FMV after all other additions and deductions had been made.

Cost of Production

Based on petitioner's allegations, and in accordance with section 773(b) of the Act, the Department initiated an investigation to determine whether Paulista made home market sales at prices below its COP over an extended period of time, which would not permit

the recovery of costs within a reasonable period of time. However, Paulista's COP questionnaire response is due on June 16, 1994, which is after the deadline for the preliminary determination. The response will, however, be considered for the final determination.

Currency Conversion

No certified rates of exchange, as furnished by the Federal Reserve Bank of New York, were available for the POI. In place of the official certified rates, we used the daily official exchange rates for Brazilian currency published by the Central Bank of Brazil.

In hyperinflationary economies, the Department normally converts movement charges for U.S. sales on the date that these charges become payable, and we have done so in this investigation.

Verification

As provided in section 776(b) of the Act, we will verify the accuracy of all information used in making our final determination.

Suspension of Liquidation

In accordance with section 733(d)(1) of the Act, we are directing the Customs Service to suspend liquidation of all entries of silicomanganese from Brazil that are entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**. The Customs Service shall require a cash deposit or posting of a bond equal to the estimated preliminary dumping margins as shown below. This suspension of liquidation will remain in effect until further notice. The estimated preliminary dumping margins are as follows:

Manufacturer/producer/exporter	Weighted-average margin percentages
Paulista	37.76
All others	37.76

ITC Notification

In accordance with section 733(f) of the Act, we have notified the ITC of our determination. If our final determination is affirmative, the ITC will determine before the later of 120 days after the date of the preliminary determination or 45 days after our final determination whether imports of the subject merchandise are materially injuring, or threaten material injury to, the U.S. industry.

Public Comment

Interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Import Administration, U.S. Department of Commerce, Room B–099, within ten days of the publication of this notice. Requests should contain: (1) The party's name, address, and telephone number; (2) the number of participants; and (3) a list of the issues to be discussed.

In accordance with 19 CFR 353.38, case briefs or other written comments in at least ten copies must be submitted to the Assistant Secretary for Import Administration no later than September 23, 1994, and rebuttal briefs no later than September 28, 1994. A public hearing, if requested, will be held on September 30, 1994, at 10 a.m. at the U.S. Department of Commerce, Room 4830, 14th Street and Constitution Avenue NW., Washington, DC 20230. Parties should confirm by telephone the time, date, and place of the hearing 48 hours before the scheduled time. In accordance with 19 CFR 353.38(b), oral presentations will be limited to issues raised in the briefs.

We will make our final determination not later than 135 days after publication of this determination in the **Federal Register**.

This determination is published pursuant to section 733(f) of the Act, and 19 CFR 353.15(a)(4).

Dated: June 10, 1994.

Susan G. Esserman,

Assistant Secretary for Import Administration.

[FR Doc. 94–14850 Filed 6–16–94; 8:45 am]

BILLING CODE 3510–DS–P

(A–570–828)

Preliminary Determination of Sales at Less Than Fair Value: Silicomanganese From the People's Republic of China

AGENCY: Import Administration, International Trade Administration, Department of Commerce

EFFECTIVE DATE: June 17, 1994.

FOR FURTHER INFORMATION CONTACT: Steve Alley or Mike Ready, Office of Antidumping Investigations, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, D.C. 20230; telephone: (202) 482–5288 or (202) 482–2613, respectively.

Preliminary Determination

We preliminarily determine that silicomanganese from the People's Republic of China (PRC) is being, or is likely to be, sold in the United States at less than fair value, as provided in section 733 of the Tariff Act of 1930, as amended (the Act). The estimated margin is shown in the "Suspension of Liquidation" section of this notice.

Case History

Since the initiation of this investigation on December 2, 1993, (58 FR 64553, December 8, 1993), the following events have occurred:

On December 27, 1993, the U.S. International Trade Commission (ITC) notified us of its preliminary determination that there is a reasonable indication that an industry in the United States is being materially injured, or threatened with material injury, by reason of imports of silicomanganese from the PRC that are alleged to be sold at less than fair value.

On January 6, 1994, the Department of Commerce (the Department) sent antidumping questionnaires to 18 producers and exporters that may have sold silicomanganese to the United States during the period of investigation (POI). Company names and addresses were either obtained from the petition or from the Census Bureau's IM–115 data. In the accompanying cover letter, the Department requested that companies without U.S. sales during the POI advise the Department of this fact.

Also, on January 6, 1994, the Department sent a copy of the antidumping questionnaire to the PRC's Ministry of Foreign Trade and Economic Cooperation (MOFTEC). In our transmittal letter, the Department requested MOFTEC to 1) furnish the questionnaire to any silicomanganese producers and exporters with U.S. sales during the POI that were not on our list of 18 companies, and 2) provide a comprehensive list of those additional companies that received the questionnaire from MOFTEC. On April 12, 1994, the Department sent a second letter to MOFTEC again requesting a list of all companies that had received the questionnaire from MOFTEC.

MOFTEC did not respond to either letter, and most of the potential respondents neither replied to our questionnaire nor notified us that they had not made any sales to the United States during the POI. The only two companies that did respond to our questionnaire, Jinzhou Ferroalloy Works (Jinzhou), a PRC producer of silicomanganese, and Bogay Investment, Ltd. (Bogay), a Hong Kong company that purchased silicomanganese from Jinzhou and exported it directly to the United States, reported one sale made four months prior to the POI. Although,

as noted above, the cover letter accompanying the questionnaire stated that companies with no sales of the subject merchandise during the POI need only notify us of this fact, Jinzhou and Bogay chose to respond to the questionnaire. Bogay submitted its questionnaire responses on February 14 and February 28, 1994, and Jinzhou submitted its questionnaire responses on March 7 and March 23, 1994.

On March 2, 1994, the Department determined that this investigation was extraordinarily complicated. Therefore, in accordance with section 733(c)(1)(B) of the Act, the Department postponed the preliminary determination until June 10, 1994. (*See Notice of Postponement of Preliminary Antidumping Duty Determination: Silicomanganese from the PRC and Ukraine*, 59 FR 11250, March 10, 1994.)

On May 20, 1994, counsel for petitioners alleged the existence of critical circumstances. The Department has investigated whether critical circumstances exist, and our preliminary results are listed below under "Critical Circumstances."

The Department determined on May 23, 1994, not to expand the POI to include Jinzhou and Bogay in the investigation (see Memorandum from Richard W. Moreland to Barbara R. Stafford, dated May 23, 1994).

Scope of Investigation

The merchandise covered by this investigation is silicomanganese. Silicomanganese, which is sometimes called ferrosilicon manganese, is a ferroalloy composed principally of manganese, silicon, and iron, and normally containing much smaller proportions of minor elements, such as carbon, phosphorous and sulfur. Silicomanganese generally contains by weight not less than 4% iron, more than 30% manganese, more than 8% silicon and not more than 3% phosphorous. All compositions, forms and sizes of silicomanganese are included within the scope of these investigations, including silicomanganese slag, fines and briquettes. Silicomanganese is used primarily in steel production as a source of both silicon and manganese. These investigations cover all silicomanganese, regardless of its tariff classification. Most silicomanganese is currently classifiable under subheading 7202.30.0000 of the *Harmonized Tariff Schedule of the United States* (HTS). Some silicomanganese may also be classifiable under HTS subheading 7202.99.5040. Although the HTS subheading is provided for convenience and customs purposes, our written description of the scope is dispositive.

Period of Investigation

The period of investigation is June 1, 1993, through November 30, 1993.

Best Information Available

U.S. Customs shipment data suggest that there were sales of subject merchandise during the POI. Because MOFTEC and most of the potential respondents failed to provide information concerning whether there were such sales, the Department, in accordance with section 776(c) of the Act, must base its preliminary determination on best information available (BIA).

In determining what to use as BIA, the Department follows a two-tiered methodology, whereby the Department normally assigns lower margins to those respondents who cooperate in an investigation and margins based on more adverse assumptions for those respondents who do not cooperate in an investigation. Since the potential respondents in this case did not cooperate, we assigned a BIA margin based on the most adverse assumptions.

In this case, BIA is the information contained in the petition, as amended on November 24, 1993. (*See Initiation of Antidumping Duty Investigations: Silicomanganese from Brazil, the People's Republic of China, Ukraine and Venezuela*, 58 FR 64553, December 8, 1993.) The amended petition provides only one margin, listed below, for all PRC producers and exporters of silicomanganese.

Critical Circumstances

Petitioner alleges that critical circumstances exist with respect to imports of silicomanganese from the PRC. Pursuant to section 733(e)(1) of the Act and 19 CFR 353.16, we analyzed the allegations using the Department's standard methodology.

To find critical circumstances, the Department must determine whether there is a reasonable basis to believe or suspect that 1) there is a history of dumping in the United States or elsewhere of the same class or kind of subject merchandise, or the importer knew or should have known that the producer or reseller was selling the subject merchandise at less than its foreign market value; and 2) there have been massive imports of the subject merchandise over a relatively short period.

We have not found a history of dumping of PRC silicomanganese in the United States or elsewhere. According to Department practice, however, we will impute knowledge of dumping to importers of subject merchandise when the dumping margin exceeds 25 percent in purchase price situations (*see Preliminary Determination on Silicon Carbide from the PRC*, 58 FR 64549, December 8, 1993). In this case, the estimated dumping margin for silicomanganese imports from the PRC is 150.00 percent.

We consider imports of merchandise under investigation to be massive if there has been an increase of 15 percent or more over a relatively short period of time. For the preliminary determination, we were able to obtain import data through the month of March. To determine whether there have been massive imports of silicomanganese from the PRC, we compared the import volume for the month in which the petition was filed, November, and the four months subsequent to that month with the import volume for the five months prior to the filing of the petition, using Department of Commerce shipment data. We found that the import volume of silicomanganese during the period subsequent to the filing of the petition was massive, increasing by 426.83 percent over the previous period's import volume.

For the foregoing reasons, the Department preliminarily finds that critical circumstances exist in this case.

Suspension of Liquidation

In accordance with section 733(d)(1) of the Act, we are directing the Customs Service to suspend liquidation of all entries of silicomanganese from the PRC that are entered, or withdrawn from warehouse, for consumption on or after the date 90 days before the date of publication of this notice in the *Federal Register*. The Customs Service shall require a cash deposit or posting of a bond equal to the amount shown below. These suspension of liquidation instructions will remain in effect until further notice.

Manufacturer/producer/exporter	Weighted-average margin percentage
All exporters	150.00

ITC Notification

In accordance with section 733(f) of the Act, we have notified the ITC of our determination. If our final determination is affirmative, the ITC will determine before the later of 120 days after the date of this preliminary determination or 45 days after our final determination whether these imports are materially injuring, or threaten material injury to, the U.S. industry.

Public Comment

Interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Import Administration, U.S. Department of Commerce, Room B–099, within ten days of the publication of this notice. Requests should contain: (1) The party's name, address, and telephone number; (2) the number of participants; and (3) a list of the issues to be discussed.

In accordance with 19 CFR 353.38, case briefs or other written comments in at least ten copies must be submitted to the Assistant Secretary for Import Administration no later than July 13, 1994, and rebuttal briefs no later than July 18, 1994. A public hearing, if requested, will be held on July 20, 1994 at 2:00 p.m. at the U.S. Department of Commerce, Room 1414, 14th Street and Constitution Avenue, NW., Washington, DC 20230. Parties should confirm by telephone the time, date, and place of the hearing 48 hours before the scheduled time. In accordance with 19 CFR 353.38(b), oral presentations will be limited to issues raised in the briefs.

We will make our final determination not later than 75 days after publication of this determination in the **Federal Register**.

This determination is published pursuant to section 733(f) of the Act, and 19 CFR 353.15(a)(4).

Dated: June 10, 1994.

Susan G. Esserman,

Assistant Secretary for Import Administration.

[FR Doc. 94–14849 Filed 6–16–94; 8:45 am]

BILLING CODE 3510–DS–P

[A–823–805]

Notice of Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination: Silicomanganese From Ukraine

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: June 17, 1994.

FOR FURTHER INFORMATION CONTACT: Stephen Alley or Donna Berg, Office of Antidumping Investigations, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW, Washington, D.C. 20230; telephone: (202) 482–5288 or (202) 482–0114, respectively.

Preliminary Determination

We preliminarily determine that silicomanganese from Ukraine is being, or is likely to be, sold in the United States at less than fair value (LTFV), as provided in section 733 of the Tariff Act of 1930, as amended (the Act). The estimated margin is shown in the "Suspension of Liquidation" section of this notice.

Case History

Since the initiation of this investigation on December 2, 1993, (58 FR 64553, December 8, 1993), the following events have occurred:

On December 27, 1993, the U.S. International Trade Commission (ITC) notified us of its preliminary determination that there is a reasonable indication that an industry in the United States is materially injured, or threatened with material injury, by reason of imports of silicomanganese from Ukraine that are alleged to be sold at less than fair value.

On January 11, 1994, the Department of Commerce (the Department) sent to the Embassy of Ukraine the antidumping questionnaire. (The antidumping questionnaire was divided into three sections. Section A requesting general information on each company, section C requesting information on, and a listing of, U.S. sales made during the period of investigation (POI), and section D requesting information on the production process, including specific amounts of each input used in manufacturing silicomanganese.) We requested that the Embassy of Ukraine forward the questionnaire to all Ukrainian exporters and producers of silicomanganese and ensure that complete questionnaire responses were submitted on their behalf.

During the week of January 31, 1994, representatives of the Department met with officials in Ukraine to provide further explanation regarding the antidumping questionnaire and to answer outstanding technical and procedural questions.

The two Ukrainian producers/exporters, Nikopol Ferroalloys Plant (Nikopol) and Zaporozhye Ferroalloys Plant (Zaporozhye) submitted responses to section A of the questionnaire on February 18, 1994, and section C of the questionnaire on March 14, 1994. Responses to section D of the questionnaire were submitted by Zaporozhye and Nikopol on March 31, 1994, and April 8, 1994, respectively. Petitioners submitted deficiency comments on April 22, 1994. The Department requested clarifications regarding the responses from both respondents on May 6, 1994, and additionally from Nikopol on May 13, 1994. Both respondents submitted these clarifications on May 26, 1994.

On March 2, 1994, the Department determined that this investigation was extraordinarily complicated due to the dramatic changes occurring in the Ukrainian economy and, in accordance with section 733(c)(1)(B)(i)(II) of the Tariff Act of 1930, extended the preliminary determination until June 10, 1994.

On March 15, 1994, the Department requested comments concerning appropriate surrogate countries for Ukraine from all interested parties. Only petitioners submitted comments.

Because this investigation involves a non-market economy (NME), on May 4, 1994, the Department sent Nikopol and Zaporozhye supplemental questionnaires to elicit information necessary to determine whether either company merits a separate antidumping rate. To date, neither respondent has submitted a response.

On May 20, 1994, petitioners alleged that critical circumstances exist with respect to imports of silicomanganese from Ukraine. Pursuant to the Department's request, respondents submitted shipment data on June 1, 1994.

Petitioners provided surrogate value information on May 27, 1994, and on May 31, 1994, submitted comments to be considered for the preliminary determination.

Postponement of Final Determination

In accordance with 19 CFR 353.20(b), Nikopol and Zaporozhye, which together account for all exports of the merchandise covered in this proceeding, have requested that, in the event of an affirmative determination, the Department postpone the final determination until 135 days after the date of publication of the preliminary determination. Because we find no compelling reason to deny the request, we are postponing the date of the final determination until not later than 135 days after the date of publication of this notice.

Scope of Investigation

The merchandise covered by this investigation is silicomanganese. Silicomanganese, which is sometimes called ferrosilicon manganese, is a ferroalloy composed principally of manganese, silicon, and iron, and normally containing much smaller proportions of minor elements, such as carbon, phosphorous and sulfur. Silicomanganese generally contains by weight not less than 4% iron, more than 30% manganese, more than 8% silicon and not more than 3% phosphorous. All compositions, forms and sizes of silicomanganese are included within the

scope of these investigations, including silicomanganese slag, fines and briquettes. Silicomanganese is used primarily in steel production as a source of both silicon and manganese. These investigations cover all silicomanganese, regardless of its tariff classification. Most silicomanganese is currently classifiable under subheading 7202.30.0000 of the Harmonized Tariff Schedule of the United States (HTSUS). Some silicomanganese may also be classifiable under HTSUS subheading 7202.99.5040. Although the HTSUS subheading is provided for convenience and customs purposes, our written description of the scope is dispositive.

Period of Investigation

The period of investigation (POI) is June 1, 1993, through November 30, 1993.

Surrogate Country

In past antidumping investigations, the Department has considered Ukraine to be a NME country. Ukraine has not contested this designation, and we are continuing to consider it a NME country. Therefore, in accordance with section 773(c) of the Act, the Department has based foreign market value on factors of production, and has valued the factors of production using surrogate values from market economy countries that are at a level of economic development comparable to that of Ukraine, and that are significant producers of comparable merchandise.

Due to dramatic and ongoing changes in Ukraine's economy, we were not able to identify a single preferred surrogate country for Ukraine. Therefore, we have ranked groups of surrogates into three tiers: Egypt, Colombia, Morocco, and Peru, which we determined were most similar to Ukraine in per capita GNP and population size, were assigned to tier one; Ecuador, Guatemala, Bolivia, the Dominican Republic, and Indonesia were placed in tier two; and finally, the Philippines and El Salvador were included in tier three. (*See* Memorandum from Dave Mueller, Director, Office of Policy, to Gary Taverman, dated May 2, 1994 on file in Room B–099 of the Main Commerce Department building.) It should be noted that although the tiers are ranked hierarchically, the surrogate countries are not hierarchically ranked within each tier.

We considered surrogate values for the factors of production from first-tier countries as most desirable and surrogate values from second-tier countries the next most desirable. Values from third-tier countries were used only as a last resort when factor-price data were not available from countries in the first two tiers.

In some instances, we were able to obtain surrogate values for a particular factor of production from only one country. Where surrogate values were available from more than one country within a tier, we averaged the pricing data for all of the countries. We then used the average price for that tier to value the factor of production. For purposes of this preliminary determination, we determined that this was the most objective method given that there was no basis for distinguishing countries included within the same tier.

When we were not able to value factors of production using published, publicly-available information from any surrogate country, we relied on information provided by U.S. embassies and consulates in the surrogate countries.

Fair Value Comparisons

To determine whether sales of silicomanganese from Ukraine to the United States were made at less than fair value, we compared the United States price (USP) to the foreign market value (FMV), as specified in the "United States Price" and "Foreign Market Value" sections of this notice.

United States Price

In accordance with section 772(b) of the Act, we based USP for Zaporozhye on purchase price because all sales were made to unrelated parties prior to importation into the United States. For Nikopol, we have based USP on exporter's sales price (ESP), under section 772(c) of the Act.

We calculated purchase price for Zaporozhye based on prices to an unrelated purchaser in the United States. We made deductions, where appropriate, for foreign inland freight and loading expense (which were both valued in a surrogate country), to adjust the prices to an ex-factory basis.

We calculated ESP for Nikopol based on prices at which the merchandise was sold on various terms to unrelated purchasers in the United States. We made deductions, where appropriate, for foreign inland freight and loading expense (which were both valued in a surrogate country), marine insurance, ocean freight, U.S. customs duty, U.S. customs brokerage and U.S. inland freight, to adjust the prices to an ex-factory basis.

In calculating U.S. price for Nikopol, we excluded one sale of silicomanganese fines because this sale was atypical of Nikopol's U.S. sales and represented an insignificant amount of Nikopol's total U.S. sales during the POI.

Foreign Market Value

We calculated FMV based on factors of production reported by Zaporozhye and Nikopol. The factors used to produce silicomanganese include materials, labor, and energy. To calculate FMV, the reported factors of production were valued using prices obtained in surrogate countries.

In the case of material inputs, we also used surrogate transportation rates to value the transportation of inputs from their sources to the silicomanganese factories.

To value manganese ore, we used an average of CIF import values from two first-tier surrogate countries: Colombia and Egypt. The source of both values was United Nations Trade Statistics for 1992.

We were unable to find published, publicly-available information for manganese sinter, and we received no relevant information from the U.S. diplomatic posts. Therefore, for the preliminary determination, we have valued this product using manganese ore prices.

To value quartzite, we relied on a publicly-available Moroccan import value contained in United Nations statistics. To value coke, the most current publicly-available source was a Colombian value for 1992 exports reported on an FOB basis in statistics published by the United Nations.

To value electricity, we used publicly-available information from Colombia contained in the Departamento Nacional de Planeacion's Junta Nacional de Tarifas de Servicios Publicos (June 1993). We selected this source because it provided an electricity rate for industrial use during the POI.

To value natural gas, we relied on an average of two published, publicly-available values for our first-tier surrogate countries, Colombia and Morocco. The Colombian value was reported on a FOB Colombian port basis and was obtained from U.S. import statistics for 1993. The Moroccan value was the average price at which natural gas was imported into that country in 1992. The source of this value was the 1992 International Trade Statistics Yearbook, Volume 1, 1993. Before averaging these values, we converted the Moroccan value into a price per cubic meter.

To value production labor, we used published, publicly-available values for Egypt from the 1993 Year Book of Labour Statistics, 52nd edition. We used the most recent statistics available, values from 1987, which we inflated to

the POI using statistics published by The Economist Intelligence Unit: Egypt Country Profile 1993/94.

For selling, general and administrative expenses (SG&A), and profit, we found no publicly-available, published information. In addition, we were unable to use information provided by the U.S. Embassy in Egypt for SG&A and profit because we were unable to determine the cost bases upon which the Egyptian percentages were calculated. Therefore, we relied on the statutory minimums of ten percent for SG&A and eight percent for profit (see section 773(e)(1)(B) of the Act).

For factory overhead, we also found no publicly-available, published information. In addition, we were unable to use the information provided by the U.S. Embassy in Egypt for factory overhead because we were unable to determine the cost basis upon which the overhead percentage was calculated. Furthermore, the statute does not provide any minimum percentage for factory overhead. Therefore, we relied upon information from the second-tier surrogate country of Bolivia provided by the U.S. Embassy in Bolivia. This information was used during the recent antidumping investigation of Refined Antimony Trioxide (See Final Determination of Sales at Less Than Fair Value: Refined Antimony Trioxide From the People's Republic of China, 57 FR 6801, February 28, 1992.) The information is in a cable in the public file for this case (*see* La Paz Cable 14178, September 23, 1991). Except as noted below, where necessary, we adjusted the above surrogate country prices for inflation to the POI using the wholesale price indices published for each of the surrogate countries by the International Monetary Fund (IMF). In the case of Peru, we used the consumer price index of the IMF because the IMF does not publish a wholesale price index for that country. In the case of Egypt, for which the IMF publishes neither wholesale nor consumer price indices, we adjusted for inflation, where necessary, using statistics published by The Economist Intelligence Unit: Egypt Country Profile 1993/94.

Verification

As provided in section 776(b) of the Act, we will verify the accuracy of all information used in making our final determination.

Critical Circumstances

Petitioners alleged that critical circumstances exist with respect to imports of silicomanganese from Ukraine. Pursuant to section 733(e)(1) of the Act and 19 CFR 353.16 (1993), we requested shipment information from Zaporozhye and Nikopol and attempted to analyze that information using the Department's standard methodology. To find critical circumstances, we must determine whether there is a reasonable basis to believe or suspect that 1) there is a history of dumping in the United States or elsewhere of the same class or kind of subject merchandise, or the importer knew or should have known that the producer or reseller was selling the subject merchandise at less than its foreign market value; and 2) there have been massive imports of the subject merchandise over a relatively short period.

We have not found a history of dumping of Ukrainian silicomanganese in the United States or elsewhere. According to Department practice, however, we will impute knowledge of dumping to importers of subject merchandise when the dumping margin exceeds 25 percent in purchase price situations. In this case, the estimated dumping margin for silicomanganese imports from Ukraine is 123.02 percent, a rate which exceeds our benchmark for imputing knowledge of dumping. Therefore, we have preliminarily found that importers should be imputed knowledge of dumping of the subject merchandise.

Pursuant to 19 CFR 353.16(f)(2), the Department considers imports of subject merchandise to be massive if there has been an increase of 15 percent or more over a relatively short period of time. We also consider, when possible, the respondent's share of import penetration of the domestic market in making this determination. In this case, evidence indicates that Ukrainian U.S. market penetration has increased.

To determine whether imports increased, we have examined the volume of imports by comparing volumes for the five months subsequent to the filing of the petition (November 1993 through March 1994) to the five months prior to the filing of the petition (June 1993 through October 1993). Although Zaporozhye has provided adequate information to perform an analysis of whether imports have increased, Nikopol has not done so. Specifically, the shipment information provided by Nikopol was inconsistent with its sales data. (*See* the concurrence memorandum, dated June 10, 1994.) Given that neither company has established its eligibility for separate dumping margins, the data concerning critical circumstances must be considered in a consolidated manner. Accordingly, given the lack of adequate information, we preliminarily determined that there have been massive imports of silicomanganese from the Ukraine.

Based on the foregoing, the Department preliminarily finds that critical circumstances exist in this case.

Suspension of Liquidation

In accordance with section 733(d)(1) of the Act, we are directing the Customs Service to suspend liquidation of all entries of silicomanganese from Ukraine that are entered, or withdrawn from warehouse, for consumption on or after 90 days prior to the date of publication of this notice in the **Federal Register**. The Customs Service shall require a cash deposit or posting of a bond equal to the estimated amount by which the FMV exceeds the USP as shown below. These suspension of liquidation instructions will remain in effect until further notice.

The weighted-average dumping margin is as follows:

Manufacturer/producer/exporter	Weighted-average margin percentage
All exports	123.02

ITC Notification

In accordance with section 733(f) of the Act, we have notified the ITC of our determination. If our final determination is affirmative, the ITC will determine before the later of 120 days after the date of this preliminary determination or 45 days after our final determination whether these imports are materially injuring, or threaten material injury to, the U.S. industry.

Public Comment

In accordance with 19 CFR 353.38, case briefs or other written comments in at least ten copies must be submitted to the Assistant Secretary for Import Administration no later than September 23, 1994, and rebuttal briefs no later than September 28, 1994. In accordance with 19 CFR 353.38(b), we will hold a public hearing, if requested, to afford interested parties an opportunity to comment on arguments raised in case or rebuttal briefs. Tentatively, the hearing will be held on September 30, 1994, at 2 p.m. at the U.S. Department of Commerce, Room 3708, 14th Street and Constitution Avenue NW., Washington, DC 20230. Parties should confirm by telephone the time, date, and place of the hearing 48 hours before the scheduled time.

Interested parties who wish to request a hearing, or to participate if one is requested, must submit a written request to the Assistant Secretary for Import Administration, U.S. Department

of Commerce, Room B–099, within ten days of the publication of this notice. Requests should contain: (1) The party's name, address, and telephone number; (2) the number of participants; and (3) a list of the issues to be discussed. In accordance with 19 CFR 353.38(b), oral presentations will be limited to issues raised in the briefs. We will make our final determination not later than 135 days from the date of publication of this notice.

This determination is published pursuant to section 733(f) of the Act and 19 CFR 353.15(a)(4).

Dated: June 10, 1994.

Susan G. Esserman,

Assistant Secretary for Import Administration.

[FR Doc. 94–14851 Filed 6–16–94; 8:45 am]

BILLING CODE 3510–DS–P

[A–307–811]

Notice of Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination: Silicomanganese From Venezuela

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: June 17, 1994.

FOR FURTHER INFORMATION CONTACT: Donna Berg or Stephen Alley, Office of Antidumping Investigations, Import Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, D.C. 20230; telephone (202) 482–0114 or 482–5288, respectively.

Preliminary Determination

We preliminarily determine that silicomanganese from Venezuela is being, or is likely to be, sold in the United States at less than fair value, as provided in section 733 of the Tariff Act of 1930, as amended, (the Act). The estimated margins are shown in the "Suspension of Liquidation" section of this notice.

Case History

Since the initiation of this investigation on December 2, 1993 (58 FR 64553, December 8, 1993), the following events have occurred:

On December 27, 1993, the U.S. International Trade Commission (ITC) issued an affirmative preliminary determination in this case (*see* USITC Publication 2714, December, 1993).

On January 14, 1994, we issued the antidumping questionnaire to Hornos Electricos de Venezuela, S.A. (Hevensa), which accounted for at least sixty percent of the exports of the subject merchandise to the United States. On January 20, 1994, representatives of the Department of Commerce (the Department) met with Hevensa officials in Venezuela to provide further explanation of the antidumping questionnaire and to answer outstanding technical and procedural questions.

Responses to the questionnaire were received on February 14, 1994, and March 1, 1994. On March 10, 1994, petitioners in this investigation, Elkem Metals Company and the Oil, Chemical & Atomic Workers, Local 3–639, submitted comments regarding deficiencies in Hevensa's questionnaire responses. A supplemental questionnaire was issued to Hevensa on March 25, 1994. Hevensa submitted responses to this questionnaire on April 19, 1994, and May 25, 1994.

On March 15, 1994, petitioner submitted an allegation that Hevensa had sales below the cost of production (COP) in the home market.

At the request of petitioners, on March 30, 1994, the Department postponed its preliminary determination until no later than June 10, 1994 (59 FR 16177, April 6, 1994).

On May 9, 1994, based on petitioner's March 15, 1994 allegation, the Department initiated an investigation of sales below COP in accordance with section 773(b) of the Act (*see* decision memorandum from Richard Moreland to Barbara Stafford, dated May 9, 1994). We issued a COP questionnaire on May 9, 1994. However, because Hevensa's COP response is not due until June 22, 1994, this information could not be considered for the preliminary determination. It will be considered for the final determination.

Petitioners and Hevensa submitted comments regarding certain issues throughout May and June, 1994.

Postponement of Final Determination

Pursuant to section 735(a)(2)(A) of the Act, on May 27, 1994, Hevensa requested that, in the event of an affirmative preliminary determination in this investigation, the Department postpone its final determination until 135 days after the date of publication of an affirmative preliminary determination. Pursuant to 19 CFR 353.20(b), because our preliminary determination is affirmative, and no compelling reasons for denial exist, we are postponing the final determination until the 135th day after the date of publication of this notice in the **Federal Register**.

Scope of Investigation

The merchandise covered by this investigation is silicomanganese. Silicomanganese, which is sometimes called ferrosilicon manganese, is a ferroalloy composed principally of manganese, silicon, and iron, and normally containing much smaller proportions of minor elements, such as carbon, phosphorous and sulfur. Silicomanganese generally contains by weight not less than 4% iron, more than 30% manganese, more than 8% silicon and not more than 3% phosphorous. All compositions, forms and sizes of silicomanganese are included within the scope of this investigation, including silicomanganese slag, fines and briquettes. Silicomanganese is used primarily in steel production as a source of both silicon and manganese. This investigation covers all silicomanganese, regardless of its tariff classification. Most silicomanganese is currently classifiable under subheading 7202.30.0000 of the Harmonized Tariff Schedule of the United States (HTSUS). Some silicomanganese may also be classifiable under HTS subheading 7202.99.5040. Although the HTS subheading is provided for convenience and customs purposes, our written description of the scope of this proceeding is dispositive.

Period of Investigation

The period of investigation (POI) is June 1, 1993, through November 30, 1993.

Such or Similar Comparisons

We have determined that the class or kind of merchandise subject to this investigation constitutes two such or similar categories: silicomanganese lumps and silicomanganese fines. In making our fair value comparisons, in accordance with the Department's standard methodology, we first compared identical merchandise. Where there were no sales of identical merchandise in the home market (third country market with respect to silicomagnese fines) to compare to U.S. sales, we made similar merchandise comparisons on the basis of the criteria defined in Appendix V to the antidumping questionnaire, on file in Room B–099 of the main building of the Department of Commerce. In accordance with 19 CFR 353.58, we made comparisons at the same level of trade, where possible.

Fair Value Comparisons

To determine whether Hevensa's sales of silicomanganese from Venezuela to the United States were made at less than fair value, we compared the United

States price (USP) to the foreign market value (FMV), as specified in the "United States Price" and "Foreign Market Value" sections of this notice.

United States Price

We based USP for Hevensa on purchase price (PP), in accordance with section 772(b) of the Act, because all sales were made to unrelated parties prior to importation into the United States.

We calculated PP based on FOB Venezuelan port prices to unrelated customers in the United States. We made deductions, where appropriate, for freight, loading expenses and rebates. We added an amount, where appropriate, for duty drawback, in accordance with section 772(d)(1)(B) of the Act.

On October 7, 1993, the Court of International Trade (CIT), in *Federal-Mogul Corp. and The Torrington Co.* v. *United States*, Slip Op. 93–194 (CIT, October 7, 1993), rejected the Department's methodology for calculating an addition to USP under section 772(d)(1)(C) of the Act to account for taxes that the exporting country would have assessed on the merchandise had it been sold in the home market. The CIT held that the addition to USP should be the result of applying the foreign market tax rate to the price of the United States merchandise at the same point in the chain of commerce that the foreign market tax was applied to foreign market sales. Federal-Mogul, Slip Op. 93–194 at 12.

In accordance with the CIT decision in Federal-Mogul, we have multiplied the foreign market tax rate by the price of the United States merchandise at the same point in the chain of commerce that the foreign market tax was applied to foreign market sales, and have added the product to the USP. We have also deducted from the USP and the FMV those portions of the respective home market tax and the USP tax adjustments attributable to expenses included in the foreign market and United States bases of the tax if those expenses are later deducted to calculate FMV and USP. These adjustments to the foreign market tax and the USP tax adjustment are necessary to prevent the methodology for calculating the USP tax adjustment from creating antidumping duty margins where no margins would exist if no taxes were levied upon foreign market sales.

This margin creation effect is due to the fact that the basis for calculating both the amount of tax included in the price of the foreign market merchandise and the amount of the USP tax adjustment include many expenses that are later deducted when calculating USP and FMV. After these deductions are made, the tax included in FMV and the USP tax adjustment still reflect the inclusion of these expenses in the bases. Thus, a margin may be created that is not dependent upon a difference between adjusted USP and FMV, but is the result of differences between the expenses in the United States and the home market that were deducted through adjustments.

The adjustment to avoid the margin creation effect is in accordance with the United States Court of Appeals' holding that the application of the USP tax adjustment under section 772(d)(1)(C) of the Act should not create an antidumping duty margin if pre-tax FMV does not exceed USP. *Zenith Electronics Corp.* v. *United States*, 988 F.2d 1573, 1581 (Fed. Cir. 1993). In addition, the CIT has specifically held that an adjustment should be made to mitigate the impact of expenses that are deducted from FMV and USP upon the USP tax adjustment and the amount of tax included in FMV. *Daewoo Electronics Co., Ltd.* v. *United States*, 760 F. Supp. 200, 208 (CIT, 1991). However, the mechanics of the Department's adjustments to the USP tax adjustment and the foreign market tax amount as described above are not identical to those suggested in *Daewoo*.

In this investigation, Venezuela began collecting a value added tax (IVA) during the POI, on October 1, 1993. Consequently, for those U.S. sales invoiced on or after October 1, 1993, we added an amount for this tax, calculated as described above, that would have been collected had the U.S. sale not been exported. For the U.S. sales invoiced prior to October 1, 1993, we also added an amount for value-added tax when no home market comparison sales were made prior to October 1, 1993 (see below).

Foreign Market Value

In order to determine whether there was a sufficient volume of sales in the home market to serve as a viable basis for calculating FMV, we compared the volume of home market sales of subject merchandise to the volume of third country sales of subject merchandise, in accordance with section 773(a)(1)(B) of the Act. Since Hevensa's volume of home market sales of silicomanganese lump was greater than five percent of the aggregate volume of third country sales, we determined that the home market was viable and, therefore, based FMV for silicomanganese lump on home market sales, in accordance with 19 CFR 353.48(a). We found that the home market was not viable for silicomanganese fines. We selected Peru as our third country market for sales of silicomanganese fines, pursuant to 19 CFR 353.49.

In accordance with 19 CFR 353.46, we calculated FMV for silicomanganese lump based on delivered or FOB plant prices to unrelated customers. In light of the Court of Appeals of the Federal Circuit's (CAFC) decision in *Ad Hoc Committee of AZ–NM–TX–FL Producers of Gray Portland Cement* v. *United States*, Slip Op. 93–1239 (Fed. Cir., January 5, 1994), the Department no longer deducts home market movement charges from FMV pursuant to its inherent power to fill in gaps in the antidumping statute. We instead adjust for those expenses under the circumstance-of-sale provision of 19 CFR 353.56 and the exporter's sales price offset provision of 19 CFR 353.56(b)(1) and (2), as appropriate.

Accordingly, in the present case, we made circumstance of sale adjustments for post-sale home market movement charges under 19 CFR 353.56. This adjustment included home market inland freight and loading charges. Pursuant to 19 CFR 353.56(a)(2), we also made circumstance-of-sale adjustments, where appropriate, for differences in credit expenses and royalties.

As discussed above, the IVA was only levied on sales in the home market invoiced on or after October 1, 1993. Therefore, we divided the reported home market sales into two categories, one covering home market sales invoiced during the period June-September, 1993, and one covering sales invoiced on or after October, 1993. We accounted for the application of the IVA tax only on sales invoiced on or after October 1, 1993.

As the basis for FMV, we selected the home market group depending on when the U.S. sale was invoiced. For U.S. sales invoiced prior to October 1, 1993, we used the former group, and for those sales invoiced after September 30, 1993, we used the latter group.

We also calculated the amount of the tax that was due solely to the inclusion of price deductions in the original tax base (i.e., the sum of any amounts that were deducted from the tax base). See the "United States Price" section of this notice, above. This amount was deducted from the FMV after all other additions and deductions had been made.

In accordance with 19 CFR 353.49, we calculated FMV for silicomanganese fines on FOB plant prices, inclusive of packing, to unrelated customers in Peru. Pursuant to 19 CFR 353.56(a)(2), we made circumstance-of-sale adjustments,

where appropriate, for differences in credit expenses and royalties. We deducted third country packing and added U.S. packing costs, in accordance with section 773(a)(1) of the Act.

Cost of Production

Based on petitioner's allegations, and in accordance with section 773(b) of the Act, the Department initiated an investigation to determine whether Hevensa made home market sales at prices below its COP, and over an extended period of time. Although Hevensa's COP questionnaire response will be received too late for consideration for the preliminary determination, it will be considered for the final determination.

Currency Conversion

Because certified exchange rates from the Federal Reserve were unavailable, we made currency conversions based on the official monthly exchange rates in effect on the dates of the U.S. sales as certified by the International Monetary Fund.

Verification

As provided in section 776(b) of the Act, we will verify the accuracy of all information used in making our final determination.

Suspension of Liquidation

In accordance with section 733(d)(1) of the Act, we are directing the Customs Service to suspend liquidation of all entries of silicomanganese from Venezuela that are entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**. The Customs Service shall require a cash deposit or posting of a bond equal to the estimated preliminary dumping margins as shown below. This suspension of liquidation will remain in effect until further notice. The estimated preliminary dumping margins are as follows:

Manufacturer/producer/exporter	Weighted-average margin percentages
Hevensa	8.31
All others	8.31

ITC Notification

In accordance with section 733(f) of the Act, we have notified the ITC of our determination. If our final determination is affirmative, the ITC will determine before the later of 120 days after the date of the preliminary determination or 45 days after our final determination whether imports of the subject merchandise are materially injuring, or threaten material injury to, the U.S. industry.

Public Comment

Interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Import Administration, U.S. Department of Commerce, Room B–099, within ten days of the publication of this notice. Requests should contain: (1) the party's name, address, and telephone number; (2) the number of participants; and (3) a list of the issues to be discussed.

In accordance with 19 CFR 353.38, case briefs or other written comments in at least ten copies must be submitted to the Assistant Secretary for Import Administration no later than September 21, 1994, and rebuttal briefs no later than September 26, 1994. A public hearing, if requested, will be held on September 28, 1994, at 2 p.m. at the U.S. Department of Commerce, Room 3708, 14th Street and Constitution Avenue, NW, Washington, DC 20230. Parties should confirm by telephone the time, date, and place of the hearing 48 hours before the scheduled time. In accordance with 19 CFR 353.38(b), oral presentations will be limited to issues raised in the briefs.

We will make our final determination not later than 135 days after publication of this determination in the **Federal Register**.

This determination is published pursuant to section 733(f) of the Act, and 19 CFR 353.15(a)(4).

Dated: June 10, 1994.

Susan G. Esserman

Assistant Secretary for Import Administration

[FR Doc. 94–14852 Filed 6–16–94; 8:45 am]
BILLING CODE 3510–DS–P

North American Free-Trade Agreement, Article 1904 Binational Panel Reviews; Request for Panel Review

AGENCY: NAFTA Secretariat, United States Section, International Trade Administration, Department of Commerce.

ACTION: Notice of first request for panel review.

SUMMARY: On May 30, 1994 Bridon Cordage Inc. and Bridon Pacific Limited filed a First Request for Panel Review with the Canadian Section of the NAFTA Secretariat pursuant to Article 1904 of the North American Free-Trade Agreement. Panel review was requested of the final determination made by the Canadian International Trade Tribunal respecting Synthetic Baler Twine with a knot strength of 200 lbs. or less, originating in or exported from the United States of America. This determination was published in the *Canada Gazette*, Part I, Vol. 128, No. 18 on April 30, 1994. The NAFTA Secretariat has assigned Case Number CDA–94–1904–02 to this request.

FOR FURTHER INFORMATION CONTACT: James R. Holbein, United States Secretary, NAFTA Secretariat, Suite 2061, 14th and Constitution Avenue, Washington, DC 20230, (202) 482–5438.

SUPPLEMENTARY INFORMATION: Chapter 19 of the North American Free-Trade Agreement ("Agreement") establishes a mechanism to replace domestic judicial review of final determinations in antidumping and countervailing duty cases involving imports from a NAFTA country with review by independent binational panels. When a Request for Panel Review is filed, a panel is established to act in place of national courts to review expeditiously the final determination to determine whether it conforms with the antidumping or countervailing duty law of the country that made the determination.

Under Article 1904 of the Agreement, which came into force on January 1, 1994, the Government of the United States, the Government of Canada and the Government of Mexico established Rules of Procedure for Article 1904 Binational Panel Reviews ("Rules"). These Rules were published in the **Federal Register** on February 23, 1994 (59 FR 8686).

A first Request for Panel Review was filed with the Canadian Section of the NAFTA Secretariat, pursuant to Article 1904 of the Agreement, on May 30, 1994, requesting panel review of the final injury determination described above.

Rule 39(1)(c) of the Rules provides that:

(a) A Party or interested person may challenge the final determination in whole or in part by filing a Complaint in accordance with Rule 39 within 30 days after the filing of the first Request for Panel Review (the deadline for filing a Complaint is June 29, 1994);

(b) A Party, investigating authority or interested person that does not file a Complaint but that intends to appear in support of any reviewable portion of the final determination may participate in the panel review by filing a Notice of Appearance in accordance with Rule 40 within 45 days after the filing of the first Request for Panel Review (the deadline for filing a Notice of Appearance is July 14, 1994); and

(c) The panel review shall be limited to the allegations of error of fact or law,

including the jurisdiction of the investigating authority, that are set out in the Complaints filed in the panel review and the procedural and substantive defenses raised in the panel review.

Dated: June 9, 1994.

James R. Holbein,

United States Secretary, NAFTA Secretariat.

[FR Doc. 94–14844 Filed 6–16–94; 8:45 am]

BILLING CODE 3510–GT–M

Notice of Disposition of Application for Duty-Free Entry of Scientific Instrument

The applicant requested withdrawal of its application since no duty was levied on the entry covered by Docket Number 94-028 (See notice at 59 FR 18994, April 21, 1994). Pursuant to § 301.5(g) of the regulations, we hereby discontinue processing this application.

Pamela Woods,

Acting Director, Statutory Import Programs Staff

[FR Doc. 94–14847 Filed 6–16–94; 8:45 am]

BILLING CODE 3510–DS–F

Notice of Disposition of Application for Duty-Free Entry of Scientific Instrument

The applicant requested withdrawal of its application since no duty was levied on the entry covered by Docket Number 94-030 (See notice at 59 FR 18994, April 21, 1994). Pursuant to § 301.5(g) of the regulations, we hereby discontinue processing this application.

Pamela Woods,

Acting Director, Statutory Import Programs Staff

[FR Doc. 94–14848 Filed 6–16–94; 8:45 am]

BILLING CODE 3510–DS–F

Texas A&M University, et al.; Notice of Consolidated Decision on Applications for Duty-Free Entry of Scientific Instruments

This is a decision consolidated pursuant to Section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89–651, 80 Stat. 897; 15 CFR 301). Related records can be viewed between 8:30 A.M. and 5:00 P.M. in Room 4211, U.S. Department of Commerce, 14th and Constitution Avenue, N.W., Washington, D.C.

Comments: None received. *Decision:* Approved. No instrument of equivalent scientific value to the foreign instruments described below, for such purposes as each is intended to be used, is being manufactured in the United States.

Docket Number: 93–132. *Applicant:* Texas A&M University, Corpus Christi, TX 78412. *Instrument:* Rapid Kinetics Spectrometer Accessory, Model RX.1000. *Manufacturer:* Applied Photophysics Ltd., United Kingdom. *Intended Use:* See notice at 58 FR 63924, December 3, 1993. *Reasons:* The foreign instrument provides anaerobic operation and accurate temperature control to ± 0.2°C. *Advice Received From:* National Institutes of Health, April 21, 1994.

Docket Number: 93–134. *Applicant:* State University of New York at Buffalo, Buffalo, NY 14214. *Instrument:* Topographic Measuring System, Model TS 100. *Manufacturer:* Oxford Metrics Limited, United Kingdom. *Intended Use:* See notice at 58 FR 63924, December 3, 1993. *Reasons:* The foreign instrument provides non-invasive assessment without use of x-ray imaging methods. *Advice Received From:* National Institutes of Health, April 21, 1994.

Docket Number: 93–143. *Applicant:* University of California, Berkeley, Berkeley, CA 94720. *Instrument:* Electron Spin Resonance Spectrometer System, Model ESP300E-10/2.7. *Manufacturer:* Bruker Instruments, Germany. *Intended Use:* See notice at 58 FR 65158, December 13, 1993. *Reasons:* The foreign instrument provides: (1) a 10-inch magnet with a 2.7 kW power supply, (2) an electron paramagnetic resonance (EPR) data system, and (3) capability for stopped flow EPR. *Advice Received From:* National Institutes of Health, April 21, 1994.

Docket Number: 93–145. *Applicant:* Brigham Young University, Provo, UT 84602. *Instrument:* Microvolume Stopped Flow Spectrofluorimeter, Model SX.17MV. *Manufacturer:* Applied Photophysics, United Kingdom. *Intended Use:* See notice at 58 FR 68875, December 29, 1993. *Reasons:* The foreign instrument provides: (1) time resolved spectra, (2) 12.5 μs interval between spectra and (3) sample volume to 25 μl. *Advice Received From:* National Institutes of Health, April 21, 1994.

Docket Number: 93–149. *Applicant:* The George Washington University Medical Center, NW., Washington, DC 20037. *Instrument:* Mass Spectrometer, Model Delta S. *Manufacturer:* Finnigan MAT, Germany. *Intended Use:* See notice at 59 FR 2825, January 19, 1994. *Reasons:* The foreign instrument provides an internal precision of 0.006 per mil for 100 bar μl samples of CO_2. *Advice Received From:* National Institutes of Health, April 21, 1994.

Docket Number: 93–150. *Applicant:* Centers for Disease Control and Prevention, Atlanta, GA 30341-3724. *Instrument:* Mass Spectrometer, Model VG AutoSpec. *Manufacturer:* VG Analytical, United Kingdom. *Intended Use:* See notice at 59 FR 2825, January 19, 1994. *Reasons:* The foreign instrument provides: (1) double focusing trisector (EBE) geometry, (2) mass range to 2000 amu at 8kV and (3) scan rate to 5 per second. *Advice Received From:* National Institutes of Health, April 21, 1994.

Docket Number: 93–151. *Applicant:* Smithsonian Environmental Research Center, Edgewater, MD 21037. *Instrument:* Chlorophyll Fluorometer, Model PAM-101. *Manufacturer:* Heinz Walz, GmbH, Germany. *Intended Use:* See notice at 59 FR 2825, January 19, 1994. *Reasons:* The foreign instrument provides time-resolved fluorescence measurements in ambient light with a resolution of 10 μs using a pulse modulated light source. *Advice Received From:* National Institutes of Health, April 21, 1994.

Docket Number: 93–152. *Applicant:* Texas A&M University, College Station, TX 77843. *Instrument:* Muscle Research System, Model OPT1S. *Manufacturer:* Scientific Instruments, Germany. *Intended Use:* See notice at 59 FR 2825, January 19, 1994. *Reasons:* The foreign instrument provides fixtures for mounting and exposing muscle fibers and force measurement on a single muscle cell in the 0 to 30 mg range. *Advice Received From:* National Institutes of Health, April 21, 1994.

Docket Number: 93–154. *Applicant:* University of Wisconsin - Madison, WI 53706. *Instrument:* Mass Spectrometer, Model VG AutoSpec-3000 with Accessories. *Manufacturer:* Fisons Instruments, United Kingdom. *Intended Use:* See notice at 59 FR 5178, February 3, 1994. *Reasons:* The foreign instrument provides: (1) mass range to 5000, (2) a scan rate of 5 scans per second and (3) trisector (EBE) geometry. *Advice Received From:* National Institutes of Health, May 6, 1994.

Docket Number: 94–018. *Applicant:* Penn State University, Hershey, PA 17033. *Instrument:* Stopped-Flow Spectrofluorimeter, Model SX.17MV. *Manufacturer:* Applied Photophysics, United Kingdom. *Intended Use:* See notice at 59 FR 12893, March 18, 1994. *Reasons:* The foreign instrument provides: (1) a dead time of 850 ms, (2) a 10 mm observation pathway and (3) time resolved emission capability. *Advice Received From:* National Institutes of Health, May 6, 1994.

The National Institutes of Health advises in its memoranda that (1) the

capabilities of each of the foreign instruments described above are pertinent to each applicant's intended purpose and (2) they know of no domestic instrument or apparatus of equivalent scientific value for the intended use of each instrument.

We know of no other instrument or apparatus being manufactured in the United States which is of equivalent scientific value to any of the foreign instruments.

Pamela Woods

Acting Director, Statutory Import Programs Staff

[FR Doc. 94–14845 Filed 6–16–94; 8:45 am]

BILLING CODE 3510–DS–F

Applications for Duty-Free Entry of Scientific Instruments

Pursuant to Section 6(c) of the Educational, Scientific and Cultural Materials Importation Act of 1966 (Pub. L. 89–651; 80 Stat. 897; 15 CFR 301), we invite comments on the question of whether instruments of equivalent scientific value, for the purposes for which the instruments shown below are intended to be used, are being manufactured in the United States.

Comments must comply with Subsections 301.5(a)(3) and (4) of the regulations and be filed within 20 days with the Statutory Import Programs Staff, U.S. Department of Commerce, Washington, D.C. 20230. Applications may be examined between 8:30 A.M. and 5:00 P.M. in Room 4211, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington, D.C.

Docket Number: 94–064. *Applicant:* University of California, Berkeley, Physics Department, Berkeley, CA 94720. *Instrument:* Superconducting Solenoid. *Manufacturer:* Atomimpex, CIS. *Intended Use:* The instrument will be used for the study of the properties of the pure electron plasmas which will be contained in a trap inserted into the solenoid. The primary experiments will use the analogy between pure electron plasmas and 2-d inviscid, incompressible fluids to study large number vortex dynamics. *Application Accepted by Commissioner of Customs:* May 10, 1994.

Docket Number: 94–065. *Applicant:* Argonne National Laboratory, 9700 South Cass Avenue, Argonne, IL 60439. *Instrument:* Rapid Scanning Diode Array. *Manufacturer:* Hi-Tech Scientific Limited, United Kingdom. *Intended Use:* This is an accessory to an existing instrument which will be used in the investigation of the chemical properties of new chelating agents for isolation, separation and recovery of heavy metals. In particular, the investigations focus on lanthanides, actinides, d-transition elements, and other toxic heavy metals, and their complexes. *Application Accepted by Commissioner of Customs:* May 10, 1994.

Docket Number: 94–066. *Applicant:* University of Rhode Island, Graduate School of Oceanography, South Ferry Road, Narragansett, RI 02882-1197. *Instrument:* Two Large Volume In-situ Pumps, with accessories Model C/4. *Manufacturer:* Challenger Oceanic Systems & Services, United Kingdom. *Intended Use:* The instruments will be used to collect samples for analysis of trace metals, natural radionuclides and particulate matter in seawater during oceanographic research cruises. In addition, the instruments will be used in part of the course "Marine Particles" which deals with the role of particles in various ocean processes and techniques for collecting particles in seawater. *Application Accepted by Commissioner of Customs:* May 10, 1994.

Docket Number: 94–067. *Applicant:* United States Geological Survey, 12201 Sunrise Valley Drive, Reston, VA 22092. *Instrument:* Mass Spectrometer. *Manufacturer:* Mass Analyzer Products, Ltd., United Kingdom. *Intended Use:* The instrument will be used to perform geochronologic investigations (age determination of rocks and minerals by methods including natural radioactive decay) using the $^{40}Ar/^{39}Ar$ method. *Application Accepted by Commissioner of Customs:* May 12, 1994.

Docket Number: 94–068. *Applicant:* University of Illinois at Chicago, Psychology Department, 1007 West Harrison Street, Chicago, IL 60607-7137. *Instrument:* Monocular Oculometer for the Human Eye. *Manufacturer:* Devices for Movement Measurements, Germany. *Intended Use:* The instrument will be used to analyze eye movements and provide valuable new data in an extended research project entitled The Effect of Word Frequency During Two Readings of a Text and another study focussing on clarification of the role of meaning and context in text comprehension. In addition the instrument will be used by students enrolled in courses that provide research experience at both the undergraduate and graduate levels. *Application Accepted by Commissioner of Customs:* May 18, 1994.

Docket Number: 94–069. *Applicant:* University of Hawaii, SOEST Engineering Support Facility, 2525 Correa Road, Rm 153, Honolulu, HI 96822. *Instrument:* Nitrogen Liquefier, Model MNP 10/1/300. *Manufacturer:* Stirling Cryogenics and Refrigeration, The Netherlands. *Intended Use:* The instrument will be used to supply liquid nitrogen used to provide cryogenic cooling for a variety of scientific instruments including mass spectrometer, nuclear magnetic resonance spectrometer, mapping infrared spectrometer, refrigerators for biological samples, X-ray fluorescence microscopes, high vacuum cold traps and other instruments which are used in many different research programs. *Application Accepted by Commissioner of Customs:* May 19, 1994.

Docket Number: 94–071. *Applicant:* University of Arkansas for Medical Sciences, College of Pharmacy, 4301 W. Markham, Little Rock, AR 72205-7122. *Instrument:* Rapid Kinetics Accessory, Model SFA-20. *Manufacturer:* Hi Tech Ltd., United Kingdom. *Intended Use:* The instrument will be used to study the reduction of a series of nitroaromatic compounds using several bacterial and mammalian nitroreductases. The kinetic constants K_m and K_{cat} will be determined. In addition, the instrument will be used in the course Biopharm 3223 Pharmaceutical Analysis a study of the general chemical and biochemical procedures, techniques and instrumentation involved in quantitative and qualitative analysis. *Application Accepted by Commissioner of Customs:* May 20, 1994.

Pamela Woods

Acting Director, Statutory Import Programs Staff

[FR Doc. 94–14846 Filed 6–16–94; 8:45 am]

BILLING CODE 3510–DS–F

National Institute of Standards and Technology

[Docket No. 940370–4070]

Announcement of an Opportunity To Join a Cooperative Research and Development Agreement on Healthcare Information Technology Architecture Standards (HITAS)

AGENCY: National Institute of Standards and Technology, Commerce.

ACTION: Notice.

SUMMARY: The National Institute of Standards and Technology (NIST) invites interested parties to participate in a Cooperative Research and Development Agreement (CRADA) to establish a healthcare information system. The infrastructure will include application platform, application software, storage, human/computer interaction, and communication technologies. It will share medical information while maintaining confidentiality of patient data.

Through the CRADA, called the "Forum on Healthcare Information Technology Architecture Standards", NIST will provide the mechanism for industry and users to resolve standards-related technical issues that currently inhibit deployment of medical information technology products. Parties interested in participating in the CRADA should be prepared to invest adequate resources in the collaboration and be firmly committed to the goal of rapid development and deployment of new healthcare information technology.

The program will be within the scope and confines of The Federal Technology Transfer Act of 1986 (Public Law 99–502, 15 U.S.C. 3710a), which provides federal laboratories including NIST, with the authority to enter into cooperative research agreements with qualified parties. Under this law, NIST may contribute personnel, equipment and facilities—but no funds—to the cooperative research program. Members will be expected to make a contribution to the forum's efforts in the form of materials, equipment, personnel, and/or funds. The program is expected to last three years. This is not a grant program.

DATES: Detailed planning for the consortium began on March 1, 1994. Interested parties should contact NIST to confirm their interest at the address, telephone number or FAX number shown below no later than July 15, 1994.

ADDRESSES: Mr. F. Schulz, Building 225, Room B–266, National Institute of Standards and Technology, Gaithersburg, MD 20899.

FOR FURTHER INFORMATION CONTACT: Mr. F. Schulz, Telephone: 301–975–2192; FAX 301–926–3696.

SUPPLEMENTARY INFORMATION: The National Institute of Standards and Technology (NIST) invites interested parties to participate in a forum to establish a healthcare information system infrastructure. Through the CRADA, NIST will provide a venue and process for industry and users to resolve standards-related technical issues.

This project is based upon a shared, global vision of a large scale distributed healthcare information infrastructure which will encompass application platform, application software, storage, human/computer interaction, and communication technologies, integrated via object oriented middleware. The new infrastructure will share medical information while maintaining the security and confidentiality of patient data.

The CRADA will also provide links among the user requirement-driven Open Systems Environment Implementors Workshop (OIW), the consensus-driven base standards community, and the market-driven technical community to reduce time-to-market for complex technical products requiring simultaneous consensus in a variety of technical areas.

International market input from the workshops and the standards community are crucial to meeting government and industry objectives for common solutions across the global marketplace. Coordination with accredited U.S. and international standards groups is an important aspect of this partnership.

Participants will be assured of the technical and economic feasibility of the resultant technical products. This will accelerate acceptance of the specifications, promote rapid development of commercial products, and contribute to earlier deployment of technology to meet user needs.

Dated: June 13, 1994.

Samuel Kramer,

Associate Director.

[FR Doc. 94–14776 Filed 6–16–94; 8:45 am]

BILLING CODE 3510–13–M

[Docket No. 940541–4141]

RIN No. 0693–AB30

Proposed Revision of Federal Information Processing Standard (FIPS) 153, Programmer's Hierarchical Interactive Graphics Systems (PHIGS)

AGENCY: National Institute of Standards and Technology (NIST), Commerce.

ACTION: Notice; request for comments.

SUMMARY: A revision of FIPS 153, PHIGS, is being proposed. This proposed revision will add features to the basic PHIGS functionality defined in FIPS 153, which adopts voluntary industry standards, ANSI/ISO 9592.1–3:1989, and ANSI/ISO 9593–1:1990, 9593–3:1990, 9593–4:1991. The basic PHIGS functionality provides for control and data interchange between an application program and its graphic support systems and for a set of functions and programming language bindings for the definition, display and modification of two-dimensional (2D) or three-dimensional (3D) graphic data. New features will be provided by the proposed adoption of voluntary industry specifications ANSI/ISO 9592.1a,2a,3a,4:1992 for PHIGS PLUS. PHIGS PLUS will augment the basic PHIGS functionality by providing facilities for specifying curved lines, curved and facetted surfaces, lighting and shading, and color. In addition, the proposed revision will add a requirement for the validation of PHIGS implementations using either FORTRAN or C bindings.

Prior to the submission of this proposed revision to FIPS 153 to the Secretary of Commerce for review and approval, it is essential to assure that consideration is given to the needs and views of manufacturers, the public, and State and local governments. The purpose of this notice is to solicit such views.

This proposed revision contains two sections: (1) An announcement section, which provides information concerning the applicability, implementation, and maintenance of the standard; and (2) a specifications section. Only the announcement section of the standard is provided in this notice. Interested parties may obtain copies of the specifications (ANSI/ISO 9592.1–3:1989, ANSI/ISO 9592.1a,2a,3a,4:1992, and ANSI/ISO 9593–1:1990, 9593–3:1990, 9593–4:1991) from American National Standards Institute (ANSI), 11 West 42nd Street, 13th floor, New York, NY 10036, (212) 642–4900.

DATES: Comments on this proposed revision must be recived on or before September 15, 1994.

ADDRESSES: Written comments concerning the adoption of this proposed revision should be sent to: Director, Computer Systems Laboratory, ATTN: Proposed Revision of FIPS 153, PHIGS, Technology Building, room B154, National Institute of Standards and Technology, Gaithersburg, MD 20899.

Written comments received in response to this notice will be made part of the public record and will be made available for inspection and copying in the Central Reference and Records Inspection Facility, room 6020, Herbert C. Hoover Building, 14th Street between Pennsylvania and Constitution Avenues, NW., Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Mr. Kevin G. Brady, National Institute of Standards and Technology, Gaithersburg, MD 20899, telephone (301) 975–3644.

Dated: June 13, 1994.

Samuel Kramer,

Associate Director.

Proposed Federal Information Processing Standards Publication 153–1

(date)

Announcing the Standard for Programmer's Hierarchical Interactive Graphics System (PHIGS)

Federal Information Processing Standards Publications (FIPS PUBS) are issued by the National Institute of Standards and

Technology after approval by the Secretary of Commerce pursuant to section 111(d) of the Federal Property and Administrative Services Act of 1949 as amended by the Computer Security Act of 1987, Public Law 100–235.

1. Name of Standard. Programmer's Hierarchical Interactive Graphics System (PHIGS) (FIPS PUB 153–1).

2. Category of Standard. Software Standard, Graphics.

3. Explanation. This publication is a revision of FIPS PUB 153 and supersedes that document in its entirety. This revision provides a substantial, upward-compatible enhancement of the basic PHIGS functionality known as Plus Lumiere and Surfaces, PHIGS PLUS (ANSI/ISO 9592.1a,2a,3a,4:1992). PHIGS PLUS adds facilities for the specification of curved lines, curved and facetted surfaces, lighting and shading, and adds a mechanism for color specification to allow non-indexed color specification. Amendments to each part of the PHIGS specification detail revisions required by PHIGS PLUS. Also, each language binding of PHIGS has been amended as a result of PHIGS PLUS. The specifications and amendments that comprise the complete PHIGS standard as a result of this revision are detailed in the Specification section of this document.

In addition this revision adds a requirement for validation of PHIGS implementations using either FORTRAN or C bindings. However, validation is currently limited to basic PHIGS functionality, and therefore does not include the new functionality of PHIGS PLUS added by this revision.

FIPS 153–1 adopts the American National Standard Programmer's Hierarchical Interactive Graphics System, ANSI/ISO 9592.1–3:1989, and ANSI/ISO 9592.1a,2a,3a,4:1992, and 9593.1:1990, 9593.3:1990, 9593.4:1991, as a Federal Information Processing Standard (FIPS). This standard specifies the control and data interchange between an application program and its graphic support system. It provides a set of functions and programming language bindings for the definition, display and modification of two-dimensional (2D) or three-dimensional (3D) graphical data. In addition, these language bindings allow for the definition, display and modification of geometrically related objects, graphical data, and the relationships between the graphical data. The purpose of the standard is to promote portability of graphics application programs between different installations. The standard is for use by implementors as the reference authority in developing graphics software systems; and by other computer professionals who need to know the precise syntactic and semantic rules of the standard.

4. Approving Authority. Secretary of Commerce.

5. Maintenance Agency. U.S. Department of Commerce, National Institute of Standards and Technology (NIST), Computer Systems Laboratory (CSL).

6. Cross Index.

a. ANSI/ISO 9592.1:1989, Information Processing Systems—Computer Graphics—Programmer's Hierarchical Interactive Graphics System (PHIGS), Part 1, Functional Description.

b. ANSI/ISO 9592.1a:1992, Amendment 1, Information Processing Systems—Computer Graphics—Programmer's Hierarchical Interactive Graphics System (PHIGS), Part 1, Functional Description.

c. ANSI/ISO 9292.2:1989, Information Processing Systems—Computer Graphics—Programmer's Hierarchical Interactive Graphics System (PHIGS), Part 2, Archive File Format.

d. ANSI/ISO 9492.2a:1992, Amendment 1, Information Processing Systems—Computer Graphics—Programmer's Hierarchical Interactive Graphics System (PHIGS), Part 2, Archive File Format.

e. ANSI/ISO 9592.3:1989, Information Processing Systems—Computer Graphics—Programmer's Hierarchical Interactive Graphics System (PHIGS), Part 3, Clear Text Encoding of Archive File.

f. ANSI/ISO 9592.3a:1992, Amendment 1, Information Processing Systems—Computer Graphics—Programmer's Hierarchical Interactive Graphics System (PHIGS), Part 3, Clear Text Encoding of Archive File.

g. ANSI/ISO 9592.4:1992, Information Processing Systems—Computer Graphics—Programmer's Hierarchical Interactive Graphics System (PHIGS), Part 4, Plus Lumiere and Surfaces, PHIGS PLUS.

h. ANSI/ISO 9593.1:1990, Information Processing Systems—Computer Graphics—Programmer's Hierarchical Interactive Graphics System (PHIGS), Language Bindings, FORTRAN.

i. ANSI/IEC 9593.1:1990 Tech. Corrigendum, Programmer's Hierarchical Interactive Graphics System (PHIGS), Language Bindings, FORTRAN.

j. ANSI/ISO 9593.3:1990, Information Processing Systems—Computer Graphics—Programmer's Hierarchical Interactive Graphics System (PHIGS), Language Bindings, Ada.

k. ISO/IEC 9593.3:1990, Tech. Corrigendum, Programmer's Hierarchical Interactive Graphics System (PHIGS) Language Bindings, Ada.

l. ANSI/ISO 9593.4:1991, Information Processing Systems—Computer Graphics—Programmer's Hierarchical Interactive Graphics System (PHIGS), Language Bindings, C.

7. Related Documents.

a. Federal Information Resources Management Regulations (FIRMR) subpart 201.20.303, Standards, and subpart 201.39.1002, Federal Standards.

b. Federal ADP and Telecommunications Standards Index, U.S. General Services Administration, Information Resources Management Service, (updated periodically).

c. NIST, Validated Products List: Programming Languages, Database Language SQL, Graphics, GOSIP, POSIX, Security, Published quarterly and available by subscription from the National Technical Information Service (NTIS), U.S. Department of Commerce, Springfield, VA 22161.

d. FIPS PUB 69–1, Programming Language FORTRAN, adopts ANSI X3.9–1978/R1989.

e. FIPS PUB 119, Programming Language Ada, adopts ANSI/MIL–STD–1815A–1983.

f. FIPS PUB 120–1, Graphical Kernel System (GKS), adopts NISI X3.124–1985.

g. FIPS PUB 128–1, Computer Graphics Metafile (CGM), adopts ANSI/ISO 8632: 1992.

h. FIPS PUB 160, Programming Language C, adopts ANSI/ISO 9899: 1992.

i. ANSI/ISO 8632: 1992, Information Processing Systems—Computer Graphics Metafile for the Storage and Transfer of Picture Description Information (Part 1: Functional Specifications; Part 2: Character Encoding; Part 3: Binary Encoding; Part 4: Clear Text Encoding).

j. ISO/IEC 646: 1991, Information Processing—7–Bit Coded Character Set for Information Interchange.

k. ISO 2022: 1986, Information Processing—ISO 7–Bit and 8–Bit Coded Character Sets—Code Extension Techniques.

l. ISO 2382/13: 1984, Data Processing—Vocabulary—Part 13: Computer Graphics.

m. ISO 6093: 1985, Information Processing—Representation of Numeric Values in Character Strings for Information Interchange.

n. ISO 7942: 1985, Information Processing Systems—Computer Graphics—Functional Specification of the Graphical Kernel System (GKS).

o. ISO 7942/Amendment 1: 1991, Computer Graphics—Graphical Kernel Systems (GKS) Functional Descriptions.

p. ISO 8805: 1988, Information Processing—Computer Graphics—Graphical Kernel System (GKS–3D) Extensions Functional Description.

8. Objectives. The primary objectives of this standard are:

—to allow very highly interactive graphics application programs using 2D or 3D hierarchically structured graphics data to be easily transported between installations. This will reduce costs associated with the transfer of programs among different computers and graphic devices, including replacement devices.

—to aid the understanding and use of dynamic hierarchical graphics methods by application programmers.

—to aid manufacturers of graphics equipment by serving as a guideline for identifying useful combinations of graphics capabilities in a device.

—to encourage more effective utilization and management of graphics application programmers by ensuring that skills acquired on one job are transportable to other jobs, thereby reducing the cost of graphics programmer retraining.

—to aid graphics application programmers in understanding and using graphics methods by specifying well-defined functions and names. This will avoid the confusion of incompatibility common with operating systems and programming languages.

9. Applicability. PHIGS is one of the computer graphics standards (Appendix A discusses the family of computer graphics standards) provided for use by all Federal departments and agencies. These graphics standards should be used for all computer graphics applications and programs that are either developed or acquired for government use.

9.1 The FIPS for PHIGS is intended for use in computer graphics applications that are either developed or acquired for

government use. It is specifically designed to meet the performance requirements of such demanding applications as Computer Aided Design/Computer Aided Engineering/ Computer Aided Manufacturing, command and control, molecular modelling, simulation and process control. It emphasizes the support of applications needing a highly dynamic, highly interactive operator interface and expecting rapid screen update of complex images to be performed by the display system. The PHIGS Plus functionality is designed to support graphics applications requiring lighting and shading, curved lines, curved and facetted surfaces, and non-indexed color specification.

9.2 The use of this standard is compulsory and binding when one or more of the following situations exist:

—The graphics application is very highly interactive, or contains hierarchically structured graphics data, or requires rapid modification of 2D or 3D graphics data and the relationships among the data.

—It is anticipated that the life of the graphics program will be longer than the life of the presently utilized graphics equipment.

—The graphics application or program is under constant review for updating of the specifications, and changes may result frequently.

—The graphics application is being designed and programmed centrally for a decentralized system that employs computers of different makes and models and different graphic devices.

—The graphics program will or might be run on equipment other than that for which the program is initially written.

—The graphics program is to be understood and maintained by programmers other than the original ones.

—The graphics program is or is likely to be used by organizations outside the Federal government (*i.e.*, State and local governments, and others).

9.3 Nonstandard features of implementations of PHIGS should be used only when the needed operation or function cannot reasonably be implemented with the standard features alone. Although nonstandard features can be very useful, it should be recognized that the use of these or any other nonstandard elements may make the interchange of graphics programs and future conversion more difficult and costly.

10. Specifications. American National Standard Programmer's Hierarchical Interactive Graphics System, ANSI/ISO 9592.1-3:1989 and ANSI/ISO 9592.1a, 2a, 3a, 4:1992, define the scope of the specifications, the syntax and semantics of the PHIGS elements and requirements for conforming implementations. All of these specifications apply to Federal Government implementations of this standard.

ANSI/ISO 9592.103:1989 and ANSI/ISO 9592.1a,2a,3a,4:1992 define a language independent nucleus of a graphics system for integration into a programming language. Thus, it is embedded in a language layer obeying the particular conventions of the language. FIPS 153-1 is therefore divided into two parts. Part 1 represents the functional aspects of PHIGS. Part 1 consists of the following:

(1) Functional description (ANSI/ISO 9592.1:1989) and (ANSI/ISO 9592.1a:1992, Amendment 1)

The functional description of PHIGS provides a set of functions for the definition, display and modification of 2D or 3D graphical data. It also provides for the definition, display and manipulation of geometrically related objects, along with the modification of graphics data and the relationships between that graphical data.

(2) Archive file format (ANSI/ISO 9592.2:1989) and (ANSI/ISO 9592.2a:1992, Amendment 1)

The archive file provides a file format suitable for the storage and retrieval of PHIGS structures and structure network definitions. It allows structure definitions to be stored in an organized way on a graphical software system. And, facilitates transfer of structure definitions between different graphical software systems.

(3) Clear-text encoding (ANSI/ISO 9592.3:1989) and (ANSI/ISO 9592.3a:1992, Amendment 1)

The clear-text encoding provides a representation of the archive file syntax that is easy to type, edit and read. The file is human-readable (allows editing), human friendly (easy and natural to read) and machine readable (parsable by software).

(4) Plus Lumiere and Surfaces, PHIGS PLUS (ANSI/ISO 9592.4:1992)

The Programmer's Hierarchical Interactive Graphics System (PHIGS) Plus Lumiere and Surfaces (PHIGS PLUS) extends the basic PHIGS functionality by adding facilities for the specification of curved lines, curved and facetted surfaces, lighting and other effects such as depth modulation.

Part 2 of FIPS 153-1 consists of the bindings of PHIGS and PHIGS PLUS functions to actual programming languages, defined in ANSI/ISO 9593:1990. These bindings are developed in cooperation with the voluntary standards committees of the various languages. The following bindings currently exist, and form part 2 of FIPS 153-1:

—The FORTRAN Language binding for PHIGS (ANSI/ISO 9593.1:1990);

—The ADA Language binding for PHIGS (ANSI/ISO 9593.3:1990);

—The C Language binding for PHIGS (ANSI/ISO 9593.4:1991).

Subsequent language bindings, including those for PHIGS PLUS, will be added periodically as they become available. As these bindings are approved by ANSI, each language binding will become part of this standard.

11. Implementation. Implementation of this standard involves four areas of consideration: the effective date, acquisition of PHIGS software system implementations, interpretations of PHIGS implementations, and validation of PHIGS implementations.

11.1 Effective Date. This revised standard is effective six (6) months after approval by the Secretary of Commerce. Requirements for the use of basic PHIGS functionality (defined in ANSI/ISO 9592.1-3;1989 and ANSI/ISO 9593.1:1990, 9593.3:1990, 9593.4:1991) are unchanged and continue in effect. Validation of PHIGS implementations is required after the effective date in accordance with section 11.4.

11.2 Acquisition of Implementations. Conformance to FIPS for PHIGS is required whether PHIGS toolbox packages are developed internally, acquired as part of an ADP system procurement, acquired by separate procurement, used under an ADP leasing arrangement, or specified for use in contracts for programming services. Recommended terminology for procurement of FIPS for PHIGS is contained in the *U.S. General Services Administration publication Federal ADP & Telecommunications Standards Index*, chapter 4 part 1.

11.3 Interpretation of this FIPS. NIST provides for the resolution of questions regarding FIPS for PHIGS specifications and requirements, and issues official interpretations as needed. Procedures for interpretations are specified in FIPS PUB 29–3. All questions about the interpretation of FIPS for PHIGS should be addressed to: Director, Computer Systems Laboratory (CSL), ATTN: PHIGS Interpretation, National Institute of Standards and Technology, Gaithersburg, MD 20899, Telephone: (301) 975–3265.

11.4 Validation of PHIGS Implementations. Implementations of FIPS for PHIGS using either FORTRAN or C bindings shall be validated in accordance with NIST Computer Systems Laboratory (CSL) validation procedures for FIPS for PHIGS. Recommended procurement terminology for validation of FIPS for PHIGS is contained in the *U.S. General Services Administration publication Federal ADP & Telecommunications Standards Index*, Chapter 4 Part 2. This GSA publication provides terminology for three validation options: Delayed Validation, Prior Validation Testing and Prior Validation. The agency shall select the appropriate validation option. The agency is advised to refer to the NIST publication *Validated Products List* for information about the validation status of PHIGS products. This information may be used to specify validation time frames that are not unduly restrictive of competition.

The agency shall specify the criteria used to determine whether a Validation Summary Report (VSR) or Certificate is applicable to the hardware/software environment of the PHIGS implementation offered. The criteria for applicability of a VSR or Certificate should be appropriate to the size and timing of the procurement. A large procurement may require that the offered version/release of the PHIGS implementation shall be validated in a specified hardware/software environment and that the validation shall be conducted with specified hardware/software features or parameter settings; e.g., the sema parameter settings to be used in a performance benchmark. An agency with a single-license procurement may review the *Validated Products List* to determine the applicability of existing VSRs or Certificates to the agency's hardware/software environment.

PHIGS implementations using either FORTRAN or C bindings shall be validated using the NIST PHIGS Test Suite, a suite of automated validation tests for PHIGS implementations. The NIST PHIGS Test Suite was first released in July 1990 to help users and vendors determine compliance with FIPS for PHIGS. The most recent version of the test suite will be used for validating conformance of PHIGS implementations after the effective date of FIPS PUB 153–1. The results of validation testing by the PHIGS Testing Service are published on a quarterly basis in the *Validated Products List*, available from the National Technical Information Service (NTIS). See related documents section.

Each release of the test suite has provided additional language bindings and test cases to increase the test suite's coverage of PHIGS functionality. Version 2.1 of the NIST PHIGS Test Suite, released in April 1994, provides testing for PHIGS implementations using either the FORTRAN or C language binding. Version 2.1 does not include tests for the functionality of PHIGS PLUS added by this revision of FIPS for PHIGS.

A PHIGS Test Suite license includes all of the tests described above, documentation, and automatic notifications of approved changes to the PHIGS Test Suite for a six month period. A license for the most recent version of the PHIGS Test Suite is a necessary requirement for an organization that desires to be tested by the NIST PHIGS Testing Service after the effective date of FIPS 153–1.

Current information about the NIST PHIGS Validation Service and validation procedures for FIPS for PHIGS is available from: National Institute of Standards and Technology, Computer Systems Laboratory, Graphics Software Group, Building 225, room A266, Gaithersburg, MD 20899, (302) 975–3265.

12. Waivers. Under certain exceptional circumstances, the heads of Federal departments and agencies may approve waivers to Federal Information Processing Standards (FIPS). The head of such agency may redelegate such authority only to a senior official designated pursuant to section 3506(b) of Title 44, United States Code.

Waivers shall be granted only when:

a. Compliance with a standard would adversely affect the accomplishment of the mission of an operator of a Federal computer system, or

b. Cause a major adverse financial impact on the operator which is not offset by Governmentwide savings.

Agency heads may act upon a written waiver request containing the information detailed above. Agency heads may also act without a written waiver request when they determine that conditions for meeting the standard cannot be met. Agency heads may approve waivers only by a written decision which explains the basis upon which the agency head made the required finding(s). A copy of each such decision, with procurement sensitive or classified portions clearly identified, shall be sent to: National Institute of Standards and Technology; ATTN: FIPS Waiver Decisions, Technology Building, room B–154; Gaithersburg, MD 20899. In addition notice of each waiver granted and each delegation of authority to approve waivers shall be sent promptly to the Committee on Government Operations of the House of Representatives and the Committee on Governmental Affairs of the Senate and shall be published promptly in the **Federal Register.**

When the determination on a waiver applies to the procurement of equipment and/or services, a notice of the waiver determination must be published in the *Commerce Business Daily* as a part of the notice of solicitation for offers of an acquisition or, if the waiver determination is made after that notice is published, by amendment to such notice.

A copy of the waiver, any supporting documents, the document approving the waiver and any supporting and accompanying documents, with such deletions as the agency is authorized and decides to make under 5 U.S.C. Sec. 552(b), shall be part of the procurement documentation and retained by the agency.

13. Where to Obtain Copies. Copies of this publication are for sale by the National Technical Information Service, U.S. Department of Commerce, Springfield, VA 22161. (Sale of the included specifications document is by arrangement with the American National Standards Institute.) When ordering, refer to Federal Information Processing Standards Publication 153–1 (FIPSPUB153–1) and title. Payment may be made by check, money order, or deposit account.

Appendix A

The Family of Graphics Standards

The following computer graphics standards are now available to address the needs of government applications in creating, modifying, manipulating, and exchanging computer-generated pictures:

- FIPS PUB 120–1, the Graphical Kernel System (GKS), which adopts ANSI X3.124–1985;
- FIPS PUB 153–1, the Programmer's Hierarchical Interactive Graphics System (PHIGS), which adopts ANSI/ISO 9592–1989;
- FIPS PUB 128–1, the Computer Graphics Metafile (CGM), which adopts ANSI/ISO 8632–1992 and
- FIPS PUB 177, the Initial Graphics Exchange Specification (IGES), which adopts ASME/ANSI Y14.24M–1989.

In addition, the Computer Graphics Interface (CGI) has recently become an International standard, and is expected to be issued as a FIPs.

These standards fall into two categories: Application Programmer's Interface (API) standards, and Interoperability standards. The goal of API standards is to enhance the portability of graphics programs (and programmers) between installations and environments. The goal of Interoperability standards is to enable graphics data to be exchanged successfully between graphics systems and devices.

Figure 1 is a very simple reference model of a computer graphics operating environment. The model emphasizes that a graphics application program interacts with physical devices and human operators via a computer graphics environment. Figure 1 also shows that the application may receive information from an external database.

The output of the graphics program, as shown in Figure 1, is directed to a virtual graphics device (i.e., Virtual Device Interface or VDI) rather than directly to a physical device. A Device Driver provides an interface, implemented in either hardware or software, for translating virtual device commands to commands understood by a particular physical device. By substituting one device driver for another, an application can run on a different physical device. This device independent is a central concept of this graphics reference model.

In Figure 1, the API standards reside in the box labelled the Device Independent Graphics Package. Interoperability standards are related to the boxes in Figure labelled Metafile, Database and Virtual Device Interface. Figure 2 depicts the various graphics standards associated with the general model shown in Figure 1. These are discussed below.

BILLING CODE 3510–CN–M

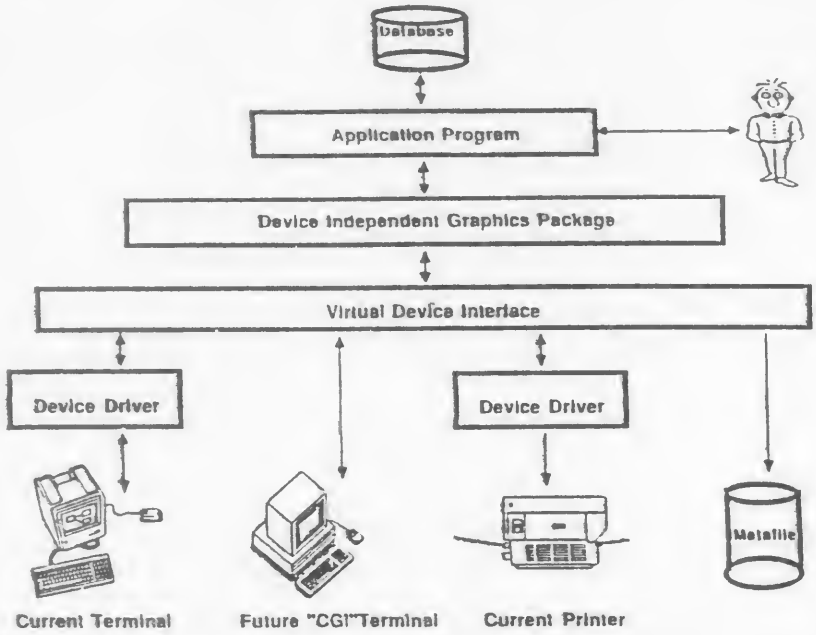

Figure 1. *Computer Graphics Reference Model*

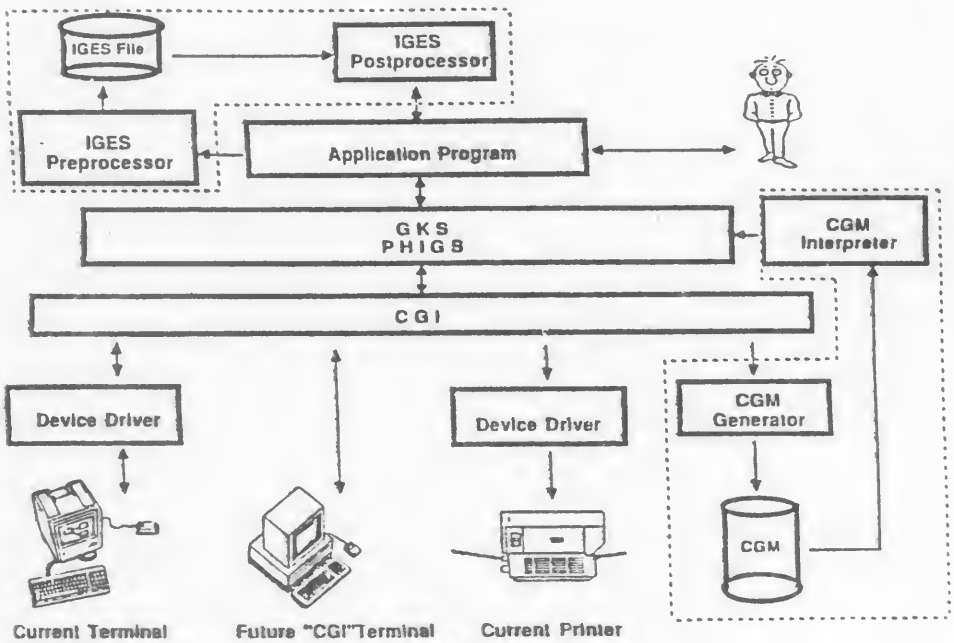

Figure 2. *Standards in the Computer Graphics Reference Model*

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Application Programmer's Interface (API) Standards

Standards at the API promote program and programmer portability. A standard at this level specifies a set of operations on a variety of graphics objects. An API standard provides for the portability of applications across a wide range of computer hardware, operating systems, programming languages, and graphics devices. A program written to an API standard at one facility in one environment should be easily transferable to another facility in a different environment. Facility dependencies should be the major area requiring modification.

The specific functions supported by a particular API standard provide certain capabilities. The application programmer, by identifying the capabilities needed, determines the API better suited for the application. As shown in Figure 2, there are currently two graphics API standards, GKS and PHIGS.

GKS provides a functional description of a two-dimensional (2D) graphics interface. It provides the basic graphics support required by a wide variety of applications requiring the production of computer-generated pictures. A procedural language binding of a functional standard specifies the exact name for each operation, its parameter sequence, and the data types for the parameters. FORTRAN, Pascal, Ada and C language bindings are parts of GKS.

GKS is suitable for use in graphics programming applications that employ a broad spectrum of graphics, from simple passive graphics output (where pictures are produced solely by output functions without interaction with an operator) to interactive applications; and which control a whole range of graphics devices, including but not limited to vector and raster devices, microfilm recorders, storage tube displays, refresh displays, and color displays.'

PHIGS provides for the definition, display, modification, and manipulation of 2D and 3D graphical data. It provides functionality to support storage of graphics and application data in a hierarchical form. Information may be inserted, changed, and deleted from the hierarchical data storage with the functions provided by PHIGS. Language binding specifications for PHIGS include FORTRAN, C and Ada.

PHIGS is specifically designed to meet the performance requirements of such demanding applications as Computer Aided Design/Computer Aided Engineering/ Computer Aided Manufacturing, command and control, molecular modeling, simulation and process control.

Capabilities in PHIGS but not in GKS include: the centralized hierarchical data storage: the dynamic and responsive nature of interactions; the addition of a modeling capability; and support for color models other than Red-Green-Blue (RGB).

Interoperability Standards

Graphics Interoperability standards allow graphical data to be interchanged between graphics devices. As shown in Figure 2, there are three graphics interoperability standards, CGM, (future) CGI, and IGES.

CGM is used for the storage and transfer of picture description information. It enables pictures to be recorded for long term storage, and to be exchanged between graphics devices, system, and installations. As indicated in Figure 2, the storage mechanism for CGM is in the form of a neutral file formal called a metafile. The software which creates the metafile is known as a CGM Generator. The software which reads and displays a CGM metafile is known as an Interpreter.

CGM specifies a semantic interface that describes 2D graphical entities using primitives (like polyline, text, and ellipse) and attributes (like color, line width, interior style, and fonts). CGM is compatible with the specification of 2D elements in GKS. A data encoding specifies the exact sequence of bits used to represent each operation and its parameters. CGM contains three types of data stream encodings (binary, character, and clear text) to provide the implementor choices depending on the particular application.

IGES provides a method for representing and storing geometric, topological, and nongeometric product definition data that is independent of any one system. Where CGM transfers graphical pictures, IGES transfers a graphical database which can be processed to represent a picture. Thus IGES represents more than just purely graphical data. As Figure 2 indicates, the storage mechanism for IGES is in the form of a neutral file format that must be translated by a Preprocessor and Postprocessor for conversion between systems. IGES permits the compatible exchange of product definition data used by various computer aided design/computer aided manufacturing (CAD/CAM) systems.

The future CGI standard is designed to specify the exchange of information at the Virtual Device Interface. It will provide an interface between the device independent and device dependent parts of a graphics system. Since CGI contains information at a virtual level, it can be used to create a CGM. A CGM can also be output on a CGI device in a straightforward manner.

[FR Doc. 94–14779 Filed 6–16–94; 8:45 am]

BILLING CODE 3510–CN–M

Patent Licenses; Notice

AGENCY: National Institute of Standards and Technology Commerce.

ACTION: Notice of prospective grant of exclusive patent license.

SUMMARY: This is a notice in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i) that the National Institute of Standards and Technology ("NIST"), U.S. Department of Commerce, is contemplating the grant of a field of use exclusive license in the United States and outside the United States to practice the invention embodied in U.S. Patent Application Serial Number 08/154,459, titled, "Improved Apparatus For Precisely Measuring Accelerating Voltages Applied to X-Ray Sources" to Radcal Corporation, having a place of business in Monrovia, California. The patent rights in this invention have been assigned to the United States of America.

FOR FURTHER INFORMATION CONTACT: Bruce E. Mattson, National Institute of Standards and Technology, Industrial Partnerships Program, Building 221, room B–256, Gaithersburg, MD 20899.

SUPPLEMENTARY INFORMATION: The prospective exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless, within sixty days from the date of this published Notice, NIST receives written evidence and argument which establish that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

U.S. Patent Application Serial Number 08/154,459 provides an improved method of precisely measuring the accelerating voltage applied to an x-ray tube using a simple apparatus with a direct reading taken from a spectrographic image of the radiation produced by the x-ray tube.

The availability of the invention for licensing was published in the Federal Register, Vol. 59, No. 61 (March 30, 1994). A copy of the patent application may be obtained from NIST at the foregoing address.

Dated: June 13, 1994.

Samuel Kramer,

Associate Director.

[FR Doc. 94–14778 Filed 6–16–94; 8:45 am]

BILLING CODE 3510–13–M

[Docket No. 940557–4157]

Announcement of the American Petroleum Institute's Standards Activities

AGENCY: National Institute of Standards and Technology Commerce.

ACTION: Notice of intent to develop or revise standards and request for public comments and participation in standards development.

SUMMARY: The American Petroleum Institute (API), with the assistance of other interested parties, continues to develop standards, both national and international, in several areas. This notice lists the standardization efforts currently being conducted. The publication of this notice by the National Institute of Standards and Technology (NIST) on behalf of API is being undertaken as a public service. NIST does not necessarily endorse, approve, or recommend the standards referenced in this notice.

SUPPLEMENTARY INFORMATION:

Background

The American Petroleum Institute develops and publishes voluntary standards for equipment, operations, and processes. These standards are used by both private industry and by governmental agencies. All interested persons should contact in writing the appropriate source as listed for further information. Currently the following standardization efforts are being conducted:

General Committee on Pipelines

1115 Operation of Solution Mined Underground Storage Facilities
1122 Emergency Preparedness and Response
1123 Pipeline Public Education Program
1129 Pipeline Integrity Standards

FOR FURTHER INFORMATION CONTACT: M.H. Matheson, Manufacturing, Distribution, and Marketing, American Petroleum Institute, 1220 L Street, NW, Washington, DC 20005.

General Committee on Marketing

Pollution Prevention Wholesale
Pollution Prevention Retail
1500 Storage and Handling of Aviation Fuels at Airports
1584 Four-inch Aviation Hydrant System
1604 Removal & Disposal of Used Underground Storage Tanks
1615 Installation of Underground Petroleum Storage Tanks
1628 A Guide to the Assessment and Remediation of Underground Petroleum Releases
1632 Cathodic Protection of Underground Storage Tanks and Piping Systems
1637 Using the API Color-Symbol System to Mark Equipment and Vehicles for Product Identification at Service Stations and Distribution Terminals
1637A Using the API Color-Symbol System to Mark Equipment and Vehicles for Identification at Service Stations and Distribution Terminals

FOR FURTHER INFORMATION CONTACT: Gary Carroll, Manufacturing, Distribution, and Marketing, American Petroleum Institute, 1220 L Street, NW, Washington, DC 20005

General Committee on Refining

Technical Data Book, Petroleum Refining
521 Guide For Pressure-Relieving & Depressurizing Systems
526 Flanged Steel Safety Relief Valves
530 Calculation of Heater Tube Thickness in Petroleum Refineries
531M Measurement of Noise From Fired Process Heaters
575 Inspection of Atmospheric and Low-Pressure Storage Tanks
541 Squirrel-Cage Induction Motors 250 HP and larger
553 Control Valve Applications
619 Rotary-Type Positive Displacement Compressors for General Refinery Services
620 Design and Construction of Large, Welded, Low-Pressure Storage Tanks
631 Measurement of Noise From Air Cooled Heat Exchange
650 Welded, Steel Tanks for Oil Storage
653 Tank Inspection, Repair, Alt. & Reconstruction
662 Plate Type Heat Exchangers
672 Packaged, Integrally Geared for General Refinery Service Centrifugal Air Compressors
673 Special Purpose Fans
674 Positive Displacement Pumps—Reciprocating
677 General Purpose Gear Units for Refinery Service
685 Sealless Centrifugal Pumps
686 Installation of Mechanical Equipment
2508 Design and Construction Ethane & Ethylene Installations

FOR FURTHER INFORMATION CONTACT: Ron Chittim/Gary Carroll, Manufacturing, Distribution, and Marketing, American Petroleum Institute, 1220 L Street, NW., Washington, DC 20005

Safety and Fire Protection Subcommittee

2003 Protection Against Ignitions Arising Out of Static, Lightning, and Stray Currents
2005 Service Station Safety
2009 Safe Welding and Cutting Practices in Refineries, Gasoline Plants, and Petrochemical Plants
2023 Guide for Safe Storage and Handling of Heated Petroleum Derived Asphalt Products and Crude Oil Residue
2026 Safe Descent onto Floating Roofs of Tanks in Petroleum Service
2027 Ignition Hazards Involved in Abrasive Blasting of Atmospheric Hydrocarbon Tanks in Service
2030 Guidelines for Application of Water Spray Systems for Fire Protection in Petroleum Industry
2217A Guidelines for Work in Inert confined Spaces in the Petroleum Industry
2219 Safety Operating Guidelines for Vacuum Trucks in Petroleum Service
2350 Overfill Protection for Petroleum Storage Tanks

FOR FURTHER INFORMATION CONTACT: Myron N. Price, Health and Environmental Affairs, Safety and Fire Protection, American Petroleum Institute, 1220 L Street, NW., Washington, DC 20005

Committee on Petroleum Measurement

MPMS Chapter 12.2 (Parts 1–5) Calculation of Petroleum Quantities Using Dynamic Measurement Methods and Volumetric Correction Factors
MPMS Chapter 12.3 Volumetric Shrinkage Resulting From Blending Light Hydrocarbon with Crude Oils
MPMS Chapter 14.3 Part 2 Specification and Installation Requirements for Orifice Plates, Meter Tubes and Associated Fittings
MPMS Chapter 21.2 Liquid Flow Measurements Using Electronic Metering Systems
MPMS Chapter 19.2 Evaporation Loss From Internal and External Floating Roof Storage Tanks
Testing Protocol for Roof Seals and Fittings Internal and External Floating Roof Tanks

FOR FURTHER INFORMATION CONTACT: S.P. Chamberlain/L. Slagle, Exploration & Production Department, American Petroleum Institute, 1220 L Street, NW., Washington, DC 20005

General Committee on Exploration and Production Oilfield Equipment and Material Standards

1B Oil Field V–Belting
2C Offshore Cranes
2D Operation and Maintenance of Offshore Cranes
2T Planning, Designing and Constructing Tension Leg Platforms
4F Drilling and Well Servicing Structures
4G Maintenance and Use of Drilling and Well Servicing Structures
5A2 Thread Compounds for Casing, Tubing, and Line Pipe
5A5 Field Inspection of New Casing, Tubing, and Plain End Drill Pipe
5B Threading, Gaging, and Thread Inspection of Casing, Tubing, and Line Pipe Threads
5C3 Formulas and Calculations for Casing, Tubing, Drill Pipe, and Line Pipe Properties
5C5 Evaluation Procedures for Casing and Tubing Connections
5CT Casing and Tubing (U.S. Customary Units)
5CT Casing and Tubing (Metric Units)
5D Drill Pipe
5L Line Pipe
5LC CRA Line Pipe
5LD CRA Clad or Lined Steel Pipe
5L9 Unprimed External Fusion Bonded Epoxy Coating of Line Pipe
5T1 Imperfection Terminology
6A Valves and Wellhead Equipment

6A1 Ring Groove Measurement
6AF Capabilities of API Flanges Under Combinations of Load
6AM Material Toughness
6D Pipeline Valves (Steel Gate, Plug, Ball and Check Valves)
7 Rotary Drilling Equipment
7A1 Testing of Thread Compounds for Rotary Shouldered Connections
7G Drill Stem Design and Operating Limits
7K Rotary Drill Stem Elements
8A Drilling and Production Hoisting Equipment
8B Procedures for Inspection, Maintenance, Repair, and Remanufacture of Hoisting Equipment
8C Drilling and Production Hoisting Equipment (PSL 1 and PSL 2)
9A Wire Rope
9B Application, Care, and Use of Wire Rope for Oil Field Services
10A Well Cements
10B Cement Testing
10D Bow-Spring Casing Centralizers
xxx Cement Sheath Evaluation
xxx Well Cementing Temperatures
11AX Subsurface Sucker Rod Pumps and Fittings
11B Sucker Rods
11C Reinforced Plastic Sucker Rods
11E Pumping Units
11S Operation, Maintenance and Troubleshooting of Electric Submersible Pump Installations
11S3 Electric Submersible Pump Installations
11S4 Sizing and Selection of Electric Submersible Pump Installations
11V1 Gas Lift Valves, Orifices, Reverse Flow Valves and Dummy Valves
500 Classification of Locations for Electrical Installations at Petroleum Facilities
xxx Oilfield Packers
xxx Inspection and Maintenance of Production Piping
12P Fiberglass Reinforced Plastic Tanks
3B–1 Standard Procedure for Field Testing Water-Based Drilling Fluids
13B–2 Standard Procedures for Field Testing Oil-Based Drilling Fluids
13C Drilling Fluid Processing Equipment
13D The Rheology of Oil-Well Drilling Fluids
13I Standard Procedure for Laboratory Testing Drilling Fluids
13J Testing Heavy Brines
14F Design and Installation of Electrical Systems for Offshore Production Platforms
15HR High Pressure Fiberglass Line Pipe
15LE Polyethylene Line Pipe (PE)
15LR Low Pressure Fiberglass Line Pipe
15 TR Fiberglass Tubing
16A Specification for Drill Through Equipment
16C Specification for Choke and Kill Systems
16F Marine Drilling Riser Equipment
16R Design, Rating and Testing Marine Drilling Riser Couplings
xxx Temperature Effects of Non-Metallics in Drill Through Equipment
17D Subsea Wellhead and Christmas Tree Equipment
17F Subsea Control Systems
17G Design and Operation of Completion/Workover Riser Systems
17H ROV Interfaces with Subsea Equipment
17I Installation of Subsea Control Umbilicals
27 Determining Permeability of Porous Media
31 Standard Format for Electromagnetic Logs
33 Standard Calibration & Format for Gamma Ray & Neutron Logs
34 Standard Format for Hydrocarbon Mud Logs
40 Core Analysis Procedures
41 Performance Data on Cementing & Hydraulic Fracturing Equipment
43 Evaluation of Well Perforated Systems
44 Sampling Petroleum Reservoir Fluids
45 Analysis of Oilfield Waters
49 Drilling & Drill Stem Testing of Wells Containing Hydrogen Sulfide
50 Protection of the Environment for Gas Processing Plant Operations
51 Protection of the Environment for Production Operations
52 Protection of the Environment for Drilling Operations
53 Blowout Prevention Equipment Systems for Drilling Wells
55 Production & Gas Processing Plant Operations Involving Hydrogen Sulfide
66 Digital Well Data Standard Interchange Format
D12A API Well Number & Standard State, County, Offshore Area Codes
Model Form of Offshore Operating Agreement
xx Well Servicing/Workover Operations Involving Hydrogen Sulfide
xx Rheology of Cross Linked Fracturing Fluids
xx Evaluation of Cartridge Filters (E&P Operations)
xx Cargo Handling at Offshore Facilities
xx Long Term Conductivity Testing of Proppants

ADDRESSES: Exploration & Production, American Petroleum Institute, 700 North Pearl, Suite 1840 (LB 382), Dallas, TX 75201

FOR FURTHER INFORMATION CONTACT: Write the following persons for information on indicated standards at the above address: Jim Greer—API 6, 16 and 17 series standards; Chuck Liles—API Drilling and Production Practices; Mike Loudermilk—API 1B, 11, 12 and 14 series; Randy McGill—API 5 and 15 series; Jennifer Six—API 4, 7, 8, 9, 10 and 13 series; Mike Spanhel—API 2 series.

Dated: June 13, 1994.

Samuel Kramer,

Associate Director.

[FR Doc. 94–14777 Filed 6–16–94; 8:45 am]

BILLING CODE 3510–13–M

National Oceanic and Atmospheric Administration

[I.D. 052694B]

Marine Mammals

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Issuance of marine mammal permit modification (P501).

SUMMARY: Notice is hereby given that Dr. Raymond J. Tarpley, Assistant Professor, Department of Veterinary Anatomy, Texas A&M University, College Station, TX 77843, applied and was granted a modification to Scientific Research Permit No. 780. This modification becomes effective upon signature.

ADDRESSES: Documents submitted in connection with this permit, as modified, are available for review, by appointment, in the Permit Division, Office of Protected Resources, NMFS, NOAA, 1335 East-West Hwy., Silver Spring, MD 20910, (301/713–2289);

Director, Southeast Region, NMFS, NOAA, 9721 Executive Center Drive, St. Petersburg, FL 33702 (813/893–3141); and Director, Alaska Region, NMFS, NOAA, P.O. Box 21668, Juneau, AK 99802 (907/568–7221).

SUPPLEMENTARY INFORMATION: On May 2, 1994, notice was published in the **Federal Register** (59 FR 22593) that a modification of Permit No. 780, issued May 20, 1992 (57 FR 21396), had been requested by the above named individual. Notice is hereby given that the Permit, as modified, was issued pursuant to the provisions of Sections 216.33(d) and (e) of the Regulations Governing the Taking and Importing of Marine Mammals (50 CFR Part 216), and Section 222.25 of the regulations governing endangered fish and wildlife permits.

The Permit authorized collection of tissue samples from up to 30 bowhead whales (*Balaena mysticetus*) and 40 beluga whales (*Delphinapterus leucas*) taken during the Alaskan Eskimo subsistence harvest, import tissue samples from 10 beluga whales taken for subsistence purposes by the Inuit in Canada, and import tissue samples from harbor porpoise (*Phocoena phocoena*), Dall's porpoise (*Phocoenoides dalli*) and killer whales (*Orcinus orca*) found dead as a result of stranding. The modification authorizes an unlimited number of sample collections from all bowhead and beluga whales landed in the Alaskan Eskimo subsistence harvest and beluga whale samples imported from Canada.

Dated: June 10, 1994.

Herbert W. Kaufman,

Deputy Director, Office of Protected Resources, National Marine Fisheries.

[FR Doc. 94–14725 Filed 6–16–94; 8:45 am]

BILLING CODE 3510–22–F

[I.D. 060694D]

Marine Mammals

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Issuance of scientific research permit No. 926 (P562).

SUMMARY: Notice is hereby given that Mr. Robin Baird, of the Marine Mammal Research Group, Victoria, B.C., Canada, V8P 5L5, has been issued a permit to take killer whales (*Orcinus orca*) for purposes of scientific research.

ADDRESSES: The permit and related documents are available for review upon written request or by appointment, in the following offices:

Permits Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13130, Silver Spring, MD 20910 (301/713–2289); and

Director, Northwest Region, NMFS, NOAA, 7600 Sand Point Way, NE., BIN C15700, Seattle, WA 98115 (206/526–6150).

SUPPLEMENTARY INFORMATION: On April 19, 1994, notice was published in the **Federal Register** (59 FR 18522) that a request for a scientific research permit to tag killer whales (*Orcinus orca*) had been submitted by the above-named individual. The requested permit has been issued under the authority of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*) and the Regulations Governing the Taking and Importing of Marine Mammals (50 CFR part 216).

Dated: June 10, 1994.

Herbert W. Kaufman,

Deputy Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 94–14756 Filed 6–16–94; 8:45 am]

BILLING CODE 3510–22–F

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Addition

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Addition to the procurement list.

SUMMARY: This action adds to the Procurement List a commodity to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

EFFECTIVE DATE: July 18, 1994.

ADDRESS: Committee for Purchase From People Who Are Blind or Severely Disabled, Crystal Square 3, Suite 403, 1735 Jefferson Davis Highway, Arlington, Virginia 22202–3461.

FOR FURTHER INFORMATION CONTACT: Beverly Milkman, (703) 603–7740.

SUPPLEMENTARY INFORMATION: On April 22, 1994, the Committee for Purchase From People Who Are Blind or Severely Disabled published notice (59 F.R. 19164) of proposed addition to the Procurement List. Comments were received from the current contractor for the applicator in response to a request for sales data. The contractor indicated that it is near a labor surplus area that is home to most of its workers and that it is experiencing less demand than it can supply. The contractor indicated that most of its workers are the sole support for their families. Consequently, the contractor believes that addition of the applicator to the Procurement List would have a severe adverse impact on the company.

The proportion of the contractor's sales which it would lose if it were unable to sell this applicator to the Government is very small. It was not the current contractor for another item mentioned in its comments at the time the item was added to the Procurement List. Consequently, the loss of sales would not constitute severe adverse impact on the company.

As the contractor admitted, it is not located in a labor surplus area even though some of its workers live in one. The contractor also did not state that workers would be discharged if the applicator is added to the Procurement List. Because these workers live near an area which is not considered a labor surplus area, they may well secure other employment if they are discharged. People with severe disabilities, on the other hand, have unemployment rates exceeding 65% nationally. Like the contractor's workers, people with severe disabilities are often the sole support for their families. Consequently, the Committee believes that the definite creation of jobs for people with severe disabilities by addition of the applicator to the Procurement List outweighs the possible loss of employment for people who can more easily find other jobs.

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the commodity, fair market price, and impact of the addition on the current or most recent contractors, the Committee has determined that the commodity listed below is suitable for procurement by the Federal Government under 41 U.S.C. 46–48c and 41 CFR 51–2.4.

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the commodity to the Government.

2. The action does not appear to have a severe economic impact on current contractors for the commodity.

3. The action will result in authorizing small entities to furnish the commodity to the Government.

4. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the commodity proposed for addition to the Procurement List.

Accordingly, the following commodity is hereby added to the Procurement List:

Applicator, Disposable
6515–00–059–5235

This action does not affect current contracts awarded prior to the effective date of this addition or options exercised under those contracts.

E. R. Alley, Jr.,

Deputy Executive Director.

[FR Doc. 94–14821 Filed 6–16–94; 8:45 am]

BILLING CODE 6820–33–P

Procurement List Additions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Additions to the Procurement List.

SUMMARY: This action adds to the Procurement List commodities and a service to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

EFFECTIVE DATE: June 18, 1994.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Crystal Square 3, Suite 403, 1735 Jefferson Davis Highway, Arlington, Virginia 22202–3461.

FOR FURTHER INFORMATION CONTACT: Beverly Milkman (703) 603–7740.

SUPPLEMENTARY INFORMATION: On March 25, April 22 and May 2, 1994, the Committee for Purchase From People Who Are Blind or Severely Disabled published notices (59 F.R. 14154, 19164 and 22596) of proposed additions to the Procurement List.

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the commodities and service, fair market price, and impact of the additions on the current or most recent contractors, the Committee has determined that the commodities and service listed below are suitable for procurement by the Federal Government under 41 U.S.C. 46–48c and 41 CFR 51–2.4.

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the commodities and service to the Government.

2. The action does not appear to have a severe economic impact on current contractors for the commodities and service.

3. The action will result in authorizing small entities to furnish the commodities and service to the Government.

4. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the commodities and service proposed for addition to the Procurement List. Accordingly, the following commodities and service are hereby added to the Procurement List:

Commodities

Container, Wood, Rocket Motor
8140–01–004–9410
(Requirements for the Naval Air Warfare Center, Lakehurst, NJ)

Sleeve, Protective
9330–LL–N01–0397
(Requirements for the Fleet and Industrial Supply Center, Bremerton, Washington)

Service

Food Service Attendant
Hanscom Air Force Base, Massachusetts

This action does not affect current contracts awarded prior to the effective date of this addition or options exercised under those contracts.

E.R. Alley, Jr.,

Deputy Executive Director.

[FR Doc. 94–14822 Filed 6–16–94; 8:45 am]

BILLING CODE 6820–33–P

Procurement List; Proposed Additions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed additions to procurement list.

SUMMARY: The Committee has received proposals to add to the Procurement List commodities and a service to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

COMMENTS MUST BE RECEIVED ON OR BEFORE: July 18, 1994.

ADDRESS: Committee for Purchase From People Who Are Blind or Severely Disabled, Crystal Square 3, Suite 403, 1735 Jefferson Davis Highway, Arlington, Virginia 22202–3461.

FOR FURTHER INFORMATION CONTACT: Beverly Milkman (703) 603–7740.

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 47(a)(2) and 41 CFR 51–2–3. Its purpose is to provide interested persons an opportunity to submit comments on the possible impact of the proposed actions.

If the Committee approves the proposed additions, all entities of the Federal Government (except as otherwise indicated) will be required to procure the commodities and service listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the commodities and service to the Government.

2. The action does not appear to have a severe economic impact on current contractors for the commodities and service.

3. The action will result in authorizing small entities to furnish the commodities and service to the Government.

4. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the commodities and service proposed for addition to the Procurement List. Comments on this certification are invited. Commenters should identify the statement(s) underlying the certification on which they are providing additional information.

The following commodities and service have been proposed for addition to Procurement List for production by the nonprofit agencies listed:

Commodities

Cap, Garrison

8410–01–213–4783
8410–01–213–4784
8410–01–213–4785
8410–01–213–4786
8410–01–213–4787
8410–01–213–4788
8410–01–213–4789
8410–01–213–4790
8410–01–213–4791
8410–01–213–4792

NPA: Goodwill Industries of South Florida, Inc., Miami, Florida

Service

Commissary Shelf Stocking and Custodial
Columbus Air Force Base, Mississippi

NPA: Alabama Goodwill Industries, Inc. Birmingham, Alabama

E.R. Alley, Jr.,

Deputy Executive Director.

[FR Doc. 94–14823 Filed 6–16–94; 8:45 am]

BILLING CODE 6820–33–P

Proposed Addition to the Procurement List: Correction

In notice document 94–13078 beginning on page 27538 in the issue of Friday, May 27, 1994, make the following correction:

Delete the following item:

Janitorial/Custodial, for the following Asheville, North Carolina, locations:
Asheville Federal Building, Patton Avenue & N. French Broad Avenue

Federal Building & U.S. Courthouse, Otis & Post Streets

NPA: Goodwill Industries of Northwest North Carolina, Inc., Winston-Salem, North Carolina

This item was included in notice document 94–10980, which appeared beginning on page 23700 in the issue of Friday, May 6, 1994. The comment period for items in notice document 94–10980, which ended June 6, 1994, applies to the above-mentioned item deleted from notice document 94–13078, and not the comment period announced in the later published document.

E.R. Alley, Jr.,

Deputy Executive Director.

[FR Doc. 94–14824 Filed 6–16–94; 8:45 am]

BILLING CODE 6820–33–P

CONSUMER PRODUCT SAFETY COMMISSION

Notification of Request for Approval of a Collection of Information—Hotline Customer Service Survey

AGENCY: Consumer Product Safety Commission.

ACTION: Notice.

SUMMARY: In accordance with provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35), the Consumer Product Safety Commission has submitted to the Office of Management and Budget a request for approval, through September 30, 1994, of a collection of information consisting of a survey of persons who call the Commission's hotline.

Each year, about 170,000 members of the public call the Commission's toll-free hotline to report unsafe products or to obtain information on product recalls, general safety information, or referrals to other federal, state, or local health, safety or consumer agencies.

On September 11, 1993, President Clinton issued Executive Order 12862, which includes the requirement that agencies "survey customers to determine the kind and quality of services they want and their level of satisfaction with existing services." The Commission's hotline is a major point of contact between the Commission and the public, and is one of the few activities of the Commission for which customer service can be objectively measured. Therefore, it is critical for CPSC to determine how hotline callers are being served.

The Commission plans to conduct a Customer Satisfaction Survey by sampling approximately 600 hotline callers. This survey will be conducted by telephone and will require about four minutes for each interview. The Commission will use the results of this survey to implement E.O. 12862 and to determine both the current level of customer satisfaction and the additional kind and quality of services desired by the public.

Additional Details About the Request for Approval of a Collection of Information

Agency address: Consumer Product Safety Commission, Washington, DC 20207.

Title of information collection: CPSC Hotline Customer Service Survey.

Type of request: New collection.

Frequency of collection: One-time for each respondent.

General description of respondents: Persons who have called the Commission's hotline.

Estimated number of respondents: 600.

Estimated average number of hours per respondent: .066.

Estimated number of hours for all respondents: 40.

Comments: Comments on the request for approval of this collection of information should be addressed to Donald Arbuckle, Desk Officer, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503; telephone: (202) 395–7340. Copies are available from Francine Shacter, Office of Planning and Evaluation, Consumer Product Safety Commission, Washington, DC 20207; telephone (301) 504–0416.

This is not a proposal to which 44 U.S.C. section 3504(h) is applicable.

Dated: June 13, 1994.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

[FR Doc. 94–14710 Filed 6–16–94; 8:45 am]

BILLING CODE 6355–01–M

COOPERATIVE STATE RESEARCH SERVICE

Animal Health Science Research Advisory Board: Meeting

According to the Federal Advisory Committee Act of October 6, 1972. Pub. L. No. 92–463, Cooperative State Research Service announces the following meetings:

Name: Animal Health Science Research Advisory Board.

Date: August 15 and 16, 1994.

Time: 8:30 a.m.

Place: Room 338–C, Aerospace Building, U.S. Department of Agriculture, 901 "D" Street, SW., Washington, DC 20024.

Type of meeting: Open to the public. Persons may participate in the meeting as time and space permit.

Comments: The public may file written comments before or after the meeting with the contact person below.

Purpose: The Board will consult with and advise the Secretary of Agriculture on implementing animal health and disease research programs. Recommendations will be made also on priorities of research in these programs.

Board member names and agenda: Available from contact person below.

Contact person: George E. Cooper, Executive Secretary, Animal Health Science Research Advisory Board, Cooperative State Research Service, U.S. Department of Agriculture, Ag Box 2220, Washington, DC 20024, telephone (202) 401–4847.

Done at Washington, DC, this 13th day of June, 1994.

John Patrick Jordan,

Administrator.

[FR Doc. 94–14794 Filed 6–16–94; 8:45 am]

BILLING CODE 3410–22–M

DEPARTMENT OF DEFENSE

Office of the Secretary

Notice of Availability, Department of Defense Pollution Prevention Written Strategy

AGENCY: Office of the Secretary, DOD.

ACTION: Notice of availability.

SUMMARY: As part of the requirements under Executive Order 12856 "Federal Compliance with Right-To-Know Laws and Pollution Prevention Requirements," this notice announces the availability of the Department of Defense written pollution prevention strategy.

ADDRESSES: Requests for copies of the strategy and comments on the strategy may be submitted to the Office of the Deputy Under Secretary of Defense (Environmental Security), Attn: Andy Porth, OADUSD (PP), Skyline 6 suite 310, 5109 Leesburg Pike, Falls Church, VA 22041.

FOR FURTHER INFORMATION CONTACT: Mr. Andy Porth at (703) 756–5643.

Dated: June 14, 1994.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 94–14808 Filed 6–16–94; 8:45 am]

BILLING CODE 5000–04–M

Defense Intelligence Agency Joint Military Intelligence College Board of Visitors; Closed Meeting

AGENCY: Defense Intelligence Agency Joint Military Intelligence College.

ACTION: Notice of closed meeting.

SUMMARY: Pursuant to the provisions of Subsection (d) of section 10 of Public Law 92–463, as amended by section 5 of Public Law 94–409, notice is hereby given that a closed meeting of the DIA Joint Military Intelligence College Board of Visitors has been scheduled as follows:

DATES: Thursday, 28 July 1994, 0900 to 1700; and Friday, 29 July 1994, 0800 to 1200.

ADDRESSES: The DIAC, Washington, DC.

FOR FURTHER INFORMATION CONTACT: General Charles J. Cunningham, Jr., Lieutenant General, USAF (Ret), Commandant, DIA Joint Military Intelligence College, Washington, DC 20340–5100 (202/373–3344).

SUPPLEMENTARY INFORMATION: The entire meeting is devoted to the discussion of classified information as defined in section 552b(c)(1), title 5 of the U.S. Code and therefore will be closed. The Board will discuss several current critical intelligence issues and advise the Director, DIA, as to the successful accomplishment of the mission assigned to the Joint Military Intelligence College.

Dated: June 14, 1994.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 94–14809 Filed 6–16–94; 8:45 am]

BILLING CODE 5000–04–M

DOD Advisory Group on Electron Devices; Closed Meeting

ACTION: Notice.

SUMMARY: Working Group A (Microwave Devices) of the DoD Advisory Group on Electron Devices (AGED) announces a closed session meeting.

DATES: The meeting will be held at 0900, Wednesday, 22 June 1994.

ADDRESSES: The meeting will be held at Palisades Institute for Research Services, 2011 Crystal Drive, suite 307, Arlington, VA 22202.

FOR FURTHER INFORMATION CONTACT: Walter Gelnovatch, AGED Secretariat, 2011 Crystal Drive, suite 307, Arlington, Virginia 22202.

SUPPLEMENTARY INFORMATION: The mission of the Advisory Group is to provide the Under Secretary of Defense for Acquisition and Technology, the Director, Advanced Research Projects Agency (ARPA) and the Military Departments with technical advice on the conduct of economical and effective research and development programs in the area of electron devices.

The Working Group A meeting will be limited to a review of research and development programs which the Military Departments propose to initiate with industry, universities or in their laboratories. This microwave device area includes programs on developments and research related to microwave tubes, solid state microwave devices, electronic warfare devices, millimeter wave devices, and passive devices. The review will include details of classified defense programs throughout.

A special agenda item for this meeting is the review of the draft ARPA Microwave and Analog Front End Technology (MAFAT) Broad Area Announcement (BAA). Because comments on the BAA are due immediately, and since the members necessary for review of this planning document could not be brought together except on this date, the normal 15 day advance notice requirement specified in the General Services Administration Final Rule, "Federal Advisory Committee Management, 41 CFR part 101–6" could not be met for this meeting.

In accordance with section 10(d) of Public Law 92–463, as amended, (5 U.S.C. App. II section 10(d)(1988)), it has been determined that this Advisory Group meeting concerns matters listed in 5 U.S.C. section 552b(c)(1)(1988), and that accordingly, this meeting will be closed to the public.

Dated: June 14, 1994.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 94–14810 Filed 6–16–94; 8:45 am]

BILLING CODE 5000–04–M

Defense Science Board Task Force on Cruise Missile Defense; Meeting

ACTION: Notice of advisory committee meetings.

SUMMARY: The Defense Science Board Task Force on Cruise Missile Defense will meet in closed session on July 28–29, 1994 at Science Applications International Corporation, McLean, Virginia.

The mission of the Defense Science Board is to advise the Secretary of Defense through the Under Secretary of Defense for Acquisition and Technology on scientific and technical matters as they affect the perceived needs of the Department of Defense. At this meeting the Task Force will focus on the land attack Cruise Missile threat, and should be comprehensive enough to address operational issues, (offensive as well as defensive), organizational matters, connections to other programs and investment strategy as well as technical issues.

In accordance with section 10(d) of the Federal Advisory Committee Act, Public Law No. 92–463, as amended (5 U.S.C. App. II, (1988)), it has been determined that this DSB Task Force meeting, concerns matters listed in 5 U.S.C. 552b(c)(1) (1988), and that accordingly this meeting will be closed to the public.

Dated: June 14, 1994.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 94–14806 Filed 6–16–94; 8:45 am]

BILLING CODE 5000–04–M

Defense Science Board Task Force on Global Positioning System (GPS); Meeting

ACTION: Notice of advisory committee meeting.

SUMMARY: The Defense Science Board Task Force on Global Positioning System (GPS) will meet in closed session on July 12–14, 1994 at the Los Angeles AFB, California; and on August 3–4, 1994 at Lincoln Laboratory, Lexington, Massachusetts.

The mission of the Defense Science Board is to advise the Secretary of Defense through the Under Secretary of Defense for Acquisition and Technology on scientific and technical matters as they affect the perceived needs of the Department of Defense. At these meetings the Task Force will review and recommend options available to improve GPS jam resistance with particular emphasis on GPS tactical weapon applications. The main focus of the Task Force shall be the investigation of techniques for improving the resistance of GPS embedded receivers in tactical missiles and precision munitions and their delivery platforms.

In accordance with section 10(d) of the Federal Advisory Committee Act, Public Law No. 92–463, as amended (5 U.S.C. App. II, (1988)), it has been determined that these DSB Task Force meetings concern matters listed in 5 U.S.C. 552b(c)(1) (1988), and that accordingly these meetings will be closed to the public.

Dated: June 14, 1994.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 94–14807 Filed 6–16–94; 8:45 am]

BILLING CODE 5000–04–M

Defense Science Board Task Force on Military Operations in Built-up Areas; Meeting Cancellation

ACTION: Cancellation of meeting.

SUMMARY: The meeting notice for the Defense Science Board Task Force on Military Operations in Built-up Areas scheduled for June 16, 1994 as published in the **Federal Register** (Vol. 59, No. 99, Page 26785, Tuesday, May 24, 1994, FR Doc 94–12576) has been cancelled. In all other respects the original notice remains unchanged.

Dated: June 14, 1994.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 94–14805 Filed 6–16–94; 8:45 am]

BILLING CODE 5000–04–M

Department of the Army

Committee Meeting Notice

AGENCY: U.S. Army Cadet Command, DoD.

ACTION: Notice of meeting.

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), announcement is made of the following committee meeting:

Name of Committee: Collegiate Education Advisory Committee.

Date of Meeting: 1 July 1994.

Place of Meeting: Officers' Club, Fort Bragg, North Carolina.

Time of Meeting: 0830–1230.

Proposed Agenda: Review and discussion of the status of Army ROTC since the July '93 meeting at fort Lewis, Washington.

1. Purpose of meeting: The Committee will review the significant changes in ROTC scholarships, missioning, advertising strategy, marketing, camps and on-campus training, the Junior High School Program and ROTC Nursing.

2. Meeting of the Advisory Committee is open to the public. Due to space limitations, attendance may be limited to those persons who have notified the Advisory Committee Management Office in writing at least five days prior to the meeting of their intent to attend the 1 July meeting.

3. Any members of the public may file a written statement with the Committee before, during or after the meeting. To the extent that time permits, the Committee Chairman may allow public presentations of oral statements at the meeting.

4. All communications regarding this Advisory Committee should be addressed to Mr. Roger Spadafora, U.S. Army Cadet Command, ATCC–TE, Fort Monroe, Virginia 23669–5000. Telephone number (804) 727–4595.

Gregory D. Showalter,

Alternate Army Federal Register Liaison Officer.

[FR Doc. 94–14762 Filed 6–16–94; 8:45 am]

BILLING CODE 3710–08–M

Army Science Board; Notice of Closed Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), announcement is made of the following Committee Meeting:

Name of Committee: Army Science Board (ASB)

Date of Meeting: 13 July 1994

Time of Meeting: 1200–1500 (classified)

Place: Pentagon, Washington, DC

Agenda: The Threat Team III of the Army Science Board's 1994 Summer Study on "Capabilities Needed to Counter Current and Evolving Threat" will meet to receive an Analytical Efforts Status Report. This meeting will be closed to the public in accordance with section 552b(c) of title 5, U.S.C., specifically subparagraph (1) thereof, and title 5, U.S.C., appendix 2, subsection 10(d). The unclassified and classified matters to be discussed are so inextricably intertwined so as to preclude opening all portions of the meeting. The ASB Administrative Officer Sally Warner, may be contacted for further information at (703) 695–0781.

Sally A. Warner,

Administrative Officer, Army Science Board.

[FR Doc. 94–14730 Filed 6–16–94; 8:45 am]

BILLING CODE 3710–08–M

Availability of Patents for Exclusive, Partially Exclusive or Nonexclusive Licenses

AGENCY: U.S. Army Corps of Engineers Command, DOD.

ACTION: Notice of Availability.

SUMMARY: The Department of the Army, U.S. Army Corps of Engineers announces the general availability of exclusive, partially exclusive, or nonexclusive licenses under the following patents. Any licenses granted shall comply with 35 USC 209 and 37 CFR part 404.

Issued patent	Title	Issued date
5,283,569	Float Actuated Flood Warning System with Remote Telephone Reporting	02/01/94
5,291,779	High-Wind Snow Collector	03/08/94
5,292,375	Removal of Lead Based Coating by Vitrification	03/08/94
5,294,133	Fluid-Filled O-Ring for Maintaining a Seal Under Low Temperature Conditions	03/15/94
5,295,759	Snow Plow Compatible Speed Bumps	03/22/94
5,296,028	Antifreeze Admixture for Concrete	03/22/94
5,305,287	High-Frequency Borehole Seismic Source	04/19/94
5,309,994	Method and Apparatus for Installing a Well	05/10/94
5,310,284	Weak Link Prop for Wicket Dam	05/10/94
5,311,856	Gas Gun and Quick Release Mechanism for Large Loads	05/17/94
5,313,825	Dual Mass Dynamic Cone Penetrometer	05/24/94

ADDRESSES: Department of the Army, Humphreys Engineer Center Support Activity, ATTN: CEHEC–OC—Kingman Building, 7701 Telegraph Road, Alexandria, VA 22310–2860.

FOR FURTHER INFORMATION CONTACT: Patricia L. Howland or Alease J. Berry, telephone (703) 355–2160.

Gregory D. Showalter,

Alternate Army Federal Register Liaison Officer.

[FR Doc. 94–14798 Filed 6–16–94; 8:45 am]

BILLING CODE 3710–08–M

Availability of Draft Environmental Impact Statement (DEIS) for the Proposed Anacostia River and Tributaries, District of Columbia and Maryland Feasibility Study

AGENCY: U.S. Army Corps of Engineers, Baltimore District, DOD.

ACTION: Extension of comment period.

SUMMARY: this Notice of Availability previously published in the **Federal Register** on May 6, 1994 (59 FR 23710)

is being republished to extend the comment period from June 5, 1994 to 27 June 1994, and to correct a number of typographical errors. The Baltimore District of U.S. Army Corps of Engineers investigated the feasibility of construction of fish and wildlife restoration measures in the Anacostia River basin. The District Engineer recommends the restoration of 80 acres of wetlands, 5 miles of streams and 33 acres of bottomland habitat. The feasibility study of the potential restoration actions was conducted under authority of a U.S. House of Representatives Committee on Public Works and Transportation resolution adopted September 8, 1988. The non-Federal sponsors for the feasibility phase of the project are: Montgomery County, Prince George's County, the District of Columbia, the State of Maryland, the Interstate Commission on the Potomac River Basin, and the Metropolitan Washington Counsel of Governments.

DATES: Comments must be received not later than 27 June 1994.

ADDRESSES: Send comments to: Colonel J. Richard Capka, District Engineer, P.O. Box 1715, Attn: CENAB–PL–PR, Baltimore, Maryland 21203–1715.

FOR FURTHER INFORMATION CONTACT: Mr. Mark McKevitt, Study Manager, (401) 962–2650.

SUPPLEMENTARY INFORMATION: 1. The U.S. House of Representatives, Committee on Public Works and Transportation, authorized the Anacostia River and Tributaries study in a re solution adopted on September 8, 1988. The resolution requested the Corps of Engineers to determine if further improvements for flood control, navigation, erosion, sedimentation, water quality and other related water resources needs are advisable on the Anacostia River and tributaries.

2. The Anacostia River basin is a 170-square mile sub-basin of the Potomac River. Headwaters of the Anacostia River are in the piedmont and coastal plain areas of Montgomery and Prince George's Counties, Maryland and it joins with the Potomac River in the District of Columbia. The entire river system is freshwater; although, the tidal influence extends for approximately 9 miles above the confluence with the Potomac River.

3. The Corps of Engineers involvement in the basin dates back more than 115 years and includes projects and programs for navigation, flood control, debris removal and aquatic vegetation control. These Federal actions have served their intended purposes well and have benefited the area in terms of improved navigation and reduced flood damages. However, from 1902 through the 1960s, project construction eliminated approximately 2,600 acres of wetlands, 99,000 linear feet of aquatic habitat and 700 acres of bottomland hardwoods. These ecosystems performed numerous beneficial ecological functions for the Anacostia basin and the associated Potomac River and Chesapeake Bay. One of the primary functions of these ecosystems is fish and wildlife habitat. Historically, the Anacostia River basin contained a diverse assemblage of fish and wildlife species. However, populations of many species have sharply declined due to the habitat loss and degradation in the Anacostia basin.

Site	Action	Target stream	Location
Wetland Restoration			
Kingman Lake	WR	Anacostia River	Washington, DC.
River Fringe Wetlands	WR	Anacostia River	Washington, DC.
Fordham Street Wetland	WR	Northwest Branch	Prince George's Co.
Aquatic Restoration			
NW Branch-PG Co.	SR	Northwest Branch	Prince George's Co.
Tanglewood Retrofit	WR/SM/SR	Little Paint Branch	Montgomery Co.
Snowden's Mill I	WR/SM/SR	Paint Branch	Montgomery Co.
Snowden's Mill II	WR/SM/SR	Paint Branch	Montgomery Co.
Stewart/April Lane	WR/SM/SR	Paint Branch	Montgomery Co.
Lockridge Drive	WR/SM/SR	Nothwest Branch	Montgomery Co.
Gum Springs	SR	Gum Springs	Montgomery Co.
Sligo Creek	SR	Sligo Creek	Montgomery Co.
NW Branch-Mont. Co. Paint Branch	SR	Paint Branch	Montgomery Co.

*WR—Wetland Restoration; SM—Stormwater Management; SR—Stream Restoration.

5. The Baltimore District has prepared a DEIS which describes the impacts of the proposed projects on environmental and cultural resources in the study area and the overall public interest. The DEIS also apply guidelines issued by the Environmental Protection Agency, under authority of Section 404 of the Clean Water Act of 1977 (P.L. 95–217). An evaluation of the proposed actions on the waters of the United States was performed pursuant to the guidelines of the Administrator, U.S. Environmental Protection Agency, under authority of Section 404 of the Clean Water Act. The Section 404(b)(1) evaluations show that the proposed actions meet all guidelines under the Clean Water Act, and an exemption under Section 404(r) of Public Law 92–500, as amended is therefore requested.

6. The public involvement included meetings and close coordination with interested private individuals and organizations, as well as concerned Federal, state and local agencies. A public notice requesting comments on the proposed project and DS IS being provided to appropriate agencies and the public through printed media and mailings. The Baltimore District invites potentially affected Federal, state and local agencies, and other interested organizations and parties to comment on the study recommendations. Agencies that are currently involved in the feasibility study and EIS process include, but are not limited to the U.S. Environmental Protection Agency, U.S. Fish and Wildlife Service, National Marine Fisheries Service, U.S. Geological Service, U.S. Soil Conservation Service, National Park Service, National Capital Planning Commission, Montgomery County Department of Environmental Protection, Prince George's County Department of Environmental Resources, District of Columbia Department of Consumer and Regulatory Affairs and Department of Public Works, Maryland Department of Natural Resources, Maryland Department of the Environment, Maryland National Capital Park and Planning Commission, Interstate Commission on the Potomac River

Basin, and the Metropolitan Washington Council of Governments.

7. In accordance with the National Environmental Policy Act (NEPA) and the Clean Water Act, the Corps of Engineers is soliciting comments from the public, Federal, state and local agencies and officials, and other interested parties. Any comments received will be considered by the Corps of Engineers in the decision to implement the projects. To make this decision, comments are used to assess impacts on endangered species, historic properties, water quality, general environmental effects, and other interest factors listed above. Comments are also used to determine the overall public interest and the need for a public hearing on the proposed activities. This public notice is being sent to organizations and individuals known to have an interest in the restoration of the Anacostia River basin. Please bring this notice to the attention of any other individuals with an interest in this matter.

8. Any person who has an interest in the proposed projects may make comments and/or request a public hearing. Comments must clearly set forth the interest which may be adversely affected by these activities and the manner is which the interest may be adversely affected. Copies of the DEIS are available upon request. Written comments must be submitted within 30 calendar days of the date of the notice in the Federal Register.

Kenneth L. Denton,

Army Federal Register Liaison Officer.

[FR Doc. 94–14761 Filed 6–16–94; 8:45 am]

BILLING CODE 3710–08–M

DEPARTMENT OF ENERGY

Savannah River Operations Office (SR); Financial Assistance Award, Intent To Award a Noncompetitive Grant

AGENCY: Savannah River Operations, Office, DOE.

ACTION: Notice.

SUMMARY: The DOE announces that it plans to accept an unsolicited proposal and award a grant to Benedict College, Harden and Blanding Streets, Columbia, South Carolina. The grant, "Mathematics and Science Enrichment Program," will be awarded for a three-year period at a DOE funding level of $648,000. Funds of $200,000 will be awarded for the first budget period, and subject to the availability of funds, the remainder will be awarded for the second and third budget period. Pursuant to 10 CFR 600.7(b) and 600.14, eligibility for this award has been limited to Benedict College as a result of acceptance of their unsolicited proposal, and DOE has determined that award of a grant is appropriate.

FOR FURTHER INFORMATION CONTACT: Beth O'Rear, Prime Contracts and Financial Assistance Branch, U.S. Department of Energy, Savannah River Operations Office, P.O. Box A, Aiken, SC 29802. Telephone: (803) 725–1345.

SUPPLEMENTARY INFORMATION:

Procurement Request Number

09–94SR18432.000.

Project Scope

The objective of this program is to identify, motivate, and begin preparation of students for science-based careers. The proposed program will offer a year-round science and mathematics enrichment program for 75 youths in grades 4 through 9. The participants in this program will be among those underrepresented in science-based careers (minorities and females). This program will provide to participants assistance in acquiring basic communication, computation and reasoning skills, as well as exposure to a variety of science-based careers through field trips and the use of role models.

Benedict College is a Historically Black College or University (HBCU) and falls within the meaning and intent of Executive Orders 12320, 12677 and 12876 pertaining to Government assistance to HBCUs. The participation of HBCUs in federally supported programs is relatively limited. In order to overcome some of these limitations, the Executive Orders directed federal agencies to increase the participation of HBCUs in federally-funded programs and to strengthen their capabilities to provide quality education. This award represents an effort to strengthen the HBCU community. The program proposed in the application is considered meritorious, and the activities to be carried out under this award would not be eligible for financial assistance under any recent, current, or planned solicitation. Based on documentation presented and appropriate evaluation, it is determined to be in the best interest of DOE to award a grant to Benedict College.

Issued in Aiken, South Carolina, on June 6, 1994.

Robert E. Lynch,

DOE Savannah River Operations Office, Head of Contracting Activity.

[FR Doc. 94–14836 Filed 6–16–94; 8:45 am]

BILLING CODE 6450–01–M

Golden Field Office; Notice of Financial Assistance Award to Electric Power Research Institute

AGENCY: Department of Energy.

ACTION: Notice of financial assistance award in response to a non-competitive financial assistance application.

SUMMARY: The U.S. Department of Energy (DOE) pursuant to the DOE Financial Assistance Rules, 10 CFR § 600.7(b)(2) is announcing its intention make a financial assistance award to the Electric Power Research Institute to perform a study on the next generation geothermal power plant.

ADDRESSES: Questions regarding this announcement may be addressed to the U.S. Department of Energy, Golden Field Office, 1617 Cole Blvd., Golden CO 80401, Attention: Ruth E. Adams, Contract Specialist or at (303) 275–4722. The Contracting Officer for this action is John W. Meeker and the Project Officer is Jeffrey L. Hahn.

SUPPLEMENTARY INFORMATION: This proposal was a solicited application. The Electric Power Research Institute (EPRI) issued a Request for Proposal (RFP), RFP3657–01 "Next Generation Geothermal Power Plant (NGGPP)—Phase 1 Studies" on June 2, 1993. The purpose of the RFP was to conduct studies that would expedite development of the next generation of geothermal power plants. This includes development, evaluation and comparison of power plant concepts and ranking of the suitability of these concepts for various geothermal resources. After a competitive evaluation process, EPRI selected the Ben Holt Company to perform the study. Negotiations with the Department of Energy (DOE) for additional funding resulted in 3 additional power plant concepts to be added to the scope of work. Competition for this effort would not be appropriate for this effort since EPRI has already gone through a competitive process and it would have a significant impact on the continuance and completion of the study.

The proposed project will contribute to the DOE mission of "* * * providing the scientific foundation [and] technology * * * necessary to achieve efficiency in energy use, diversity in energy sources, and access to technical information * * *". The results of the study will be published, presented at several geothermal conferences and made available to the geothermal industry and to the public. The proposed study to be completed by the Ben Holt Company are in harmony with the direction of the Geothermal Energy Conversion Program.

The objectives of this effort are to evaluate the feasibility, efficiency, environmental impacts and the economics of geothermal power plant technologies. This study is envisioned to be vital to developers in determining which technology to use to most efficiently utilize their geothermal resource.

Technologies that will be covered through this study are the following: Commercial air-cooled binary plants; commercial flash plants; advanced binary cycles, which includes the use of mixed and alternative working fluids, alternative cooling systems, advanced turbines and supersaturated turbine expansion; the Kalina cycle, which uses an ammonia-water mixture as the working fluid and regenerative pre-heating and partial vaporization; advanced flash concepts that will incorporate the use of equipment advances and cycle modifications; the use of rotary separator turbines in lieu of steam flash tanks; sub-atmospheric flash cycles; hot dry rock; steam flash/binary hybrid plants; and geothermal/natural gas hybrid plants.

The above listed technologies will be optimized and rated for various geothermal resources. The geothermal resources that will be used in this evaluation provide a cross section of possible temperature and pressure ranges available.

The probability of meeting the objectives listed above are very high. The Ben Holt Company has been involved in the geothermal industry for over 30 years, and the individuals involved have the experience and education that are needed and required for this study.

The staff of the Ben Holt Company are qualified and positioned to provide this service. Part of the competitive process accomplished by EPRI was to verify that the applicants personnel were qualified to preform this task. DOE has also verified that the individuals involved in this study have the appropriate education and experience.

The Ben Holt Company's base of operations is an office in Pasadena, California, and is fully capable of meeting their needs.

The budget proposed for the anticipated work was reviewed and is considered to be appropriate and adequate.

The public benefit to be derived from the proposed study will be an evaluation that shows utilities, independent power producers and developers how to optimize the geothermal resources that are available to them. This study will also show the economics and the environmental benefits of using geothermal energy.

The evaluation accomplished through the proposed cooperative agreement support the geothermal energy conversion program's direction and objectives. EPRI has competitively chosen the Ben Holt Company to perform this evaluation. Therefore, issuing a solicitation for a competitive bid to accomplish a study of the Next Generation Geothermal Power Plant would be inappropriate and would have a significant adverse impact on the accomplishment and completion of the desired report.

John W. Meeker,

Chief, Procurement, Golden Field Office.

[FR Doc. 94–14827 Filed 6–16–94; 8:45 am]

BILLING CODE 6450–01–M

Golden Field Office; Financial Assistance Award to International Geothermal Association Secretariat

AGENCY: Department of Energy.

ACTION: Notice of Financial Assistance Award in Response to a Non-Competitive Financial Assistance Application.

SUMMARY: The U.S. Department of Energy (DOE) pursuant to the DOE Financial Assistance Rules, 10 CFR 600.7(b)(2) is announcing its intention make a financial assistance award to the International Geothermal Association to encourage research, development and utilization of geothermal resources worldwide through the compilation, publication and dissemination of scientific and technical data and information.

ADDRESSES: Questions regarding this announcement may be addressed to the U.S. Department of Energy, Golden Field Office, 1617 Cole Blvd., Golden CO 80401, Attention: Ruth E Adams, Contract Specialist or at (303) 275–4722. The Contracting Officer for this action in John W. Meeker.

SUPPLEMENTARY INFORMATION: This proposal was a solicited application. The International Geothermal Association (IGA) Secretariat is the U.S. office, located in Berkeley, California, of the International Geothermal Association which is the parent organization with its headquarters in New Zealand. The objective of the IGA is to assist the Berkeley office in its outreach activities, encourage research, development and utilization of geothermal resources worldwide through the compilation publication and dissemination of scientific and technical data and information, both within the community of geothermal specialists and between geothermal specialists and the general public. The IGA Secretariat has been supported in the past by the Department of Energy through a contract with Sandia National Laboratory; however, the Department believes that the proposed effort will provide a benefit to the public and therefore a grant mechanism is a more appropriate funding method. Competition for this effort would have an adverse effect on continuity and completion of activities.

The proposed project will contribute to the DOE mission of "* * * providing the scientific and educational foundation and technology * * * necessary to achieve efficiency in energy use, diversity in energy sources, and access to technical information * * *". The International Geothermal Association (IGA) will do this by supporting the U.S. geothermal industry through various activities and will work to create data bases and a business environment in which the U.S. geothermal industry can thrive, globally.

The objectives of the IGA Secretariat, located in Berkeley, California, are to provide assistance in preparing and distributing the IGA newsletter (produced and published in the United States), developing educational programs appropriate for the IGA membership, stimulating international interest in geothermal energy, identifying potential international development opportunities, and continuing involvement in the Organizing Committee of the World Geothermal Conference 1995. The Secretariat also provides coordination of all activities, correspondence and meetings for the IGA, maintains the master list of the IGA membership as well as their potential members and works to enhance the benefits of IGA membership.

The probability of meeting the objectives listed above are very high, given that the IGA has been successful in the past for similar endeavors.

The staff of the International Geothermal Association Secretariat are qualified and positioned to provide this service. George Frye has been the Executive Director of the IGA Secretariat since February 1993, Mr. Frye has 20 years experience within the oil/gas/geothermal industry and is a registered professional engineer.

The IGA Secretariat's base of operations is in the Lawrence Berkeley Laboratory in Berkeley, California, and is fully capable of meeting their needs.

The budget proposed for the anticipated work has been reviewed and

is considered to be appropriate and adequate.

The public benefit to be derived through this grant with the IGA Secretariat is the increased awareness of international opportunities for the U.S. geothermal industry. Many countries throughout the world have the resources for geothermal energy. The U.S. geothermal industry is a world leader and is poised to exploit these resources. The IGA provides an invaluable global link where contacts are found and made, thereby facilitating the world-wide utilization of geothermal energy.

The Services provided through the proposed grant fully supports the program's direction and objectives. The International Geothermal Association Secretariat is qualified and positioned to perform the above mentioned tasks. The IGA is an accepted and respected industry association and has approximately 1,970 members largely from the geothermal service industries. The IGA has established an information network which is continually growing. Competition for this effort would have a significant adverse impact on the continuation of the proposed activities.

John W. Meeker,

Chief, Procurement, Golden Field Office.

[FR Doc. 94–14835 Filed 6–16–94; 8:45 am]

BILLING CODE 6450–01–M

Golden Field Office; Federal Assistance Award to Southern California Edison Company

AGENCY: Department of Energy.

ACTION: Notice of Financial Assistance Award in Response to an Unsolicited Financial Assistance Application.

SUMMARY: The U.S. Department of Energy (DOE), pursuant to the DOE Financial Assistance Rules, 10 CFR 600.7, is announcing its intention to enter into a cooperative agreement with Southern California Edison (SCE) Company for an on-grid photovoltaics (PV) implementation program.

ADDRESSES: Questions regarding this announcement may be addressed to the U.S. Department of Energy, Golden Field Office, 1617 Cole Blvd., Golden, Colorado 80401, Attention: J.W. Meeker, Contract Specialist. The telephone number is 303–275–4748. Dr. Paul K. Kearns is the Contracting Officer.

SUPPLEMENTARY INFORMATION: DOE has evaluated, in accordance with § 600.14 of the Federal Assistance Regulations, the unsolicited proposal entitled "PV Implementation Program" and recommends that the unsolicited proposal be accepted for support without further competition in accordance with § 600.14 of the Federal Assistance Regulations.

DOE is actively pursuing a program towards solar energy conversion, with one major objective being the cost-effective application of photovoltaics (PV) in utility applications. This SCE activity directly relates to the program objective and could be a significant step toward the implementation of PV in utility applications. The proposal from SCE is a unique opportunity to install PV in a utility application which is likely to be one of the closest to being cost effective in the near term. In addition, SCE is active in the promotion of renewable energy sources and is an ideal utility candidate to pursue the proposed PV application.

The proposed application involves using PV to meet peak load requirements on selected SCE electric distribution circuits. The circuits of interest are old, underground 4 kV circuits which have reached the limit of their load-carrying capability. The circuits serve residential areas which have seen recent growth in peak load requirements so that the circuits will soon exceed their limit during the summer peak load period. Without PV, the main alternative is to replace the circuits by excavating city streets and landscaping to install new underground, high-capacity cable. Installing PV to meet the peak load requirements on these circuits results in the deferment of this significant cable replacement expense. SCE estimated that replacement of about 200 miles of underground 4 kV circuits in their system could be deferred by the use of grid-connected PV. This would require approximately 25 MW of PV to meet the peak loads on these circuits.

The successful implementation of this project would provide:

1. The installation of on-grid PV systems in high-value, distributed-generation locations.
2. Major sustained PV procurements over several years, resulting in a stimulus to suppliers.
3. PV price reductions which are expected to occur from large, sequential installations.
4. Consistent, professionally-designed PV installations which will serve as demonstrations for other utilities and industries.
5. A cleaner environment in the SCE service area.

The proposed on-grid PV installations are well-suited to the SCE service area. Several candidate 4 kV circuits have been identified for the displacement of peak loads by grid-connected PV, with a sufficiently large number of potential additional circuits to allow the project to develop into a major PV demonstration if warranted. Preliminary surveys conducted by SCE indicate that sufficient space will be available in the residential areas to allow PV installations.

SCE has significant previous experience in PV systems, and has the necessary facilities to perform design and monitoring functions. SCE has been involved with PV since 1978, and has been one of the most active utilities in the field of renewable energy. By assigning a Manager of PV Applications, SCE has increased its commitment to PV development and implementation.

SCE has proposed a two-phase program, including a project feasibility assessment and project implementation. The feasibility assessment will identify all technical, regulatory, budget/schedule, and environmental issues related to the program in combination with the installation and monitoring of several small, pilot PV systems. The results of this initial project phase will be used by SCE and DOE to determine the merits of proceeding to the second phase. Phase II will include PV system final design, installation, and performance monitoring, and will proceed only after completion of Phase I and after approval from DOE.

The team proposed by SCE has sufficient experience in the development and deployment of PV systems, and should be capable of successfully implementing the proposed on-grid PV program. As noted above, SCE has appointed a Manager of PV Applications to strengthen the emphasis on PV implementation.

The proposed multi-disciplinary team includes personnel with experience in project management, cost/schedule development and control, project engineering, PV applications, system planning, environmental affairs, and customer service. As a major electric utility which has successfully completed complex energy generation projects, SCE has the expertise required to perform all functions associated with PV implementation and monitoring in the proposed application.

In addition, a Project Review Committee (PRC) will be established during the initial project phase to assist in technical, analysis, data collection, and information dissemination issues. The PRC will have members from SCE, DOE, UPVG, and national laboratories.

The proposal has been found to be meritorious as stated above in the evaluation. The SCE program represents a unique approach to utility applications of PV which has potential for near-term cost effectiveness. SCE has the capabilities and commitment to

renewable energy sources which should provide a basis for successful PV implementation in the proposed application. The proposed project is not eligible for financial assistance under a recent, current, or planned solicitation.

The program cost is estimated to be $5,000,000 total, with the DOE share being $2,500,000 and the SCE share being $2,500,000.

John W. Meeker,

Chief, Procurement, GO.

[FR Doc. 94–14833 Filed 6–16–94; 8:45 am]

BILLING CODE 6450–01–M

Golden Field Office; Federal Assistance Award to Utility Photo Voltaic Group

AGENCY: Department of Energy.

ACTION: Notice of Financial Assistance Award in Response to a Financial Assistance Application.

SUMMARY: The U.S. Department of Energy (DOE), pursuant to the DOE Financial Assistance Rules, 10 CFR 600.7, is announcing its intention to renew a Cooperative Agreement with the Utility PhotoVoltaic Group (UPVG) for a multi-task photovoltaics (PV) program intended to continue outreach efforts to electric utilities and to begin a multi-year PV hardware initiative.

ADDRESSES: Questions regarding this announcement may be addressed to the U.S. Department of Energy, Golden Field Office, 1617 Cole Blvd., Golden, Colorado 80401, Attention: J.W. Meeker, Contract Specialist. The telephone number is 303–275–4748. Dr. Paul K. Kearns is the Contracting Officer.

SUPPLEMENTARY INFORMATION: DOE has evaluated, in accordance with § 600.7 of the Federal Assistance Regulations, the proposal entitled "Phase 2 Plan for the Utility PhotoVoltaic Group" submitted by UPVG. DOE recommends that the proposal for work continuation be accepted for support without further competition in accordance with § 600.7 of 10 CFR part 600.

The project extension will be performed in ten tasks, with emphasis toward outreach to educate utility and other audiences and toward building a foundation for accelerated utility PV purchase commitments. The overall UPVG objective is the establishment of an accelerated market for PV systems that allows reduced PV costs through economy of scale. The program is intended to develop and disseminate PV information for utilities, prompt utility purchases, and develop a foundation for a multi-year PV hardware initiative.

The programmatic evaluation [see 10 CFR 600.7(b)(2)(ii)(D)] completed for this proposal resulted in a recommendation to fund this grant application for the following reasons:

A. Overall Merit and Relevance to the DOE Mission

DOe is actively pursuing a program towards solar energy conversion, with a major program objective being the cost-effective use of photovoltaics (PV) in utility applications. The UPVG activities directly support the DOE objectives by involving a large group of member electric utilities in the near-term implementation of large-scale PV systems. The UPVG represents an ideal and totally unique mechanism to encourage the use of PV through DOE financial support of the large, unified group of interested utilities.

B. Anticipated Objectives and Probability of Success in Meeting Them

The proposed activities continue a multi-year program at UPVG intended to result in the achievement of PV acceptance and use by electric utilities. The program involves several different tasks, with an overall objective being the installation of 50 MW of new utility PV generation capacity within 5 years.

The current UPVG program includes ten overall tasks, each with multiple subtasks. The ten tasks include:

1. Technology Transfer and Member Development.
2. Commercialization Strategies.
3. Applications and Markets.
4. Planning and Evaluation.
5. Engineering and Demonstrations.
6. External Outreach and Coordination.
7. TEAM-UP Organization Development.
8. Initiate Small-Scale Applications.
9. Initiate Large-Scale Applications.
10. Management and Administration.

Each of these tasks is a required element of the overall program to develop a utility market for PV.

The successful implementation of this project would result in:

1. Continued UPVG member utility involvement with PV technology.
2. Recruitment of additional utility members in UPVG.
3. PV information dissemination to utilities and other groups.
4. Refined market analysis and PV evaluation tools, such as a cost estimating guide and PV-SCREEN, for analysis of grid-connected PV systems.
5. Initiation of PV utility applications via large- and small-scale demonstrations.

From the previous project phase, UPVG has developed a working relationship with its member utilities and has the expertise to recruit additional utility members. Most of the other tasks in this phase are also extensions of work previously begun by UPVG, such as information dissemination and PV market analysis. The techniques required for successful completion of the proposed tasks are available at UPVG and have already been demonstrated in the previous activities. Thus, the probability of success is high.

C. Quality of the Applicant's Personnel and Facilities

The proposed efforts by UPVG do not require unique facilities or equipment.

The team proposed by UPVG has significant experience in the development and deployment of PV systems, and should be capable of successfully implementing the proposed PV program. The team includes senior personnel from several different organizations, including private consultants with experience in utility projects, the Electric Power Research Institute, and several electric utilities. The UPVG Executive Director has significant experience in technology transfer and the management of associations since, in addition to UPVG, he also provides management and staff support to the Fuel Cell Commercialization Group, the National Hydrogen Association, and the Utility Biomass Energy Technology Association.

In addition, a UPVG Board of Directors was previously established to assist in management, financial, technical, and other issues. The Board is composed of personnel from member utilities.

D. Appropriateness and Adequacy of the Proposed Budget

The budget proposed for the anticipated work was reviewed and is considered to be appropriate and adequate. A total of $1,209,000 will be required for the program, with $1,000,000 provided by DOE for the period of February 15, 1994 to March 31, 1995. Cost sharing will be provided by UPVG in the amount of $209,000.

The UPVG program represents a unique approach to achieving utility involvement with PV. The program has potential to result in near-term utility applications of PV technology and is consistent with DOE objectives. The proposed project is not eligible for financial assistance under a recent, current, or planned solicitation.

Competition for the effort would have a significant adverse impact on the continuity and completion of the proposed activity. The UPVG is the only organization whose sole purpose is the advancement and development of cost-effective utility applications of PV. UPVG has established relationships with all the utility participants and has

developed an understanding of the technical and management issues required for successful and timely accomplishment of program objectives. Therefore, recompetition would cause a time delay of numerous months in task completion and would require a significant duplication of costs to enable a new awardee to perform the proposed tasks.

John W. Meeker,

Chief, Procurement, GO.

[FR Doc. 94–14834 Filed 6–16–94; 8:45 am]

BILLING CODE 6450–01–M

Federal Energy Regulatory Commission

[Docket No. ER94–1019–000, et al.]

Arkansas Power & Light Co., et al. Electric Rate and Corporate Regulation Filings

June 10, 1994.

Take notice that the following filings have been made with the Commission.

1. Arkansas Power & Light Co.

[Docket No. ER94–1019–000]

Take notice that on June 1, 1994, Entergy Services, Inc. (Entergy Services), on behalf of Arkansas Power & Light Company (AP&L), tendered for filing amendments to the rates submitted on March 7, 1994 in accordance with the Power Coordination, Interchange and Transmission Service Agreements between AP&L and Conway, West Memphis; and Osceola, Arkansas (Arkansas Cities); Campbell and Thayer, Missouri (Missouri Cities); City Water & Light Plant of Jonesboro, Arkansas; and Arkansas Electric Cooperative Corporation (AECC); the Transmission Service Agreements between AP&L and the Louisiana Energy & Power Authority (LEPA) and the City of Hope, Arkansas; the Hydroelectric Power Transmission Distribution Service Agreement between AP&L and the City of North Little Rock, Arkansas; the Interchange Agreement between AP&L and Oglethorpe Power Corporation; and the Settlement Agreement in Docket No. ER92–341–000 between AP&L, Arkansas Cities, Missouri Cities, AECC, and LEPA. Entergy Services explains that the rate amendments are made to reflect corrections to certain underlying cost data.

Comment date: June 24, 1994, in accordance with Standard Paragraph E at the end of this notice.

2. San Diego Gas & Electric Co.

[Docket No. ER94–1333–000]

Take notice that on May 2, 1994, San Diego Gas & Electric Company tendered for filing a letter requesting that FERC No. 79 Supplement No. 1 be reinstated because it was inadvertently cancelled under Docket Nos. ER94–1031–000 and ER94–1032–000 filed on March 14, 1994.

Comment date: June 24, 1994, in accordance with Standard Paragraph E at the end of this notice.

3. Interstate Power Co.

[Docket No. ER94–1143–000]

Take notice that on June 7, 1994, Interstate Power Company tendered for filing additional information to its April 4, 1994 filing in the above-referenced docket.

Comment date: June 24, 1994, in accordance with Standard Paragraph E at the end of this notice.

Standard Paragraphs

E. Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 18 CFR 385.214). All such motions or protests should be filed on or before the comment date. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 94–14840 Filed 6–16–94; 8:45 am]

BILLING CODE 6717–01–P

[Projects No. 2325, 2389, 2552, 2555, 2556, 2557, 2559, 2329, 2671, and 2613; 11433]

Central Maine Power Co., et al; Edwards Manufacturing, Inc., and Town of Madison, Maine; Notice of Intent To Prepare An Environmental Impact Statement and Conduct Public Scoping Meetings

June 13, 1994.

The Federal Energy Regulatory Commission (FERC) has received an application for license of hydroelectric projects within the Kennebec River Basin in the State of Maine. The hydropower projects are located north of the City of Augusta along the Kennebec River. The projects are: Weston No. 2325, Ft. Halifax No. 2552, Automatic No. 2555, Union Gas No. 2556, Rick Rips No. 2557, Oakland No. 2559, Wyman No. 2329, Moosehead No. 2671, Moxie No. 2613, Edwards No. 2389 and Sandy River No. 11433.

The FERC staff has determined that licensing these projects would constitute a major federal action significantly affecting the quality of the human environment. Therefore, the staff intends to prepare an Environmental Impact Statement (EIS) on the hydroelectric projects in accordance with the National Environmental Policy Act.

The staff's EIS will objectively consider both site specific and cumulative environmental impacts of the projects and reasonable alternatives, and will include an economic, financial and engineering analysis.

A draft EIS will be issued and circulated for review by all the interested parties. All comments filed on the draft EIS will be analyzed by the staff and considered in a final EIS. The staff's conclusions and recommendations will then be presented for the consideration of the Commission in reaching its final licensing decision.

Scoping Meetings

The FERC staff will conduct two scoping meetings. An evening scoping meeting is primarily for public input while a morning meeting will focus on resource agency concerns. All interested individuals, organizations, and agencies are invited to attend and assist the staff in identifying the scope of environmental issues that should be analyzed in the EIS.

The first scoping meeting will be held on Wednesday, July 13, 1994, from 7:30 p.m. until 10:30 p.m. in the Cushnoc Auditorium, Augusta Civic Center, Augusta, Maine. Issues of primary concern to to general public will be the focus of the meeting. The second scoping meeting will be held on Thursday, July 14, 1994, from 8:30 a.m. until 12:30 p.m. at the Augusta Civic Center Drive, in the Washington and York rooms.

The Augusta Civic Center can be reached from the Maine Turnpike by taking Exit 31-South onto Civic Center Drive; proceed one-half mile to the Civic Center entrance.

Prior to the meetings, Scoping Document 1 Revised (SD 1–R) will be mailed to the list of interested parties. SD 1–R identifies resources issues to be address in the EIS. Copies of SD 1–R

will also be available at the scoping meetings or can be obtained by writing: FERC-Kennebec Projects, c/o Doug Hjorth, Stone Webster, 245 Summer Street, Boston, MA 02210.

Objectives

At the scoping meetings the staff will: (1) Summarize the environmental issues tentatively identified for analysis in the planned EIS; (2) determine the relative depth of analysis for issues to be addressed in the EIS; (3) identify resource issues that are not important and do not require detailed analysis; (4) solicit from the meeting participants all available information, especially quantified data, on the resources at issue; and (5) encourage statements from experts and the public on issues that should be analyzed in the EIS, including points of view in opposition to, or in support of, the staff's preliminary views.

Procedures

The meetings will be recorded by a stenographer and all statements (oral and written) thereby become a part of the formal record of the Commission proceedings. Individuals presenting statements at the meetings will be asked to clearly identify themselves for the record.

Individuals, organizations, and agencies with environmental expertise and concerns are encouraged to attend the meetings and to assist the staff in defining and clarifying the issues to be addressed in the EIS.

Participants at the public meetings are asked to keep oral comments brief and concise.

Persons choosing not to speak at the meetings, but who have views on the issues or information relevant to the issues, may submit written statements for inclusion in the public record. In addition, written scoping comments may be filed with the Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE, Washington, DC 20426, until August 15, 1994.

All written correspondence should clearly show the following caption on the first page: Kennebec River Basin EIS.

All those that are formally recognized by the Commission as intervenors in the licensing proceeding are asked to refrain from engaging staff or its contractor in discussions of the merits of the projects outside of any announced meetings.

Further, parties are reminded of the Commission's Rules of Practice and Procedure, requiring parties filing documents with the Commission, to serve a copy of the document on each person whose name is on the official service list.

For further information, please contact John Blair (202) 219–2845.

Lois D. Cashell,

Secretary.

[FR Doc. 94–14749 Filed 6–16–94; 8:45 am]

BILLING CODE 6717–01–M

Federal Agency Regulatory Commission

Montana Power Company and Confederated Salish and Kootenai Tribes; Notice Of Intent To Prepare An Environmental Impact Statement And To Conduct a Scoping Meeting

June 13, 1994.

In accordance with the National Environmental Policy Act of 1969 and the Federal Agency Regulatory Commission's regulations, 18 CFR part 380 (Order No. 486, 52 FR 47910), the Office of Hydropower Licensing has reviewed the licensee's post-licensing filing that proposes modifications to project facilities and operation. Staff's initial evaluation of the proposed modifications was issued on May 31, 1994, in a draft environmental assessment (DEA). The transmittal letter for the DEA stated our intent to prepare an environmental impact statement (EIS).

A draft EIS will be issued and circulated for review by all interested parties. All comments filed on the draft EIS will be analyzed by staff and considered in the final EIS. Staff's conclusions and recommendations will then be presented for the consideration of the Commission in reaching its final decision.

Scoping Meeting

A scoping meeting will be held on Wednesday, July 13, 1994, at Cavanaugh's, 20 North Main Street, Kalispell, Montana. The meeting will begin at 2 p.m., adjourn at 5:30 p.m., reconvene at 7:00 p.m., and continue to midnight. All interested individuals, organizations, and agencies are invited to attend and assist staff in identifying the scope of environmental issues that should be analyzed in the EIS.

The DEA will be considered the initial scoping document. Copies of the DEA have been mailed to all entities who have expressed interest in this proceeding. The DEA is also available in the Commission's Reference and Information Center, room 3308, of the Commission's offices at 941 North Capitol Street, NE., Washington, DC 20426 and will be available at the scoping meeting. We encourage all interested parties to read the DEA prior to the scoping meeting.

Objectives

At the meeting staff will: (1) Describe the range of issues being considered in this post-licensing proceeding; (2) review the conclusions and recommendations in the DEA; (3) receive input from meeting participants on the alternatives considered in the DEA; (4) identify any additional issues that should be included in the EIS; and (5) obtain any additional information that any entity feels should be considered during the preparation of the EIS.

Procedures

The scoping meeting will be recorded by a stenographer and all statements (oral and written) will become part of the Commission's public record for this proceeding that was noticed on September 21, 1990. Interested persons who are unable to attend, or do not choose to speak at the scoping meeting, may submit written statements for inclusion in the public record. All written comments must be filed with the Secretary, Federal Energy Regulatory Commission, 825 North Capital Street NE., Washington, DC 20426, on or before August 15, 1994.

All written correspondence should clearly show on the first page of each document the following caption: Kerr Project, FERC Project No. 5-021.

Further, please note the Commission's Ruled of Practice and Procedure, requiring all entities to file an original and eight copies of any filing with the Commission and parties filing documents, must also serve the documents on each person whose name is on the official service list.

For further information, place contact John A. Schnagl at (202) 219–2661.

Lois D. Cashell,

Secretary.

[FR Doc. 94–14750 Filed 6–16–94; 8:45 am]

BILLING CODE 6717–01–M

[Project Nos. 2232–300, et al.]

Hydroelectric Applications [Duke Power Company, et al.]; Applications

Take notice that the following hydroelectric applications have been filed with the Commission and are available for public inspection:

1 a. *Type of Application:* Non-project Use of Project Lands and Dredging in Project Waters.

b. *Project No.:* 2232–300.

c. *Date filed:* March 17, 1994.

d. *Applicant:* Duke Power Company.

e. *Name of Project:* Catawba-Wateree (Cowan's Ford Development).

f. *Location:* The proposed project would be located at Brown's Cove on Lake Norman, Mecklenburg County, North Carolina.

g. *Filed pursuant to:* Federal Power Act, 16 U.S.C. § 791(a)–825(r).

h. *Applicant contact:* Karol P. Mack, Senior Attorney, Duke Power Company, 422 South Church Street, Charlotte, NC 28202, (704) 382–8104.

i. *FERC contact:* John K. Hannula, (202) 219–0116.

j. *Comment date:* July 15, 1994.

k. *Description of Application:* The applicant proposes to permit the construction and operation of a water intake facility on Lake Norman to provide 108 million gallons per day to the Charlotte-Mecklenburg Utility Department. Approximately 30,000 cubic yards of lake bed would be excavated during construction.

l. This notice also consists of the following standard paragraphs: B. C1. and D2.

2 a. *Type of Application:* Major License.

b. *Project No.:* 11478–000.

c. *Date filed:* May 9, 1994.

d. *Applicant:* Central Vermont Public Service Corp.

e. *Name of Project:* Silver Lake Project.

f. *Location:* on Sucker Brook in Addison County, Vermont.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Mr. Robert de R. Stein, Central Vermont Public Service Corporation, 77 Grove Street, Rutland, VT 05701, (802) 747–5552.

i. *FERC Contact:* Michael Dees (202) 219–2807.

j. *Comment Date:* 60 days from the filing date in paragraph c.

k. *Description of Project:* The project consists of the following features: (1) an existing diversion dam, headpond and storage reservoir; (2) an existing powerhouse housing a hydropower unit with a capacity of 2,200 kW, and (3) appurtenant facilities.

l. With this notice, we are initiating consultation with the Vermont STATE HISTORIC PRESERVATION OFFICER (SHPO), as required by Section 106, National Historic Preservation Act, and the regulations of the Advisory Council on Historic Preservation, 36 CFR 800.4.

m. Pursuant to § 4.32(b)(7) of 18 CFR of the Commission's regulations, if any resource agency, Indian Tribe, or person believes that an additional scientific study should be conducted in order to form an adequate factual basis for a complete analysis of the application on its merit, the resource agency, Indian Tribe, or person must file a request for a study with the Commission not later than 60 days from the filing date and serve a copy of the request on the applicant.

3 a. *Type of Application:* Preliminary Permit.

b. *Project No.:* P–11479–000.

c. *Date filed:* May 10, 1994.

d. *Applicant:* Trenton Falls Hydroelectric Company.

e. *Name of Project:* Hawkinsville Project.

f. *Location:* On the Black River, Oneida County, New York.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–625(r).

h. *Applicant Contact:* Mr. Steven C. Samel, Trenton Falls Hydroelectric Company, P. O. Box 169, Prospect, NY 13435, (315) 896–6351.

i. *FERC Contact:* Robert Bell (dt) (202) 219–2806.

j. *Comment Date:* August 3, 1994.

k. *Description of Project:* The proposed project would consist of: (1) the existing 360-foot-long, 14-foot-high Hawkinsville Dam, a concrete gravity structure; (2) new 2-foot-high flashboards; (3) an existing impoundment having a surface area of 30-acres, with a storage capacity of 130 acre-feet, and a normal water surface elevation of 1,052 feet msl; (4) the existing intake structure; (5) a new powerhouse containing 3 generating units with a total installed capacity of 725-kW; (6) a new tailrace; (7) a new 13.2-kV transmission line; and (8) appurtenant facilities.

The existing Hawkinsville Dam is owned by the Hudson River Black River Regulatory District of the State of New York. The estimated annual generation would be 2,400,000-kWh.

l. *Purpose of Project:* All project energy produced would be sold to a local utility.

m. This notice also consists of the following standard paragraphs: A5, A7, A9, A10, B, C, and D2.

n. *Available Location of Application:* A copy of the application, as amended and supplemented, is available for inspection and reproduction at the Commission's Public Reference and Files Maintenance Branch, located at 941 North Capitol Street, NE., room 3104, Washington, DC, 20426, or by calling (202) 208–1371. A copy is also available for inspection and reproduction at Trenton Falls Hydroelectric Company, P. O. Box 169, Prospect, NY 13435, (315) 896–6351.

4 a. Action and Type of Application: Potential Applicant Issues Draft Application Intended for an Original License To Be Processed in Association with the Third Party Contract Provisions of Section 2403 of the National Energy Policy Act of 1992.

b. *Preliminary Permit No.:* P–11181–000.

c. *Preliminary Permit Filed:* December 31, 1991.

d. *Potential Applicant:* Energy Storage Partners.

e. *Name of Project:* Lorella Pumped Storage Project.

f. *Location:* Near the Lost River and the town of Lorella in Klamath County, Oregon

g. *Issued by Potential Applicant in Anticipation of a Filing Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Potential Applicant Contact:* Doug Spaulding, Vice President, Independent Hydro Developers, Inc., 5402 Parkdale Drive, Minneapolis, MN 55416.

i. *FERC Contact:* Sabina Joe (202) 219–1648.

j. *Deadline Date:* 90 and 135 days from June 2, 1994.

Filing and Service of Responsive Documents—

(1) The draft application is being issued by the potential applicant at this time and the Commission's Draft Environmental Impact Statement (EIS) is being developed under third party contract arrangements as provided by Section 2403 of the National Energy Policy Act of 1992. At this time, the Commission is requesting preliminary comments, reply comments, recommendations, terms and conditions, and prescriptions.

The Commission directs, pursuant to section 4.34(b) of the regulations (see Order No. 533 issued May 8, 1991, 56 FR 23108 (May 20, 1991)), that all preliminary comments, recommendations, terms and conditions be filed with the Commission within 90 days from the issuance date of this notice and the date of issuance of the draft application, whichever is later. All reply comments must be filed with the Commission within 135 days from the date of this notice and the date of issuance of the draft application, whichever is later.

Anyone may obtain an extension of time for these deadlines from the Commission only upon a showing of good cause or extraordinary circumstances in accordance with 18 CFR 385.2008.

All filings must: (1) Bear in all capital letters the title "COMMENTS", "REPLY COMMENTS", "RECOMMENDATIONS", "TERMS AND CONDITIONS", or "PRESCRIPTIONS"; (2) set forth in the heading the name of the potential applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person

submitting the filing; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, recommendations, terms and conditions or prescriptions must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b), except as amended by this notice with respect to deadline, mailing list, and the requirement to file all comments upon issuance of this notice rather than upon notice of an application being ready for environmental analysis. Any of these documents must be filed by providing the original and eight copies to: Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426. An additional copy must be sent to: Director, Division of Project Review, Office of Hydropower Licensing, Federal Energy Regulatory Commission, Room 1027, at the above address. Each filing must be accompanied by proof of service on all persons listed in the service list prepared by the Commission, in accordance with 18 CFR 4.34(b) and the procedures set forth in this notice. The procedures for service of all comments (including preliminary recommendations, terms and conditions, and prescriptions) filed with the Commission for the Lorella Project shall be: (1) All comments (and any attachments) must be served on the Commission's service list which includes all entities receiving a draft application and final application; (2) a letter notification that comments have been filed with the Commission must be served on the general mailing list (exclusive of service list entities) prepared for this project by the Commission; (3) for convenience, the Commission will make available on request to any entity filing comments a computer diskette of these mailing lists. Commenters may obtain computerized copies of these mailing lists from Sabina Joe at (202) 219–1648.

(2) Pursuant to § 4.32(b)(7) of 18 CFR of the Commission's regulations, if any resource agency, Indian Tribe, or person believes that an additional scientific study should be conducted in order to form an adequate factual basis for a complete analysis of the application on its merit, the resource agency, Indian Tribe, or person must formally file a request for a study with the Commission not later than 90 days from the issuance date of this notice and issuance date of the draft application, whichever is later, and serve a copy of the request on the potential applicant. (See j(1) above for filing and service). Except for the filing deadline set forth in this notice, Section 4.32(b)(7) shall apply. This shall be the last opportunity in the Lorella licensing process to request additional scientific studies. This substitutes for the request for additional scientific studies made at the time of tendering for filing of an application under the Commission's traditional licensing process.

k. Status of Environmental Analysis: Under third party contract provisions of the National Energy Policy Act of 1992, the Commission is supervising the selected third party contractor's ongoing preparation of a Draft Environmental Impact Statement (DEIS) for the Lorella Project. The Commission plans to issue a DEIS at the same time as (or shortly after) the potential applicant files a final application with the Commission. Preliminary comments, terms, conditions, and prescriptions, and additional scientific study requests solicited with this notice are critical to the development of the DEIS. Final comments, recommendations, terms, conditions, and prescriptions will be solicited at the time of filing of the final application and issuance of the DEIS.

l. With this notice, we are initiating consultation with the Oregon STATE HISTORIC PRESERVATION OFFICER (SHPO), as required by Section 106, National Historic Preservation Act, and the regulations of the Advisory Council on Historic Preservation, 36 CFR 800.4.

m. *Description of Project:* The proposed project would consist of the following:

(1) An upper reservoir with a surface area of 199 acres created by two compacted rock fill dams and an asphaltic concrete or geomembrane liner. The northern dam would be 178 feet high and have a crest length of 1,910 feet; the southern dam would be 100 feet high and have a crest length of 2,520 feet. The gross volume of the upper reservoir would be 15,990 acre-feet. The water surface would fluctuate 123 vertical feet on a weekly cycle. (2) A lower reservoir with a surface area of 405 acres created by an earth zoned embankment having an average height of 49 feet, a maximum height of 57 feet, and a length of 9,690 feet. The volume of the lower reservoir would be 18,646 acre-feet, and the water surface would fluctuate 44 vertical feet. (3) A 4-mile long single circuit 500-Kv overhead transmission line would lie within a 180 foot wide corridor from the substation to the existing Captain Jack substation on the California-Oregon transmission line. (4) Overground water supply lines 20 inches and 8 inches in diameter and 13,900 feet long and 2,900 feet long, respectively; (5) A 50-gallons-per-minute (gpm) water treatment facility. (6) Service roads. (7) Underground features including a powerhouse with 4 pump-turbines with a nominal rated capacity of 250 megawatts (MW) each, a 3,200 foot long 24-foot diameter concrete-lined power tunnel and 1,326 foot long, 24-foot diameter concrete lined power shaft.

n. *Purpose of Project:* Project power would be utilized by the applicant for sale to its customers.

o. No competing applications or notices of intent may be filed in response to this notice. Under the Commission's regulations, any competing development application must be filed in response to and in compliance with the public notice of the initial development application, which has not yet been filed.

p. *Available Location of Draft Application:* A copy of the draft application is available for inspection and reproduction at Independent Hydro Developers, Inc., 5402 Parkdale Drive, Suite 104, Minneapolis, MN 55416 or by calling (612) 525–1445. Copies are also available for inspection and reproduction at: Klamath County Library, 126 South Third, Klamath Falls, OR 97601 or by calling (503) 882–8894; Bonanza Library, North, Bonanza, OR 97623 or by calling (503) 545–6944; and Multnomah County Library, Science and Business Section, 801 SW. Tenth Street, Portland, OR 97205 or by calling (503) 248–5234.

5 a. *Type of Application:* New Major License.

b. *Project No.:* 2315–002 .

c. *Date filed:* December 20, 1991.

d. *Applicant:* South Carolina Electric & Gas Company.

e. *Name of Project:* Neal Shoals Hydroelectric Project.

f. *Location:* Within Sumter National Forest, on the Broad River in Union and Chester Counties, South Carolina.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Mr. Randolph R. Mahan, South Carolina Electric & Gas Co., Columbia, SC 29218–0001, (803) 748–3538.

i. *FERC Contact:* Mr. Surender M. Yepuri, P.E., (202) 219–2847.

j. *Deadline Date:* Sixty days from the issuance date of this notice. (August 2, 1994).

k. *Status of Environmental Analysis:* The application has been accepted for filing and is ready for environmental analysis at this time—see attached standard paragraph D9.

Note: The Commission will be preparing a Multiple Environmental Assessment for three hydroelectric projects—Neal Shoals Project No. 2315, Ninety-Nine Islands Project No. 2331, and Gaston Shoals Project No. 2332—in accordance with the National

Environmental Policy Act. Project Nos. 2331 and 2332 are being noticed concurrently.

l. *Description of Project:* The project as proposed for licensing consists of: (1) a concrete/granite-block dam that is about 24.5 feet high (maximum) and 1,087 feet long; (2) a reservoir with a surface area of about 600 acres; (3) a powerhouse containing four turbine generator units with a total rated capacity of 4.42 MW; (4) a 13.2-kV transmission line that is about 13 miles long; and (5) other appurtenant structures. The average annual generation is 24.6 GWh.

m. *Purpose of Project:* Power generated from the project is used primarily to help meet peak load demands of customers.

n. *This notice also consists of the following standard paragraph:* D9.

o. *Available Locations of Application:* A copy of the application, as amended and supplemented, is available for inspection and reproduction at the Commission's Public Reference and Files Maintenance Branch, located at 941 North Capitol Street, N.E., Room 3104, Washington, D.C. 20426, or by calling (202) 208–1371. A copy is also available for inspection and reproduction at the applicant's office (see item (h) above).

6 a. *Type of Applications:* New Major License.

b. *Project Nos.:* 2331–002 & 2332–003.

c. *Date filed:* December 19, 1991.

d. *Applicant:* Duke Power Company.

e. *Names of Projects:* Ninety-Nine Islands and Gaston Shoals.

f. *Location:* (A) Ninety-Nine Islands: On the Broad River in Cherokee County, South Carolina.

(B) Gaston shoals: On the Broad River in Cherokee County, South Carolina, and Cleveland County, North Carolina.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Karol P. Mack Esq., Duke Power Company, 422 South Church Street, Charlotte, NC 28242–0001, (704) 382–8104.

i. *FERC Contact:* Mr. Surender M. Yepuri, P.E., (202) 219–2847.

j. *Deadline Date:* Sixty days from the issuance date of this notice. (August 2, 1994).

k. *Status of Environmental Analysis:* These applications have been accepted for filing and are ready for environmental analysis at this time—see attached standard paragraph D9.

Note: The Commission will be preparing a Multiple Environmental Assessment for three hydroelectric projects—Ninety-Nine Islands Project No. 2331, Gaston Shoals Project No. 2332, and Neal Shoals Project No. 2315—in accordance with the National Environmental Policy Act. Project No. 2315 is being noticed concurrently.

l. *Descriptions of Projects:* (A) Ninety-Nine Islands Project: The project as proposed for licensing consists of: (1) a concrete dam that is about 88 feet high (maximum) and 1,567 feet long; (2) a concrete intake structure that is about 94 feet high (maximum) and 197 feet long; (3) a reservoir at elevation 511 feet msl with a surface area of 433 acres; (4) a powerhouse containing six turbine generator units with a total rated capacity of 18 MW; (5) a tailrace that is about 300 feet long; and (6) other appurtenant structures. The average annual generation is 59.6 Gwh.

(B) Gaston Shoals Project: The project as proposed for licensing consists of: (1) a masonry rubble/concrete dam that is about 43 feet to 71 feet high and 1,560 feet long; (2) a concrete intake structure integral with the powerhouse; (3) a reservoir at elevation 605 feet msl with a surface area of 300 acres; (4) a powerhouse containing five turbine generator units with a total rated capacity of 9.14 MW; (5) a tailrace that is 0.7 mile long; and (6) other appurtenant structures. The average annual generation is 28.2 Gwh.

m. *Purpose of Projects:* Power generated from the projects is used primarily to help meet peak load demands of customers.

n. *This notice also consists of the following standard paragraph:* D9.

o. *Available Locations of Applications:* A copy of these applications, as amended and supplemented, is available for inspection and reproduction at the Commission's Public Reference and Files Maintenance Branch, located at 941 North Capitol Street, NE., Room 3104, Washington, DC 20426, or by calling (202) 208–1371. A copy is also available for inspection and reproduction at the applicant's office (see item (h) above).

7 a. *Type of Application:* Surrender of Exemption (5MW or Less).

b. *Project No.:* 5399–006.

c. *Date filed:* May 23, 1994.

d. *Applicant:* Gardiner Water District.

e. *Name of Project:* New Mills Dam Project.

f. *Location:* On Cobbosseecontee Stream, in Gardiner, Kennebec County, Maine.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. §§ 791(a)–825(r).

h. *Applicant contact:* Donald Tracy, Superintendent, Gardiner Water District, 246 Water Street, P.O. Box 536, Gardiner, ME 04345, (207) 582–5500.

i. *FERC contact:* Etta Foster, (202) 219–2679.

j. *Comment Date:* July 20, 1994.

k. *Description of Proposed Action:* The exemptee is requesting surrender of its exemption because the project is not economically feasible.

l. *This notice also consists of the following standard paragraphs:* B. C1. and D2.

8 a. *Type of Application:* Subsequent Minor License.

b. *Project No.:* P–2444–002.

c. *Date Filed:* December 20, 1991.

d. *Applicant:* Northern States Power Company.

e. *Name of Project:* White River Hydroelectric Project.

f. *Location:* On the White River, Montreal River Basin, in Ashland County, Wisconsin.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Anthony G. Schuster, Vice President, Power Supply, Northern States Power Company, 100 North Barstow Street, P.O. Box 8, Eau Claire, WI 54702–0008, Telephone (715) 839–2621.

i. *FERC Contact:* Sabina Joe (202) 219–1648.

j. *Deadline Date:* 60 days and 105 days from June 8, 1994.

Filing and Service of Responsive Documents—The application is being re-noticed as ready for environmental analysis due to the recent filing of additional information related to minimum flow studies. The Commission is requesting comments, reply comments, recommendations, terms and conditions, and prescriptions for the project only on those aspects of the license application which relate to the minimum flow additional information filed. Comments, reply comments, recommendations, terms and conditions, and prescriptions which have already been filed with the Commission in response to the Commission's July 13, 1993, notice of the application's readiness for environmental analysis, need not be re-filed.

The Commission directs, pursuant to section 4.34(b) of the regulations (see Order No. 533 issued May 8,1991, 56 FR 23108 (May 20, 1991), that all comments, recommendations, terms and conditions and prescriptions concerning the additional information be filed with the Commission within 60 days from the issuance date of this notice. All reply comments must be filed with the Commission within 105 days from the date of this notice.

Anyone may obtain an extension of time for these deadlines from the Commission only upon a showing of good cause or extraordinary circumstances in accordance with 18 CFR 385.2008.

All filings must: (1) Bear in all capital letters the title "COMMENTS," "REPLY

COMMENTS," "RECOMMENDATIONS," "TERMS AND CONDITIONS," or "PRESCRIPTIONS;" (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person submitting the filing; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, recommendations, terms and conditions or prescriptions must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). Any of these documents must be filed by providing the original and the number of copies required by the Commission's regulations to: Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426. An additional copy must be sent to: Director, Division of Project Review, Office of Hydropower Licensing, Federal Energy Regulatory Commission, Room 1027, at the above address. Each filing must be accompanied by proof of service on all persons listed in service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b) and 385.2010.

k. Status of Environmental Analysis: This application has been accepted for filing and is ready for environmental analysis at this time—see j above.

l. Description of the Project: The existing project consists of the following:

(1) Two existing earthen embankments, a 400 foot long northern section and a 300 foot long southern section, with a maximum height of 48 feet; (2) an existing reservoir with a surface area of 56 acres and an estimated 391 acre-feet of total storage volume at the normal maximum surface elevation of 711.2 mean sea level (MSL); (3) an existing reinforced concrete spillway section, 70 feet long, composed of (a) a gated spillway section with two 25 feet long by 26.5 foot tall bays, each housing a radial steel Taintor gate, and (b) a reinforced concrete non-overflow section, approximately 20 feet long, with an intake structure for the 7 foot diameter pipeline; (4) existing intake and outlet works consisting of (a) a 7 foot diameter reinforced concrete pipeline, 1,345 feet long, (b) a steel surge tank, 16 feet in diameter by 65 feet tall, and (c) a 54 inch steel y-shaped penstock; (5) an existing powerhouse, constructed of reinforced concrete and brick masonry, 39 feet by 69 feet and 1 story tall, containing (a) two horizontal Francis turbines with a combined hydraulic capacity of 280 cubic feet per second (cfs), manufactured by S. Morgan Smith, (b) two Westinghouse generators, rated at 500 kilowatts (KW) each for a total of 1,000 KW; and (6) appurtenant facilities.

m. Purpose of Project: Project power would be utilized by the applicant for sale to its customers.

n. Development Application—Public notice of the filing of the initial development application, which has already been given, established the due date for filing competing applications or notices of intent. Under the Commission's regulations, any competing development application must be filed in response to and in compliance with the public notice of the initial development application. No competing applications or notices of intent may be filed in response to this notice.

o. Available Location of Application: A copy of the application, as amended and supplemented is available for inspection and reproduction at the Commission's Public Reference and Files Maintenance Branch, located at 941 North Capitol Street, NE., Room 3104, Washington, DC 20426, or by calling (202) 208–1371. A copy is also available for inspection and reproduction at Northern States Power Company, 100 North Barstow Street, Eau Claire, WI 54702- 0008 or by calling (715) 839–2621.

p. Scoping Process: In gathering background information for preparation of the Environmental Assessment for the issuance of a Federal hydropower license, staff of the Federal Energy Regulatory Commission conducted a scoping process to identify significant environmental issues related to the continued operation of the hydropower project. A scoping document was issued January 13, 1994, and comments were invited. Anyone who wishes to provide staff with further scoping comments related to the minimum flow additional information, may do so by filing comments with the Commission. (See j above for filing procedure.) All scoping comments will be considered by staff in the preparation of the Environmental Assessment. Any further scoping comments should be filed by the deadline established in j above.

9 a. Type of Application: Major License.

b. Project No.: 10854–002.

c. Date Filed: September 1, 1993.

d. Applicant: Upper Peninsula Power Company.

e. Name of Project: Cataract Hydro Project.

f. Location: On the Middle Branch Escanaba River in Marquette County, near Gwinn, Michigan.

g. Filed Pursuant to: Federal Power Act 16 U.S.C. §§ 791 (a) 825(r).

h. Applicant Contact: Clarence R. Fisher, Upper Peninsula Power Company, P.O. Box 130, 600 Lakeshore Drive, Houghton, MI 49931–0130, (906) 487–5000.

i. FERC Contact: Ed Lee (202) 219–2809.

j. Deadline Date: August 9, 1994.

k. Status of Environmental Analysis: This application has been accepted for filing and is ready for environmental analysis at this time—see attached paragraph D9.

l. Description of Project: The project consists of the following: (1) A concrete diversion dam about 265 feet long and 8 feet high (maximum) having (a) a spillway/weir section about 185.3 feet long with 19 bays (18 bays about 10 feet wide and one bay 5.3 feet wide), three bays with crest elevation at 1,166.5 feet (USGS), and sixteen bays with crest elevation at 1,170.4 feet; (b) wooden flashboards 7.4 feet and 3.5 feet high with top of flashboards elevation at 1,173.9 feet; (2) an 860-acre-foot reservoir with normal maximum pool elevation at 1,173.9 feet; (3) an intake structure 19.83 feet wide, 11.9 feet high and 42 feet long, with trashracks and stoplog type gate; (4) a vertical rectangular tunnel (excavated in rock) about 8 feet by 16 feet in size and about 30 feet long; (5) a horizontal tunnel (excavated in rock) about 8.5–10 feet by 9.5–10 feet in size and about 500 feet long (upper section) and 900 feet long (lower section); (6) two steel pipes each 8 feet in diameter consisting of a mid section about 1,300 feet long, and a penstock section about 120 feet long; (7) a powerhouse 54 feet long, 34 feet wide and 34 feet high with one 2,000 kW turbine-generator unit; and (8) appurtenant electric and mechanical facilities. The applicant estimates the average annual generation for this project would be 8,413 MWh. The dam and existing project facilities are owned by the applicant.

m. Purpose of Project: Project power would be utilized by the applicant for sale to its customers.

n. This notice also consists of the following standard paragraphs: A4 and D9.

o. Available Location of Application: A copy of the application, as amended and supplemented, is available for inspection and reproduction at the Commission's Public Reference and Files Maintenance Branch, located at 941 North Capitol Street, N.E., Room 3104, Washington, D.C., 20426, or by calling (202) 208–1371. A copy is also available for inspection and reproduction at Upper Peninsula Power

Company P.O. Box 130, 600 Lakeshore Drive, Houghton, MI 49931–0130 or by calling (906) 487–5000.

p. Scoping Process: In gathering background information for preparation of the environmental document for the issuance of a Federal hydropower license, staff of the Federal Energy Regulatory Commission, is using a scoping process to identify significant environmental issues related to the construction and operation or the continued operation of hydropower projects. The staff will review all issues raised during the scoping process and identify issues deserving of study and also deemphasize insignificant issues, narrowing the scope of the environmental analysis as well. If preliminary analysis indicates that any issues presented in the scoping process would have little potential for causing significant impacts, the issue or issues will be identified and the reasons for not providing a more detailed analysis will be given.

q. Request for Scoping Comments: Federal, state, and local resource agencies; licensees, applicants and developers; Indian tribes; other interested groups and individuals, are requested to forward to the Commission, any information that they believe will assist the Commission staff in conducting an accurate and thorough analysis of the site-specific and cumulative environmental effects of the proposed licensing activities of the project(s). Therefore you are requested to provide information related to the following items:

- Information, data, maps or professional opinion that may contribute to defining the geographical and temporal scope of the analysis and identifying significant environmental issues.
- Identification of and information from any other EIS or similar study (previous, on-going, or planned) relevant to the proposed licensing activities in the subject river basin.
- Existing information and any data that would aid in describing the past and present effects of the project(s) and other developmental activities on the physical/chemical, biological, and socioeconomic environments. For example, fish stocking/management histories in the subject river, historic water quality data and the reasons for improvement or degradation of the quality, any wetland habitat loss or proposals to develop land and water resources within the basin.
- Identification of any federal, state or local resource plans and future project proposals that encompass the subject river or basin. For example, proposals to construct or operate water treatment facilities, recreation areas, or implement fishery management programs.
- Documentation that would support a conclusion that the project(s) does not contribute, or does contribute to adverse and beneficial cumulative effects on resources and therefore should be excluded from further study or excluded from further consideration of cumulative impacts within the river basin. Documentation should include, but not be limited to: how the project(s) interact with other projects within the river basin or other developmental activities; results from studies; resource management policies; and, reports from federal, state, and local agencies.

Comments concerning the scope of the environmental document should be filed by the deadline established in paragraph D9.

10 a. Type of Application: Minor License.

b. Project No.: 11482–000.

c. Date filed: May 23, 1994.

d. Applicant: Consolidated Hydro Maine, Inc.

e. Name of Project: Marcal Project.

f. Location: on the Little Androscoggin River in Androscoggin County, Maine.

g. Filed Pursuant to: Federal Power Act 16 U.S.C. 791 (a)–825(r).

h. Applicant Contact: Mr. Wayne E. Nelson, Consolidated Hydro Maine, Inc., Andover Business Park, 200 Bulfinch Drive, Andover, MA 01810, (508) 681–1900.

i. FERC Contact: Robert Bell (202) 219–2806.

j. Comment Date: July 22, 1994.

k. Description of Project: The constructed project consists of: (1) the existing 145-foot-long, 15.4-foot-high concrete and granite block Marcal Dam; (2) 2-foot-high flashboards; (3) the existing impoundment having a surface area of 27 acres, with a storage capacity of 103 acre-feet, and a normal water surface elevation of 273.3 feet msl; (4) the existing intake structure; (5) the existing 120-foot-long, 38-foot-wide, and 9-foot-deep forbay canal; (5) the existing 470-foot-long, 11-foot-diameter steel penstock; (6) the existing powerhouse containing 2 existing generating units with a total installed capacity of 1,310-kW; (7) the existing 290-foot-long, 40-foot-wide tailrace; (8) the existing 34.5-kV transmission line; and (9) appurtenant facilities.

All project facilities are owned by the applicant. The average annual generation is 4,500,000-kWh. The applicant proposes the sale of all power generated from this project to Central Maine Power Company.

l. With this notice, we are initiating consultation with the Maine State Historic Preservation Officer (SHPO), as required by § 106, National Historic Preservation Act, and the regulations of the Advisory Council on Historic Preservation, 36 CFR 800.4.

m. Pursuant to Section 4.32(b)(7) of 18 CFR of the Commission's regulations, if any resource agency, Indian Tribe, or person believes that an additional scientific study should be conducted in order to form an adequate factual basis for a complete analysis of the application on its merit, the resource agency, Indian Tribe, or person must file a request for a study with the Commission not later than 60 days from the filing date and serve a copy of the request on the applicant.

Standard Paragraphs

A4. Development Application—Public notice of the filing of the initial development application, which has already been given, established the due date for filing competing applications or notices of intent. Under the Commission's regulations, any competing development application must be filed in response to and in compliance with public notice of the initial development application. No competing applications or notices of intent may be filed in response to this notice.

A5. Preliminary Permit—Anyone desiring to file a competing application for preliminary permit for a proposed project must submit the competing application itself, or a notice of intent to file such an application, to the Commission on or before the specified comment date for the particular application (see 18 CFR 4.36). Submission of a timely notice of intent allows an interested person to file the competing preliminary permit application no later than 30 days after the specified comment date for the particular application. A competing preliminary permit application must conform with 18 CFR 4.30(b)(1) and (9) and 4.36.

A7. Preliminary Permit—Any qualified development applicant desiring to file a competing development application must submit to the Commission, on or before a specified comment date for the particular application, either a competing development application or a notice of intent to file such an application. Submission of a timely notice of intent to file a development application allows an interested person to file the competing application no later than 120 days after the specified comment date for the particular

application. A competing license application must conform with 18 CFR 4.30(b)(1) and (9) and 4.36.

A9. Notice of intent—A notice of intent must specify the exact name, business address, and telephone number of the prospective applicant, and must include an unequivocal statement of intent to submit, if such an application may be filed, either a preliminary permit application or a development application (specify which type of application). A notice of intent must be served on the applicant(s) named in this public notice.

A10. Proposed Scope of Studies under Permit—A preliminary permit, if issued, does not authorize construction. The term of the proposed preliminary permit will be 36 months. The work proposed under the preliminary permit would include economic analysis, preparation of preliminary engineering plans, and a study of environmental impacts. Based on the results of these studies, the Applicant would decide whether to proceed with the preparation of a development application to construct and operate the project.

B. Comments, Protests, or Motions to Intervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

C. Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title "COMMENTS", "NOTICE OF INTENT TO FILE COMPETING APPLICATION', "COMPETING APPLICATION", "PROTEST", "MOTION TO INTERVENE", as applicable, and the Project Number of the particular application to which the filing refers. Any of the above-named documents must be filed by providing the original and the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426. An additional copy must be sent to Director, Diviion of Project Review, Federal Energy Regulatory Commission, Room 1027, at the above-mentioned address. A copy of any notice of intent, competing application or motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

C1. Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title "COMMENTS", "RECOMMENDATIONS FOR TERMS AND CONDITIONS", "PROTEST", OR "MOTION TO INTERVENE", as applicable, and the Project Number of the particular application to which the filing refers. Any of the above-named documents must be filed by providing the original and the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426. A copy of any motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

D2. Agency Comments—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's must also be sent to the Applicant's representatives.

D9. Filing and Service of Responsive Documents—The application is ready for environmental analysis at this time, and the Commission is requesting comments, reply comments, recommendations, terms and conditions, and prescriptions.

The Commission directs, pursuant to section 4.34(b) of the regulations (see Order No. 533 issued May 8, 1991, 56 FR 23108, May 20, 1991) that all comments, recommendations, terms and conditions and prescriptions concerning the application be filed with the Commission within 60 days from the issuance date of this notice. (August 2, 1994 for Project Nos. 2315–002, 2331–002 and 2332–003; August 9, 1994 for Project No. 10854–002). All reply comments must be filed with the Commission within 105 days from the date of this notice. (September 16, 1994 for Project Nos. 2315–002, 2331–002 and 2332–003; September 23, 1994 for Project No. 10854–002).

Anyone may obtain an extension of time for these deadlines from the Commission only upon a showing of good cause or extraordinary circumstances in accordance with 18 CFR 385.2008.

All filings must (1) bear in all capital letters the title "COMMENTS", "REPLY COMMENTS", "RECOMMENDATIONS," "TERMS AND CONDITIONS," or "PRESCRIPTIONS;" (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person submitting the filing; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, recommendations, terms and conditions or prescriptions must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). Any of these documents must be filed by providing the original and the number of copies required by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426. An additional copy must be sent to Director, Division of Project Review, Office of Hydropower Licensing, Federal Energy Regulatory Commission, Room 1027, at the above address. Each filing must be accompanied by proof of service on all persons listed on the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b), and 385.2010.

Dated: June 13, 1994.

Lois D. Cashell,

Secretary.

[FR Doc. 94–14842 Filed 6–16–94; 8:45 am]

BILLING CODE 6717–01–P

[Docket No. CP94–574–000, et al.]

Peach Ridge Pipeline, Inc., et al.; Natural Gas Certificate Filings

June 10, 1994.

Take notice that the following filings have been made with the Commission.

1. Peach Ridge Pipeline, Inc.

[Docket No. CP94–574–000]

Take notice that on May 27, 1994, Peach Ridge Pipeline, Inc. (Peach Ridge), 801 Cherry Street, Mail Station 4010, Fort Worth, Texas 76102, filed in Docket No. CP94–574–000 a petition pursuant to Rule 207 of the Commission's Rules of Practice and Procedure (18 CFR 385.207) for a declaratory order that certain compression and pipeline facilities, with appurtenances, to be abandoned by sale to Peach Ridge by Northern Natural Gas Company (Northern), would be production and gathering facilities, upon the acquisition by Peach Ridge, and therefore would be exempt from the jurisdiction of the Commission under Section 1(b) of the Natural Gas Act.

Peach Ridge states that the facilities consists of approximately 112 miles of

pipeline and appurtenant facilities, with pipe diameters ranging between 2-inches and 12-inches, and four lateral compressor stations. Peach Ridge states further that Peach Ridge's petition is the companion to the application filed by Northern on March 14, 1994, and now pending in Docket No. CP94–286–000, to abandon the subject facilities.

It is stated that the facilities are located in Crockett County, Texas.

Comment date: July 1, 1994, in accordance with the first paragraph of Standard Paragraph F at the end of this notice.

2. Transcontinental Gas Pipe Line Corp.

[Docket No. CP94–584–000]

Take notice that on June 3, 1994, Transcontinental Gas Pipe Line Corporation (TGPL), P.O. Box 1396, Houston, Texas 77251, filed in Docket No. CP94–584–000 a request pursuant to Sections 157.205 and 157.212 of the Commission's Regulations under the Natural Gas Act (18 CFR §§ 157.205, 157.212) for authorization to operate an existing delivery point under TGPL's blanket certificate issued in Docket No. CP82–426–000 pursuant to Section 7 of the Natural Gas Act, all as more fully set forth in the request that is on file with the Commission and open to public inspection.

TGPL proposes to operate the existing delivery point facilities for the Town of Melville, St. Landry Parish, Louisiana (Melville Delivery Point), which have been constructed pursuant to Section 311(a)(1) of the Natural Gas Policy Act of 1978 and Section 284.3(c) of the Commission's regulations.

TGPL states that it has constructed the Melville Delivery Point to enable TGPL to transport gas for the account of various customers pursuant to Section 311 and Part 284(B) of the regulations.

TGPL states that the Melville Delivery Point facilities consist of a 2-inch skid-mounted meter station at M.P. 559.52 on TGPL's Main Line "A" in St. Landry Parish, Louisiana, and that the Melville Delivery Point is utilized to provide delivery of up to 100 Mcf per day of natural gas to the Town of Melville, St. Landry Parish, Louisiana.

TGPL further states that it is seeking certificate authority for such facilities so that service under any blanket certificate transportation arrangements may be provided through such facilities. TGPL states that the Melville Delivery Point is the only remaining delivery point on TGPL's system constructed pursuant to Section 311 which has not been converted to certificate status. Accordingly, TGPL requests Natural Gas Act certification pursuant to Section 7 of the Natural Gas Act and Sections 157.205 and 157.212 of the Commission's regulations to operate the Melville Delivery Point.

TGPL submits that (1) receipt of the authorization requested will not cause the total volumes authorized prior to the request for any customer on TGPL's system to be exceeded, (2) the operation of the Melville Delivery Point is not prohibited by TGPL's tariff, (3) TGPL has sufficient capacity to accomplish deliveries through the Melville Delivery Point for transportation customers without detriment or disadvantage to TGPL's other customers, (4) the delivery capacity of the Melville Delivery Point will remain at 100 Mcf of gas per day, and (5) receipt of the authorization requested in TGPL's filing will have little or no impact on TGPL's peak day or annual deliveries.

TGPL states that in constructing the Melville Delivery Point, it complied with the environmental requirements of the Commission's regulations applicable to construction under Section 311 and Section 284.3(c) and in effect at the time of such construction.

Comment date: July 25, 1994, in accordance with Standard Paragraph G at the end of this notice.

3. Tennessee Gas Pipeline Co.

[Docket No. CP94–585–000]

Take notice that on June 3, 1994, Tennessee Gas Pipeline Company (Tennessee), P.O. Box 2511, Houston, Texas 77252–2511, filed in Docket No. CP94–585–000 an application pursuant to Section 7(b) of the Natural Gas Act for permission and approval to abandon an exchange of natural gas service between Tennessee and Algonquin Gas Transmission Company (Algonquin), all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Tennessee proposes to abandon the sale and transportation service provided under the Gas Service Contract (Contract) between Tennessee and Algonquin dated December 22, 1982, under Tennessee's Rate Schedule X–65. Tennessee states that (1) Algonquin delivers up to 523 dt of natural gas per hour in the Town of Danbury, Connecticut to the Connecticut Light and Power Company for the account of Tennessee and Tennessee redelivers equivalent quantities to Algonquin; (2) Tennessee delivers up to 418 dt of natural gas per hour near the Town of Thompsonville, Connecticut to Algonquin for sale to CL&P and Algonquin redelivers equivalent quantities to Tennessee; and (3) Tennessee delivers up to 314 dt of natural gas per hour in the Town of Milford, Connecticut to Southern Connecticut Gas Company for the account of Algonquin and Algonquin redelivers equivalent quantities to Tennessee. The redelivery points are interconnects between Tennessee and Algonquin located in Hartford and New Haven Counties, Connecticut; Bergen County, New Jersey; Worcester and Middlesex County, Massachusetts; and the delivery points in Fairfield and New Haven Counties, Connecticut and Hampden County, Massachusetts, it is indicated.

Tennessee states that Tennessee and Algonquin no longer make sales to the customers in the contract and pursuant to the contract have agreed to the termination of the contract effective March 16, 1995.

No facilities are proposed to be abandoned herein.

Comment date: July 1, 1994, in accordance with Standard Paragraph F at the end of this notice.

4. East Tennessee Natural Gas Co.

[Docket No. CP94–588–000]

Take notice that on June 7, 1994, East Tennessee Natural Gas Company (East Tennessee), P.O. Box 2511, Houston, Texas 77252, filed in Docket No. CP94–588–000 a request pursuant to Sections 157.205 and 157.212 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205, 157.212) for authorization to construct and operate a new delivery point for continued service to Jefferson-Cocke County Utility District, (JCUD) in Tennessee, under East Tennessee's blanket certificate issued in Docket No. CP82–412–000 pursuant to Section 7 of the Natural Gas Act, all as more fully set forth in the request that is on file with the Commission and open to public inspection.

East Tennessee proposes to add a new delivery point consisting of a 2 inch hot tap assembly on East Tennessee's Newport Lateral Line, downstream of existing delivery meter No. 75–9043, located in Jefferson County, Tennessee in order to continue service to JCUD. The estimated cost is $8,500 to be reimbursed by JCUD. East Tennessee states that the total quantities to be delivered will not exceed the total quantities authorized and will not effect its delivery to other customers.

Comment date: July 25, 1994, in accordance with Standard Paragraph G at the end of this notice.

5. Northwest Pipeline Corp.

[Docket No. CP94–589–000]

Take notice that on June 7, 1994, Northwest Pipeline Corporation (Northwest), 295 Chipeta Way, Salt Lake

City, Utah 84158, filed in Docket No. CP94–589–000 a request pursuant to Sections 157.205, 157.211 and 157.216 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205, 157.211 and 157.216) for authorization to abandon facilities at the Yakima Meter Station in Yakima County, Washington, and to construct and operate replacement facilities at this station under Northwest's blanket certificate issued in Docket No. CP82–433–000 pursuant to Section 7 of the Natural Gas Act, all as more fully set forth in the request that is on file with the Commission and open to public inspection.

Northwest proposes to replace the two existing 2-inch regulators with two new 4-inch regulators and the two existing 6-inch orifice meters with two new 8-inch turbine meters. This facility change will increase the maximum design delivery capacity of this station from 18,666 Dth per day to approximately 30,000 Dth per day at a pressure of 200 psig. It is stated that these changes are necessary in order to eliminate operational problems in serving existing firm requirements of Cascade Natural Gas Corporation.

Comment date: July 25, 1994, in accordance with Standard Paragraph G at the end of this notice.

6. Williams Natural Gas Co.

[Docket No. CP94–591–000]

Take notice that on June 7, 1994, Williams Natural Gas Company (WNG), P.O. Box 3288, Tulsa, Oklahoma 74101, filed in Docket No. CP94–591–000 a request pursuant to Sections 157.205, 157.211, and 157.212 of the Commission's Regulations under the Natural Gas Act (18 CFR §§ 157.205, 157.211, and 157.212) for authorization to construct and operate a pipeline tap and related facilities to deliver transportation gas to Associated Milk Products, Inc. (AMPI), under WNG's blanket certificate issued in Docket No. CP82–479–000 pursuant to Section 7 of the Natural Gas Act, all as more fully set forth in the request that is on file with the Commission and open to public inspection.

WNG proposes to install a tap and appurtenant facilities to deliver transportation gas to AMPI in Marion County, Kansas. The estimated cost is $4,960 to be reimbursed by AMPI. WNG states that the total volume (2,200 Dth per day and 210,000 Dth per year) does not exceed the volume authorized prior to this request and WNG has sufficient capacity to accomplish the delivery without detriment to its other customers.

Comment date: July 25, 1994, in accordance with Standard Paragraph G at the end of this notice.

7. Columbia Gas Transmission Corp.

[Docket No. CP94–594–000]

Take notice that on June 7, 1994, Columbia Gas Transmission Corporation (Columbia), 1700 MacCorkle Avenue, S.E., Charleston, West Virginia 25314–1599, filed in Docket No. CP94–594–000 a request pursuant to Sections 157.205 and 157.211 of the Commission's Regulations under the Natural Gas Act (18 CFR §§ 157.205 and 157.211) for authorization under its blanket certificate issued in Docket No. CP83–76–000, to construct and operate an additional point of delivery for interruptible transportation service in Clark County, Kentucky under Part 284 of the Commission's Regulations, all as more fully set forth in the request that is on file with the Commission and open to public inspection.

Columbia states the additional point of delivery in Clark County, Kentucky was requested by Winchester Farms Dairy (Winchester), an end-user. Columbia indicates that the transportation service will be provided under Columbia's Rate Schedule ITS or it may be provided under firm capacity released by other shippers. The use of the gas will be industrial.

Columbia states that the estimated cost to establish this delivery point will be approximately $57,000 and Winchester will reimburse Columbia for the cost, plus any gross-up for tax purposes. Columbia further states that the estimated quantities of gas to be delivered at the new point of delivery are 250 Dth per day and 91,250 Dth annually and the service will be provided pursuant to Columbia's blanket certificate issued in Docket No. CP86–240–000. Additionally, Columbia states that the quantities to be provided through the new point will be provided initially on an interruptible basis and, therefore, there is no impact on its existing design day and annual obligations to its customers as a result of the construction of the new point of delivery.

Comment date: July 25, 1994, in accordance with Standard Paragraph G at the end of this notice.

8. Koch Gateway Pipeline Co.

[Docket No. CP94–597–000]

Take notice that on June 8, 1994, Koch Gateway Pipeline Company (Koch Gateway), P.O. Box 1478, Houston, Texas 77251–1478, filed in Docket No. CP94–597–000 a request pursuant to Sections 157.205 and 157.211 of the Commission's Regulations under the Natural Gas Act (18 CFR §§ 157.205, 157.211) for authorization to construct and operate a sales tap through which it would deliver natural gas to Entex, Inc. (Entex) under Koch Gateway's blanket certificate issued in Docket No. CP82–430–000 pursuant to Section 7 of the Natural Gas Act, all as more fully set forth in the request that is on file with the Commission and open to public inspection.

Koch Gateway proposes to construct and operate a six-inch sales tap, located on its Jackson-Magnolia line in Hinds County, Mississippi, which would be used to deliver gas to the town of Byram which is a customer of Entex. Koch Gateway states that the estimated cost of the tap is $8,000. Koch Gateway proposes to deliver up to 1,000 MMBtu per day under its NNS Rate Schedule and an additional 4,200 MMBtu per day under its ITS Rate Schedule. Koch Gateway also states that the new tap will not change the existing certificated entitlements for Entex.

Comment date: July 25, 1994, in accordance with Standard Paragraph G at the end of this notice.

Standard Paragraphs

F. Any person desiring to be heard or to make any protest with reference to said application should on or before the comment date, file with the Federal Energy Regulatory Commission, Washington, DC 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR § 385.214 or 385.211) and the Regulations under the Natural Gas Act (18 CFR § 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a motion to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Energy Regulatory Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on this application if no motion to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate and/or permission and approval for the proposed abandonment

are required by the public convenience and necessity. If a motion for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for applicant to appear or be represented at the hearing.

G. Any person or the Commission's staff may, within 45 days after issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR § 385.214) a motion to intervene or notice of intervention and pursuant to Section 157.205 of the Regulations under the Natural Gas Act (18 CFR § 157.205) a protest to the request. If no protest is filed within the time allowed therefor, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to Section 7 of the Natural Gas Act.

Lois D. Cashell,

Secretary.

[FR Doc. 94–14841 Filed 6–16–94; 8:45 am]

BILLING CODE 6717–01–P

Office of Fossil Energy

[FE Docket No. 94–40–NG]

ARCO Products Company, Division of Atlantic Richfield Company; Order Granting Blanket Authorization to Import Natural Gas From Canada

AGENCY: Office of Fossil Energy, DOE.

ACTION: Notice of an order.

SUMMARY: The Office of Fossil Energy of the Department of Energy gives notice that it has issued an order granting ARCO Products Company, Division of Atlantic Richfield Company, authorization to import up to 25 billion cubic feet of natural gas from Canada over a two-year term beginning on the date of first delivery after September 19, 1994.

This order is available for inspection and copying in the Office of Fuels Programs Docket Room, 3F–56, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586–9478. The docket room is open between the hours of 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, DC, May 31, 1994.

Clifford P. Tomaszewski,

Director, Office of Natural Gas, Office of Fuels Programs, Office of Fossil Energy.

[FR Doc. 94–14826 Filed 6–16–94; 8:45 am]

BILLING CODE 6450–01–P

Federal Energy Regulatory Commission

[Docket No. CP94–576–000]

Williston Basin Interstate Pipeline Co.; Notice of Petition To Amend

June 10, 1994.

Take notice that on June 1, 1994, Williston Basin Interstate Pipeline Company (Williston), 200 North Third Street, suite 300, Bismarck, North Dakota 58501, filed in Docket No. CP94–576–000 a petition to amend the order issued March 30, 1992, the Docket No. CP91–1897–000,[1] a request to add a receipt point and to reassign transportation quantities among receipt and delivery points applicable to transportation service provided to Northern States Power Company (NSP), all as more fully set forth in the petition to amend which is on file with the Commission and open to public inspection.

Williston requests authority to amend the transportation service that it provides to NSP under Williston's FERC Gas Tariff, Volume No. 2, Rate Schedule X–13 to add the Many Islands Pipe Line-Portal Interconnect as a new receipt point. Williston also requests authorization to reassign a portion of the currently effective transportation Maximum Daily Receipt Quantity (MDRQ) and Maximum Daily Delivery Quantity (MDDQ) among receipt and delivery points, as follows:

Delivery points	MDDQ	
	Present	Proposed
Mapleton Interconnect	7,905	7,535
Casselton Border Station	85	455
Receipt points	**MDRQ**	
	Present	Proposed
West Short Pine Hills	500	250
Little Knife Plant	5,000	2,500
Lignite Plant	2,500	1,250
Many Islands Pipe Line	0	4,000

Williston states that is has posted on its Electronic Bulletin Board NSP's request for uncommitted firm capacity in accordance with section 10 of the General Terms and Conditions of Williston's FERC Gas Tariff, Second Revised Volume No. 1. Williston does not propose any new facilities to effect its request.

Any person desiring to be heard or to make any protest with reference to said petition to amend should on or before June 27, 1994, filed with the Federal Energy Regulatory Commission, Washington, DC 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's rules of Practice and Procedure (18 CFR §§ 385.214 or 385.211) and the Regulations under the National Gas Act (18 CFR § 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a motion to intervene in accordance with the Commission's Rules.

Lois D. Cashell,

Secretary.

[FR Doc. 94–14751 Filed 6–16–94; 8:45 am]

BILLING CODE 6717–01–M

[1] 58 FERC ¶ 61,344.

Office of Fossil Energy

[FE Docket No. 94–37–NG]

Renaissance Energy (U.S.) Inc.; Long-Term Authorization To Import Natural Gas From Canada

AGENCY: Office of Fossil Energy, DOE.

ACTION: Notice of order.

SUMMARY: The Office of Fossil Energy of the Department of Energy gives notice that it has granted Renaissance Energy (U.S.) Inc. (Renaissance U.S.) authorization to import from Renaissance Energy Ltd. up to 5,000 Mcf per day of Canadian natural gas over a ten-year period ending October 31, 2003.

Renaissance U.S.'s order is available for inspection and copying in the Office of Fuels Programs Docket Room, 3F–056, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586–9478. The docket room is open between the hours of 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, DC, May 31, 1994.

Clifford P. Tomaszewski,

Director, Office of Natural Gas, Office of Fuels Programs, Office of Fossil Energy.

[FR Doc. 94–14825 Filed 6–16–94; 8:45 am]

BILLING CODE 6450–01–M

ENVIRONMENTAL PROTECTION AGENCY

[FRL–5000–3]

Agency Information Collection Activities Under OMB Review

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this notice announces that the Information Collection Request (ICR) abstracted below has been forwarded to the Office of Management and Budget (OMB) for review and comment. The ICR describes the nature of the information collection and its expected cost and burden; where appropriate, it includes the actual data collection instrument.

DATES: Comments must be submitted on or before July 18, 1994.

FOR FURTHER INFORMATION CONTACT: For further information, or a copy of this ICR contact Sandy Farmer at EPA, (202) 260–2740.

SUPPLEMENTARY INFORMATION:

Office of Solid Waste and Emergency Response

Title: Collection of Economic and Regulatory Support Data Under RCRA (ICR No. 1641.01). This ICR requests approval for a new collection.

Abstract: EPA's Office of Solid Waste (OSW) is requesting approval for a generic clearance to collect economic and regulatory impact data through surveys, interviews, or focus group meetings with industry or other parties in support of the Resource Conservation and Recovery Act (RCRA) rulemaking actions.

RCRA, as amended by the Hazardous and Solid Waste Amendments, requires EPA to establish a national regulatory program to ensure that hazardous waste is managed in a manner protective of human health and the environment. EPA is authorized under sections 2002 and 3007 of RCRA to collect information from industry and other parties when necessary to carry out its regulatory responsibilities.

The information collected will be used to assess the costs and benefits of various potential regulatory and nonregulatory actions.

The first collection to be administered under the generic clearance, the Hazardous Waste Identification Rule (HWIR) Expert Elicitations, is included in this ICR. Information will be collected through interviews (expert elicitations) with hazardous and industrial solid waste experts to support development of alternative approaches for hazardous waste identification. The Agency will conduct two sets of expert elicitations, one for each HWIR regulatory option: Contaminated Soil and Sediment Media; and Contaminated Debris.

Burden Statement: The public reporting burden for this generic collection is estimated to average 3 hours per response and the burden for the HWIR Expert Elicitations collection ranges from 15 minutes to 1.5 hours per respondent. These estimates include all aspects of the information collection including the time for reviewing instructions, searching existing data sources, gathering the data needed, and completing and reviewing the collection of information.

Respondents: Hazardous waste generators, scientists, industry experts, and treatment, storage and disposal facilities.

Estimated Number of Respondents: 3,000.

Estimated Number of Responses per Respondent: 1.4.

Estimated Total Annual Burden on Respondents: 12,780 hours.

Frequency of Collection: On Occasion.

Send comments regarding the burden estimate, or any other aspect of this collection of information, including suggestions for reducing the burden, to:

Sandy Farmer, U.S. Environmental Protection Agency, Information Policy Branch (2136), 401 M Street, SW., Washington, DC 20460.

and

Jonathan Gledhill, Office of Management and Budget, Office of Information and Regulatory Affairs, 725 17th Street, NW., Washington, DC 20503.

Dated: June 13, 1994.

Paul Lapsley,

Director, Regulatory Management Division.

[FR Doc. 94–14819 Filed 6–16–94; 8:45 am]

BILLING CODE 6560–50–F

[FRL–4998–6]

Conformity; General Preamble for Exemption From Nitrogen Oxides Provisions

AGENCY: Environmental Protection Agency (EPA).

ACTION: General preamble for future proposed rulemakings.

SUMMARY: This General Preamble clarifies how EPA believes that nonclassifiable (i.e., submarginal, transitional, and incomplete/no data) ozone nonattainment areas which are outside the Northeast ozone transport region and have ambient monitoring data demonstrating attainment of the national ambient air quality standard for ozone may be exempted from the conformity rules' nitrogen oxides (NO_x) requirements. This notice also references a recent memorandum which states EPA's preliminary interpretation for such ozone nonattainment areas which are classified as marginal or above.

Clarification of EPA policy for areas with monitoring data which demonstrates attainment is particularly important because many areas already have such data and appear to qualify for exemption from the conformity NO_x requirements.

In order to avoid repetition, this General Preamble describes guidance on NOx exemptions with respect to the transportation conformity rule. However, this guidance for transportation conformity is intended to also apply with respect to general conformity.

This General Preamble explains EPA's policy generally for future notice-and-comment rulemakings taking action on requests for NOx exemptions for specific areas. It contains EPA's preliminary interpretations of relevant provisions of the Clean Air Act and the conformity rules. The interpretations contained herein are not binding as a matter of law until final rulemaking action is taken on each specific area. Opportunity for public comment on NOx exemption determinations made by EPA will be provided separately for each area during these individual rulemakings.

FOR FURTHER INFORMATION CONTACT: For issues related to transportation conformity, Kathryn Sargeant, Emission Control Strategies Branch, Emission Planning and Strategies Division, U.S. Environmental Protection Agency, 2565 Plymouth Road, Ann Arbor, MI 48105. (313) 668–4441. For issues related to redesignation, David Cole, (919) 541–5565, and for issues related to general conformity and NOx RACT and NSR, Doug Grano, (919) 541–3292, Ozone/CO Programs Branch (MD–15), Air Quality Management Division, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711.

SUPPLEMENTARY INFORMATION:

I. Background

A. Transportation Conformity Rule

The transportation conformity final rule, entitled "Criteria and Procedures for Determining Conformity to State or Federal Implementation Plans of

Transportation Plans, Programs, and Projects Funded or Approved Under title 23 U.S.C. or the Federal Transit Act," was published in the **Federal Register** on November 24, 1993 (58 FR 62188). This action was required under section 176(c)(4) of the Clean Air Act, as amended in 1990.

Conformity to an implementation plan is defined in the Clean Air Act as conformity to an implementation plan's purpose of eliminating or reducing the severity and number of violations of the national ambient air quality standards and achieving expeditious attainment of such standards. In addition, Federal activities may not cause or contribute to new violations of air quality standards, exacerbate existing violations, or interfere with timely attainment or required interim emission reductions towards attainment. The transportation conformity final rule establishes the process by which the Federal Highway Administration and the Federal Transit Administration of the United States Department of Transportation and metropolitan planning organizations determine the conformity of highway and transit projects. Under the rule, conformity applies in nonattainment and maintenance areas.

The transportation conformity rule requires ozone nonattainment and maintenance areas to perform a regional emissions analysis of motor vehicle NOx emissions in order to determine the conformity of transportation plans and programs. This analysis must demonstrate that the NO_x emissions which would result from the transportation system if the proposed transportation plan and program were implemented are within the total allowable level of NO_x emissions from highway and transit motor vehicles ("motor vehicle emissions budget"), as identified in a submitted or approved attainment demonstration or maintenance plan.

Until an attainment demonstration or (for nonclassifiable areas) a maintenance plan is approved by EPA, the regional emissions analysis of the transportation system must also satisfy the "build/no-build test." That is, the analysis must demonstrate that emissions from the transportation system if the proposed transportation plan and program were implemented would be less than the emissions from the transportation system if only the previously applicable transportation plan and program were implemented. Furthermore, the regional emissions analysis must show that emissions from the transportation system if the transportation plan and program were implemented would be lower than 1990 levels by any nonzero amount.

The transportation conformity rule as currently written provides for an exemption from these requirements with respect to NO_x if the Administrator determines under section 182(f) of the Clean Air Act that additional reductions of NO_x would not contribute to attainment. This exemption is explicitly referred to and is described in similar language in § 51.394(b)(3)(i) (the "Applicability" section of the rule) and in the preamble (58 FR 62197, November 24, 1993). The language is repeated in the provisions of the rule regarding the motor vehicle emissions budget test (§ 51.428(a)(1)(ii)) and the "build/no-build" test (§§ 51.436(e), 51.438(e)), although Clean Air Act section 182(f) is not specifically mentioned.

Section 182(f) of the Clean Air Act contains requirements for—and in some cases, exemptions for—major stationary NO_x sources in marginal and above ozone nonattainment areas and in an ozone transport region. EPA guidance for application of section 182(f) in these areas is briefly described and referenced in the next section of this preamble. Because the transportation conformity rule covers all nonattainment areas—including nonclassifiable ozone nonattainment areas (*i.e.*, submarginal, transitional, incomplete/no data areas) that are not necessarily covered under section 182(f)—corresponding guidance is needed for applying in these nonclassifiable ozone nonattainment areas the section 182(f) NO_x exemption referenced in the transportation conformity rule. This guidance is described below (section II, "EPA Policy") and is consistent with the existing guidance that applies to the marginal and above areas outside an ozone transport region. The substantive test for a NO_x exemption is the same in both sets of areas, but in nonclassifiable ozone nonattainment areas the effect of a NO_x exemption is limited solely to the issue of whether such areas may be exempted from meeting the NO_x requirements of the transportation conformity rule.

B. General Conformity

On November 30, 1993 (58 FR 63214), EPA published the general conformity final rule, entitled "Determining Conformity of General Federal Actions to State or Federal Implementation Plans." This action was required under section 176(c)(4) of the Clean Air Act, as amended in 1990.

Like the transportation conformity rule, the general conformity rule exempts an area from considering NO_x emissions if the area has been exempted under section 182(f) of the Clean Air Act (see definition of "precursors of a criteria pollutant," 58 FR 63248).

In order to avoid repetition, this General Preamble describes guidance on NO_x exemptions with respect to the transportation conformity rule. However, this guidance for transportation conformity is intended to also apply with respect to general conformity.

C. Section 182(f) of the Clean Air Act

Section 182(f) of the Clean Air Act requires states to apply the reasonably available control technology (RACT) and new source review (NSR) requirements that apply to major stationary sources of volatile organic compounds to major stationary sources of NO_x as well. NO_X RACT is required in moderate and above ozone areas, as well as in all areas within an ozone transport region. NO_X NSR regulations are required in marginal and above ozone areas, as well as in all areas within an ozone transport region.

Clean Air Act section 182(f)(1)(A) states that, for nonattainment areas not within an ozone transport region (as established under Clean Air Act section 184), these NO_X requirements shall not apply if the Administrator determines that additional reductions of NO_X would not contribute to attainment of the national ambient air quality standard (NAAQS) for ozone in the area. Furthermore, for areas within an ozone transport region, section 182(f)(1)(B) states that these stationary source NO_X requirements shall not apply if additional NO_X reductions would not produce net ozone air quality benefits in the region.

EPA issued limited guidance on section 182(f) exemptions in a September 17, 1993 memo from Michael H. Shapiro, Acting Assistant Administrator for Air and Radiation, to the Regional Air Division Directors entitled, "State Implementation Plan (SIP) Requirements for Areas Submitting Requests for Redesignation to Attainment of the Ozone and Carbon Monoxide (CO) National Ambient Air Quality Standards (NAAQS) on or after November 15, 1992." EPA issued more extensive guidance in a December 1993 document entitled, "Guideline for Determining the Applicability of Nitrogen Oxide Requirements under section 182(f)." Most recently, EPA has clarified and, in part, revised its guidance in a May 27, 1994 memorandum from John S. Seitz, Director of the Office of Air Quality Planning and Standards, to Regional Air Division Directors, "Section 182(f) NO_x

Exemptions—Revised Process and Criteria." All of these guidance documents are available by request from the contacts listed above.

Taken together, these guidance documents state that if an area (not within an ozone transport region) has attained the ozone standard, as demonstrated by adequate monitoring data consistent with EPA guidance, it is clear that additional NO_X reductions would not contribute to attainment. Therefore, such an area would meet the test under section 182(f)(1)(A) for an exemption from NO_X NSR and RACT requirements.

II. EPA Policy

A. Transportation Conformity and Section 182(f) Exemptions

The transportation conformity rule states that its NO_X provisions do not apply when the Administrator has determined under section 182(f) of the Clean Air Act that "additional reductions of NO_X would not contribute to attainment." Although two other passages of the transportation conformity rule use this language (which is borrowed from section 182(f)(1)(A)'s test for areas outside an ozone transport region) without specifically referring to section 182(f), EPA believes there is no appropriate basis to interpret this identical language differently under the transportation conformity rule than under the Clean Air Act. Consequently, EPA believes this common language should be interpreted similarly for purposes of both section 182(f) and conformity NO_X exemptions. Therefore, EPA is providing guidance which would exempt nonclassifiable ozone nonattainment areas outside an ozone transport region from the conformity rule's NO_X provisions on the same substantive basis as the applicable section 182(f) test.[1]

The transportation conformity rule applies to all nonattainment and maintenance areas, and does not distinguish between nonclassifiable nonattainment and other nonattainment areas. Consequently, EPA interprets the transportation conformity rule's reference to the need for nonattainment areas to obtain a section 182(f) exemption in order to be relieved of the NO_X conformity requirements to include nonclassifiable ozone nonattainment areas (*i.e.*, submarginal, transitional, incomplete/no data areas), even though such areas are not subject to Clean Air Act section 182(f) itself. This means that ozone nonattainment areas, including nonclassifiable ozone nonattainment areas, can only be exempted from the NO_X provisions of the transportation conformity rule if EPA determines that the area satisfies the substantive test required for an areawide section 182(f) exemption, through a process similar to that required for section 182(f) exemptions which are not related to conformity.

Thus, for nonclassifiable ozone nonattainment areas outside the Northeast ozone transport region, EPA will consider requests for determinations that additional NO_X reductions would not contribute to attainment if such areas already have air quality data that demonstrate attainment of the ozone standard, that are consistent with 40 CFR part 58 requirements, and that are recorded in EPA's Aerometric Information Retrieval System (AIRS). Once made, this determination would relieve an area of the transportation conformity rule's NO_X provisions. A more thorough explanation of the conditions and process for obtaining the 182(f) exemption is given in the May 27, 1994 Seitz memorandum.

B. Condition on NO_X Exemptions for Areas Outside the Ozone Transport Region With Monitoring Data Demonstrating Attainment

If a NO_X transportation conformity exemption request is based solely on monitoring data demonstrating attainment, EPA's approval of the exemption, if otherwise warranted, will be granted on a contingent basis, *i.e.*, the exemption would last for only as long as the area's monitoring data continues to demonstrate attainment. If subsequently it is determined that the area has violated the standard, the exemption, as of the date of the determination, would no longer apply. EPA would notify the state that the exemption no longer applies, and would also provide notice to the public in the **Federal Register**. Existing transportation plans and TIPs and past conformity determinations will not be affected by a determination that the NO_X exemption no longer applies, but new conformity determinations would have to observe the NO_X requirements of the conformity rule. The State must continue to operate an appropriate air quality monitoring network, in accordance with 40 CFR part 58, to verify the attainment status of the area. The air quality data relied on for the above determinations must be consistent with 40 CFR part 58 requirements and other relevant EPA guidance and recorded in EPA's Aorometric Information Retrieval System (AIRS).

C. Areas Inside an Ozone Transport Region

Section 182(f) of the Clean Air Act provides a different test for exempting areas in an ozone transport region from NO_X requirements (see section I.C. of this preamble). In particular, that test requires a demonstration that shows additional NO_X reductions would not produce net ozone benefits in the transport region as a whole. Since the requirement for meeting this test is substantially different from that needed to meet the contribute-to-attainment test in section 182(f)(1)(A), and since the language in the conformity rule clearly does not reflect the language of the test provided for areas in an ozone transport region, the determination of how such areas would qualify for an exemption from the rule's NO_X requirements merits more consideration before EPA can issue appropriate guidance. Today's guidance therefore applies only to NO_X exemptions for areas outside the Ozone Transport Region.

[1] As explained in footnote 6 of the May 27, 1994 memorandum from John Seitz, referenced above, for purposes of the NO_X exemption test, EPA is interpreting the term "contribute to attainment" to mean that the State (or petitioner) need only show whether additional NO_X reductions would contribute to attainment, not whether such reductions would contribute to attainment and maintenance. EPA believes that Congress could reasonably have believed it appropriate to require that States impose reasonably available control technology (RACT) and new source review (NSR) requirements on NO_X sources for areas in nonattainment, but that the States could be left to decide for themselves whether to impose these NO_X controls or other measures for maintenance purposes, even if these controls could "contribute" to maintenance. EPA believes this rationale also applies in the conformity context, where EPA believes it is reasonable to allow States that have attained the NAAQS to decide for themselves how best to ensure maintenance of the standard. And, as explained below, EPA has conditioned the monitoring-based section 182(f) and conformity exemptions on continued monitoring data that do not show violations of the NAAQS. This will provide an additional incentive for States to track NO_X emissions (and limit such emissions, where necessary) to ensure that future violations do not occur.

EPA notes that its conclusion regarding the relevance of maintenance may well be different for other Clean Air Act provisions where the test is whether emissions reduction measures are "necessary" for attainment, even if maintenance is not explicitly mentioned. See section 211(c)(4)(C) (allowing States to overcome federal preemption of State fuel controls where "necessary" to achieve a NAAQS) and section 184(c) (providing for EPA approval of ozone transport commission recommendations of additional control measures "necessary" to bring any area in the region into attainment). It may make less sense to disregard maintenance to disallow more stringent fuel controls under section 211 or to disapprove additional controls under section 184 where these measures not only contribute to but are "necessary" for maintenance. The rationale that the State might appropriately retain discretion to choose other options to ensure maintenance makes less sense when the specific measures in question are "necessary."

As noted previously, requests for conformity NO_X exemptions must consider the nonattainment area as a whole. With respect to transportation conformity, NO_X exemptions will not be granted for portions of nonattainment areas. Therefore, nonattainment areas with portions both inside and outside the Ozone Transport Region will be treated for purposes of such exemption requests as areas inside the Ozone Transport Region, and for the present time, will not be eligible for an exemption based on monitoring data as described in this notice.

EPA will give further consideration to areas in the Ozone Transport Region, and if EPA does propose to exempt some of these areas, they will be addressed in state-specific rulemaking notices unless another general preamble providing guidance for such areas is published first.

III. Process for Receiving a NO_X Exemption Based on Monitoring Data for Nonclassifiable Areas

EPA believes that section 182(f) sets up two separate procedures by which EPA may act on NO_X exemption requests. Subsections 182(f) (1) and (2) direct that action on NO_X exemption determination requests should take place "when [EPA] approves a plan or plan revision." This language appears to contemplate that exemption requests submitted under these paragraphs are limited to states, since states are the entities authorized under the Act to submit plans or plan revisions. By contrast, subsection 182(f)(3) provides that "person[s][2]" may petition for a NO_X determination "at any time" after the ozone precursor study required under section 185B of the Act is finalized,[3] and gives EPA a limit of six months after filing to grant or deny such petitions. Although subsection 182(f)(3) references section 182(f)(1), EPA believes that paragraph (f)(3)'s reference to paragraph (f)(1) encompasses only the substantive tests in paragraph (f)(1) (and, by extension, paragraph (f)(2)), not the requirement in paragraph (f)(1) for EPA to grant exemptions only when acting on plan revisions.

Accordingly, petitions submitted under subsection 182(f)(3) are not required to be submitted as state implementation plan (SIP) revisions. Consequently, the state is not required under the Act to hold a public hearing in order to petition for an areawide NO_X exemption determination under section 182(f)(3) (see Clean Air Act sections 110(a) (1) and (2)). For similar reasons, if the state is submitting an areawide petition under subsection 182(f)(3), it is unnecessary to have the Governor submit the petition. However, because of the need for consistency with the AIRS data and the requirements of 40 CFR part 58, EPA believes that, particularly in cases where the NO_X exemption request (including a request for exemption from the NO_X requirements of the conformity rules) is based on monitoring data, if such data is contained in a petition submitted by a person other than the state, the petition should be coordinated with the state air agency. Lack of endorsement by the state air agency will require more scrutiny by EPA, and therefore EPA's processing of the petition will likely take more time.

EPA will grant or deny a petition for an areawide NO_X transportation conformity exemption through a full rulemaking process. This may involve a direct final rule or a notice of proposed rulemaking followed by a final rule. Either process allows opportunity for public comment. For areas which are relying on monitoring data which demonstrates attainment, the notice and comment will provide opportunity for comment on the preliminary interpretations contained in this General Preamble. These rulemakings will also offer opportunity for comment on the appropriateness of using monitoring data which is consistent with the requirements in 40 CFR part 58 and consistent with the data recorded in AIRS as the basis of EPA's approval and rescission of the contingent NO_X exemption. If EPA issues a final rulemaking concluding that it will use such air quality monitoring data in making subsequent determination that an area has violated the standard, no further notice and comment will be required in order to rescind the NO_X exemption in the event that such data subsequently indicates that a violation has occurred.

EPA is preparing a delegation of authority to Regional Administrators to make determinations under section 182(f) for areas which are outside the Ozone Transport Region and which have three years of monitoring data demonstrating attainment. This delegation would allow the rulemaking for 182(f) determinations to be conducted by EPA's regional offices.

IV. Effect of a NO_X Transportation Conformity Exemption on Transportation Planning

This section applies to both classified and nonclassifiable areas.

Once EPA makes a finding under a separate notice which grants a NO_X transportation conformity exemption, an area is relieved of the transportation conformity rule's requirements for regional analysis of NO_X emissions.

However, EPA plans to amend the transportation conformity rule to require that once an area's maintenance plan is approved, any previously approved NO_X conformity exemption no longer applies. The area must then demonstrate as part of its conformity determinations that the transportation plan and TIP are consistent with the motor vehicle emissions budget for NO_X where such a budget is established by the maintenance plan. As currently written, none of the transportation conformity rule's NO_X requirements would ever apply to an area once such an area had received a NO_X transportation conformity exemption.

EPA believes that it is crucial for maintenance areas to demonstrate consistency with the maintenance plan's motor vehicle NO_X emissions budget because that budget represents the level of motor vehicle NO_X emissions needed for continued maintenance. However, the maintenance plan's NO_X motor vehicle emissions budget for the purposes of transportation conformity will not necessarily require annual NO_X emission reductions throughout the ten-year period.

EPA intends to promptly amend the conformity rule as stated above, so that NO_X motor vehicle emissions budgets in maintenance plans will begin to apply at the time or shortly after those plans are approved.

V. Administrative Requirements

Regulatory Flexibility Act

Whenever EPA is required by section 553 of the Administrative Procedures Act or any other law to publish general notice and proposed rulemaking for any proposed rule, EPA shall propose and make available for public comment an initial regulatory flexibility analysis.

The regulatory flexibility requirements do not apply for this General Preamble because it is not a regulatory action in the context of the Administrative Procedures Act or the Regulatory Flexibility Act.

Dated: June 8, 1994.

Carol M. Browner,

Administrator.

[FR Doc. 94–14416 Filed 6–16–94; 8:45 am]

BILLING CODE 6560–50–P

[2] Section 302(e) of the Act defines the term "person" to include states.

[3] The final section 185B report was issued July 30, 1993.

[FRL–5000–5]

Transfer of Data to Contractors

AGENCY: Environmental Protection Agency.

ACTION: Notice of transfer of data and request for comments.

SUMMARY: EPA will transfer to its contractor Industrial Economics, Inc., and its subcontractors, ABT Associates, Inc., Apogee Research, Inc., Dale W. Jorgenson Associates, Kerr and Associates, Inc., National Economic Research Associates, Inc., Oak Ridge National Laboratory, Research Triangle Institute, Resources for the future, Sciences Applications International Corp. (SAIC), Sociotechnical Research Applications, Inc., Tetra Tech, Inc., Dyncorp, Inc.; and its consultants: Scott Farrow, Robert W. Hahn, Nancy H. Hammett, Brian F. Mannix, Ann Vanino, and Marcia Williams, information which has been or will be submitted to EPA under Section 3007 of the Resources Conservation and Recovery Act (RCRA). These data pertain to facility production process and waste management practices, waste characteristics and constituent concentrations, waste volumes, waste management, treatment and disposal. Some of the information may have a claim of confidentiality.

DATE: Transfer of confidential data submitted to EPA will occur no sooner than June 27, 1994.

ADDRESSES: Comments should be sent to Margaret Lee, Document Control Officer, Office of Solid Waste (5305), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460. Comments should be identified as "Transfer of Confidential Data."

FOR FURTHER INFORMATION CONTACT: Margaret Lee, Document Control Officer, Office of Solid Waste (5305), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460, 202–260–3410.

SUPPLEMENTARY INFORMATION:

1. Transfer of Data

Under EPA Contract 68–W3–0028, Industrial Economics, Inc., its subcontractors and its consultants will assist the Communications Analyses and Budget Division of the Office of Solid Waste. The contractor will conduct a wide range of quantitative policy analysis to support the RCRA program. These studies will involve development of methods and cross-programmatic scoping studies. In particular, the contractor will conduct quantitative benefit analyses. The economic impacts of the regulations will be assessed to help determine if industry sectors are significantly impacted by facility closure. Confidential information submitted under 3007 of RCRA will be used to complete the above-noted analyses. The CBI information will pertain to facility production process and waste management practices, waste characteristics and constituent concentrations, waste volumes, waste management, treatment and disposal.

In accordance with 40 CFR 2.305(h), EPA has determined that Industrial Economics, Inc., its subcontractors and its consultants, require access to CBI submitted to EPA under the authority of RCRA to perform work satisfactorily under the above-noted contract. EPA is submitting this notice to inform all submitters of CBI that EPA may transfer to this firm, on a need-to-know basis, CBI collected under the authority of RCRA. Upon completing their review of materials submitted, Industrial Economics will return all such materials to EPA.

Industrial Economics, Inc., its subcontractors and its consultants have been authorized to have access to RCRA CBI under the EPA "Contractor Requirements for the Control and Security of RCRA Confidential Business Information Security Manual." EPA will approve the security plan of the contractor and approve it prior to RCRA CBI being transmitted to the contractor. Industrial Economics, Inc., its subcontractors and its consultants will be required to sign non-disclosure agreements and be briefed on appropriate security procedures before they are permitted access to confidential information.

Dated: June 9, 1994.

Elliott P. Laws,

Assistant Administrator.

[FR Doc. 94–14814 Filed 6–16–94; 8:45 am]

BILLING CODE 6560–50–M

[ER–FRL–4712–4]

Environmental Impact Statements and Regulations; Availability of EPA Comments

Availability of EPA comments prepared May 30, 1994 Through June 3, 1994, pursuant to the Environmental Review Process (ERP), under section 309 of the Clean Air Act and section 102(2)(C) of the National Environmental Policy Act as amended. Requests for copies of EPA comments can be directed to the Office of Federal Activities At (202) 260–5076.

An explanation of the ratings assigned to draft environmental impact statements (EISs) was published in FR dated April 08, 1994 (59 FR 16807).

Draft EISs

ERP No. D–DOE–L05205–00 Rating LO, PacifiCorp Capacity Power Sale Contract for 1100 Megawatts (MW) Long-Term Contract for Peaking Capacity, Implementation, WA, OR, ID, MT, WY, UT, CO, CA, NV, AZ, NM and British Columbia.

Summary: EPA had no objections to the draft EIS.

ERP No. D–COE–E39034–KY Rating EC2, Louisville Waterfront Park/Falls Harbor Development Project, Construction, COE Section 10 and 404 Permits, Ohio River, Louisville, Jefferson County, KY.

Summary: EPA had an environmental concern regarding the uncertainty/lack of data associated with the historical contamination at the site. Additional data regarding the environmental consequences are needed.

ERP No. D–DOD–A10067–00 Rating LO, Ballistic Missile Defense (BMD) Program, Implementation, which includes the Theater Missile Defense (TMD) and National Missile Defense (NMD) Initiatives, Programmatic EIS, United States.

Summary: EPA had a lack of objections to the document.

ERP No. D–DOD–G11010–00 Rating LO, Joint Task Force (JTF)—Six Support Services Continuation Program, Implementation, Programmatic EIS, TX, NM, AZ, CA, U.S./Mexico Border and Texas Gulf Coast.

Summary: EPA had no objections to the continuation of Joint Task Force Six's program.

ERP No. D–DOE–L03007–OR Rating EC1, Hermiston Generating Project, Construction of a Gas-fired Cogeneration Power Plant, Approval of Permits, Umatilla County, OR.

Summary: EPA requested additional information be included in the final EIS concerning wetlands, air quality, and mitigation measures for transmission lines.

ERP No. D–FAA–G51027–AR Rating LO, Northwest Arkansas Regional Airport, Construction of Replacement Airport for Drake Field in Fayetteville, Funding, Land Acquisition and Airport Layout Plan, City of Fayetteville, AR.

Summary: EPA had no objections to the proposed action.

ERP No. D–SFW–G64011–LA Rating EC2, Bayou Savauge National Wildlife Refuge Master Plan, Implementation, Orleans Parish, LA.

Summary: EPA had environmental concerns with the potential adverse impacts from hazardous substances

found at the sites on and near refuge boundaries and requests further investigation in the final EIS.

ERP No. D–UAF–B11015–ME Rating EO2, Loring Air Force Base (AFB) Disposal and Reuse, Implementation, Aroostook County, ME.

Summary: EPA expressed environmental objections relating to the magnitude of potential wetland impacts up to 418 acres; and the failure to include adequate provisions for minimizing and mitigating wetland impacts. EPA requested additional clarifying information be included in the final EIS.

ERP No. D–USN–B11008–RI Rating EC2, Davisville Naval Construction Battalion Center, Base Reuse and Development Plan, Implementation, Town of North Kingstown, Washington County, RI.

Summary: EPA expressed environmental concerns with the insufficient alternatives analysis; inadequate analysis of potential air quality problems from increased traffic; lack of cumulative traffic impacts, water supply alternatives, and lack of mitigation commitments.

FINAL EISs

ERP No. F–AFS–L64042–AK Main Bay Salmon Hatchery Expansion, Implementation, Special-Use-Permit and COE Section 404 Permit, Prince William Sound, Chugach National Forest, Glacier Ranger District, AK.

Summary: Review of the Final EIS was not deemed necessary. No formal letter was sent to the preparing agency.

ERP No. F–AFS–L65181–WA East Curlew Creek Analysis Area, Harvesting Timber and Road Construction, Portion of Profanity Roadless Area, Colville National Forest, Republic Ranger District, Ferry County, WA.

Summary: EPA had no objections to the preferred alternative as described in the EIS.

ERP No. F–COE–G32052–00 West Pearl River Navigation Project, Operation and Maintenance, Portions of West Pearl River to the vicinity of Bogalusa, Implementation, Washington and St. Tammany Parishes, LA and Pearl River County, MS.

Summary: EPA believed that the assessment of potential environmental effects may have been insufficient to fully address recent water quality concerns regarding the effects of dredging in the West Pearl River.

ERP No. F–FHW–L40183–WA I–5/196th Street SW/WA–524 Interchange Project, Improvements, Funding, NPDES and COE Section 404 Permits, Snohomish County, WA.

Summary: EPA made numerous comments/recommendations on the draft EIS and, in general was pleased with the FHWA's responses. EPA believed that the EIS should have included a wetland mitigation plan.

Dated: June 14, 1994.

Marshall Cain,

Senior Legal Advisor, Office of Federal Activities.

[FR Doc. 94–14838 Filed 6–16–94; 8:45 am]

BILLING CODE 6560–50–P

[ER–FRL–4712–3]

Environmental Impact Statements; Notice of Availability

RESPONSIBLE AGENCY: Office of Federal Activities, General Information, (202) 260–5076 or (202) 260–5075.

Weekly receipt of Environmental Impact Statements Filed June 06, 1994 Through June 10, 1994 Pursuant to 40 CFR 1506.9.

EIS No. 940219, DRAFT EIS, COE, LA, West Bank of the Mississippi River Hurricane Protection Plan, Implementation, east of the Harvey Canal, New Orleans, LA, Due: August 01, 1994, Contact: Bill Wilson (504) 862–2527.

EIS No. 940220, DRAFT EIS, BLM, CT, Weir Farm National Historic Site, Implementation, General Management Plan, Possible COE Section 404 Permit, Towns of Ridgefield and Walton, Fairfield County, CT, Due: August 10, 1994, Contact: Sarah Olson (203) 834–1896.

EIS No. 940221, DRAFT EIS, EPA, TX, Eagle Pass Coal Mine, Issuing a New Source NPDES Permit and COE Section 404 Permit, Maverick County, TX, Due: August 01, 1994, Contact: Norm Thomas (214) 655–2260.

EIS No. 940222, FINAL SUPPLEMENT, AFS, MT, Lewis and Clark National Forest Noxious Weed Control Program, Updated Information, Implementation, several counties, MT, Due: July 18, 1994, Contact: Bob Casey (406) 791–7700.

EIS No. 940223, DRAFT EIS, FHW, MD, MD–140 Westminster Bypass Transportation Improvements, Hughes Shop Road to Reese Road, Funding, Carroll County, MD, Due: August 08, 1994, Contact: David Lauton (410) 962–4440.

EIS No. 940224, FINAL EIS, GSA, CA, Sacramento Federal Building—United States Courthouse, Site Selection and Construction within a portion of the Central Business District, City of Sacramento, Sacramento County, CA, Due: July 18, 1994, Contact: Albert P. Liu (415) 744–5256.

EIS No. 940225, FINAL EIS, AFS, NC, TN, Nolichucky Gore Segment, Wild and Scenic River Study, Eligibility and Suitability, National Wild and Scenic Rivers System, Nondesignation or Designation, Nolichucky River, Pisgah National Forest, Mitchell and Yancey Counties, NC and Cherokee National Forest, Unicoi County, TN, Due: July 18, 1994, Contact: David Hammond (704) 257–4253.

EIS No. 940226, DRAFT EIS, BIA, SD, Rosebud and Cheyenne River Sioux Indian Reservations, Management of Livestock Grazing and Prairie Dog Control Plan, Funding, Todd and Mellette Counties, SD, Due: August 20, 1994, Contact: Ken Parr (605) 226–7621.

EIS No. 940227, DRAFT EIS, BLM, CA, Owen Lake Soda Ash Mining Processing Project, Construction and Operation, COE Section 404, NPDES, Right-of-Way and Conditional-Use Permits, Inyo County, CA, Due: August 16, 1994, Contact: Ahmed Mohsen (619) 375–7125.

EIS No. 940228, DRAFT EIS, AFS, AK, Exxon Valdez Oil Spill Restoration Plan, Implementation, Prince William Sound, Gulf of Alaska, AK, Due: August 01, 1994, Contact: Rod Kuhn (907) 278–8012.

EIS No. 940229, FINAL SUPPLEMENT, COE, FL, Fort Pierce Harbor Navigation Improvement, Updated Information concerning Plan Modifications, Indian River, City of Fort Pierce, St. Lucie County, FL Due: July 18, 1994, Contact: Jonathan D. Moulding (904) 232–2286.

EIS No. 940230, FINAL EIS, FHW, AR, Newport/US 63/US 67 Construction, Newport to Walnut Ridge/Hoxie, Funding and COE Section 404 Permit, Jackson, Lawrence, Craighead and Poinsett Counties, AR, Due: July 18, 1994, Contact: Wendall Meyer (501) 324–6430.

EIS No. 940231, FINAL EIS, GSA, CA, Ronald Reagan Federal Building—United States Courthouse, Site Selection and Construction in the Central Business Area and Approval of Permits, City of Santa Ana, Orange County, CA, Due: July 18, 1994, Contact: Mitra Nejad (415) 744–5252.

EIS No. 940232, FINAL EIS, BLM, WY, Enron Burly Field Oil and Gas Leasing, Permit to Drill, Temporary Use Permits, COE Section 404 Permit and Right-of-Way Grants, Pinedale Resource Area, Sublette County, WY, Due: July 18, 1994, Contact: Teresa Deakins (307) 382–5350.

Amended Notices

EIS No. 940118, REVISED DRAFT EIS, FRC, NB, Kingsley Dam Project

(FERC. No. 1417) and North Platte/ Keystone Diversion Dam (FERC. No. 1835) Hydroelectric Project, Updated Information, Application for Licenses, Near the Confluence of the North/ South Platte, Keith, Lincoln, Garden, Dawson and Grasper Counties, NB, Due: July 25, 1994, Contact: J. Ronald McKitrick (202) 219–2783.

Published FR 04–08–94—Review period extended.

Dated: June 14, 1994.

Marshall Cain,

Senior Legal Advisor, Office of Federal Activities.

[FR Doc. 94–14839 Filed 6–16–94; 8:45 am]

BILLING CODE 6560–50–V

FEDERAL COMMUNICATIONS COMMISSION

Public Information Collection Requirement Submitted to Office of Management and Budget for Review

June 13, 1994.

The Federal Communications Commission has submitted the following information collection requirement to OMB for review and clearance under the Paperwork Reduction Act of 1980 (44 U.S.C. 3507).

Copies of this submission may be purchased from the Commission's copy contractor, International Transcription Service, Inc., 2100 M Street NW., suite 140, Washington, DC 20037, (202) 857–3800. For further information on this submission contact Judy Boley, Federal Communications Commission, (202) 632–0276. Persons wishing to comment on this information collection should contact Timothy Fain, Office of Management and Budget, Room 3221 NEOB, Washington, DC 20503, (202) 395–3561.

OMB Number: 3060–0481.

Title: Application for Renewal of Private Radio Station License.

Form Number: FCC Form 452–R.

Action: Extension of a currently approved collection.

Respondents: Individuals or households, state or local governments, non-profit institutions, and businesses or other for-profit (including small businesses).

Frequency of Response: On occasion reporting requirement and other: every 5 years.

Estimated Annual Burden: 2,700 responses; .166 hours average burden per response; 448 hours total annual burden.

Needs and Uses: In accordance with FCC rules, Aviation Ground and Marine Coast Radio Station licensees are required to apply for renewal for their radio station authorization every five years. FCC Form 452–R is used for that purpose. Commission personnel will use the data to determine eligibility for a renewal authorization and issue a radio station license. Data is also used by Compliance Division personnel in conjunction with field engineers for enforcement purposes.

Federal Communications Commission.

William F. Caton,

Acting Secretary.

[FR Doc. 94–14774 Filed 6–16–94; 8:45 am]

BILLING CODE 6712–01–M

Public Information Collection Requirement Submitted to Office of Management and Budget for Review

June 13, 1994.

The Federal Communications Commission has submitted the following information collection requirement to OMB for review and clearance under the Paperwork Reduction Act of 1980 (44 U.S.C. 3507).

Copies of this submission may be purchased from the Commission's copy contractor, International Transcription Service, Inc., 2100 M Street, NW., suite 140, Washington, DC 20037, (202) 857–3800. For further information on this submission contact Judy Boley, Federal Communications Commission, (202) 632–0276. Persons wishing to comment on this information collection should contact Timothy Fain, Office of Management and Budget, room 3221 NEOB, Washington, DC 20503, (202) 395–3561.

OMB Number: 3060–0068.

Title: Application for Consent to Assignment of Radio Station. Construction Authorization or License—For Stations in Services Other than Broadcast.

Form Number: FCC Form 702.

Action: Revision of a currently approved collection.

Respondents: Businesses or other for-profit (including small businesses).

FFrequency of Response: On occasion reporting requirement.

Estimated Annual Burden: 1,000 responses; 5 hours average burden per response; 5,000 hours total annual burden.

Needs and Uses: FCC Form 702 is used to request Commission approval of assignment of radio station construction authorization or license. Applicants are advised to refer to the governing rulepart before completing the form to determine whether other showings are necessary in addition to those specified in the form. Also applicants may be called upon to produce further showings in order for the Commission to make its determination. If the Commission consents to assignment, it must be completed within 45 days of date of consent and the Commission must be notified within 10 days if a part 21 facility is involved. The form has been revised to incorporate a certification required by the Commission's rules implementing the provisions of Section 5301 of the Anti-Drug Abuse Act of 1988. The data will be used by the Commission staff to determine the financial, legal and technical qualifications of the applicant.

Federal Communications Commission.

William F. Caton,

Acting Secretary.

[FR Doc. 94–14775 Filed 6–16–94; 8:45 am]

BILLING CODE 6712–01–M

[DA 94–553]

Interpretive Ruling on Broadcast Annual Employment Report

AGENCY: Federal Communications Commission.

ACTION: Interpretive Ruling; extension of deadline for filing FCC Form 395–B for 1994.

SUMMARY: This Interpretive Ruling explains how the Federal Communications Commission requires radio stations involved in time brokerage or multiple ownership circumstances to report employees on Annual Employment Reports, FCC Form 395–B. For licensees affected by the Interpretive Ruling, the Ruling extends the deadline for filing 1994 Form 395–B's. The former deadline of May 31, 1994, is extended to July 18, 1994. The FCC requires radio stations to file a Form 395–B each year listing station employees for Equal Employment Opportunity purposes. The Interpretive Ruling provides greater guidance about how employees should be reported by stations involved in a time brokerage or by multiple stations owned by the same licensee in the same market.

EFFECTIVE DATE: June 17, 1994.

SUPPLEMENTARY INFORMATION:

In the Matter of: Petition for Issuance of Interpretive Ruling Concerning FCC Form 395–B, Broadcast Annual Employment Report.

Interpretive Ruling

Issued: May 27, 1994.

Released: May 27, 1994.

By the Chief, Mass Media Bureau.

I. Introduction

1. The Mass Media Bureau has before it a petition for an interpretive ruling regarding how the employees of radio station time brokers should be reported on the FCC Form 395–B, Annual Employment Report for broadcast stations.[1] The request was filed on May 2, 1994, by the law firms of Arent, Fox, Kintner, Plotkin & Kahn; Hardy & Carey; and attorney David Tillotson (the Firms).[2] The Firms allege that there are a variety of different factual situations involving time brokerage and different ways in which employees engaged in providing brokered services could be reported. They request that the Commission issue an interpretive ruling to clarify how employees in various situations should be reported.

II. Pleadings

2. The Firms describe several specific situations and ask how reports should be filed for each. In the first example, a broker is a licensee of another station in the same market as the brokered station to which the broker provides programming services. In this case, all employees are employed by the licensee-broker, but some employees' duties relate exclusively to the broker's station, some to the brokered station, and some to both stations. The Firms then analyze the merits of various reporting methods. In the second example, a broker is not a licensee of a station in the same market as the brokered station. Moreover, the broker may or may not be a Commission licensee. Again, while all employees are employed by the broker, their duties relate variably to the broker's station (in the case of licensee-brokers), the brokered station, or both. The Firms, as before, offer their analyses of various reporting methods. Finally, in a third example, the Firms ask how shared employees should be reported where stations in the same radio service are under common ownership or control in the same market, such as occurs where a licensee owns two FM stations in the same market.

III. Discussion

3. In response to petitioners' request, this Interpretive Ruling sets forth general Commission policy on how to report employees on Form 395–B for broadcast stations involved in time brokerage arrangements. As a general matter, we believe that, consistent with the EEO Rule which measures licensee performance, employees hired in concert with time brokerages and LMAs should be reported on the Form 395–B submitted by the licensee that employs them. Thus, in the first example above, all employees hired and employed by the licensee-broker and whose duties include providing program services or other duties in support of the LMA should, as a general matter, be reported on the 395–B filed by the licensee-broker's station. This is because all such employees are either employed by, or under the control of, the licensee-broker. The licensee of the brokered station should file a Form 395–B for any employees it may retain or hire after commencement of the brokerage agreement.

4. In the second example above, whether the broker is a licensee or not, there is no cognizable brokerage agreement because the broker does not hold an interest in a station in the same market as the brokered station. See 47 CFR 73.3555(a)(2)(i). However, where the broker is a licensee, the reporting requirements are, as a general matter, no different from the first example above. The licensee of the brokered station should file a Form 395–B for any employees it may retain or hire after commencement of the brokerage agreement. Similarly, the licensee-broker should file a Form 395–B for its employees. If personnel employed by the licensee-broker perform duties for both stations, the licensee-broker should report them on its Form 395–B. If the licensee-broker employes personnel to work at the brokered station, they should also be reported on the Form 395–B for the licensee-broker's station.

5. These policies are not inconsistent with prior Commission statements in Policy Statement on Part-time Programming, 82 FCC 2d 107, 115 (1980) (Policy Statement). The Policy Statement only considered whether employees of a non-licensee time broker should be reported by licensees selling blocks of their airtime to brokers. The Commission declined to require licensees of brokered stations to report employees of a non-licensee broker as part of the EEO employment profile. Our ruling here merely indicates that, as a general matter, time brokers who are themselves licensees should report individuals under their employ, whether they work at the licensee-broker's station or a station operated by the broker under an LMA. The two rulings are, therefore, fully consistent. In addition, the Policy Statement was directed at the typical time brokerage existing in 1980, which involved the brokerage by non-licensees of short, discrete periods of broadcast time. The more common practice today is for large blocks of time or the entire programming schedule of a station to be brokered. When that practice is engaged in by a licensee-broker, we believe it generally appropriate that the licensee-broker comply with the EEO Rule and its attendant reporting obligations.

6. In accordance with the reasoning set forth in Policy Statement, if the broker is not a licensee, as in the second example above, the broker is not required to file a Form 395–B. However, we will closely watch to see that such agreements are not used to circumvent our EEO Rule and policies.

7. Turning to the third example outlined by petitioners involving the reporting of shared employees of commonly owned stations in the same radio service in the same market, current data processing technology available to the Commission does not allow for the employment profile of more than one station to be reported on the same Form 395–B except in cases involving an AM/FM combination. Therefore, if a licensee owns two FM stations or two AM stations in the same market, the licensee should file a separate report for each station, dividing employees between the stations according to their primary duties. If the duties of one or more employees involve work for both stations equally the licensee should file a Form 395–B for one station with all employees from both stations listed. It should then file a separate Form 395–B for the other station explaining that the station's employees are reported on the Form 395–B filed for the licensee's other station in the same market. We expect the licensees of multiple stations in the same market to file the Form 395–B attributing employees to the stations according to the manner in which the stations operate.

IV. Conclusion

8. Accordingly, it is ordered that this Interpretive Ruling is issued, to be

[1] Time brokerage is defined in 47 CFR 73.3555(a)(3)(iv) of the Commission's rules as "the sale by a licensee of discrete blocks of time to a 'broker' that supplies the programming to fill that time and sells the commercial spot announcements in it." A cognizable time brokerage agreement (often referred to as a "Local Marketing Agreement" or "LMA") is a time brokerage agreement between two broadcast licensees of stations whose principal community contours overlap and under which more than 15% of broadcast time per week of one station is brokered by the other station. If a brokerage agreement is entered into by (1) a licensee and a non-licensee broker or (2) between two licensees in separate markets, the agreement is not cognizable under Commission rules. See 47 CFR 73.3555(a)(2)(i).

[2] In addition, the National Association of Broadcasters filed a Statement on May 5, 1994, in support of the Firms' petition.

effective upon publication in the **Federal Register.**[3]

9. It is further ordered that the May 31, 1994, due date for the filing of 1994 Form 395–B is extended for those affected by this Interpretive Ruling until 30 days after publication of this Interpretive Ruling in the **Federal Register.** Licensees who have already filed their 1994 Form 395–B may amend them prior to that date.

Federal Communications Commission.

Roy J. Stewart,

Chief, Mass Media Bureau.

[FR Doc. 94–14771 Filed 6–16–94; 8:45 am]

BILLING CODE 6712–01–M

FCC Reestablishes Charter for Small Business Advisory Committee

AGENCY: Federal Communications Commission.

ACTION: Notice of Advisory Committee Renewal.

SUMMARY: In accordance with the GSA Final Rule on Federal Advisory Committee Management, 41 CFR §§ 101–106, the Federal Communications Commission is giving official notice of the reestablishment of the charter for the Small Business Advisory Committee. The term of the current charter is for a two-year period and expires on May 31, 1996.

DATES: May 31, 1994.

ADDRESSES: Federal Communications Commission, 1919 M Street, NW., Washington, DC 20554.

FOR ADDITIONAL INFORMATION CONTACT: John Winston, Director, Office of Small Business Activities, Federal Communications Commission, at (202) 632–1571.

SUPPLEMENTARY INFORMATION: The Small Business Advisory Committee advises the FCC on small business issues, including minority and female participation issues, with regard to reviewing existing policies, recommending changes to policies as appropriate, and promoting new telecommunications services.

Federal Communications Commission.

William F. Caton,

Secretary.

[FR Doc. 94–14706 Filed 6–16–94; 8:45 am]

BILLING CODE 6712–01–M

[3] See 5 U.S.C. Section 553(d)(2).

FCC Renews Advisory Committee to Enhance Network Reliability and Amends Charter

AGENCY: Federal Communications Commission.

ACTION: Notice of Advisory Committee Renewal.

SUMMARY: As of January 6, 1994, the Federal Communications Commission has renewed for two years the charter for an advisory committee, the "Network Reliability Council," and has also subsequently amended its charter. As amended, the charter directs the committee to provide recommendations to the Commission and to the industry on the effects of increasing interconnection and new technologies on telecommunications reliability, review the recommendations contained in the industry publication, "Network Reliability: A Report to the Nation," propose guidelines that will enhance availability of essential telecommunications services, such as E911, during network outages and collect data on whether network outages have disproportionate geographic or demographic impact.

In order to ensure a balanced membership on the Council, the Commission has carefully selected members on the basis of their technical knowledge and the significance of questions of network reliability for their organizations and for those they represent. Any new members will be chosen so that the largest possible diversity of interests, given the function to be performed, will continue to be represented.

The continuation of the advisory committee is necessary and in the public interest to prepare and evaluate recommendations to the industry and to the FCC for avoiding, and minimizing the impact of, future network outages, to monitor and encourage the implementation of its prior recommendations by the telecommunications industry, and to assess the effectiveness of the implemented recommendations on network access during outages.

DATES: May 4, 1994.

ADDRESSES: Federal Communications Commission, 1919 M Street, NW., Washington, DC 20554.

FOR ADDITIONAL INFORMATION CONTACT: Jim Keegan, Chief, Domestic Facilities Division, Common Carrier, Federal Communications Commission, at (202) 634–1867.

SUPPLEMENTARY INFORMATION:

Federal Communications Commission.

William F. Caton,

Secretary.

[FR Doc. 94–14707 Filed 6–16–94; 8:45 am]

BILLING CODE 6712–01–M

FEDERAL RESERVE SYSTEM

Firstbank of Illinois, Inc., et al.; Notice of Applications to Engage de novo in Permissible Nonbanking Activities

The companies listed in this notice have filed an application under § 225.23(a)(1) of the Board's Regulation Y (12 CFR 225.23(a)(1)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to commence or to engage *de novo*, either directly or through a subsidiary, in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than July 7, 1994.

A. Federal Reserve Bank of Chicago (James A. Bluemle, Vice President) 230 South LaSalle Street, Chicago, Illinois 60690:

1. Firstbank of Illinois, Inc., Springfield, Illinois; to engage *de novo* through its subsidiary, FFG Trust, Inc.,

Springfield, Illinois, in trust company functions pursuant to § 225.25(b)(3); and real estate and personal property appraising pursuant to § 225.25(b)(13) of the Board's Regulation Y. These activities are to be conducted in the State of Illinois.

B. Federal Reserve Bank of Minneapolis (James M. Lyon, Vice President) 250 Marquette Avenue, Minneapolis, Minnesota 55480:

1. Norwest Corporation, Minneapolis, Minnesota; to engage *de novo* through its subsidiary, Norwest Mortgage, Inc., in real estate and personal property appraising activities pursuant to § 225.25(b)(13) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, June 13, 1994.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 94-14768 Filed 6-16-94; 8:45 am]

BILLING CODE 6210-01-F

George W. Moody; Change in Bank Control Notice; Acquisition of Shares of Banks or Bank Holding Companies

The notificant listed below has applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notice is available for immediate inspection at the Federal Reserve Bank indicated. Once the notice has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for the notice or to the offices of the Board of Governors. Comments must be received not later than July 7, 1994.

A. Federal Reserve Bank of Dallas (Genie D. Short, Vice President) 2200 North Pearl Street, Dallas, Texas 75201-2272:

1. George W. Moody, White Oak, Texas; to acquire 22.74 percent of the voting shares of First White Oak Bancshares, Inc., White Oak, Texas, and thereby indirectly acquire White Oak State Bank, White Oak, Texas.

Board of Governors of the Federal Reserve System, June 13, 1994.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 94-14769 Filed 6-16-94; 8:45 am]

BILLING CODE 6210-01-F

Old National Bancorp, et al.; Formations of; Acquisitions by; and Mergers of Bank Holding Companies

The companies listed in this notice have applied for the Board's approval under section 3 of the Bank Holding Company Act (12 U.S.C. 1842) and § 225.14 of the Board's Regulation Y (12 CFR 225.14) to become a bank holding company or to acquire a bank or bank holding company. The factors that are considered in acting on the applications are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank or to the offices of the Board of Governors. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Unless otherwise noted, comments regarding each of these applications must be received not later than July 11, 1994.

A. Federal Reserve Bank of St. Louis (Randall C. Sumner, Vice President) 411 Locust Street, St. Louis, Missouri 63166:

1. Old National Bancorp, Evansville, Indiana; to merge with O.C.B. Bancorp, Paoli, Indiana, and thereby indirectly acquire Orange County Bank, Paoli, Indiana.

B. Federal Reserve Bank of Kansas City (Stephen E. McBride, Assistant Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. Commerce Bancshares, Inc., Kansas City, Missouri, and CBI Security Corporation, Kansas City, Missouri; to acquire 100 percent of the voting shares of Liberty Bancshares, Inc., Liberty, Missouri, and thereby indirectly acquire Commercial Bank of Liberty, N.A., Liberty, Missouri.

Board of Governors of the Federal Reserve System, June 13, 1994.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 94-14770 Filed 6-16-94; 8:45 am]

BILLING CODE 6210-01-F

FEDERAL TRADE COMMISSION

[Dkt. 9249]

Griffin Systems, Inc., et al.; Prohibited Trade Practices and Affirmative Corrective Actions

AGENCY: Federal Trade Commission.

ACTION: Final order.

SUMMARY: This final order prohibits the respondents from making misrepresentations about any material terms or conditions of any automobile service contract, from cancelling service contracts when they have not disclosed that they have a right to do so before selling the contract, from substantially hindering customers from performing a condition on obtaining a benefit, from denying valid claims, and from refusing to comply promptly with any term or condition of any service contract they sell. In addition, the order requires the respondents to disclose to potential buyers whether the contracts cover the full cost of repairs, whether they include a rental car allowance, and the number and total dollar value of claims that may be submitted.

DATES: Complaint issued October 8, 1991. Final order issued April 29, 1994.[1]

FOR FURTHER INFORMATION CONTACT: Lawrence Hodapp, FTC/H-238, Washington, DC 20580. (202) 326-3105.

(Sec. 6, 38 Stat. 721; 15 U.S.C. 46. Interprets or applies sec. 5, 38 Stat. 719, as amended; 15 U.S.C. 45)

Donald S. Clark,

Secretary.

[FR Doc. 94-14782 Filed 6-16-94; 8:45 am]

BILLING CODE 6750-01-M

[Dkt. C-3301]

Institut Merieux S.A.; Prohibited Trade Practices and Affirmative Corrective Actions

AGENCY: Federal Trade Commission.

ACTION: Modifying Order.

SUMMARY: This order reopens the proceeding and modifies the Commission's consent order issued on August 6, 1990, by deleting the requirement to lease to a third party the rabies vaccine business that the company acquired when it purchased Connaught BioSciences, Inc. The Commission concluded that the record

[1] Copies of the Complaint, Initial Decision, Opinion of the Commission, Final Order, and Statements of Commissioners Owen and Starek are available from the Commission's Public Reference Branch, H-130, 6th Street and Pennsylvania Avenue, NW., Washington, DC 20580.

does not show any approvable lessee despite Merieux's efforts to find one, and that retaining the lease requirement imposes significant costs on Merieux and could result in adverse impact on public health needs.

DATES: Consent Order issued August 6, 1990. Modifying Order issued April 22, 1994.[1]

FOR FURTHER INFORMATION CONTACT: Elizabeth Piotrowski, FTC/S–2115, Washington, DC 20580. (202) 326–2687.

SUPPLEMENTARY INFORMATION: In the Matter of Institut Merieux S.A. The prohibited trade practices and/or corrective actions as set forth at 55 FR 38854, are changed, in part, as indicated in the summary.

(Sec. 6, 38 Stat. 721; 15 U.S.C. 46. Interpret or apply sec. 5, 38 Stat. 719, as amended; sec. 7, 38 Stat. 731, as amended; 15 U.S.C. 45, 18)

Donald S. Clark,

Secretary.

[FR Doc. 94–14783 Filed 6–16–94; 8:45 am]

BILLING CODE 6750–01–M

[DkL C–3494]

Jockey International, Inc.; Prohibited Trade Practices, and Affirmative Corrective Actions

AGENCY: Federal Trade Commission.

ACTION: Consent Order.

SUMMARY: In settlement of alleged violations of federal law prohibiting unfair acts and practices and unfair methods of competition, this consent order requires, among other things, a Wisconsin-based manufacturer of underwear, hosiery, and sportsware to disclose the country where its clothing is made and to use the correct generic fiber name for clothing. The consent order also requires the respondent to distribute copies of the order to each of its employees, agents, licensees and other representatives who are selling or advertising any of its textile products through mail order catalogs and promotional materials.

DATES: Compliant and Order issued May 10, 1994.[1]

FOR FURTHER INFORMATION CONTACT: Robert Easton, FTC/S–4631, Washington, DC 20580. (202) 326–3029).

SUPPLEMENTARY INFORMATION: On Wednesday, February 23, 1994, there was published in the **Federal Register**, 59 FR 8643, a proposed consent agreement with analysis In the Matter of Jockey International, Inc., for the purpose of soliciting public comment. Interested parties were given sixty (60) days in which to submit comments, suggestions or objections regarding the proposed form of the order.

No comments having been received, the Commission has ordered the issuance of the complaint in the form contemplated by the agreement, made its jurisdictional findings and entered an order to cease and desist, as set forth in the proposed consent agreement, in disposition of this proceeding.

(Sec. 6, 38 Stat. 721; 15 U.S.C. 46. Interpret or apply sec. 5, 38 Stat. 719, as amended; 72 Stat. 1717; 15 U.S.C. 45, 70)

Donald S. Clark,

Secretary.

[FR Doc. 94–14781 Filed 6–16–94; 8:45 am]

BILLING CODE 6750–01–M

[1] Copies of the Modifying Order and the statements of Chairman Steiger, Commissioners Azcuenaga, Owen, and Starek are available from the Commission's Public Reference Branch, H–130, 6th & PA. Ave., NW., Washington, DC 20580.

[1] Copies of the Complaint and the Decision and Order are available from the Commission's Public Reference Branch, H–130, 6th Street & Pennsylvania Avenue, NW., Washington, DC 20580.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Notice of Meeting of the Advisory Committee on Services for Families with Infants and Toddlers

AGENCY: Administration on Children, Youth and Families, ACF, HHS.

ACTION: Notice of Meeting of the Advisory Committee on Services for Families with Infants and Toddlers.

SUMMARY: Notice is hereby given, pursuant to Public Law 92–463, that the Advisory Committee on Services for Families with Infants and Toddlers will hold a meeting on Thursday and Friday, July 7–8, 1994, from 9 a.m. to 5 p.m. The meeting will be held at the Hyatt Regency on Capitol Hill, 400 New Jersey Avenue, NW., Washington, DC 20001, in Room Columbia B.

The meeting of the Committee shall be open to the public. The proposed agenda includes the development of the formative activities for the operation of the Committee.

Records shall be kept of all Committee proceedings and shall be available for public inspection at 330 C Street, SW, room 2026, Washington, DC 20201.

If a sign language interpreter is needed, contact David Siegel at the address and telephone number below.

FOR FURTHER INFORMATION CONTACT: David Siegel, 370 L'Enfant Promenade, SW., 7th floor, Aerospace Building, Washington, DC 20047 (202) 401–9215.

Dated: June 13, 1994.

Mary Jo Bane,

Assistant Secretary for Children and Families.

[FR Doc. 94–14757 Filed 6–16–94; 8:45 am]

BILLING CODE 4184–01–M

Centers for Disease Control and Prevention

[CDC—466]

Agency for Toxic Substances and Disease Registry Announcement of Cooperative Agreement to Minority Health Professions Foundation

Summary

The Centers for Disease Control and Prevention (CDC) and Agency for Toxic Substances and Disease Registry (ATSDR) announce the availability of fiscal year (FY) 1994 funds for a sole source cooperative agreement with the Minority Health Professions Foundation (MHPF) and its member institutions to assist them in expanding and enhancing their educational and research opportunities for minorities and disadvantaged students. Approximately $1,000,000 is available in FY 1994 to fund the Minority Health Professions Foundation. It is expected that the award will begin on or about September 29, 1994, and will be made for a 12-month budget period within a project period of up to five years. Funding estimates may vary and are subject to change. Continuation awards within the project period will be made on the basis of satisfactory progress and the availability of funds.

The purpose of this cooperative agreement is to continue assisting the MHPF Institutions to: (1) increase the number of minority health professionals in public health; (2) improve the health status for minority and disadvantaged persons; (3) expand health services to underserved populations; (4) increase research in minority health; and (5) enhance both didactic curricula and practical experience for students at the member institutions and strengthen the curricula of the school. Students will be better prepared to improve the health status of minorities and disadvantaged people and be more focused as a centralized group of minority health professionals to implement the strategies for health promotion/disease prevention. Further, this will encourage public health research among investigators at all member institutions of the MHPF.

The CDC will: (1) Collaborate with MHPF and member institutions in expanding the opportunities for faculty, staff and students for field experience in

environmental and occupational health, and preventive medicine public health; (2) Collaborate with MHPF to help identify research issues that its member institutions are uniquely able to investigate related to the "Healthy People 2000" National Health Objectives; (3) Assist the MHPF with the activities of member medical, dental, pharmacy and veterinary medical schools in strengthening their research infrastructure; (4) Assist the MHPF in working with medical, dental, pharmacy, and veterinary medical schools and public health agencies in strengthening instruction in the theory and practice of disease prevention and health promotion; (5) Provide technical assistance to MHPF in developing, coordinating, and distributing, and evaluating instructional materials for preventive practices and clinical preventive services; (6) Provide technical assistance to MHPF in (i) the publication of a professional journal, (ii) the distribution of information on graduate programs in public health, and (iii) recruitment of professionals, especially those who represent minority groups; (7) Assist the MHPF in information exchange through conferences and workshops on instruction, practice, and research in environmental, medical, and public health objectives listed in "Healthy People 2000"; and (8) Collaborate with MHPF in the implementation of the program activities under this agreement.

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the priority areas of Educational and Community-Based Health Programs and Clinical Preventive Services. (For ordering a copy of "Healthy People 2000," see the section **WHERE TO OBTAIN ADDITIONAL INFORMATION.**)

Authority

This program is authorized under Section 301 (a) of the Public Health Service Act, 42 U.S.C. 241 (a) as amended and the President's Executive Order 12876 of 1993 as amended.

Smoke-Free Workplace

The Public Health Service strongly encourages all grant recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

Eligible applicant

Assistance will be provided only to the Minority Health Professions Foundation and the member schools. No other applications are solicited. The program announcement and application kit have been sent to MHPF.

MHPF is the only organization capable of administering this cooperative agreement program because through the collective effort of the member schools, it is the only organization that has:

(1) Established a comprehensive database related to teaching and other activities of all African-American medical, dental, pharmacy and veterinary schools;

(2) Developed and evaluated an inventory of essential disease prevention and health promotion skills needed by all medical and health profession students;

(3) Assessed the current education, research and disease prevention and health promotion activities for students and its member institutions;

(4) Developed a national organization whose member institutions are all predominately minority health professions institutions with excellent professional performance records.

(5) Developed an inventory of critical knowledge, skills and abilities related to instruction in medical and health professional preparation. Through the collective efforts of its member institutions, the MHPF has demonstrated: (1) the ability to work with academic institutions and official health agencies on mutual education, service, and research endeavors; and (2) the leadership necessary to attract minority health professionals into public health careers.

Executive Order 12372 Review

The application is not subject to review as governed by Executive Order 12372, entitled "Intergovernmental Review of Federal Programs."

Public Health System Reporting Requirements

This program is not subject to the Public Health System Reporting Requirements.

Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance number is 93.283.

Where To Obtain Additional Information

If you are interested in obtaining additional information regarding this project, please refer to Announcement 466 and contact Van Malone, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 320, Mailstop E–15, Atlanta, GA 30305, telephone (404) 842–6872.

A copy of "Healthy People 2000" (Full Report, Stock No. 017–001–00474–0) or "Healthy People 2000" (Summary Report, Stock No. 017–001–00473–1) referenced in the **SUMMARY** may be obtained through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325, telephone (202) 783–3238.

Dated: June 13, 1994.

Claire V. Broome,

Acting Deputy Director Centers for Disease Control and Prevention (CDC) and Acting Deputy Administrator Agency for Toxic Substances and Disease Registry (ATSDR).

[FR Doc. 94–14754 Filed 6–16–94; 8:45 am]

BILLING CODE 4163–18–P

Food and Drug Administration

[Docket No. 93N–0471]

American Cyanamid Co.; Withdrawal of Approval of NADA; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of February 18, 1994 (59 FR 8197). The document withdrew the approval of a new animal drug application (NADA) held by American Cyanamid Co. The document inadvertently omitted the language providing for the concomitant withdrawal of applications providing for the manufacture of animal feeds bearing or containing the combination of maduramicin ammonium with chlortetracycline. This document corrects that error.

EFFECTIVE DATE: February 28, 1994.

FOR FURTHER INFORMATION CONTACT: Mohammad I. Sharar, Center for Veterinary Medicine (HFV–216), Food and Drug Administration, 7500 Standish Pl., Rockville MD 20855, 301–594–0749.

In FR Doc. 94–3714, appearing on page 8197, in the **Federal Register** of Friday, February 18, 1994, the following correction is made: On page 8198, in the 1st column, after the 1st full paragraph, the following paragraph is added:

"Under the provisions of 21 CFR 514.115(e), applications providing for the manufacture of animal feeds bearing or containing the combination of

maduramicin ammonium with chlortetracycline and approved pursuant to section 512(m)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(m)(2)) are deemed withdrawn on the effective date of withdrawal of the NADA's."

Dated: April 29, 1994.

Richard H. Teske,

Acting Director, Center for Veterinary Medicine.

[FR Doc. 94–14853 Filed 6–16–94; 8:45 am]

BILLING CODE 4160–01–F

Health Resources and Services Administration

Final Minimum Percentages for "High Rate" and "Significant Increase in the Rate" for Implementation of the Statutory General Funding Preference and Final Funding Priority for Grants for Establishment of Departments of Family Medicine—Fiscal Year 1994

The Health Resources and Services Administration (HRSA) announces the final minimum percentages for "high rate" and "significant increase in the rate" for implementation of the statutory general funding preference and final funding priority for fiscal year (FY) 1994 Grants for Establishment of Departments of Family Medicine authorized under the authority of section 747(b) of the Public Health Service (PHS) Act, title VII, as amended by the Health Professions Education Extension Amendments of 1992, Public Law 102–408, dated October 13, 1992.

Purpose

Section 747(b) of the PHS Act authorizes support to schools of medicine and osteopathic medicine to meet the costs of projects to establish, maintain, or improve family medicine academic administrative units (which may be departments, divisions, or other units) to provide clinical instruction in family medicine. Funds awarded will be used to: (1) Plan and develop model educational predoctoral, faculty development and graduate medical education programs in family medicine which will meet the requirements of section 747(a), by the end of the project period of section 747(b) support; and (2) support academic and clinical activities relevant to the field of family medicine.

The program may also assist schools to strengthen the administrative base and structure that is responsible for the planning, direction, organization, coordination, and evaluation of all undergraduate and graduate family medicine activities. Funds are to complement rather than duplicate programmatic activities for actual operation of family medicine training programs under section 747(a).

Statutory General Funding Preference

As provided in section 791(a) of the PHS Act, preference will be given to any qualified applicant that—

(A) has a high rate for placing graduates in practice settings having the principal focus of serving residents of medically underserved communities; or

(B) during the 2-year period preceding the fiscal year for which an award is sought, has achieved a significant increase in the rate of placing graduates in such settings. This preference will only be applied to applications that rank above the 20th percentile that have been recommended for approval by the peer review group.

Statutory Funding Preference

Establishment and Expansion

In addition, Public Law 102–408 has amended section 747(b) to include the following statutory funding preference for this program.

Section 747(b)(2) provides that preference shall be given to any qualified applicant that agrees to expend the award for one of the following purposes:

(a) Establishing an academic administrative unit (defined as a department, division, or other unit), for programs in family medicine; or

(b) substantially expanding the programs of such a unit.

A program will meet the definition of "substantial expansion" if it has developed an acceptable plan for a 50 percent increase in a sufficient number of the following areas to qualify for 70 points. The expansion must be completed within 3 years.

	Points
(1) Required 3rd Year Clerkship	30
(2) Required Preceptorship	20
(3) Family Medicine Research	10
(4) Expansion of Faculty	10
(5) Faculty Development Program for Community Based Faculty	10
(6) Family Medicine Faculty Represented on Medical School Standing Committees of Admissions or Curriculum	10
(7) Family Medicine Faculty Represented on Dean's Executive Committee that determines Tenure	10

A proposed notice was published in the Federal Register on January 6, 1994, at 59 FR 767 for public comment. Several comments were received during the 30-day comment period from one respondent regarding the statutory funding preferences, which are established by law and the established funding priorities for which comments were not requested. The respondent also expressed concern with the proposed funding priority. The respondent suggests that we focus more on the results than activities. These comments will be given serious consideration in the development of funding priorities in future cycles.

Therefore, the final minimum percentages for "high rate" and "significant increase in the rate" and final funding priority for this program will be retained as follows:

Final Minimum Percentages for "High Rate" and "Significant Increase in the Rate"

"High rate" means that 20 percent of all graduates of the medical school in 1989 or 1990, whichever is greater, are spending at least 50 percent of their work time in clinical practice in the specified settings.

"Significant increase in the rate" means that, between academic years 1991–92 and 1992–93, the rate of placing 1989 or 1990 graduates in the specified settings has increased by at least 50 percent and that not less than 15 percent of graduates from the most recent year (1990) are working in these settings.

Final Funding Priority for FY 1994

In addition, a funding priority will be given to applicants based on their level of accomplishment in relation to the outcome *or* process measures cited below:

Outcome measures	Points	Process measures
—25% of students who graduated in 1991, 1992 and 1993 entered family practice residencies.	100	
—20% of students who graduated in 1991, 1992 and 1993 entered family practice residencies.	75	

Outcome measures	Points	Process measures
—15% of students who graduated in 1991, 1992 and 1993 entered family practice residencies.	50	—Required 3rd Yr. Clerkship * (of at least 4 weeks duration).
—12% of students who graduated in 1991, 1992 and 1993 entered family practice residencies.	35	—Required primary care preceptorship/mentorship program * in preclinical years.

* Curricular elements must be in place at the time of application or the applicant must provide satisfactory evidence (including commitments from institutional officials) that the clerkship or preceptorship will be operational by the beginning of the third year of the grant.

Applicants May Only Receive Priority Points in One of the Above Six Categories.

Additional Information

Questions regarding programmatic information should be directed to: Ms. Shelby Biedenkapp, Program Specialist, Primary Care Medical Education Branch, Division of Medicine, Bureau of Health Professions, Health Resources and Services Administration, Parklawn Building, room 9A–20, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone: (301) 443–3614 FAX: (301) 443–8890.

This program is listed at 93.984 in the Catalog of Federal Domestic Assistance. It is not subject to the provisions of Executive Order 12372, Intergovernmental Review of Federal Programs (as implemented through 45 CFR part 100).

This program is not subject to the Public Health System Reporting Requirements.

Dated: June 13,1994.

Ciro V. Sumaya,

Administrator.

[FR Doc. 94–14711 Filed 6–16–94; 8:45 am]

BILLING CODE 4160–15–P

Final Minimum Percentages for "High Rate" and "Significant Increase in the Rate" for Implementation of the General Statutory Funding Preference, Final Funding Priority and Special Consideration for Grants for Predoctoral Training in Family Medicine

The Health Resources and Services Administration (HRSA) announces the final minimum percentages for "high rate" and "significant increase in the rate" for implementation of the General Statutory Funding Preference and final funding priority and special consideration for fiscal year (FY) 1994 for Grants for Predoctoral Training in Family Medicine authorized under the authority of section 747(a), title VII of the Public Health Service (PHS) Act, as amended by the Health Professions Education Extension Amendments of 1992, Public Law 102–408, dated October 13, 1992.

Purpose

Section 747(a) of the Public Health Service Act authorizes the award of grants to assist in meeting the cost of planning, developing and operating or participating in approved predoctoral training programs in the field of family medicine. Grants may include support for the program only or support for both the program and the trainees.

General Statutory Funding Preference

As provided in section 791(a) of the PHS Act, preference will be given to any qualified applicant that—

(A) has a high rate for placing graduates in practice settings having the principal focus of serving residents of medically underserved communities; or

(B) during the 2-year period preceding the fiscal year for which an award is sought, has achieved a significant increase in the rate of placing graduates in such settings. This preference will only be applied to applications that rank above the 20th percentile of applications that have been recommended for approval by the peer review group.

A proposed notice was published in the **Federal Register** on October 5, 1993 at 58 FR 51836 for public comment. No comments were received during the 30-day comment period. Therefore, the final minimum percentages for "high rate" and "significant increase in the rate", final funding priority and special consideration for this program will be retained as follows:

Final Minimum Percentages for "High Rate" and "Significant Increase in the Rate" for Implementation of the General Statutory Funding Preference

"High rate" is defined as a minimum of 20 percent of graduates of the medical school in academic year 1988–89 or 1989–90.

"Significant increase in the rate" means that the rate of placing academic year 1989–90 graduates in the specified settings is at least 50 percent higher than the rate of placing academic year 1988–89 graduates in such settings and that not less than 15 percent of academic year 1989–90 graduates are working in these areas. Academic years 1988–89 and 1989–90 are used because they are the two most recent years that medical school graduates would have entered practice following the completion of residency training.

Final Funding Priority

In addition, a funding priority will be given to applicants based on their level of accomplishment in relation to the outcome or process measures cited below:

Outcome measures	Points	Process measures
—25% of students who graduated in 1991, 1992 and 1993 entered family practice residencies.	100	
—20% of students who graduated in 1991, 1992 and 1993 entered family practice residencies.	75	
—15% of students who graduated in 1991, 1992 and 1993 entered family practice residencies.	50	—Required 3rd year Family Medicine clerkship * (of at least 4 weeks).
—12% of students who graduated in 1991, 1992 and 1993 entered family practice residencies.	35	—Required primary care preceptorship/mentorship program * in preclinical years.
	20	—Full departmental status at time of application.

* Curricular elements must be in place at the time of application or the applicant must provide satisfactory evidence (including commitments from institutional officials) that the clerkship or preceptorship will be operational by the beginning of the third year of the grant.

Applicants may only receive priority points in one of the above seven categories.

Final Special Consideration

Special consideration will be given to the degree to which applicants demonstrate that prior year funding has increased the percentage of graduates who select Graduate Training in Family Practice.

Additional Information

If additional programmatic information is needed, please contact:

Mrs. Betty Ball, Primary Care Medical Education Branch, Division of Medicine, Bureau of Health Professions, Health Resources and Services Administration, 5600 Fishers Lane, Room 9A–20, Parklawn Building, Rockville, Maryland 20857, Telephone: (301) 443–3614, FAX: (301) 443–8890.

This program is listed at 93.896 in the Catalog of Federal Domestic Assistance. It is not subject to the provisions of Executive Order 12372, Intergovernmental Review of Federal Programs, (as implemented through 45 CFR part 100).

This program is not subject to the Public Health System Reporting Requirements.

Dated: June 13, 1994.

Ciro V. Sumaya, M.D., M.P.H.T.M.,

Administrator.

[FR Doc. 94–14712 Filed 6–16–94; 8:45 am]

BILLING CODE 4160–15–P

Indian Health Service

List of Recipients of Indian Health Scholarships Under the Indian Health Scholarship Program: Correction

AGENCY: Indian Health Service, HHS.

ACTION: Notice correction.

SUMMARY: In Federal Register Notice doc. 94–9705 beginning on page 19186 in the issue of Friday, April 22, 1994, the following corrections are made:

1. On page 19189 in the second column, the Tribe previously listed for MacGregor, Mike G. was "Unknown". This line should be changed to read MacGregor, Mike G., Portland State University, Jamestown Klallam.

2. On page 19190 in the third column, the Tribe previously listed for Wahnee, Kari Kay was "Unknown". This line should be changed to read Wahnee, Kari Kay, Central State University, Kiowa.

3. On page 19192 in the second column, the Tribe previously listed for Hunt, Erin Marie was "Non-Indian". This line should be changed to read Hunt, Erin Marie, Portland State University, Klamath.

4. Beginning on page 19187, the Tribal names have been misspelled for the following Indian Health Professions Scholarship Recipients. Corrections should read:

Adams, Michelle Dette, Pikes Peak Community College, Assinniboine & Sioux Bancroft, Trina Ann, University of Colorado, Ute Mountain

Claymore-Lahammer, Vickie M., University of South Dakota, Cheyenne River Sioux

Dubray, Kansas Lee, University of Minnesota, Duluth, Cheyenne River Sioux

Ducheneaux, Darren Chance, Lake Area Voc., Tech. Inst., Cheyenne River Sioux

Ducheneaux, Lorelei D., Cheyenne River Lakota CC, Cheyenne River Sioux

Esquiro, Jennifer G. Azure, University of Washington, Thlingit & Haida

Gesinger, Ruthie, Cheyenne River Lakota CC, Cheyenne River Sioux

Jones, Anna Marie, Mount Marty College, Lower Brule Sioux

Halfred, Franklin Darcy, Cheyenne River Lakota CC, Cheyenne River Sioux

Lefthandbull, Marvella Nancy, Medcenter One, Cheyenne River Sioux

Lesmeister, Katherine P., Cheyenne River Lakota CC, Cheyenne River Sioux

Lewis, Lance D., University of Washington, Gila River Pima-Maricopa

MacDonald, Deborah Ann, University of PA, Assiniboine & Sioux

Mack, Beatrice Marie, Glendale Community College, Gila River Pima-Maricopa

Melbourne, Linda A., Salish Kootenai College, Assiniboine & Sioux

Moran, Michelle Meredith, Mary College, Cheyenne River Sioux

Pond, Leland James, University of Montana, Assiniboine & Sioux

Sanders, Jay D., Southwestern State College, Choctaw

Simon, Ramona Patricia, University of Mary, Cheyenne River Sioux

Smiley, Bennett, Fort Lewis College, Gila River Pima-Maricopa

Smith, Margie Ida, University of Washington, Kiowa

Smith, Martin Douglas, Washington State University, Assiniboine & Sioux

Sockbeson, Dorothy A., University of Maine, Penobscot of Maine

Welch, Trudy E., University of North Dakota, Eastern Band/Cherokee of NC

Wells, Craig James, South Dakota Sch. of Mines & Tech., Cheyenne River Sioux

West, Jess, Bishop Clarkson College, Cheyenne River Sioux

West, Sophia, University of North Dakota, Cheyenne River Sioux

Westbrook, Sonja, California School of Prof. Psychology, Comanche of Oklahoma

5. Beginning on page 19191, the Tribal names have been misspelled for the following Preparatory Scholarship Recipients Funded Under Section 103. Corrections should read:

Brown-Stephens, Heather D., Oklahoma State University, Choctaw

Clark, Leroy Allen, South Dakota State University, Cheyenne River Sioux

Dolezal-Ducheneaux, Colette Ann, University of South Dakota, Cheyenne River Sioux

Doney-Sibley, Doral Lee, Northern Montana College, Assiniboine & Sioux

Garza, Daniel, University of Oklahoma, Comanche of Oklahoma

Gray, Lisa Irene, Tulsa Junior College, Chickasaw

Griggs, Roger Lee, University of Arizona, White Mountain Apache

Hall, Wynne Lee, Portland Community College, Klamath

Hanley, Nelvin, University of New Mexico, Navajo

Hayes, Robert Wayne, University of Oklahoma, Chickasaw

LaPlant, Henrietta, Caroll College, Blackfeet

Lance, Billy George, University of Science & Arts, Chickasaw

LeBeau, Michael Edward, Minot State University, Cheyenne River Sioux

Logg, Michael J., University of Texas/San Antonio, Cheyenne River Sioux

Merriman, Anna Marie, Oklahoma City Community College, Chickasaw

Pablo, Faith Stephanie, Pima Community College, Tohono O'odham

Parker, Catherine Joyce, University of Oklahoma, Comanche of Oklahoma

Preslopski, Michelle A., University of Pittsburgh, Otoe-Missouri of Oklahoma

Redelk, Michael Ray, East Central Oklahoma State University, Comanche of Oklahoma

Schindler, Dancia Viola, University of North Dakota, Turtle Mt. Chippewa

Vander Velden, Shelly Howlett, University of Montana, Salish & Kootenai

Watty, Mandel, Southwestern Community College, Eastern Band/Cherokee of NC

Williams, Gypsy Robyn, University of Nevada/Las Vegas, Walker River Paiute

Dated: June 13, 1994.

Michel R. Lincoln,

Acting Director.

[FR Doc. 94–14856 Filed 6–16–94; 8:45 am]

BILLING CODE 4160–16–M

Indian Health Service Research Program Grants Application Announcement

AGENCY: Indian Health Service, HHS.

ACTION: Notice of final funding emphases for competitive grant applications for the Indian Health Service (IHS) Research Program.

SUMMARY: The IHS announces the final funding emphases for fiscal year (FY) 1995 IHS Research Program authorized

by Section 208 of the Indian Health Care Improvement Act, as amended, 25 U.S.C. 1621g. There will be only one funding cycle during FY 1995. Grants shall be administered in accordance with applicable Office of Management and Budget (OMB) Circulars and HHS polices.

This program is described at 93.905 in the Catalog of Federal Domestic Assistance. Executive Order 12372 requiring intergovernmental review is not applicable to this program.

General Program Goals

1. To support practice and community-based research projects likely to improve the health of American Indians and Alaska Natives (AI/AN) served by the IHS. Projects that are basic science or laboratory research are not considered as conforming to the program goals, and will be returned to the applicant.

2. To develop research skills among IHS and tribal health professional. The applicant, as the direct and primary recipient of PHS funds, must perform a substantive role in carrying out project activities and not merely serve as a conduit for an award to another party, or to provide funds to another party.

3. These grants will be awarded and administered in accordance with the published program announcement in the **Federal Register** of March 18, 1994 (59 FR 12964) and the Indian Health Care Improvement Act, as amended, 25 U.S.C. 1621g.

Research Funding Emphases

Proposed funding emphases were published in the **Federal Register** of March 18, 1994 (59 FR 12964) for public comment. No comments were received during the 30-day comment period. Therefore, as proposed, the following funding emphases will be retained as listed below.

1. Studies of documented high importance to the community in which the research is to be done.

2. Studies with high relevance for the AI/AN populations. (The series "The Research Agenda for Indian Health" in *the IHS Primary Care Provider,* lists many relevant research subjects. Reprints are available from the IHS Research Program and the Area Research Offices.)

3. For studies that involve problems that are both social and medical (e.g, dysfunctional families), research on factors that enable the community or individuals to overcome the problems.

4. Competing continuations of previously-funded research projects.

Review Process

Applications meeting eligibility requirements that are complete and conform to the published program announcement in the **Federal Register** of March 18, 1994 (59 FR 12964) will be reviewed in accordance with the following process.

1. Review by authorized Institutional Review Boards (IRB). All applications involving human subjects will be reviewed by the authorized Area or National IRBs in the IHS for compliance with requirements to protect human subjects contained in 45 CFR 46, and as specified in the IHS Multiple Project Assurance (MPA). It is suggested but not required that the application be sent to the appropriate Area IRB(s) two months before the deadline, for the IRB review of the proposal to permit making the changes before the final submission. The IRB will review only IRB issues, not purely technical methods. Any applications involving investigators from institutions with IRBs with MPAs and involving human subjects must also be reviewed by the IRBs of the respective institution(s). The researcher should contact non-IHS IRBs for their deadline requirements. No research project can be funded by IHS unless it has been approved by, and has met the conditions of, all applicable IRBs.

2. Review by the Indian Health Research Study Section (IHRSS). Applications meeting eligibility requirements that are complete, responsive, and conform to this program announcement will be reviewed for merit by the IHRSS appointed by the IHS to review these applications. The IHRSS review will be conducted in accordance with the IHS objective review procedures. The technical review process ensures selection of quality research projects in a national competition for limited funding. The IHRSS will include at least 60 percent non-IHS, Federal or non-Federal, individuals, all experts in research. For each application, the IHRSS will decide to disapprove, or to defer pending more information, or to approve the project. If the IHRSS decides to approve the project, it will review the application against established criteria, and will assign a numerical score to the application. The members of the IHRSS will use the following criteria and weights to make the score.

Weights

(Criteria "a" through "f" refer to section I. Research Plan.)

4a. Specific Aims: Statement of study question(s) and objective(s).

Are the study questions stated clearly and precisely? Does the rest of the Research Plan follow logically from the study questions?

10b. Background in Research Literature. Does the background in research literature include the important existing research and knowledge relevant to the study question(s), and pilot data (if applicable)? Do the conclusions follow from the review?

4c. Progress Report (for competing continuation studies, only). What is the progress to date? Is the report timely? Does the progress report demonstrate that investigators will achieve the objective(s) of the research?

15d. Research design and methods to be used. Does the Research Plan adequately describe the research design? Is the proposed approach appropriate for the objective9s) of the research? Does the Plan adequately describe: the population to be studied; the inclusion and exclusion criteria, and how the investigators will determine inclusion and exclusion; the sampling techniques; selection of controls (if any); the definition of the independent and dependent variables (if any) and how to measure them; the interventions (if any) and how to assure that they are done in fact; and the definition of the expected outcomes or effects (if any) and how to measure them? Are these methods appropriate to achieve the objective(s) of the research? Are sample size calculations included, if needed? Is the projected sample size achievable, and sufficient to achieve the objective(s) of the research? Does the Plan adequately account for alternative explanations of expected findings? If the application's timeline, with completion dates of all major tasks, appropriate and feasible?

10e. Data sources, management, quality control, and analysis. Does the Research Plan adequately describe: the data to be collected, by whom, and at what time; the data sources, and how access to the sources will be attained; the procedures to collect, receive, code, and prepare for analysis of the data; the contents of interviews (if they are to be done), and the connection between the interview question and the variables to be studied; how the data will be made secure; how completeness of the data will be assured and low response rates dealt with; how accuracy of the data will be measured and assured; the plan for analysis; the statistical analyses to be done (if any); and the non-statistical analyses to be done (if any)? Are these plans appropriate and adequate for the research questions?

4f. Originality. Will this research likely develop *new* methods, or directly lead to *new* information, useful for research *in general*?

(Criteria "g" through "k" refer to section *J. Importance and Utility.*)

10g. Importance of the health problem(s) for the community(ies) involved. Are the health problems addressed by the research project of high importance in the community(ies) involved?

9h. Importance of the health problem(s) for all AI/AN people and the IHS Area. Are the health problems addressed by the research project of high importance in all or major segments of AI/AN people, and in the IHS Area?

4i. Setting of the study. Should the research be done only, or be done best, in an AI/AN population, and in the proposed community(ies)?

10J. Utility of the product and experience to the community(ies) and Service Units (SUs) involved. Does the research project have a high expected utility of the product (*e.g., new* information) or of the experience (*e.g., new* research skills, capabilities, resources, or liaisons to do practice-based or community-based research) to the community(ies) and/or SUs involved?

5 k. Utility of the product and experience to the IHS and other AI/AN people. Does the research project have a high expected utility of the product (*e.g., new* information) or of the experience (*e.g., new* research skills, capabilities, resources, or liaisons to do practice-based or community-based research) to the IHS, to the IHS Area, and/or to other AI/AN people?

5 1. Budget. (This criterion refers to section *G. Budget.*) Is the proposed budget sufficient to do the project? Is the proposed budget excessive? Is the proposed budget being used for the purchase of computers or other expensive equipment? If the research project is a competing continuation, are the additional years necessary? Is the cost justified by the expected benefit?

10 m. Key Personnel and Research Team. (This criterion refers to section *H. Key Personnel and Research Team.*) Does the principal investigator have the training, experience, and time necessary to do and to manage the proposed research projects? Does the research team have the capabilities to carry out and complete the project successfully?

FOR FURTHER INFORMATION CONTACT: William L. Freeman, M.D., Director, IHS Research Program or Donna Pexa, Research Program Coordinator, Office of Health Program Research and Development, 7900 South J. Stock Road, Tucson, AZ 85746–9352, (602) 295–2503.

This program is described at 93.905 in the Catalog of Federal Domestic Assistance. Executive Order 12372 requiring intergovernmental review is not applicable to this program.

Dated: June 13, 1994.

Michel E. Lincoln,

Acting Director.

[FR Doc. 94–14857 Filed 6–16–94; 8:45 am]

BILLING CODE 4160–16–M

National Institutes of Health

National Cancer Institute; Meeting of the Development Therapeutics Contracts Review Committee

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the Developmental Therapeutics Contracts Review Committee, National Cancer Institute, National Institutes of Health, on June 23, 1994, at Gaithersburg Hilton, 620 Perry Parkway, Gaithersburg, Maryland 20877.

This meeting will be open to the public from 12 p.m. to 1 p.m. on June 23 to discuss administrative details. Attendance by the public will be limited to space available.

In accordance with provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5, U.S.C. and section 10(d) of Public Law 92–463, the meeting will be closed to the public on June 23 from 1:00 p.m. to adjournment for the review, discussion, and evaluation of individual contract proposals. These proposals and the discussions could reveal confidential trade secrets or comercial property such as patentable material and personal information concerning individuals associated with the proposals, disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

The Committee Management Officer, National Cancer Institute, Executive Plaza North, room 630E, National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20892–9903, (301/496–5708), will provide a summary of the meeting and a roster of the committee members upon request.

Dr. Courtney Michael Kerwin, Scientific Review Administrator, Contracts Review Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, Executive Plaza North, room 601A, 9000 Rockville Pike, Bethesda, Maryland 20892–9903, Tel. (301) 496–7421, will furnish substantive program information.

Individuals who plan to attend and need special assistance such as sign language interpretation or other reasonable accommodations should contact Ms. Alma O. Carter on (301) 496–7523 in advance of the meeting.

This notice is being published less than 15 days prior to the meeting due to the difficulty of coordinating the attendance of members because of conflicting schedules.

(Catalog of Federal Domestic Assistance Program Numbers: 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control.)

Dated: June 10, 1994.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 94–14828 Filed 6–16–94; 8:45 am]

BILLING CODE 4140–01–M

National Cancer Institute; Meeting of the National Cancer Advisory Board, Subcommittee To Evaluate the National Cancer Program

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the National Cancer Advisory Board, Subcommittee To Evaluate the National Cancer Program, June 27, 1994 at the Skybird Meeting Center, O'Hare Airport, Chicago, Illinois.

The entire meeting will be open to the public from 9 a.m. to 5 p.m. Attendance by the public will be limited to space available. Discussions will address the Board's format, agenda items and activities of the National Cancer Advisory Board. Discussions will address the evaluation and achievements of the National Cancer Program.

Ms. Carole Frank, Committee Management Specialist, National Cancer Institute, National Institutes of Health, Executive Plaza North, room 630M, 9000 Rockville Pike, Bethesda, Maryland 20892 (301/496–5708), will provide a summary of the meeting and a roster of the Subcommittee members upon request.

Ms. Cherie Nichols, Executive Secretary, Subcommittee To Evaluate the National Cancer Program, National Cancer Advisory Board, National Cancer Institute, National Institutes of Health, Building 31, room 11A23, Bethesda, Maryland 20892 (301/496–5515), will furnish substantive program information.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Ms. Cherie Nichols on (301/496–5515) in advance of the meeting.

This notice is being published less than 15 days prior to the meeting due to the difficulty of coordinating the attendance of members because of conflicting schedules.

Dated: June 10, 1994.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 94–14829 Filed 6–16–94; 8:45 am]

BILLING CODE 4140–01–M

National Institute on Deafness and Other Communication Disorders; Meeting of the Ad Hoc Voice and Voice Disorders Subcommittee of the National Deafness and Other Communication Disorders Advisory Board

Pursuant to Public Law 92–463, notice is hereby given to the meeting of the Ad Hoc Voice and Voice Disorders Subcommittee of the National Deafness and Other Communication Disorders Advisory Board on July 8, 1994. The meeting will take place from 1 p.m. to 4 p.m. in Conference Room 7, Building 31C, National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20892, and will be conducted as a telephone conference with the use of a speaker phone.

The meeting will be open to the public from 1 p.m. to 1:15 p.m. for a discussion of Subcommittee business. Attendance by the public will be limited to the space available.

In accordance with the provisions set forth in section 552b(c)(6), title 5, U.S.C. and section 10(d) of Public Law 92–463, the meeting will be closed to the public from 1:15 p.m. until adjournment for the discussion and recommendation of individuals to serve on a scientific panel to update the voice and voice disorders section of the Research Plan. These discussions could reveal personal information concerning these individuals, disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Summaries of the Subcommittee's meeting and a roster of members may be obtained from Ms. Monica M. Davies, Executive Director, National Deafness and Other Communication Disorders Advisory Board, Building 31, room 3C08, National Institutes of Health, Bethesda, Maryland 20892, (301) 402–1129, upon request.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact the Executive Director in advance of the meeting.

(Catalog of Federal Domestic Assistance Program No. 93.173, Biological Research Related to Deafness and Communication Disorders).

Dated: June 14, 1994.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 94–14832 Filed 6–16–94; 8:45 am]

BILLING CODE 4140–01–M

Office of Inspector General

Program Exclusions: May 1994

AGENCY: Office of Inspector General, HHS.

ACTION: Notice of program exclusions.

During the month of May 1994, the HHS Office of Inspector General imposed exclusions in the cases set forth below. When an exclusion is imposed, no program payment is made to anyone for any items or services (other than an emergency item or service not provided in a hospital emergency room) furnished, ordered or prescribed by an excluded party under the Medicare, Medicaid, Maternal and Child Health Services Block Grant and Block Grants to States for Social Services programs. In addition, no program payment is made to any business or facility, e.g., a hospital, that submits bills for payment for items or services provided by an excluded party. Program beneficiaries remain free to decide for themselves whether they will continue to use the services of an excluded party even though no program payments will be made for items and services provided by that excluded party. The exclusions have national effect and also apply to all other Federal non-procurement programs.

Subject, city, state	Effective date
Program-Related Convictions	
Bishop, Timothy A., Bangor, ME	06/26/94
Gillespie, Marjorie A., Greeley, CO	05/26/94
Greenhouse, Niles F., Central Square, NY	06/06/94
Grey, Bernard, Washington, DC	06/06/94
Hornick, Richard P., Wausau, WI	05/24/94
Mahoney, Dennis M., Newport, NH	06/06/94
Mannarino, Alfred, Brooklyn, NY	06/02/94
Marshall, Peter H., Chestertown, MD	06/06/94
Massaquoi, Martha Munda, Inglewood, CA	06/05/94
Minor, Rex E., Fort Collins, CO	05/26/94
Perez, Donna M., Racine, WI	05/24/94
Stoural, Paul A., Scottsdale, AZ	05/26/94
Terrell, Darrin A., Glendale, CO	05/26/94
Thomas, Walter Lee, Fort Collins, CO	05/26/94
1st Community Health Ctr, Ltd., Chicago, IL	05/24/94
Patient Abuse/Neglect Convictions	
Bolduc, Kevin M., Gardiner, ME	06/06/94
Burcham, Robin Roberson, Tuscumbia, AL	05/24/94
Holman, Richard Scott, Apache Junction, AZ	06/05/94
Jones, David Jerome, Greenville, AL	05/24/94
Kinchloe, Alice, Mt. Vernon, AL	05/24/94
Kuriger, Carol Ann, Brush, CO	05/26/94
Morrison, Sharese I., Baltimore, MD	06/06/94
Torres, Ariel, Denver, CO	05/26/94
Williams, Norris Joe, Pine Bluff, AR	06/05/94
Conviction for Health Care Fraud	
Brookhaven Clinical Lab Inc., Old Westbury, NY	06/02/94
Butera, Diane P., Jamestown, NY	06/02/94
Cadolino, Silvio J., N. Massapequa, NY	06/02/94
Cohen, Kenneth, New York, NY	06/02/94
Edwards, Sherif F., New York, NY	06/02/94
Fass, Joel, Brooklyn, NY	06/02/94
Ferretti, Julie A., Riverside, RI	06/06/94
Geller, Herbert, North Bellmore, NY	06/02/94
Goldfarb, Steven, Jericho, NY	06/02/94
Lippman, Richard, Dix Hills, NY	06/02/94
Lobasso, Nicholas, Brooklyn, NY	06/02/94
Mahon, John, Setauket, NY	06/02/94
Paniccioli, Anthony C., Brooklyn, NY	06/02/94
Richards, Jane E., Fairfield, ME	06/06/94
Richardson, Valarie C., Nashville, NC	05/24/94
Rodman, Steven, Coram, NY	06/02/94
Rosen, Leslie, Rockaway, NY	06/02/94
Thomas, Charles W., Philadelphia, PA	06/06/94
Controlled Substance Convictions	
Fredal, Thomas H., Gross Pointe Farms, MI	05/24/94
Veal, Dennis J., Detroit, MI	05/24/94
License Revocation/ Suspension	
Boren, Kathleen S., Concord, NH	06/06/94
Fulgenzi, Karen A., Sylvan Lake, MI	05/24/94
Gomez, Fabian S., Montebello, CA	06/05/94
Grier, Barnett J.W. Jr., Huntington Beach, CA	06/05/94
Hulet, Mark Sylvester, Apple Valley, CA	06/05/94
Krinos, Demetrios, Manchester, NH	06/06/94
Mees, Leonard R., Chatham, MA	06/06/94

Subject, city, state	Effective date
Van Every, David B., Upland, CA	06/05/94
Entities Owned/Controlled by Convicted	
Family Footcare, Jackson Hgts, NY	06/02/94
Orthotic Fitters & Services, Jackson Hgts, NY	06/02/94
Default on Heal Loan	
Aitken, Steven T., Parma, OH	05/24/94
Allen, Richard L., Morristown, NJ	06/02/94
Baker, James W. III, Jacksonville, FL	05/24/94
Beckett, James E., Des Plaines, IL	05/24/94
Benton, Craig R., Lampasas, TX	06/05/94
Brightman, Brenda B., East Cleveland, OH	05/24/94
Buchalter, Keith M., Hollywood, FL	05/24/94
Carageorge, Dawn C., Tampa, FL	05/24/94
Carpenter, Richard P., Saginaw, MI	05/24/94
Ciepiela, Michael D., Tampa, FL	05/24/94
Cully, Milton A. Jr., Cary, IL	05/24/94
Dewilde, Steven B., Algonac, MI	05/24/94
Dyess, Stephen J., Deer Park, TX	06/05/94
Erwin, Herbert F., St. Louis, MO	05/24/94
Farrell, Robert J., Oceanside, CA	06/05/94
Flores, Otto O., Santa Ana, CA	06/05/94
Foster, Heyward J. III, Easley, SC	05/24/94
Gill, Joseph C., Fayetteville, GA	05/24/94
Haines, Donna J., McKinleyville, CA	06/05/94
Hall, Frederick J., Stone Mountain, GA	05/24/94
Hart, Cindy G., Lewisville, TN	06/05/94
Harvey, Robert L., Bridgeport, TN	06/05/94
Hempstead, Kenneth E., Portland, OR	06/05/94
Huntley, Norbert E., Portland, OR	06/05/94
Jackson, Douglas, Forest Park, GA	05/24/94
Kadoe, David D., Brooklyn, NY	06/02/94
Kermani, Aspen Dior, Quanah, TX	06/05/94
Keyes-Gross, Charles A., Lansing, IL	05/24/94
Lavender, Anthony G., Joliet, MT	05/26/94
Lawrence, Doris J.M., Marietta, GA	05/24/94
Leaver, Janet M., Stoughton, MA	06/06/94
Lopez, Luis E., Palm Desert, CA	06/05/94
Mack, William E. Jr., Brookfield, OH	05/24/94
McMillion, Doddjerry J., Richmond, VA	06/06/94
McSurdy, Bruce J., N. Ridgeville, OH	05/24/94
Miller, Micheal J., Hill City, KS	05/26/94
Naddat, Jamileh K., Newton, IL	05/24/94
Newton, Helen Denise, West Palm Beach, FL	05/24/94
Pellerin, Stephen P., Ahwahnee, CA	06/05/94
Scott, Thamos L., Oakland, CA	06/05/94
Sheick, Steven A., Smyrna, GA	05/24/94
Stephens, Charles N., Marietta, GA	05/24/94
Stratso, Nicholas, Pilot Point, TX	06/05/94
Stratton, Christopher L., Tucson, AZ	06/05/94
Urbanek, Michelle M., Flemington, NJ	06/02/94
Vance, Richard B., College Station, TX	06/05/94
Section 1128Aa	
Ikpe, Nsidibe, Ft. Lauderdale, FL	05/13/94
Ikpe Medical Center, P.A., Ft. Lauderdale, FL	05/13/94
Peer Review Organization Cases	
Burke, Bernard James, Little Falls, NY	05/23/94

Dated: June 3, 1994.

James F. Patton,

Director, Health Care Administrative Sanctions.

[FR Doc. 94-14802 Filed 6-16-94; 8:45 am]

BILLING CODE 4150-04-P

Public Health Service

Agency Forms Submitted to the Office of Management and Budget for Clearance

Each Friday the Public Health Service (PHS) publishes a list of information collection requests it has submitted to the Office of Management and Budget (OMB) for clearance in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). The following requests have been submitted to OMB since the list was last published on Friday, May 27, 1994.

(Call PHS Reports Clearance Officer on 202-690-7100 for copies of request).

1. Pretest of Screener/Baseline Round for the Household Component of the National Medical Expenditure Survey (NMES)—New—This request involves the pretest of the Screener/Baseline round of a household survey that will collect medical use, medical expenditures and health insurance coverage in subsequent rounds. The State-based pretest sample will be used to produce State estimates. Respondents: Individuals or households; Number of Respondents: 19,821; Number of Responses per Respondent: 1; Average Burden per Response: 0.45 hour; Estimated Annual Burden: 8,912 hours.

2. National Survey of Family Growth, Cycle V—0920-0314 (Revision)—The survey provides data on childbearing, family formation (including, adoption), and maternal and child health. The data are used by the Office of Population Affairs, the National Institute of Child Health and Human Development, the Centers for Disease Control and Prevention and other agencies, and are disseminated through written reports and public use computer tapes. Respondents: Individuals or households; Number of Respondents: 5,250; Number of Respondents: 5,250; Number of Responses per Respondent: 1.115; Average Burden per Response: 1.436 hours; Estimated Annual Burden: 8,410 hours.

3. The National Survey of Laboratory Animal Use, Facilities, and Resources—0925-0350 (New)—The availability of Laboratory animals for research is limited, and decisions regarding this scarce resource must be made on the basis of accurate, objective information. In addition, there is concern regarding the state of the infrastructure for housing and using research animals. This survey will gather information that was last available in 1978. OMB has previously granted concept approval for this survey. Respondents: State or local governments, Businesses or other for-profit, Federal agencies or employees, Non-profit institutions, Small businesses or organizations; Number of Respondents: 3,000; Number of Responses per Respondent: 1; Average Burden per Responses: 1.4 hours; Estimated Annual Burden: 4,246 hours.

4. Indian Health Service Hospital Dental and Other Contract Health Service Reports—0917-0002 (Extension, no charge)—These forms provide a description of the patient's diagnosis, procedures performed, health care services provided and fee charged to the Indian Health Service as a legal document for health car rendered. Copies of the form are used for billing purposes and the provision of the IHS program statistics. Respondents: State or local governments, Businesses or other for-profit, Non-profit institutions, and Small businesses or organizations; Number of Respondents: 8,809; Number of Responses per Respondent: 39; Average Burden per Response: 0.17 hours; Estimated Annual Burden: 60,267 hours.

5. IHS Project Proposal for the Provision of Sanitation Facilities (P.L. 86-121)/Technical Assistance—0917-0001 (Reinstatement)—Form IHS-62 solicits information from tribes regarding their needs for sanitation

facilities, their willingness and/or ability to operate and maintain the needed sanitation facilities, their ability and willingness to contribute funds/labor to the needed sanitation facilities, source of outside funding and their desire to develop ordinances/regulations dealing with public health. Respondents: Individuals or households, State or local government; Number of Respondents: 500; Number of Responses per Respondent: 1; Average Burden per Response: 1 hour; Estimated Annual Burden: 500 hours.

Written comments and recommendations concerning the proposed information collections should be sent within 30 days of this notice directly to the OMB Desk Officer designated below at the following address: Shannah Koss, Human Resources and Housing Branch, New Executive Office Building, room 3002, Washington, DC 20503.

Dated: June 14, 1993.

James Scanlon,

Director, Division of Data Policy, Office of Health Planning and Evaluation.

[FR Doc. 94–14795 Filed 6–16–94; 8:45 am]

BILLING CODE 4160–17–M

Office of Refugee Resettlement

Refugee Resettlement Program: Allocations to States of FY 1994 Funds for Refugee Social Services and for Refugees Who Are Former Political Prisoners From Vietnam

AGENCY: Office of Refugee Resettlement (ORR), ACF, HHS.

ACTION: Final notice of allocations to States of FY 1994 funds for refugee [1] social services and for refugees who are former political prisoners from Vietnam.

SUMMARY: This notice establishes the allocations to States of FY 1994 funds for social services under the Refugee Resettlement Program (RRP). In order to help meet the special needs of former political prisoners from Vietnam, the Director has added to the formula allocation $2,000,000 in funds previously set aside for social services discretionary projects. This notice eliminates the set-aside for mutual assistance associations (MAAs) as a separate component of the social service allocations.

EFFECTIVE DATE: June 17, 1994.

ADDRESSES: Office of Refugee Resettlement, Administration for Children and Families, 370 L'Enfant Promenade, SW., Washington, DC 20447.

FOR FURTHER INFORMATION CONTACT: Toyo Biddle (202) 401–9250.

SUPPLEMENTARY INFORMATION: Notice of the proposed social service allocations to States was published in the **Federal Register** on March 14, 1994 (59 FR 11794). The population estimates that were used in the proposed notice have been adjusted as a result of additional population information submitted by 7 States.

I. Allocation Amounts

The Office of Refugee Resettlement (ORR) has available $80,802,000 in FY 1994 refugee social service funds as part of the FY 1994 appropriation for the Department of Health and Human Services (Pub. L. 103–112).

Of the total of $80,802,000, the Director of ORR will make available to States $68,681,700 (85%) under the allocation formula set out in this notice. These funds would be made available for the purpose of providing social services to refugees. In addition, the Director of ORR is making available $2,000,000 from discretionary social service funds to be allocated under the formula in this notice for additional services to former political prisoners from Vietnam. ORR intends FY 1994 to be the last year in which a special set-aside will be allocated for additional services for former political prisoners from Vietnam.

A. Discretionary Social Service Funds for Vietnamese Political Prisoners

In recognition of the special vulnerability of refugees who are former political prisoners from Vietnam, the Director of ORR has set aside $2,000,000 from discretionary social service funds to be allocated under the formula set forth in this announcement, based on the number of actual political prisoner arrivals in FY 1993. This formula allocation is shown separately in Table 1 (cols. 7 and 8). States are required to use this allocation to provide additional services, as described below, to recent arrivals from Vietnam who are former political prisoners and members of their families.

Allowable services for the above-cited funds for political prisoners include the following direct services: (1) Specialized orientation and adjustment services, including peer support activities; and (2) specialized employment-related services, as needed. Adjustment services include any service listed under 45 CFR 400.155(c) of the ORR regulations. Under no circumstances may these funds be used for direct cash payments or stipends, or for the purchase of advertising space or air time.

Allowable services under this allocation for Vietnamese political prisoners are intended to supplement, not to supplant, those services provided to refugees in general under the social service formula allocation, discussed below.

ORR intends to provide technical assistance to States and organizations that request it to assure effective program development and implementation.

Because these funds are being provided specifically for services for former political prisoners from Vietnam, States which allocate social service funds to other local administrative jurisdictions, such as counties, shall do so for these funds, using a formula which reflects arrivals of this target population during FY 1993.

ORR strongly encourages States and other contracting jurisdictions, in selecting service providers for the above, to award these funds, to the extent possible, to qualified refugee mutual assistance associations with experience serving the target population. All contractors receiving these funds should have Vietnamese language capacity and Vietnamese cultural understanding.

States are required to provide to ORR program performance information on the Vietnamese political prisoner program that meets the reporting requirements contained in 45 CFR 92.40, under the terms and conditions of the social services grant awards to States. The information to be contained in the narrative portion of State quarterly performance reports must include: (1) Names of service contractors; (2) categories of activities provided; (3) numbers of persons served; and (4) outcomes, to the extent possible.

[1] In addition to persons who meet all requirements of 45 CFR 400.43, "Requirements for documentation of refugee status," eligibility for refugee social services also includes: (1) Cuban and Haitian entrants, under section 501 of the Refugee Education Assistance Act of 1980 (Pub. L. 96–422); (2) certain Amerasians from Vietnam who are admitted to the U.S. as immigrants under section 584 of the Foreign Operations, Export Financing, and Related Programs Appropriations Act, 1988, as included in the FY 1988 Continuing Resolution (Pub. L. 100–202); and (3) certain Amerasians from Vietnam, including U.S. citizens, under title II of the Foreign Operations, Export Financing, and Related Programs Appropriations Acts, 1989 (Pub. L. 100–461), 1990 (Pub. L. 101–167), and 1991 (Pub. L. 101–513). For convenience, the term "refugee" is used in this notice to encompass all such eligible persons unless the specific context indicates otherwise.

Refugees admitted to the U.S. under admissions numbers set aside for private-sector-initiative admissions are not eligible to be served under the social service program (or under other programs supported by Federal refugee funds) during their period of coverage under their sponsoring agency's agreement with the Department of State—usually two years from their date of arrival or until they obtain permanent resident alien status, whichever comes first.

B. Refugee Social Service Funds

The population figures for the social service allocation include refugees, Cuban/Haitian entrants, and Amerasians from Vietnam since these populations may be served through funds addressed in this notice. (A State must, however, have an approved State plan for the Cuban/Haitian Entrant Program in order to use funds on behalf of entrants as well as refugees.)

The Director will allocate $68,681,700 to States on the basis of each State's proportion of the national population of refugees who had been in the U.S. 3 years or less as of October 1, 1993 (including a floor amount for States which have small refugee populations).

The use of the 3-year population base in the allocation formula is required by section 412(c)(1)(B) of the Immigration and Nationality Act (INA) which states that the "funds available for a fiscal year for grants and contracts [for social services] * * *. shall be allocated among the States based on the total number of refugees (including children and adults) who arrived in the United States not more than 36 months before the beginning of such fiscal year and who are actually residing in each State (taking into account secondary migration) as of the beginning of the fiscal year."

As established in the FY 1991 social services notice published in the **Federal Register** of August 29, 1991, section I, "Allocation Amounts" (56 FR 42745), a variable floor amount for States which have small refugee populations is calculated as follows: If the application of the regular allocation formula yields less than $100,000, then—

(1) a base amount of $75,000 is provided for a State with a population of 50 or fewer refugees who have been in the U.S. 3 years or less; and

(2) For a State with more than 50 refugees who have been in the U.S. 3 years or less: (a) A floor has been calculated consisting of $50,000 plus the regular per capita allocation for refugees above 50 up to a total of $100,000 (in other words, the maximum under the floor formula is $100,000); (b) if this calculation has yielded less than $75,000, a base amount of $75,000 is provided for the State.

ORR has consistently supported floors for small States in order to provide sufficient funds to carry out a minimum service program. Given the range in numbers of refugees in the small States, we have concluded that a variable floor, as established in the FY 1991 notice, will be more reflective of needs than previous across-the-board floors.

The $12,120,300 in remaining social service funds (15% of the total funds available) will be used by ORR on a discretionary basis to provide funds for individual projects intended to contribute to the effectiveness and efficiency of the refugee resettlement program. Grant announcements on discretionary initiatives will be issued separately.

Population To Be Served

Although the allocation formula is based on the 3-year refugee population, in accordance with the requirements of 45 CFR Part 400 Subpart I—Refugee Social Services, States are not required to limit social service programs to refugees who have been in the U.S. only 3 years. In keeping with 45 CFR 400.147(a), a State must allocate an appropriate portion of its social service funds, based on population and service needs, as determined by the State, for services to newly arriving refugees who have been in the U.S. less than one year.

While 45 CFR 400.147(b) requires that in providing employability services, a State must give priority to a refugee who is receiving cash assistance, social service programs should not be limited exclusively to refugees who are cash assistance recipients. If a State intends to provide services to refugees who have been in the U.S. more than 3 years, 45 CFR 400.147(c) requires the State to specify and justify as part of its Annual Services Plan those funds that it proposes to use to provide services to those refugees.

ORR expects States to ensure that refugee social services are made available to special populations such as Amerasians and former political prisoners from Vietnam, in addition to special funding that ORR may designate to address the special needs of these populations.

ORR funds may not be used to provide services to United States citizens, since they are not covered under the authorizing legislation, with the following exceptions: (1) Under current regulations at 45 CFR 400.208, services may be provided to a U.S.-born minor child in a family in which both parents are refugees or, if only one parent is present, in which that parent is a refugee; and (2) under the FY 1989 Foreign Operations, Export Financing, and Related Programs Appropriations Act (Pub. L. 100–461), services may be provided to an Amerasian from Vietnam who is a U.S. citizen and who enters the U.S. after October 1, 1988.

Service Priorities

Refugee social service funding should be used to assist refugee families to achieve economic independence. To this end, ORR expects States to ensure that a coherent plan of services is developed for each eligible family that addresses the family's needs from time of arrival until attainment of economic independence. Each service plan should address a family's needs for both employment-related services and other needed social services.

Reflecting section 412(a)(1)(A)(iv) of the INA, the Director expects States to "insure that women have the same opportunities as men to participate in training and instruction." In addition, States are expected to make sure that services are provided in a manner that encourages the use of bilingual women on service agency staffs to ensure adequate service access by refugee women. In order to facilitate refugee self-support, the Director also expects States to implement strategies which address simultaneously the employment potential of both male and female wage earners in a family unit, particularly in the case of large families. States are expected to make every effort to assure the availability of day care services in order to allow women with children the opportunity to participate in employment services or to accept or retain employment. To accomplish this, day care may be treated as a priority employment-related service under the refugee social services program. Refugees who are participating in employment services or have accepted employment are eligible for day care services. For an employed refugee, day care funded by refugee social service dollars must be limited to one year after the refugee becomes employed. States are expected to use day care funding from other publicly funded mainstream programs as a prior resource and are expected to work with service providers to assure maximum access to other publicly funded resources for day care.

In accordance with 45 CFR 400.146, if a State's cash assistance dependency rate for refugees (as defined in § 400.146(b)) is 55% or more, funds awarded under this notice (with the exception of the political prisoner set-aside) are subject to a requirement that at least 85% of the State's award be used for employability services as set forth in § 400.154. ORR expects these funds to be used for services which directly enhance refugee employment potential, have specific employment objectives, and are designed to enable refugees to obtain jobs in less than one year as part of a plan to achieve self-sufficiency. This reflects the Congressional objective that "employable refugees should be placed on jobs as soon as possible after their arrival in the United States" and that social service funds be focused on "employment-related services, English-

as-a-second-language training (in non-work hours where possible), and case-management services" (INA, § 412(a)(1)(B)). If refugee social service funds are used for the provision of English language training, such training should be provided concurrently, rather than sequentially, with employment or with other employment-related services, to the maximum extent possible. ORR also encourages the continued provision of services after a refugee has entered a job to help the refugee retain employment or move to a better job.

Since current welfare dependency data are not available, those States that historically have had dependency rates at 55% and above are invited to submit a request for a waiver of the 85% requirement if they can provide reliable documentation that demonstrates a lower dependency rate.

ORR will consider granting a waiver of the 85% provision if a State meets one of the following conditions:

1. The State demonstrates to the satisfaction of the Director of ORR that the dependency rate of refugees who have been in the U.S. 24 months or less is below 55% in the State.

2. The State demonstrates to the satisfaction of the Director that (a) less than 85% of the State's social service allocation is sufficient to meet all employment-related needs of the State's refugees and (b) there are non-employment-related service needs which are so extreme as to justify an allowance above the basic 15%. Or

3. In accordance with section 412(c)(1)(C) of the INA, the State submits to the Director a plan (established by or in consultation with local governments) which the Director determines provides for the maximum appropriate provision of employment-related services for, and the maximum placement of, employable refugees consistent with performance standards established under section 106 of the Job Training Partnership Act.

Refugee social services should be provided in a manner that is culturally and linguistically compatible with a refugee's language and cultural background. In light of the increasingly diverse population of refugees who are resettling in this country, refugee service agencies will need to develop practical ways of providing culturally and linguistically appropriate services to a changing ethnic population. To the maximum extent possible, particularly during a refugee's initial years of resettlement, refugee social services should be provided through a refugee-specific service system rather than through a system in which refugees are only one of many client groups being served. When planning State refugee services, States are strongly encouraged to take into account the reception and placement (R & P) services provided by local resettlement agencies in order to utilize these resources in the overall program design and to ensure the provision of seamless services to refugees.

In order to provide culturally and linguistically compatible services in as cost-efficient a manner as possible in a time of limited resources, ORR encourages States and counties to promote and give special consideration to the provision of refugee social services through coalitions of refugee service organizations, such as coalitions of MAAs, voluntary resettlement agencies, or a variety of service providers. ORR believes it is essential for refugee-serving organizations to form close partnerships in the provision of services to refugees in order to be able to respond adequately to a changing refugee picture. Coalition-building and consolidation of providers is particularly important in communities with multiple service providers in order to ensure better coordination of services and maximum use of funding for services by minimizing the funds used for multiple administrative overhead costs.

States should also expect to use funds available under this notice to pay for social services which are provided to refugees who participate in alternative projects. Section 412(e)(7)(A) of the INA provides that:

> The Secretary [of HHS] shall develop and implement alternative projects for refugees who have been in the United States less than thirty-six months, under which refugees are provided interim support, medical services, support [social] services, and case management, as needed, in a manner that encourages self-sufficiency, reduces welfare dependency, and fosters greater coordination among the resettlement agencies and service providers.

This provision is generally known as the Wilson/Fish Amendment. The Department has already issued a separate notice in the **Federal Register** with respect to applications for such projects (50 FR 24583, June 11, 1985). The notice on alternative projects does not contain provisions for the allocation of additional social service funds beyond the amounts established in this notice. Therefore a State which may wish to consider carrying out such a project should take note of this in planning its use of social service funds being allocated under the present notice.

Funding to MAAs

ORR has eliminated the set-aside for refugee mutual assistance associations as a separate component under the social service notice and instead has folded these funds into the social service formula allocation to States. Elimination of the MAA set-aside, however, is not intended to represent any reduction in ORR's commitment to MAAs as important participants in refugee resettlement. ORR believes that the continued and/or increased utilization of qualified refugee mutual assistance associations in the delivery of social services helps to ensure the provision of culturally and linguistically appropriate services as well as increasing the effectiveness of the overall service system. Therefore, at a minimum, ORR expects States to continue to use MAAs as service providers at a level comparable to previous years. ORR strongly encourages States when contracting for services, including employment services, to give consideration to the special strengths of MAAs, whenever contract bidders are otherwise equally qualified, provided that the MAA has the capability to deliver services in a manner that is culturally and linguistically compatible with the background of the target population to be served. ORR also expects States to continue to assist MAAs in seeking other public and/or private funds for the provision of services to refugee clients.

ORR defines MAAs as organizations with the following qualifications:

a. The organization is legally incorporated as a nonprofit organization; and

b. Not less than 51% of the composition of the Board of Directors or governing board of the mutual assistance association is comprised of refugees or former refugees, including both refugee men and women.

State Administration

States are reminded that under current regulations at 45 CFR 400.206 and 400.207, States have the flexibility to charge the following types of administrative costs against their refugee program social service grants, if they so choose: Direct and indirect administrative costs incurred for the overall management and operation of the State refugee program, including its coordination, planning, policy and program development, oversight and monitoring, data collection and reporting, and travel. See also State Transmittal No. 88–40.

II. Discussion of Comments Received

We received 17 letters of comment in response to the notice of proposed FY 1994 allocations to States for refugee social services. The comments are summarized below and are followed in each case by the Department's response.

Comment: Fourteen commenters expressed their views regarding the proposed elimination of the MAA set-aside. Eleven commenters expressed concern over the proposed elimination of the MAA set-aside, while two commenters supported the elimination. One commenter was concerned that without the Federal requirement for a set-aside, the State would not be able to continue a State MAA set-aside in order to adhere to its general procurement requirements for contracting for social services. One commenter felt that the MAA set-aside represents the only structure through which ORR can recognize the role of MAAs in refugee resettlement. Another commenter felt that elimination of the set-aside reflected a distancing of ORR from the MAAs and did not create a level playing field for MAAs. Five commenters felt that elimination of the set-aside would represent a hardship on MAAs and would preclude MAAs from receiving any State social service funding. One commenter felt that there would be public pressure on States to award the exact amount of previous set-asides to MAAs and would create the need for a new tracking system to document the level of funding to MAAs to compare MAA funding with previous set-asides. One commenter asked for clarification on whether ORR will continue to require States to assist MAAs to seek other public and/or private funds as it has in the past.

Response: The elimination of the MAA set-aside is not intended to convey a diminution of ORR's commitment to MAAs. We continue to believe in the importance of the role of MAAs in service provision and firmly believe that the involvement of MAAs is essential to effective refugee resettlement.

ORR first instituted a set-aside for MAAs over 10 years ago as an incentive to States to work with and fund MAAs. At that time, MAAs were emerging as important organizations in the refugee resettlement field. We felt that States needed to be encouraged to begin funding these organizations as service providers. Today, the situation is quite different; we believe that MAAs are now in a position to compete effectively for refugee social services funds. Many MAAs have succeeded in becoming highly qualified and experienced service agencies and, in many States, have been able to obtain a much higher level of refugee social service funding than is available under the MAA set-aside. For this reason, we believe the MAA set-aside has served its purpose and should be discontinued at the Federal level. This in no way suggests that States should lower their commitment to using MAAs to provide services to refugees; to the contrary, we expect and encourage States to continue to use MAAs as service providers at levels comparable to previous years. In addition, MAAs may compete for funding under ORR's discretionary programs which are open to nonprofit organizations.

We inadvertently deleted the language that has appeared in previous notices requiring States to assist MAAs in seeking other public and/or private funds for the provision of services to refugee clients. We have included similar language in this notice which strongly encourages, but does not require, States to assist MAAs in seeking other public and/or private funds for the provision of services.

Comment: Two commenters requested clarification regarding ORR's expectation that States should ensure that refugee social services are provided to special populations such as Amerasians and former political prisoners from Vietnam. One commenter made the point that all refugees are special populations. Another commenter felt that while a State can ensure that services are made available to special populations, a State cannot ensure that services are provided, since it cannot ensure that refugees will access the services offered. The commenter suggested that the language in the notice be revised to acknowledge this distinction.

Response: The phrase "such as" is not intended to suggest an inclusive list of special populations, but simply to provide examples of such special populations. We agree that States can only ensure that services are made available to refugees. The language in the notice has been changed to reflect ORR's expectation that States should ensure that refugee social services are made available to special populations.

Comment: Two commenters requested clarification regarding ORR's expectation that States should ensure that a coherent plan of services is developed for each eligible family that addresses the family's needs from time of arrival until attainment of economic independence. One commenter pointed out that a plan of services can only be developed for individuals and families that access services and recommended that the language in the notice be revised to clarify this point. The commenter also questioned how the definition of an "eligible family" would apply to recent arrivals who are single. Another commenter questioned what is meant by "a coherent plan of services from time of arrival until attainment of economic independence".

Response: Our intent regarding a coherent plan of services is for such a plan to be developed for every family that applies for services or receives cash assistance. We believe that a State can ensure that this is carried out by requiring its providers to develop such plans. Refugees who are single individuals, without family, should be considered an eligible one-person family unit. "A coherent plan of services from time of arrival until attainment of economic independence" means the development of a comprehensive service plan that includes the provision of employment-related and other services needed to help a newly arrived family move to a point of economic self-support.

Comment: Three commenters commented on ORR's expectation that services should be provided in a manner that is culturally and linguistically compatible. Two of the commenters indicated that this expectation would require the provision of services through a refugee-specific system which, they felt, would be financially impractical. Both commenters felt that it would be more cost-effective to fold refugee services into the existing mainstream system. Another commenter expressed support for the provision of services through a refugee-specific system. One commenter asked for a clear definition of what "culturally and linguistically compatible" means.

Response: What ORR means by the provision of services in a manner that is culturally and linguistically compatible is that an agency providing refugee social services must employ or contract with staff who (1) speak the native language of and (2) are either from the same ethnic background as, or are culturally knowledgeable of, the refugee populations the agency serves, and must use these staff in the provision of services to refugee clients.

Regarding the cost-effectiveness of a refugee-specific service system, we believe that the investment of refugee program funds in a refugee-specific service system, particularly in the initial years after a refugee's arrival in the U.S., will prove to be more cost-effective in the long run than serving refugees through a mainstream system. The provision of services through a service provider system whose only clientele is

refugees is likely to result in more tailored and comprehensive services to refugees, resulting, we believe, in earlier employment and self-sufficiency than what would otherwise occur when refugees are served through a mainstream system. Refugees often tend to receive minimal services or are the last to be served in mainstream systems where they are one of many client groups served. We wish to emphasize, however, that there is nothing to preclude, and in fact we encourage, the use of mainstream resources to augment the services provided through a refugee-specific service system.

Comment: Two commenters had concerns regarding ORR's encouragement to States and counties to give special consideration to coalitions of refugee service organizations. One commenter expressed concern about how coalitions would be more cost-effective. The commenter also questioned how ORR envisions special consideration for coalitions in relation to the competitive procurement process. Another commenter felt that coordination should not be mandated as an end in itself. The commenter felt that if early employment is the goal, local service systems should be as uncomplicated as possible in order to get the job done efficiently. The commenter was concerned that current providers that are doing an effective job would be dismantled prematurely.

Response: We believe that the formation of coalitions among refugee service agencies ought to lead to service delivery efficiencies and to a rational downsizing of existing systems that will be necessary to keep pace with the changing nature of the refugee population to be served. We believe the formation of coalitions will enable the pooling of varied talents and skills within the agencies to more efficiently serve the changing population of refugee arrivals that will occur over the next few years. We also believe that the formation of coalitions should result in the reduction of administrative costs such as accounting and reporting costs, making coalitions more competitive. In addition, we believe the formation of coalitions will result in better coordination of services to refugees.

Encouragement of or special consideration for coalitions should not interfere with State procurement requirements. Coalitions will have to compete along with other applicants. However, States in their Requests for Proposals (RFPs) could choose to include language that encourages the formation of coalitions or could include bonus points for coalitions in the scoring criteria, as long as these actions do not violate State procurement rules.

Comment: One commenter requested clarification on whether language in the notice such as "States are strongly encouraged" and "the State should" is advisory or is a mandatory requirement.

Response: When ORR uses phrases such as "States are strongly encouraged," "States are expected to," or "the State should," the language is advisory in nature and should not be interpreted as a mandatory requirement.

Comment: Six commenters made comments regarding requirements for the use of discretionary funds for services to former political prisoners (FPP) from Vietnam. One commenter requested that ORR specify which family members are eligible for services under the FPP set-aside or allow States and counties to make that determination. The commenter also requested that ORR define what adjustment services may be provided under the FPP program and recommended that ORR use the same definition as used in 45 CFR 400.155(c) of the ORR regulations. One commenter, noting ORR's prohibition against the purchase of advertising space and air time with FPP funds, recommended that paid outreach announcements through refugee community media and Vietnamese newspapers be allowed under the FPP program.

One commenter noted that ORR requires States to allocate FPP funds using a formula that reflects recent and anticipated arrivals of former political prisoners. The commenter pointed out that there is no timely or reliable source of anticipated arrivals by State and recommended limiting the State allocation formula to recent arrivals and recommended defining the term "recent arrivals." One commenter recommended that counties which administer FPP programs be granted 10% for administrative costs and that States should be limited to no more than 2% for administrative costs.

Two commenters recommended dropping outcomes as a performance reporting requirement under the FPP program. One of the commenters questioned the increased reporting requirements when the FPP program is entering its last year of operation. Another commenter recommended accepting available individual contract data on outcomes since it would be difficult in some States with a wide range of FPP services to provide a program-wide outcomes report. One commenter supported the proposed FPP reporting requirements and did not feel the increased reporting requirements would add significantly to existing workloads. Another commenter recommended that FPP projects be supported that demonstrate accountability for outcomes such as those that occurred in the Amerasian projects. The commenter further suggested that ORR should require coordination between the agencies that provide FPP services and the voluntary agencies that resettle former political prisoners.

Response: Family members who are eligible for services under the FPP set-aside include any relative of a former political prisoner who lives in the same household with the FPP. Adjustment services are defined as those services listed under 45 CFR 400.155(c) of the ORR regulations. This definition is included in this notice. Regarding the use of FPP funds for paid outreach announcements through the refugee media, our position is unchanged on this issue; we do not feel that the purchase of advertising space and air time constitutes an effective use of FPP funds. FPP providers should work with the voluntary agencies that resettled FPP refugees to contact these refugees within the constraints of the Privacy Act.

We agree with the comment regarding the difficulty of basing a State allocation formula on anticipated arrivals and have dropped this factor from the formula. In the interest of consistency, we have changed the notice to require States to allocate FPP funds using a formula which reflects arrivals during FY 1993 to local jurisdictions, the same formula used by ORR to allocate FPP funds to States. We have no specific guidance regarding the distribution of administrative costs between county and State; this is an issue that should be resolved between the county and the State. All costs claimed against grants must be in conformity with HHS grants regulations at 45 CFR part 92 and other applicable Federal requirements.

In regard to performance requirements for the FPP program, we have not added any new reporting requirements. As in FY 1993, States are required to provide program performance information on the FPP program consistent with the reporting requirements contained in 45 CFR 92.40, under the terms and conditions of the social services grant awards to States. In addition, we have simply clarified that the information to be reported must include the four items listed in this notice. Regarding program outcomes, States may provide available outcome data from individual contracts. In regard to suggestions for additional requirements for FPP projects, we have decided not to consider additional

requirements since this is the last year of the FPP set-aside program.

Comment: Five commenters addressed the issue of ORR's use of 15% of social service funds for ORR discretionary grants. Two commenters indicated support for the 15% discretionary use, while two commenters objected it. One commenter recommended that there should be equitable distribution of discretionary funding with input and involvement of States, an expansion of selection panels, more lead time to develop proposals, and the development of meaningful evaluation criteria. Another commenter felt that the notice should describe the focus of discretionary funds for FY 1994, as has been done in previous years.

Response: We continue to believe that it is necessary to maintain a portion of social service funds for discretionary use in order to carry out national initiatives and special projects that respond to changing needs and circumstances in the refugee program. Regarding the issue of equitable distribution, discretionary funds are awarded on a competitive basis, based on the quality of applications in relation to the evaluation criteria, rather than on the basis of a population-based allocation formula. Therefore, the geographic distribution of funds awarded on the basis of merit may not be the same as a distribution by formula. Regarding more State involvement in discretionary funding, since States are frequently competitors for ORR discretionary funds, along with other applicants, it is not possible to involve States in funding decisions without creating a conflict of interest, a violation of Federal grant rules. We do not believe our selection panels need to be expanded; ORR selection panels have traditionally been broad-based, involving a varied group of experts from the resettlement field and other disciplines. We agree that sufficient lead time is necessary to develop proposals; we are committed to allowing as much lead time as the grant process timetable will bear. We also agree that the use of meaningful evaluation criteria is essential in the review of grant applications; such evaluation criteria are included in our grant announcements. We have not included a description of our discretionary focus for FY 1994 because we have been in the process of revamping our discretionary program agenda this year. FY 1994 grant announcements have recently been made available in the **Federal Register**.

Comment: Three commenters expressed support for the concurrent provision of English language training with employment and employment-related services. One commenter recommended that the provision of English language training be tied to the provision of vocational training and that the notice reflect this emphasis.

Response: We do not believe that English language training should be tied exclusively to one type of employment-related service such as vocational training. Our intent is to encourage the concurrent provision of English language training in concert with other employment-related services to speed the process of a refugee becoming employed and self-sufficient. At the same time, we want to discourage the provision of English language training in a sequential manner, as a prerequisite to receiving other employment-related services.

Comment: One commenter requested clarification regarding the meaning of "appropriate coordination" with reception and placement (R & P) agencies to ensure the provision of seamless services to refugees.

Response: Appropriate coordination means working with R & P agencies to ensure that there is a smooth transition between services provided by the R & P agencies and services provided to refugees through the State program. When planning services, a State should take into account what services are provided by R & P agencies so that there is a relationship and a continuum between R & P services and State-funded services and an absence of service gaps or service duplication.

Comment: One commenter expressed concurrence with the need for continued provision of services after employment to help a refugee retain employment or move to a better job. The commenter recommended that ORR review the list of services in 45 CFR 400.153 through 400.156 and if additional services are desired, specify them in the notice.

Response: We are reviewing the list of allowable services in 45 CFR subpart I to determine if changes should be made. Such changes would have to be made through a regulatory change, not through the notice.

Comment: Two commenters commended ORR for not restricting services to a 36-month refugee population, while one commenter expressed disappointment that ORR did not limit services to a 36-month population.

Response: As a point of clarification, a restriction of services to a time-limited population could only be effected through regulatory action.

Comment: One commenter complained that the requirement that States must specify and justify the use of funds for services to refugees who have been in the U.S. more than 3 years is a reversal from previous years when a justification was required to use social service funds for newly-arrived refugees.

Response: ORR regulations under 45 CFR 400.147 require that both the use of funds for services to newly arriving refugees (§ 400.147(a)) and the use of funds for services to refugees who have been in the U.S. more than 36 months (§ 400.147(c)) must be specified and justified as part of a State's annual services plan. This regulation has been in effect since July 1, 1989. The notice this year simply emphasized § 400.147(c) instead of § 400.147(a).

Comment: One commenter objected to the requirement that funds should be used for services designed to get refugees a job in less than one year, while one commenter supported the one-year requirement.

Response: We have responded to this comment in previous notices. Since our position remains unchanged, we refer the commenter to our response in the FY 1993 final social service notice, published in the **Federal Register** on July 28, 1993 (58 FR 40437).

Comment: One commenter recommended that the notice clarify that social service funds may be used to serve unemployed refugees who are not receiving cash assistance as long as cash assistance recipients make up a percentage of the social services caseload which is at or above the State's welfare dependency rate. The commenter indicated that the State currently interprets the ORR notice to mean that only cash assistance clients may receive services.

Response: We believe the notice is clear that social services funds may be used to serve non-cash-assistance recipients. The notice, under the section "Population to be Served," states that "social service programs should not be limited exclusively to refugees who are cash assistance recipients." However, as the wording indicates, this is not a mandatory requirement. States are not required to ensure that cash assistance recipients make up a percentage of the social services caseload that is not less than the State's welfare dependency rate. States, however, are required to give priority to a refugee who is receiving cash assistance.

Comment: One commenter objected to the use of a floor amount for small States.

Response: We have responded to this comment in previous notices. Since our

position has not changed on this issue, we refer the commenter to our response in the FY 1993 final social service notice, published in the **Federal Register** on July 28, 1993 (58 FR 40437).

Comment: Two commenters objected to unlimited State administrative costs for social services. One commenter recommended capping administrative costs at 5% for any State receiving more than $12 million in social service funds and recommended that counties be allowed a maximum of 20% for administrative costs.

Response: Since the statute does not specify a limitation on the amount of social service funds that can be used for administrative costs, we have not imposed a limit on States, choosing instead to allow States to make that determination. In regard to the percentage of funds that counties may use for administrative costs, this is an issue that needs to be resolved between county and State, not ORR. As noted earlier, all costs must meet Federal grant requirements.

Comment: One commenter suggested that ORR consider safeguards to ensure that primary emphasis is placed on serving new arrivals, with services beyond the initial period being the exception and only allowable if a State has been successful in meeting the needs of new arrivals.

Response: Such a requirement could be put into effect only through regulatory action. We are giving this issue consideration.

Comment: One commenter felt that it is unwise to rely heavily on the presence of bilingual female staff as the key factor in improving services to refugee women. The commenter felt that the relevance of service matters much more.

Response: The issue is access to services, not just relevance of service. We believe that access to services and communication between client and provider improve significantly for refugee women when there are bilingual women on staff to provide services to these clients.

III. Allocation Formula

Of the funds available for FY 1994 for social services, $58,681,700 is allocated to States in accordance with the formula specified below. A State's allowable allocation is calculated as follows:

1. The total amount of funds determined by the Director to be available for this purpose; divided by—

2. The total number of refugees and Cuban/Haitian entrants who arrived in the United States not more than 3 years prior to the beginning of the fiscal year for which the funds are appropriated and the number of Amerasians from Vietnam eligible for refugee social services, as shown by the ORR Refugee Data System. The resulting per capita amount will be multiplied by—

3. The number of persons in item 2, above, in the State as of October 1, 1993, adjusted for estimated secondary migration.

The calculation above yields the formula allocation for each State. Minimum allocations for small States are taken into account.

Allocations for political prisoners are based on FY 1993 arrival numbers for this group in each State from the Refugee Data Center and are limited to States with 170 or more political prisoner arrivals. We have limited the population base to FY 1993 political prisoner arrival numbers because these funds are intended to serve recent arrivals. We have not included States with fewer than 170 former political prisoners in the political prisoner allocations formula because the resulting level of funding would be insignificant. In these States, we believe the small number of political prisoners could be adequately served under the State's refugee social services program.

IV. Basis of Population Estimates

The population estimates for the allocation of funds in FY 1994 are based on data on refugee arrivals from the ORR Refugee Data System, adjusted as of October 1, 1993, for estimated secondary migration. The data base includes refugees of all nationalities, Amerasians from Vietnam, and Cuban and Haitian entrants.

For fiscal year 1994, ORR's formula allocations for the States for social services are based on the numbers of refugees and Amerasians who arrived, and on the numbers of entrants who arrived or were resettled, during the preceding three fiscal years: 1991, 1992, and 1993, based on final arrival data by State. Therefore, estimates have been developed of the numbers of refugees and entrants with arrival or resettlement dates between October 1, 1990, and September 30, 1993, who are thought to be living in each State as of October 1, 1993. Refugees admitted under the Federal Government's private-sector initiative are not included, since their assistance and services are to be provided by the private sponsoring organizations under an agreement with the Department of State.

The estimates of secondary migration were based on data submitted by all participating States on Form ORR–11. The total migration reported by each State was summed, yielding in- and out-migration figures and a net migration figure for each State. The net migration figure was applied to the State's total arrival figure, resulting in a revised population estimate. Because the reporting period covered on Form ORR–11 was a maximum of only 8 months as of June 1993 for the majority of States whose reporting base was their cash/medical assistance caseload, extra weight was given to the secondary migration reported by those States to arrive at estimates of secondary migration over a 36-month period. In 1993, no count of recently-arrived refugee children was available from the Department of Education for use as a comparison.

Estimates were developed separately for refugees and entrants and then combined into a total estimated 3-year refugee/entrant population for each State. Eligible Amerasians are included in the refugee figures.

Table 1, below, shows the estimated 3-year populations, as of October 1, 1993, of refugees (col. 1), entrants (col. 2), and total refugees and entrants (col. 3); the formula amounts which the population estimates yield (col. 4); and the allocation amounts after allowing for the minimum amounts (col. 5). Table 1 also shows the number of former political prisoner arrivals in FY 1993 (col. 6); and the allocation amounts for services to this population (col. 7).

V. Allocation Amounts

Funding subsequent to the publication of this notice will be contingent upon the submittal and approval of a State annual services plan, as required by 45 CFR 400.11(b)(2). The following amounts are allocated for refugee social services in FY 1994:

TABLE 1.—ESTIMATED 3-YEAR REFUGEE/ENTRANT POPULATIONS OF STATES PARTICIPATING IN THE REFUGEE PROGRAM AND SOCIAL SERVICE FORMULA AMOUNTS AND ALLOCATIONS FOR FY 1994; AND FORMER POLITICAL PRISONER ARRIVALS AND ALLOCATIONS FOR FY 1994

State	Refugees (1)	Entrants (2)	Total population (3)	Formula amount (4)	Allocation (5)	Former political prisoner arrivals from Vietnam in FY 1993 (6)	Former political prisoner allocation (7)
Alabama	894	19	913	$163,826	$163,826	39	$0
Alaska[a]	134	0	134	24,045	75,000	14	0
Arizona	4,023	40	4,063	729,053	729,053	183	16,029
Arkansas	296	0	296	53,113	94,142	64	0
California[b]	96,019	499	96,518	17,318,904	17,318,904	10,279	900,324
Colorado	3,915	2	3,917	702,855	702,855	230	20,145
Connecticut	3,401	75	3,476	623,723	623,723	130	0
Delaware	112	12	124	22,250	75,000	6	0
District of Columbia	2,760	18	2,778	498,476	498,476	181	15,854
Florida	12,898	15,989	28,887	5,183,398	5,183,398	546	47,823
Georgia	8,811	51	8,862	1,590,171	1,590,171	1,294	113,340
Hawaii	982	0	982	176,207	176,207	119	0
Idaho	925	4	929	166,697	166,697	111	0
Illinois	13,511	102	13,613	2,442,676	2,442,676	358	31,357
Indiana	1,160	6	1,166	209,224	209,224	73	0
Iowa	3,139	2	3,141	563,612	563,612	250	21,897
Kansas	2,201	3	2,204	395,479	395,479	282	24,700
Kentucky	1,911	16	1,927	345,775	345,775	159	0
Louisiana	2,503	58	2,561	459,538	459,538	306	26,802
Maine	627	0	627	112,507	112,507	4	0
Maryland	7,501	174	7,675	1,377,179	1,377,179	342	29,955
Massachusetts	10,973	294	11,267	2,021,717	2,021,717	601	52,641
Michigan	7,212	38	7,250	1,300,919	1,300,919	241	21,109
Minnesota	7,458	0	7,458	1,338,241	1,338,241	421	36,875
Mississippi	176	0	176	31,581	75,000	19	0
Missouri	5,052	26	5,078	911,181	911,181	330	28,904
Montana	345	0	345	61,906	100,000	0	0
Nebraska	2,242	0	2,242	402,298	402,298	215	18,832
Nevada	828	168	996	178,719	178,719	38	0
New Hampshire	571	0	571	102,459	102,459	88	0
New Jersey	7,558	496	8,054	1,445,186	1,445,186	262	22,948
New Mexico	1,086	164	1,250	224,296	224,296	39	0
New York	65,250	760	66,010	11,844,639	11,844,639	527	46,159
North Carolina	3,543	22	3,565	639,693	639,693	177	15,503
North Dakota	1,024	0	1,024	183,744	183,744	48	0
Ohio	6,042	39	6,081	1,091,157	1,091,157	164	0
Oklahoma	1,629	1	1,630	292,482	292,482	288	25,226
Oregon	5,913	58	5,971	1,071,419	1,071,419	373	32,671
Pennsylvania	11,048	86	11,134	1,997,852	1,997,852	353	30,919
Rhode Island	1,066	11	1,077	193,254	193,254	3	0
South Carolina	450	2	452	81,106	100,000	79	0
South Dakota	1,223	0	1,223	219,451	219,451	0	0
Tennessee	3,294	32	3,326	596,808	596,808	196	17,167
Texas	16,672	178	16,850	3,023,514	3,023,514	2,272	199,001
Utah	1,758	0	1,758	315,450	315,450	135	0
Vermont	714	0	714	128,118	128,118	16	0
Virginia	6,195	22	6,217	1,115,560	1,115,560	805	70,509
Washington	19,170	1	19,171	3,439,987	3,439,987	1,522	133,310
West Virginia	85	0	85	15,252	75,000	0	0
Wisconsin	4,876	1	4,877	875,114	875,114	22	0
Wyoming	0	0	0	0	75,000	0	0
Total	361,176	19,469	380,645	68,301,811	68,681,700	24,204	2,000,000

[a] The Alaska allocation has been awarded for a Wilson/Fish demonstration project.
[b] A portion of the California allocation is expected to be awarded to continue a Wilson/Fish project in San Diego.

VI. Paperwork Reduction Act

This notice does not create any reporting or recordkeeping requirements requiring OMB clearance.

(Catalog of Federal Domestic Assistance No. 93.566 Refugee Assistance—State Administered Programs)

Dated: June 6, 1994.

Lavinia Limon,

Director, Office of Refugee Resettlement.

[FR Doc. 94–14758 Filed 6–16–94; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Community Planning and Development

[Docket No. N–94–1917; FR–3350–N–88]

Federal Property Suitable as Facilities To Assist the Homeless; Notice

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for possible use to assist the homeless.

ADDRESSES: For further information, contact Barbara Richards, room 7262, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC 20410; telephone (202) 708–4300; TDD number for the hearing- and speech-impaired (202) 708–2565 (these telephone numbers are not toll-free), or call the toll-free Title V information line at 1–800–927–7588.

SUPPLEMENTARY INFORMATION: In accordance with 56 FR 23789 (May 24, 1991) and section 501 of the Stewart B. McKinney Homeless Assistance Act (42 U.S.C. 11411), as amended, HUD is publishing this Notice to identify Federal buildings and other real property that HUD has reviewed for suitability for use to assist the homeless. The properties were reviewed using information provided to HUD by Federal landholding agencies regarding unutilized and underutilized buildings and real property controlled by such agencies or by GSA regarding its inventory of excess or surplus Federal property. This Notice is also published in order to comply with the December 12, 1988 Court Order in National Coalition for the Homeless v. Veterans Administration, No. 88–2503–OG (D.D.C.).

Properties reviewed are listed in this Notice according to the following categories: Suitable/available, suitable/unavailable, suitable/to be excess, and unsuitable. The properties listed in the three suitable categories have been reviewed by the landholding agencies, and each agency has transmitted to HUD: (1) Its intention to make the property available for use to assist the homeless, (2) its intention to declare the property excess to the agency's needs, or (3) a statement of the reasons that the property cannot be declared excess or made available for use as facilities to assist the homeless.

Properties listed as suitable/available will be available exclusively for homeless use for a period of 60 days from the date of this Notice. Homeless assistance providers interested in any such property should send a written expression of interest to HHS, addressed to Judy Breitman, Division of Health Facilities Planning, U.S. Public Health Service, HHS, room 17A–10, 5600 Fishers Lane, Rockville, MD 20857; (301) 443–2265. (This is not a toll-free number.) HHS will mail to the interested provider an application packet, which will include instructions for completing the application. In order to maximize the opportunity to utilize a suitable property, providers should submit their written expressions of interest as soon as possible. For complete details concerning the processing of applications, the reader is encouraged to refer to the interim rule governing this program, 56 FR 23789 (May 24, 1991).

For properties listed as suitable/to be excess, that property may, if subsequently accepted as excess by GSA, be made available for use by the homeless in accordance with applicable law, subject to screening for other Federal use. At the appropriate time, HUD will publish the property in a Notice showing it as either suitable/available or suitable/unavailable.

For properties listed as suitable/unavailable, the landholding agency has decided that the property cannot be declared excess or made available for use to assist the homeless, and the property will not be available.

Properties listed as unsuitable will not be made available for any other purpose for 20 days from the date of this Notice. Homeless assistance providers interested in a review by HUD of the determination of unsuitability should call the toll free information line at 1–800–927–7588 for detailed instructions or write a letter to Barbara Richards at the address listed at the beginning of this Notice. Included in the request for review should be the property address (including zip code), the date of publication in the **Federal Register**, the landholding agency, and the property number.

For more information regarding particular properties identified in this Notice (*i.e.*, acreage, floor plan, existing sanitary facilities, exact street address), providers should contact the appropriate landholding agencies at the following addresses: Dept. of Transportation: Ronald D. Keefer, Director, Administrative Services & Property Management, DOT, 400 Seventh St. SW., room 10319, Washington, DC 20590; (202) 366–4246; U.S.Army: Elaine Sims, CECPW–FP, U.S. Army Center for Public Works, 7701 Telegraph Road, Alexandria, VA 22310–3862; (703) 355–3475; (These are not toll-free numbers).

Dated: June 10, 1994.

Jacquie M. Lawing,

Deputy Assistant Secretary for Economic Development.

Title V, Federal Surplus Property Program, Federal Register Report for 06/17/94

Suitable/To Be Excessed

Buildings (by State)

Massachusetts

Nauset Beach Light
Nauset Beach Co: Barnstable MA
Landholding Agency: DOT
Property Number: 879420001
Status: Unutilized
Comment: 48 foot tower, cylindrical cast iron, most recent use—aid to navigation

Plymouth Light Co: Plymouth MA
Landholding Agency: DOT
Property Number: 879420003
Status: Unutilized
Comment: 250 sq. ft. tower, and 2096 sq. ft. dwelling, wood frame, most recent use—aid to navigation/housing

New York

Point AuRoche Light Co: Clinton NY
Landholding Agency: DOT
Property Number: 879420002
Status: Unutilized
Comment: 471 sq. ft. tower, cut stone frame, most recent use—aid to navigation, needs rehab

Unsuitable Properties

Buildings (by State)

Louisiana

Bldg. P–2500
Louisiana Army Ammunition Plant
Doyline Co: Webster LA 71023–
Landholding Agency: Army
Property Number: 219420330
Status: Unutilized
Reason: Secured Area, Extensive deterioration

Bldg. P–2501
Louisiana Army Ammunition Plant
Doyline Co: Webster LA 71023–
Landholding Agency: Army
Property Number: 219420331
Status: Unutilized
Reason: Secured Area, Extensive deterioration

Bldg. X–5033
Louisiana Army Ammunition Plant
Doyline Co: Webster LA 71023–
Landholding Agency: Army
Property Number: 219420332
Status: Unutilized
Reason: Within 2000 ft. of flammable or explosive material, Secured Area, Extensive deterioration

Maryland

Bldg. T–322
Fort George G. Meade
Ft. Meade Co: Anne Arundel MD 21114–

Landholding Agency: Army
Property Number: 219420333
Status: Unutilized
Reason: Extensive deterioration

Bldg. 1974
Fort George G. Meade
Ft. Meade Co: Anne Arundel MD 21114–
Landholding Agency: Army
Property Number: 219420334
Status: Unutilized
Reason: Extensive deterioration

New Jersey

Bldg. 2099, Fort Monmouth
Ft. Monmouth Co: Monmouth NJ 07703–
Landholding Agency: Army
Property Number: 219420335
Status: Unutilized
Comment: Extensive deterioration

Bldg. 130
Military Ocean Terminal
Bayonne Co: Hudson NJ 07002–
Landholding Agency: Army
Property Number: 219420343
Status: Unutilized
Reason: Extensive deterioration

Pennsylvania

Bldg. P640
Carlisle Barracks
Carlisle Co: Cumberland PA 17013–5002
Landholding Agency: Army
Property Number: 219420344
Status: Unutilized
Reason: Extensive deterioration

Bldgs. T–5–1, T–20, W–34–1
Letterkenny Army Depot
Chambersburg Co: Franklin Pa 17201–
Landholding Agency: Army
Property Number: 219420399
Status: Unutilized
Reason: Secured Area, Extensive deterioration

Bldgs. T–37–3, T–43–1, T–51–2
Letterkenny Army Depot
Chambersburg Co: Franklin PA 17201–
Landholding Agency: Army
Property Number: 219420400
Status: Unutilized
Reason: Secured Area, Extensive deterioration

Bldgs. T–56–2, T–229, T–514
Letterkenny Army Depot
Chambersburg Co: Franklin PA 17201–
Landholding Agency: Army
Property Number: 219420401
Status: Unutilized
Reason: Secured Area, Extensive deterioration

Bldgs. T–228, 295, 617
Letterkenny Army Depot
Chambersburg Co: Franklin PA 17201–
Landholding Agency: Army
Property Number: 219420402
Status: Unutilized
Reason: Secured Area, Extensive deterioration

Bldgs. T–611, T–635, T–661
Letterkenny Army Depot
Chambersburg Co: Franklin PA 17201–
Landholding Agency: Army
Property Number: 219420403
Status: Unutilized
Reason: Secured Area, Extensive deterioration

Bldgs. T–662, T–692, T–1478
Letterkenny Army Depot
Chambersburg Co: Franklin PA 17201–
Landholding Agency: Army
Property Number: 219420404
Status: Unutilized
Reason: Secured Area, Extensive deterioration

Bldgs. T–1452, T–1501, T–1502
Letterkenny Army Depot
Chambersburg Co: Franklin PA 17201–
Landholding Agency: Army
Property Number: 219420405
Status: Unutilized
Reason: Secured Area, Extensive deterioration

Bldgs. T–1503, T–1504, T–1505
Letterkenny Army Depot
Chambersburg Co: Franklin PA 17201–
Landholding Agency: Army
Property Number: 219420406
Status: Unutilized
Reason: Secured Area, Extensive deterioration

Bldgs. T–1506, T–1509, T–1510
Letterkenny Army Depot
Chambersburg Co: Franklin PA 17201–
Landholding Agency: Army
Property Number: 219420407
Status: Unutilized
Reason: Secured Area, Extensive deterioration

Bldgs. T–1511, T–1512, T–1514
Letterkenny Army Depot
Chambersburg Co: Franklin PA 17201–
Landholding Agency: Army
Property Number: 219420408
Status: Unutilized
Reason: Secured Area, Extensive deterioration

Bldgs. T–1515, T–1516, T–1517
Letterkenny Army Depot
Chambersburg Co: Franklin PA 17201–
Landholding Agency: Army
Property Number: 219420409
Status: Unutilized
Reason: Secured Area, Extensive deterioration

Bldgs. T–1518, T–1519, T–1521
Letterkenny Army Depot
Chambersburg Co: Franklin PA 17201–
Landholding Agency: Army
Property Number: 219420410
Status: Unutilized
Reason: Secured Area, Extensive deterioration

Bldgs. T–1522, T–1523, T–1529
Letterkenny Army Depot
Chambersburg Co: Franklin PA 17201–
Landholding Agency: Army
Property Number: 219420411
Status: Unutilized
Reason: Secured Area, Extensive deterioration

Bldgs. T–1530, T–1531, T–1532
Letterkenny Army Depot
Chambersburg Co: Franklin PA 17201–
Landholding Agency: Army
Property Number: 219420412
Status: Unutilized
Reason: Secured Area, Extensive deterioration

Bldgs. T–1533, T–1534, T–1535
Letterkenny Army Depot
Chambersburg Co: Franklin PA 17201–
Landholding Agency: Army
Property Number: 219420413
Status: Unutilized
Reason: Secured Area, Extensive deterioration

Bldgs. T–1537, T–1538, T–1539
Letterkenny Army Depot
Chambersburg Co: Franklin PA 17201–
Landholding Agency: Army
Property Number: 219420414
Status: Unutilized
Reason: Secured Area, Extensive deterioration

Bldgs. T–1540, T–1542, T–1543
Letterkenny Army Depot
Chambersburg Co: Franklin PA 17201–
Landholding Agency: Army
Property Number: 219420415
Status: Unutilized
Reason: Secured Area, Extensive deterioration

Bldgs. T–1545, T–1546, T–1558
Letterkenny Army Depot
Chambersburg Co: Franklin PA 17201–
Landholding Agency: Army
Property Number: 219420416
Status: Unutilized
Reason: Secured Area, Extensive deterioration

Bldgs. T–1559, T–1560, T–1561
Letterkenny Army Depot
Chambersburg Co: Franklin PA 17201–
Landholding Agency: Army
Property Number: 219420417
Status: Unutilized
Reason: Secured Area, Extensive deterioration

Bldgs. T–1562, T–2281, T–2325
Letterkenny Army Depot
Chambersburg Co: Franklin PA 17201–
Landholding Agency: Army
Property Number: 219420418
Status: Unutilized
Reason: Secured Area, Extensive deterioration

Bldgs. T–2361, T–2362, S–2376
Letterkenny Army Depot
Chambersburg Co: Franklin PA 17201–
Landholding Agency: Army
Property Number: 219420419
Status: Unutilized
Reason: Secured Area, Extensive deterioration

Bldgs. 2382, S–2386, 2762
Letterkenny Army Depot
Chambersburg Co: Franklin PA 17201–
Landholding Agency: Army
Property Number: 219420420
Status: Unutilized
Reason: Secured Area, Extensive deterioration

Bldgs. T–2764, 3223, 3235
Letterkenny Army Depot
Chambersburg Co: Franklin PA 17201–
Landholding Agency: Army
Property Number: 219420421
Status: Unutilized
Reason: Secured Area, Extensive deterioration

Bldgs. T–3242, T–3401, T–3402
Letterkenny Army Depot
Chambersburg Co: Franklin PA 17201–
Landholding Agency: Army

Property Number: 219420422
Status: Unutilized
Reason: Secured Area, Extensive deterioration

Bldgs. T–3403, T–3407, T–3409
Letterkenny Army Depot
Chambersburg Co: Franklin PA 17201–
Landholding Agency: Army
Property Number: 219420423
Status: Unutilized
Reason: Secured Area, Extensive deterioration

Bldgs. T–3410, T–3412, T–3414
Letterkenny Army Depot
Chambersburg Co: Franklin PA 17201–
Landholding Agency: Army
Property Number: 219420424
Status: Unutilized
Reason: Secured Area, Extensive deterioration

Bldgs. T–3415, T–3416, T–3417
Letterkenny Army Depot
Chambersburg Co: Franklin PA 17201–
Landholding Agency: Army
Property Number: 219420425
Status: Unutilized
Reason: Secured Area, Extensive deterioration

Bldgs. T–3419, T–3420, T–3422
Letterkenny Army Depot
Chambersburg Co: Franklin PA 17201–
Landholding Agency: Army
Property Number: 219420426
Status: Unutilized
Reason: Secured Area, Extensive deterioration

Bldgs. T–3728, S–3732, S–3743
Letterkenny Army Depot
Chambersburg Co: Franklin PA 17201–
Landholding Agency: Army
Property Number: 219420427
Status: Unutilized
Reason: Secured Area, Extensive deterioration

Bldgs. S–3783, 4516, T–5313
Letterkenny Army Depot
Chambersburg Co: Franklin PA 17201–
Landholding Agency: Army
Property Number: 219420428
Status: Unutilized
Reason: Secured Area, Extensive deterioration

Bldgs. T–5315, T–5546, T–5748
Letterkenny Army Depot
Chambersburg Co: Franklin PA 17201–
Landholding Agency: Army
Property Number: 219420429
Status: Unutilized
Reason: Secured Area, Extensive deterioration

Bldgs. T–2796, 2761
Letterkenny Army Depot
Chambersburg Co: Franklin PA 17201–
Landholding Agency: Army
Property Number: 219420430
Status: Unutilized
Reason: Secured Area

Virginia

Bldg. 632, Fort Eustis
Newport News Va 23604–
Landholding Agency: Army
Property Number: 219420336
Status: Unutilized
Reason: Extensive deterioration

Bldg. 2510, Fort Eustis
Newport News VA 23604–
Landholding Agency: Army
Property Number: 219420337
Status: Unutilized
Reason: Extensive deterioration

Bldg. 520, Fort Story
Ft. Story Co: Princess Ann VA 23604–
Landholding Agency: Army
Property Number: 219420338
Status: Unutilized
Reason: Extensive deterioration

Bldg. 527, Fort Story
Ft. Story Co: Princess Ann VA 23604–
Landholding Agency: Army
Property Number: 219420339
Status: Unutilized
Reason: Extensive deterioration

Bldg. T–1525
U.S. Army Combined Arms Support Command
Fort Lee Co: Prince George VA 23801–
Landholding Agency: Army
Property Number: 219420340
Status: Unutilized
Reason: Extensive deterioration

Bldg. T–7134
U.S. Army Combined Arms Support Command
Fort Lee Co: Prince George VA 23801–
Landholding Agency: Army
Property Number: 219420341
Status: Unutilized
Reason: Extensive deterioration

Bldg. T–11619
U.S. Army Combined Arms Support Command
Fort Lee Co: Prince George VA 23801–
Landholding Agency: Army
Property Number: 219420342
Status: Unutilized
Reason: Extensive deterioration

[FR Doc. 94–14689 Filed 6–16–94; 8:45 am]
BILLING CODE 4210–29–P

Office of the Assistant Secretary for Housing-Federal Housing Commissioner

[Docket No. N–94–3785; FR–3724–N–01]

Interest Rate for the Section 235(r) Mortgage Insurance Program

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

ACTION: Notice of change in interest rate.

SUMMARY: This notice announces a change in the maximum interest rate for mortgages to be insured under section 235(r) of the National Housing Act. The section 235(r) maximum interest rate is to be determined by the Secretary of HUD and published in the Federal Register. Mortgage market conditions now dictate that the Secretary increase the section 235(r) maximum rate from 8.00 percent to 8.50 percent. There is no change being made in the maximum margin of additional percentage points that may be added to the maximum rate if the established conditions are met. Therefore, the maximum for the premium section 235(r) interest rate will be 10.00 percent (8.50 percent for the rate of interest and 1.50 percent for the margin of additional percentage points).

EFFECTIVE DATE: June 17, 1994.

FOR FURTHER INFORMATION CONTACT: John N. Dickie, Director, Program Evaluation Division, Room B–133, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410; telephone (202) 755–7470, Ext. 117; (TDD) (202) 708–4594. (These are not toll-free numbers.)

SUPPLEMENTARY INFORMATION: Section 235(r) of the National Housing Act (12 U.S.C. 1715z) authorizes the Secretary to insure mortgages that refinance existing mortgages insured under section 235. The purpose of the program is to reduce the interest rate insured and assisted under section 235 in order that the assistance payments the Department pays on behalf of mortgagors may be reduced. The regulations implementing the program are contained in subpart H of 24 CFR part 235—refinancing of mortgages under section 235(r).

The interest rate for these loans is set by the Secretary and published in the Federal Register as authorized by 24 CFR 235.1202(b)(3). The previous section 235(r) interest rate of 8.00 percent was published in the Federal Register on April 21, 1994 (59 FR 19021). The Department has determined that market conditions dictate a change in the section 235(r) interest rate. The change will take effect on the date of publication of this notice.

The most recent HUD survey of Mortgage Market conditions (i.e., Secondary Market Prices and Yields), an OMB-designated Principal Federal Indicator, found that the dominant national FHA rate being quoted to potential homebuyers for "lock-in" commitments of 60 days or more was 8.50 percent on April 1, 1994, with an average of .32 points, and an effective interest rate of 8.55 percent. The 8.50 percent rate was dominant in most parts of the country.

Most FHA mortgages are funded in the GNMA mortgage-backed securities market. There is a 50 basis point spread between FHA contract interest rates and GNMA coupon rates (this covers the GNMA guarantee fee and servicing cost). On May 12, 1994, the GNMA 7.50 percent coupon securities (8.00 percent FHA loans) were priced at about 5 points discount. This level of discount tends to impede FHA loans to finance home purchases. On the other hand, the GNMA 8.00 percent security (8.50

percent FHA loans) was trading in the two-month forward market at around two points discount, while the 8.50 percent GNMA coupons (9.00 percent FHA mortgages) continued to trade at over par (i.e., premium). Under the FHA negotiated rate/points provisions a two point discount for 8.50 percent FHA mortgages would not be burdensome.

It is expected that secondary market prices will stabilize in the near term at the 8.50 percent contract rate. The May 1, 1994, *Blue Chip Financial Forecast* showed that after mortgage rates rose in the first quarter of 1994, the average forecast was that mortgage rates would stabilize in the second, third and fourth quarters. The May summary forecast of Data Resources Incorporated projects a rise in 30 year Treasury rates during the second quarter (which is half over), then stable rates in the third and fourth quarters.

Adjusting the section 235(r) rate to 8.50 percent will bring this rate back into line with the rest of the FHA current production loans. Therefore, the maximum rate for section 235(r) mortgages is 8.50 percent beginning with the publication date of this notice. The maximum margin of additional percentage points that may be added to the maximum rate under 24 CFR 235.1202(b)(3)(i)(B) will remain at 1.50 percent.

The subject matter of this notice is categorically excluded from HUD's environmental clearance procedures, in accordance with 24 CFR 50.20(l). For that reason, no environmental finding has been prepared for this notice.

Dated: June 10, 1994.

Nicolas P. Retsinas,

Assistant Secretary for Housing-Federal Housing Commissioner.

[FR Doc. 94–14745 Filed 6–16–94; 8:45 am]

BILLING CODE 4210–27–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[OR–054–4210–05:GP4–192]

Oregon; Realty Action, Noncompetitive Sale of Public Lands in Gilliam County, OR

June 10, 1994.

AGENCY: Bureau of Land Management, Interior, Prineville District.

ACTION: Realty, noncompetitive sale of public lands in Gilliam County, Oregon.

The following land has been found suitable for direct sale under section 203 of the Federal Land Policy and Management Act of 1976 (90 Stat. 2750, 43 U.S.C. 1713). The preliminary estimate of fair market value is $500. The land will not be offered for sale until at least 60 days after the date of this notice.

Willamette Meridian

T. 1 N., R. 19 E.

Containing approximately 2.5 acres.

The land described is hereby segregated from appropriation under the public land laws, including the mining laws, pending disposition of this action or 270 days from the date of publication of this notice, whichever occurs first.

The land is being offered by direct sale to Jim Morris and the mineral interest will be conveyed simultaneously. The patent, when issued, will contain certain reservations to the United States and will be subject to an existing right-of-way. Detailed information concerning these reservations, as well as specific conditions of the sale are available for review at the Prineville District Office, Bureau of Land Management, PO Box 550, Prineville, Oregon 97754.

For a period of 45 days from the date of publication of this notice in the **Federal Register,** interested parties may submit comments to the District Manager, Prineville District, at the above address. In the absence of timely objections, this proposal shall become the final determination of the Department of the Interior.

James L. Hancock,

District Manager, Prineville District Office.

[FR Doc. 94–14800 Filed 6–16–94; 8:45 am]

BILLING CODE 4310–33–M

[OR–943–4210–06; GP4–191; OR–48510 (WASH)]

Opening of Lands in a Proposed Withdrawal; Washington

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The temporary 2-year segregation of a proposed withdrawal of 1,750 acres of National Forest System lands for the White Pass Ski Area terminates on July 23, 1994, and the lands will be opened to mining. The lands have been and remain open to surface entry and mineral leasing.

EFFECTIVE DATE: July 24, 1994.

FOR FURTHER INFORMATION CONTACT: Donna Kauffman, BLM Oregon/Washington State Office, P.O. Box 2965, Portland, Oregon 97208–2965, 503–280–7162.

SUPPLEMENTARY INFORMATION: A Notice of Proposed Withdrawal was published in the **Federal Register,** 57 FR 33006, July 24, 1992, as corrected by 57 FR 38855, August 27, 1992, which segregated the lands described therein for up to 2 years from location and entry under the mining laws, subject to valid existing rights, but not from other forms of disposition which may by law be made of National Forest System lands or to the mineral leasing laws. The 2-year segregation expires July 23, 1994. The withdrawal application will continue to be processed unless it is canceled or denied as to the following described lands:

Willamette Meridian

Snoqualmie and Gifford Pinchot National Forests

T. 13 N., R. 11 E., unsurveyed,
- Sec. 1, that portion of the N½ lying northerly of the withdrawal for State Highway 12 (PLO 2434);
- Sec. 2, that portion of the N½ lying outside the William O. Douglas Wilderness Area;
- Sec. 10, that portion of the E½ lying southerly of the withdrawal for State Highway 12 (PLO 2434);
- Sec. 11, S½S½;
- Sec. 12, that portion of the S½SW¼ lying outside the Goat Rocks Wilderness Area;
- Sec. 14, that portion lying outside the Goat Rocks Wilderness Area;
- Sec. 15, that portion lying outside the Goat Rocks Wilderness Area;
- Sec. 22, that portion lying outside the Goat Rocks Wilderness Area;
- Sec. 23, that portion lying outside the Goat Rocks Wilderness Area.

T. 14 N., R. 11 E., unsurveyed,
- Sec. 35, that portion lying outside the William O. Douglas Wilderness Area;
- Sec. 36, those portions of the S½SW¼ and SW¼SE¼ lying outside the William O. Douglas Wilderness Area.

The areas described aggregate approximately 1,750 acres in Lewis and Yakima Counties, Washington.

At 8:30 a.m. on July 24, 1994, the lands will be opened to location and entry under the United States mining laws, subject to valid existing rights, the provisions of existing withdrawals, and other segregations of record. Appropriation of any of the lands described in this order under the general mining laws prior to the date and time of restoration is unauthorized. Any such attempted appropriation, including attempted adverse possession under 30 U.S.C. 38 (1988), shall vest no rights against the United States. Acts required to establish a location and to initiate a right of possession are governed by State law where not in conflict with Federal law. The Bureau of Land Management will not intervene in disputes between rival locators over possessory rights since Congress has provided for such determinations in local courts.

Dated: June 9, 1994.

Eleanor McCauley,

Acting Chief, Branch of Lands and Minerals Operations.

[FR Doc. 94–14801 Filed 6–16–94; 8:45 am]

BILLING CODE 4310–33–P

Fish and Wildlife Service

Availability of an Environmental Assessment and Receipt of an Application for an Incidental Take Permit for Development of a Residential Lot

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice.

SUMMARY: Mr. Welton Tapper, the owner of a single family lot in the Country Cove subdivision, (Applicant) is seeking an incidental take permit from the Fish and Wildlife Service (Service) pursuant to Section 10(a)(1)(B) of the Endangered Species Act (Act). The proposed permit would authorize the incidental take of a threatened species, the Florida scrub jay, *Aphelocoma coerulescens coerulescens*, incidental to construction of a single family residence on an approximately 0.5 acre lot within the subdivision. The lot is located in the Country Cove subdivision, in the Town of Malabar, Brevard County, Florida.

The Service also announces the availability of an environmental assessment (EA) and habitat conservation plan (HCP) for the incidental take application. Copies of the EA or HCP may be obtained by making a request to the Regional Office address below. The Service is soliciting data on *Aphelocoma coerulescens* coerulescens in order to assist in the requirement of the intra-Service consultation. This notice also advises the public that the Service has made a preliminary determination that issuing the incidental take permit is not a major Federal action significantly affecting the quality of the human environment within the meaning of Section 102(2)(C) of the National Environmental Policy Act of 1969, as amended. The Finding of No Significant Impact is based on information contained in the EA and HCP. The final determination will be made no sooner than 30 days from the date of this notice. This notice is provided pursuant to Section 10(c) of the Act and National Environmental Policy Act Regulations (40 CFR 1506.6).

DATES: Written comments on the permit application, EA, and HCP should be received on or before July 18, 1994.

ADDRESSES: Persons wishing to review the application, HCP, and EA may obtain a copy by writing the Service's Southeast Regional Office, Atlanta, Georgia. Documents will also be available for public inspection by appointment during normal business hours at the Regional Office, or the Jacksonville, Florida, Field Office. Written data or comments concerning the application, EA, or HCP should be submitted to the Regional Office. Please reference permit under PRT–790906 in such comments.

Assistant Regional Director, U.S. Fish and Wildlife Service, 1875 Century Boulevard, Suite 200, Atlanta, Georgia 30345, (telephone 404/679–7110, fax 404/679–7081).

Field Supervisor, U.S. Fish and Wildlife Service, 6620 Southpoint Drive, South, Suite 310, Jacksonville, Florida 32216–0912, (telephone 904/232–2580, fax 904/232–2404).

FOR FURTHER INFORMATION CONTACT: Dawn Zattau at the Jacksonville, Florida, Field Office, or Rick G. Gooch at the Atlanta, Georgia, Regional Office.

SUPPLEMENTARY INFORMATION: *Aphelocoma coerulescens coerulescens* is geographically isolated from other subspecies of scrub jays found in Mexico and the Western United States. The Florida scrub jay is found almost exclusively in peninsular Florida and is restricted to scrub habitat. The total estimated population is between 7,000 and 11,000 individuals. Due to habitat loss and degradation throughout the State of Florida, it has been estimated that the Florida scrub jay population has been reduced by at least half in the last 100 years. Surveys have indicated that suitable Florida scrub jay habitat exists on the Applicant's property and surrounding areas. Construction of this individual homesite may therefore result in death of, or injury to, *Aphelocoma coerulescens coerulescens* incidental to the carrying out of these otherwise lawful activities. Habitat alteration associated with property development may reduce the availability of feeding, shelter, and nesting habitat.

The EA considers the environmental consequences of two alternatives. The no action alternative may result in some loss of habitat for *Aphelocoma coerulescens coerulescens* and exposure of the Applicant under Section 9 of the Act. This action is inconsistent with the purposes and intent of Section 10 of the Act. The proposed action alternative is issuance of the incidental take permit. This provides for restrictions of construction activity, monitoring Florida scrub jay activity during construction of the home, retaining natural vegetation to the maximum extent practicable, enhancing native vegetation through replanting, a prohibition on pets, and installation of a bird feeder and bird bath on the property. The HCP provides a funding mechanism for these mitigation measures.

Dated: June 9, 1994.

John R. Eadie,

Acting Regional Director

[FR Doc. 94–14753 Filed 6–16–94; 8:45 am]

BILLING CODE 4310–55–P

Availability of an Environmental Assessment/Habitat Conservation Plan and Receipt of an Application for an Incidental Take Permit for the Proposed Spicewood at Bull Creek and Canyon Mesa Developments, Austin, Travis County, TX

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice.

SUMMARY: Richland Bull Creek Associates (Applicant) has applied to the Fish and Wildlife Service (Service) for an incidental take permit pursuant to Section 10(a) of the Endangered Species Act (Act). The Applicant has been assigned Permit Number PRT–783564. The requested permit, which is for a period not to exceed 30 years, would authorize the incidental take of the endangered golden-cheeked warbler (*Dendroica chrysoparia*). The proposed take would occur as a result of construction of a residential development on 196 acres, in Austin, Travis County, Texas. The proposed development will permanently eliminate about 176 acres of occupied and/or potential endangered species habitat.

The Service has prepared an environmental assessment (EA) and habitat conservation plan (HCP) for the incidental take application. A determination of jeopardy to the species or a Finding of No Significant Impact (FONSI) will not be made before 30 days from the date of the publication of this notice. This notice is provided pursuant to Section 10(c) of the Act and National Environmental Policy Act regulations (40 CFR 1506.6).

DATES: Written comments on the application and EA/HCP should be received on or before July 18, 1994.

ADDRESSES: Persons wishing to review the application may obtain a copy by writing to the Assistant Regional Director, Ecological Services, U.S. Fish and Wildlife Service, P.O. Box 1306, Albuquerque, New Mexico 87103. Persons wishing to review the EA/HCP

may obtain a copy by contacting Robert B. Simpson, Ecological Services Field Office, U.S. Fish and Wildlife Service, 611 East Sixth Street, Suite 407, Austin, Texas 78701. Documents will be available by written request from the address below or for public inspection during normal business hours (8:00 to 4:30) at the U.S. Fish and Wildlife Service Austin Ecological Services Field Office (8:00 to 4:30). Written data or comments concerning the application and EA/HCP should be submitted to Field Supervisor, Austin Ecological Services Field Office, at the address below. Please refer to Permit Number PRT–783564 when submitting comments.

Austin Ecological Services Field Office, U.S. Fish and Wildlife Service, 611 East Sixth Street, Suite 407, Austin, Texas 78701.

FOR FURTHER INFORMATION CONTACT: Robert B. Simpson at the Austin Ecological Services Field Office at (512) 482–5436.

SUPPLEMENTARY INFORMATION: A Habitat Conservation Plan has been developed as mitigation for the incidental taking of the golden-cheeked warbler. The Applicant proposes to mitigate the incidental take via dedicating 260 acres of occupied golden-cheeked warbler habitat as a permanent preserve, providing funding for the operation and management of the preserve lands, performing golden-cheeked warbler monitoring and research studies on the preserve and project lands, and avoiding construction activities within warbler territories during the breeding season. Details of the mitigation are provided in the Environmental Assessment and Habitat Conservation Plan for the Spicewood at Bull Creek and Canyon Mesa Developments. A determination of jeopardy to the species or a Finding of No Significant Impact (FONSI) will not be made before 30 days from the date of publication of this notice. This notice is provided pursuant to Section 10(c) of the Act and National Environmental Policy Act regulations (40 CFR 1506.6). The Applicant considered four alternatives, but rejected three of them.

James A. Young,

Assistant Regional Director, Ecological Services, U.S. Fish and Wildlife Service, Southwest Region (2), Albuquerque, New Mexico.

[FR Doc. 94–14760 Filed 6–16–94; 8:45 am]

BILLING CODE 4310–55–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Registration

By Notice dated March 21, 1994, and published in the **Federal Register** on April 1, 1994, (59 FR 15457), Cambridge Isotope Lab, 50 Frontage Road, Andover, Massachusetts 01810, made application to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the basic classes of controlled substances listed below:

Drug	Schedule
Cocaine (9041)	II
Codeine (9050)	II
Methadone (9250)	II
Morphine (9300)	II

Comments were received, however, no written request for a hearing was received. Therefore, pursuant to section 303 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 and Title 21, Code of Federal Regulations, Section 1301.54(e), the Deputy Assistant Administrator, Office of Diversion Control, hereby orders that the application submitted by the above firm for registration as a bulk manufacturer of the basic classes of controlled substances listed above is granted.

Dated: June 3, 1994.

Gene R. Haislip,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 94–14791 Filed 6–16–94; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF LABOR

Employment Standards Administration

Wage and Hour Division

Minimum Wages for Federal and Federally Assisted Construction; General Wage Determination Decisions

General wage determination decisions of the Secretary of Labor are issued in accordance with applicable law and are based on the information obtained by the Department of Labor from its study of local wage conditions and data made available from other sources. They specify the basic hourly wage rates and fringe benefits which are determined to be prevailing for the described classes of laborers and mechanics employed on construction projects of a similar character and in the localities specified therein.

The determinations in these decisions of prevailing rates and fringe benefits have been made in accordance with 29 CFR part 1, by authority of the Secretary of Labor pursuant to the provisions of the Davis-Bacon Act of March 3, 1931, as amended (46 Stat. 1494, as amended, 40 U.S.C. 276a) and of other Federal statutes referred to in 29 CFR Part 1, Appendix, as well as such additional statutes as may from time to time be enacted containing provisions for the payment of wages determined to be prevailing by the Secretary of Labor in accordance with the Davis-Bacon Act. The prevailing rates and fringe benefits determined in these decisions shall, in accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on Federal and federally assisted construction projects to laborers and mechanics of the specified classes engaged on contract work of the character and in the localities described therein.

Good cause is hereby found for not utilizing notice and public comment procedure thereon prior to the issuance of these determinations as prescribed in 5 U.S.C. 553 and not providing for delay in the effective date as prescribed in that section, because the necessity to issue current construction industry wage determinations frequently and in large volume causes procedures to be impractical and contrary to the public interest.

General wage determination decisions, and modifications and supersedeas decisions thereto, contain no expiration dates and are effective from their date of notice in the **Federal Register**, or on the date written notice is received by the agency, whichever is earlier. These decisions are to be used in accordance with the provisions of 29 CFR Parts 1 and 5. Accordingly, the applicable decision, together with any modifications issued, must be made a part of every contract for performance of the described work within the geographic area indicated as required by an applicable Federal prevailing wage law and 29 CFR Part 5. The wage rates and fringe benefits, notice of which is published herein, and which are contained in the Government Printing Office (GPO) document entitled "General Wage Determinations Issued Under the Davis-Bacon and Related Acts," shall be the minimum paid by contractors and subcontractors to laborers and mechanics.

Any person, organization, or governmental agency having an interest in the rates determined as prevailing is encouraged to submit wage rate and fringe benefit information for consideration by the Department.

Further information and self-explanatory forms for the purpose of submitting this data may be obtained by writing to the U.S. Department of Labor, Employment Standards Administration, Wage and Hour Division, Division of Wage Determinations, 200 Constitution Avenue, NW., room S–3014, Washington, DC 20210.

Modification to General Wage Determination Decisions

The number of decisions listed in the Government Printing Office document entitled "General Wage Determinations Issued Under the Davis-Bacon and Related Acts" being modified are listed by Volume and State. Dates of publication in the **Federal Register** are in parentheses following the decisions being modified.

Volume I

None

Volume II

None

Volume III

Kentucky
KY940001 (Feb. 11, 1994)
KY940002 (Feb. 11, 1994)
KY940003 (Feb. 11, 1994)
KY940004 (Feb. 11, 1994)
KY940006 (Feb. 11, 1994)
KY940007 (Feb. 11, 1994)
KY940029 (Feb. 11, 1994)
KY940035 (Feb. 11, 1994)

Volume IV

Indiana
IN940002 (Fed. 11, 1994)
IN940006 (Fed. 11, 1994)
MN940003 (Feb. 11, 1994)
MN940005 (Feb. 11, 1994)
MN940007 (Feb. 11, 1994)
MN940008 (Feb. 11, 1994)
MN940012 (Feb. 11, 1994)
MN940015 (Feb. 11, 1994)
MN940017 (Mar. 25, 1994)
MN940027 (Mar. 25, 1994)
MN940031 (Mar. 25, 1994)
MN940035 (Mar. 25, 1994)
MN940039 (Mar. 25, 1994)
Minnesota
MN940043 (Mar. 25, 1994)
MN940044 (Mar. 25, 1994)
MN940045 (Mar. 25, 1994)
MN940046 (Mar. 25, 1994)
MN940047 (Apr. 1, 1994)
MN940048 (Apr. 1, 1994)
MN940049 (Apr. 1, 1994)
Ohio
OH940001 (Feb. 11, 1994)
OH940002 (Feb 11, 1994)
OH940003 (Feb. 11, 1994)
OH940014 (Feb. 11, 1994)
OH940027 (Apr. 1, 1994)
OH940029 (Feb 11, 1994)
OH940034 (Feb. 11, 1994)
OH940035 (Feb. 11, 1994)
OH940036 (Feb. 11, 1994)

Volume V

Kansas
KS940063 (Mar. 25, 1994)
Louisiana
LA940001 (Feb. 11, 1994)
LA940004 (Feb. 11, 1994)
LA940005 (Feb. 11, 1994)
LA940009 (Feb. 11, 1994)
LA940012 (Feb. 11, 1994)
LA940014 (Feb. 11, 1994)
LA940015 (Feb. 11, 1994)
LA940016 (Feb. 11, 1994)
LA940018 (Feb. 11, 1994)
Missouri
MO940002 (Feb. 11, 1994)
MO940011 (Feb. 11, 1994)
New Mexico
NM940001 (Feb. 11, 1994)
Texas
TX940009 (Feb. 11, 1994)
TX940101 (Feb. 11, 1994)

Volume VI

Alaska
AK940001 (Feb. 11, 1994)
AK940002 (Feb. 11, 1994)
AK940003 (Feb. 11, 1994)
Arizona
AZ940002 (Feb. 11, 1994)
Colorado
CO940001 (Feb. 11, 1994)
Hawaii
HI940001 (Feb. 11, 1994)
Idaho
ID940001 (Feb. 11, 1994)
South Dakota
SD940002 (Feb. 11, 1994)
Washington
WA940001 (Feb. 11, 1994)
WA940002 (Feb. 11, 1994)
WA940003 (Feb. 11, 1994)
WA940005 (Feb. 11, 1994)
WA940007 (Feb. 11, 1994)
WA940008 (Feb. 11, 1994)
Wyoming
WY940005 (Feb. 11, 1994)
WY940006 (Feb. 11, 1994)
WY940007 (Feb. 11, 1994)

General Wage Determination Publication

General wage determinations issued under the Davis-Bacon and related Acts, including those noted above, may be found in the Government Printing Office (GPO) document entitled "General Wage Determinations Issued Under The Davis-Bacon And Related Acts". This publication is available at each of the 50 Regional Government Depository Libraries and many of the 1,400 Government Depository Libraries across the country. Subscriptions may be purchased from: Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402, (202) 783–3238.

When ordering subscription(s), be sure to specify the State(s) of interest, since subscriptions may be ordered for any or all of the six separate volumes, arranged by State. Subscriptions include an annual edition (issued in January or February) which includes all current general wage determinations for the States covered by each volume. Throughout the remainder of the year, regular weekly updates will be distributed to subscribers.

Signed at Washington, DC this 10th day of June 1994.

Alan L. Moss,

Director, Division of Wage Determinations.

[FR Doc. 94–14560 Filed 6–16–94; 8:45 am]

BILLING CODE 4510–27–M

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

Humanities Panel; Meetings

AGENCY: National Endowment for the Humanities.

ACTION: Notice of meetings.

SUMMARY: Pursuant to the provisions of the Federal Advisory Committee Act (Pub. L. 92–463, as amended) notice is hereby given that the following meetings of the Humanities Panel will be held at the Old Post Office, 1100 Pennsylvania Avenue, NW., Washington, DC 20506.

FOR FURTHER INFORMATION CONTACT: David C. Fisher, Advisory Committee Management Officer, National Endowment for the Humanities, Washington, DC 20506; telephone (202) 606–8322. Hearing-impaired individuals are advised that information on this matter may be obtained by contacting the Endowment's TDD terminal on (202 606–8282.

SUPPLEMENTARY INFORMATION: The proposed meetings are for the purpose of panel review, discussion, evaluation and recommendation on applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including discussion of information given in confidence to the agency by the grant applicants. Because the proposed meetings will consider information that is likely to disclose: (1) Trade secrets and commercial or financial information obtained from a person and privileged or confidential; or (2) information of a personal nature the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, pursuant to authority granted me by the

Chairman's Delegation of Authority to Close Advisory Committee meetings, dated July 19, 1993, I have determined that these meetings will be closed to the public pursuant to subsections (c)(4), and (6) of section 552b of Title 5, United States Code.

1. *Date:* July 7–8, 1994.
Time: 8:30 a.m. to 5 p.m.
Room: 415.
Program: This meeting will review applications submitted to the Humanities Projects in Museums and Historical Organizations Program received during the June 3, 1994, submitted to the Division of Public Programs, for projects beginning after January 1, 1995.

2. *Date:* July 11, 1994.
Time: 8:30 a.m. to 5 p.m.
Room: 430.
Program: This meeting will review applications submitted for Public Challenge Grant, submitted to the Division of Public Programs, for projects beginning after December 1, 1994.

3. *Date:* July 13, 1994.
Time: 9 a.m. to 5:30 p.m.
Room: 315.
Program: This meeting will review proposals submitted to the May 1, 1994 deadline in the Challenge Grants Program, submitted to the Division of Education Programs, for projects beginning After January, 1995.

4. *Date:* July 14–15, 1994.
Time: 8:30 a.m. to 5 p.m.
Room: 415.
Program: This meeting will review applications submitted to the Humanities Projects in Museums and Historical Organizations program received during the June 3, 1994 deadline, submitted to the Division of Public Programs, for projects beginning after January 1, 1995.

5. *Date:* July 15, 1994.
Time: 9 a.m. to 5:30 p.m.
Room: 315.
Program: This meeting will review proposals submitted to the May 1, 1994 deadline in the Challenge Grants Program, submitted to the Division of Education Programs, for projects beginning after January, 1995.

6. *Date:* July 21–22, 1994.
Time: 9 a.m. to 5 p.m.
Room: M–14.
Program: This meeting will review applications submitted to the Humanities Projects in Museums and Historical Organizations program received during the June 3, 1994 deadline, submitted to the Division of Public Programs, for projects beginning after January 1 1995.

7. *Date:* July 22, 1994.
Time: 9:30 a.m. to 5 p.m
Room: 430.
Program: This meeting will review Challenge Grants applications, submitted to the Division of Research Programs/Challenge Grants, for project beginning after December 1, 1994.

8. *Date:* July 28–29, 1994.
Time: 8:30 a.m. to 5 p.m.
Room: M–07.
Program: This meeting will review applications submitted to the Humanities Projects in Museums and Historical Organizations program received during June 3, 1994 deadline, submitted to the Division of Public Programs, for projects beginning after January 5, 1995.

David Fisher,
Advisory Committee Management Officer.
[FR Doc. 94–14767 Filed 6–16–94; 8:45 am]
BILLING CODE 7536–01–M

NUCLEAR REGULATORY COMMISSION

Documents Containing Reporting or Recordkeeping Requirements; Office of Management and Budget Review

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of the OMB review of information collection.

SUMMARY: The Nuclear Regulatory Commission (NRC) has recently submitted to the Office of Management and Budget (OMB) for review the following proposal for collection of information under the provisions of the Paperwork Reduction Act of 1980 (44 U.S.C. chapter 35).

1. *Type of Submission, New, Revision, or Extension:* Revision.
2. *The Title of the Information Collection:* Proposed Rule—Amendments to 10 CFR parts 30, 40, 70, and 72: Clarification of Decommissioning Funding Requirements.
3. *The Form Number if Applicable:* Not applicable.
4. *How Often Is the Collection Required:* Semiannually.
5. *Who Will Be Required or Asked To Report:* Material licensees that have an approved decommissioning plan and desire to have their financial assurance requirements reduced as decommissioning progresses and radiological contamination is reduced at the site.
6. *An Estimate of the Number of Annual Responses:* 200.
7. *An Estimate of the Number of Hours Needed Annually To Complete the Requirement or Request:* 1200 (6 hours per response).
8. *An Indication of Whether Section 3504(h), Public Law 96–511 Applies:* Applicable.
9. *Abstract:* The proposed rule would allow material licensees who have an approved decommissioning plan to semiannually request the NRC to reduce the amount of their decommissioning financial assurance requirement amount as decommissioning proceeds and contamination is reduced at the site. This semiannual licensee request would then be evaluated by the NRC before granting a licensee a reduction in the amount of funds required for financial assurance.

Copies of the submittal may be inspected or obtained for a fee from the NRC Public Document Room, 2120 L Street NW. (lower level), Washington, DC.

Comments and questions can be directed by mail to the OMB reviewed:

Troy Hillier, Office of Information and Regulatory Affairs, (3150–0017, 3150–0020, 3150–0009, and 3150–0132), NEOB–3019, Office of Management and Budget, Washington, DC 20503.

Comments may also be communicated by telephone at (202) 395–3084.

The NRC Clearance Officer is Brenda Jo. Shelton, (301) 415–7232.

Dated at Rockville, Maryland, this 3rd day of June, 1994.

For the Nuclear Regulatory Commission.

Gerald F. Cranford,
Designated Senior Official for Information Resources Management.
[FR Doc. 94–14765 Filed 6–16–94; 8:45 am]
BILLING CODE 7590–01–M

[Docket No. 50–440]

Cleveland Electric Illuminating Company, et al.; Environmental Assessment and Finding of No Significant Impact

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an amendment to Facility Operating License No. NPF–58 issued to the Cleveland Electric Illuminating Company, Centerior Service Company, Duquesne Light Company, Ohio Edison Company, Pennsylvania Power Company, and Toledo Edison Company (the licensees) for operation of the Perry Nuclear Power Plant, Unit No. 1, located in Lake County, Ohio.

Environmental Assessment

Identification of Proposed Action

The Proposed action would revise the provisions in the Technical Specifications (TS) to delete the area critically monitors for the fuel preparation pool, spent fuel storage pool and the upper containment pools.

The proposed action is in accordance with the licensee's application for amendment dated February 28, 1992.

The Need for the Proposed Action

The proposed amendment is needed to reflect that area criticality monitors for the fuel preparation pool, spent fuel storage pool and the upper containment pools are monitors only and do not prevent inadvertent criticality and are not considered in any design basis accident or transient. Therefore, these monitors can be adequately controlled by plant documents and procedures similar to other area radiation monitors.

Environmental Impact of the Proposed Action

The NRC staff has completed its evaluation of the proposed revision to the TS and concludes that removing the area criticality monitors from TS and placing operability and surveillance requirements in plant documents and procedures will not increase offsite releases. These monitors are not relied upon to successfully mitigate a fuel handling accident outside of containment. Therefore, the proposed changes do not increase the probability or consequences of accidents, no changes are being made in the types of any effluents that may be released offsite, and there is no significant increase in the allowable individual or cumulative occupational radiation exposure. Accordingly, the NRC staff concludes that this proposed action would result in no significant radiological environmental impact.

With regard to potential nonradiological impacts, the proposed changes to the TS involve systems located within the restricted area as defined in 10 CFR part 20. It does not affect nonradiological plant effluents and has no other environmental impact. Therefore, the NRC staff concludes that there are no significant nonradiological environmental impacts associated with the proposed amendment.

Alternative to the Proposed Action

Because the Commission's staff has concluded that there are no significant environmental impacts associated with the proposed action, any alternatives would have either no significantly different environmental impact or greater environmental impact.

The principal alternative would be to deny the requested amendment. This would not reduce environmental impacts as a result of plant operations.

Alternative Use of Resources

This action does not involve the use of resources not previously considered in the Final Environmental Statement related to operation of the Perry Nuclear Power Plant, Units 1 and 2, dated August 1982.

Agencies and Persons Consulted

The NRC staff reviewed the licensee's request and consulted with the State of Ohio.

Finding of No Significant Impact

The Commission has determined not to prepare an environmental impact statement for the proposed license amendment.

Based upon the foregoing environmental assessment, we conclude that the proposed action will not have a significant effect on the quality of the human environment.

For further details with respect to this action, see the licensee's application for amendment dated February 28, 1992, which is available for public inspection at the Commission's Public Document Room, Gelman Building, 2120 L Street, NW., Washington, DC 20555 and at the local public document room at the Perry Public Library, 3753 Main Street, Perry, Ohio 44081.

Dated at Rockville, Maryland, this 13th day of June 1994.

For the Nuclear Regulatory Commission.

John N. Hannon,

Director, Project Directorate III–3, Division of Reactor Project—III/IV, Office of Nuclear Reactor Regulation.

[FR Doc. 94–14766 Filed 6–16–94; 8:45 am]

BILLING CODE 7590–01–M

Generic Letter 94–01, "Removal of Accelerated Testing and Special Reporting Requirements for Emergency Diesel Generators"

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of issuance.

SUMMARY: The Nuclear Regulatory Commission (NRC) has issued Generic Letter 94–01 on "Removal of Accelerated Testing and Special Reporting Requirements for Emergency Diesel Generators". This generic letter is available in the Public Document Rooms under accession number 9405190384. The resolution of public comments received on this generic letter is discussed in a memorandum to the Chairman of the Committee to Review Generic Requirements which is also available in the Public Document Rooms under accession number 9406030019. This generic letter is also discussed in Commission information paper SECY–94–129 which is also available in the Public Document Room under accession number 9406090123.

DATES: The generic letter was issued on May 31, 1994.

ADDESSES: Not applicable.

FOR FURTHER INFORMATION CONTACT: Om Chopra, NRR (301) 504–3265; Tom Dunning, NRR (301) 504–1189.

Dated at Rockville, Maryland, this 9th day of June, 1994.

For the Nuclear Regulatory Commission.

Richard J. Kiessel,

Acting Chief, Generic Communications Branch, Division of Operating Reactor Support, Office of Nuclear Reactor Regulation.

[FR Doc. 94–14747 Filed 6–16–94; 8:45 am]

BILLING CODE 7590–01–M

[Docket No. 70–3070–ML; ASLBP No. 91–641–02–ML Special Nuclear Material License]

Louisiana Energy Services, L.P., Clairborne Enrichment Center, Notice of Prehearing Conference and Evidentiary Hearing

June 10, 1994.

This proceeding concerns the licensing of a proposed uranium enrichment facility in Clairborne Parish, Louisiana. Notice is hereby given that an evidentiary hearing in this proceeding will commence on Wednesday, July 20, 1994, at the First Floor Magistrate's Courtroom, United States Federal Courthouse, 300 Fannin Street, Shreveport, Louisiana 71101. The evidentiary hearing will begin immediately after a prehearing conference that will commence at 10 a.m. The evidentiary hearing will continue, to the extent necessary, on July 21–22 and July 25–28 at that same location, beginning at 9 a.m. each day.

Notice is also given that, in accordance with 10 CFR § 2.715(a), the Licensing Board will hear oral limited appearance statements from the general public on Saturday, July 23, 1994, from 10 a.m. to 12 p.m., and from 1:30 p.m. to 3 p.m., (or such lesser time as is necessary to accommodate speakers who are present). Such statements will be heard at the Auditorium of the Homer High School, 1008 North Main Street, Homer, Louisiana 71101.

Any person not a party to the proceeding will be permitted to make a limited appearance statement, setting forth his or her position on the licensing issues. The number of persons making oral statements and the time allotted for each statement may be limited depending on the number of persons present at the designated times. In general, an oral statement should be limited to no more than five (5) minutes. Interested persons may submit a written statement in lieu of an oral statement or a written statement to accompany the oral statement. Requests to make oral

statements may be submitted to the Office of the Secretary, Docketing and Service Branch, U.S. Nuclear Regulatory Commission, Washington, DC 20555. A copy of each such request should also be submitted to the Chairman of this Licensing Board, U.S. Nuclear Regulatory Commission, Atomic Safety and Licensing Board Panel, Washington, DC 20555.

It is so Ordered.

For The Atomic Safety and Licensing Board, Bethesda, Maryland, June 10, 1994.

Thomas S. Moore,

Chairman, Administrative Judge.

[FR Doc. 94–14748 Filed 6–16–94; 8:45 am]

BILLING CODE 7590–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release Nos. 33–7066; 34–34176; International Series Release No. 671]

Exemptions From Rules 10b–6, 10b–7, and 10b–8 During Distributions of Certain French Securities

June 7, 1994

Pursuant to delegated authority, the Division of Market Regulation issued the following letter granting class exemptions ("Exemptions") from rules 10b–6, 10b–7, and 10b–8 ("Trading Practices Rules") under the Securities Exchange Act of 1934 to facilitate distributions in the United States of securities of certain highly capitalized French issuers. The Exemptions permit distribution participants and their affiliated purchases to effect transactions in France that otherwise would be prohibited by the Trading Practices Rules, subject to certain disclosure, recordkeeping, record production, and notice requirements.

The Exemptions have been issued in the context of a continuing review of the Trading Practices Rules, and are published to provide notice of their availability.

Margaret H. McFarland,

Deputy Secretary.

English Translation of the Letter

Dear Mr. Becker,

I am writing in connection with possible offerings of equity securities of certain French companies involving a distribution of some or all of the Securities in the United States.[1]

With reference to the policy statement issued by the Securities and Exchange Commission on November 3, 1993, I am writing to request exemptions from rules 10b–6, 106–7 and 10b–8 under the Securities Exchange Act of 1934 for French issuers to the extent set forth in part III below.

I. Offerings By French Companies

The structure of an offering of equity securities in a French company varies depending on whether it is a primary or a secondary offering.

A. Primary Offerings

French law grants shareholders of a French company pre-emptive rights to subscribe for shares issued by such company. French law also authorizes shareholders, voting at a shareholders meeting, to renounce such pre-emptive rights. In practice, in the case of a renunciation of such pre-emptive rights, most offerings are conducted so as to grant current shareholders a priority right to purchase new shares before the general public during a period of 5 to 10 days.

1. Offerings With Pre-emptive Rights

Offerings with pre-emptive rights permit the current shareholders to participate in the capital increase *pro rata* or to sell their pre-emptive rights, which are securities separable from the shares, on the market. The existence of a negotiable pre-emptive right permits detachment of the offering price from the stock market price, because the shareholders who do not want to participate in an offering can, by selling their rights on the market, be compensated for the dilution which could result from an offering price which is significantly less than the market price and/or than their share in the net assets. The discount from the stock market price is generally 10% to 20%. The technique of an offering with pre-emptive rights is principally used for offerings of shares rather than for those of "composite securities", such as bonds with warrants or bonds convertible into shares, for reasons of valuation and quotation on the appropriate stock market.

2. Offerings Without Pre-emptive Rights

French law permits an issuer, when it is authorized by its shareholders, to issue shares (or securities exchangeable for, or convertible into, shares) without pre-emptive rights. In this case, the law limits the discount at which the issuer may offer the shares from the stock market price.[15] The issue price must be at least equal to the average of the stock market prices for any 20 consecutive business days during the 40-day period immediately preceding the date of the offering (the "20/40 rule"). The 20/40 rule protects shareholders to the extent that it limits the discount that can be set for an offering of shares without pre-emptive rights. In addition, the COB has recommended a priority period in the case of an offering without pre-emptive rights, permitting current shareholders to subscribe for new shares on a priority basis. This period provides existing shareholders the ability to maintain their shareholding in the capital of a company of which they are shareholders, even if they have waived their pre-emptive rights. The practice of the priority period has been widely followed for offerings without pre-emptive rights; offerings without a priority period are rare today in France (1 or 2 per year).

The 20/40 rule applies, according to the text of the law, only to straight share offerings; however, to avoid circumvention of the law, the COB requires that the 20/40 rule be applied in the case of offerings of convertible bonds or warrants. In applying the 20/40 rule, issuers generally choose a reference period that is close to the offering date in order to limit the amount of the discount.

In order to facilitate an underwritten offering in France and/or on the international market at the same time as an offering with a priority period, the COB has accepted that the priority period only apply to a substantial part (*i.e., at least two thirds) of the offering.*

3. Offerings Without a Priority Period

Offerings without a priority period are extremely rare. Such offerings are used under very limited circumstances, such as when an issuer needs to offer shares publicly on a foreign market. Such an offering can only take place if one or both of the following two conditions are met:

—It must be at the closest possible price to the stock market price; and/or

—The existing shareholders are compensated, for example in the form of a distribution of free shares or warrants.

Offerings without a priority period will probably remain atypical, because shareholders generally want to avoid dilution through the use of pre-emptive rights or a priority period.

[1] The term equity securities shall include equity related securities such as convertible or exchangeable bonds and warrants. Such equity related securities may be issued by the issuer of the equity securities itself or by a subsidiary of such issuer. Offerings of straight debt securities are outside the scope of this letter.

[15] Article 186–1, second paragraph of the law of July 24, 1966 on commercial companies.

4. Underwritten Offerings

In the case of offerings with a priority period, an underwritten offering can occur during the period when the existing shareholders have a priority right to subscribe for new shares, by anticipating that a fraction of the existing shareholders will not subscribe for new shares. Underwritten offerings in France and/or on the international market can therefore take place during the priority period granted to existing shareholders without extending the offering period. In order to accommodate the differences between the actual behavior of the existing shareholders and the level of anticipated purchases, several techniques are used: "claw-back" arrangements, over-allotment options and arrangements whereby a majority shareholder renounces his priority subscription rights.

B. Secondary Offerings

1. Public Offerings

Public offerings are the traditional means of selling a large number of shares of a listed company on the market. Public offerings are regulated both by the general rules of the CBV (title 7) and by the rules of the COB 89.03, chapter III. Public offerings are at a price different from the market price. sellers, however, generally offer the shares at a price which is close to the market. price Privatizations, which are a particular kind of public offerings, because of the nature of the seller (the State) and of the volume of capital involved (up to several dozen billion francs per transaction), can be carried out with a substantial discount from the last quoted market price (*e.g.*, 10 to 15%).

Public offerings require the following:

—approval of the CBV;
—the clearance of the prospectus by the COB;
—The centralization of subscription orders by the Société des Bourses Françaises;

In addition, public tender offers are market transactions which require a high level of disclosure.

In a public offering, all financial institutions, such as banks (but also other financial intermediaries such as the French National Post Office and brokerage houses), can receive orders from the public. Such orders are transmitted to the SBF where they are centralized. None of the financial institutions has any influence over the allocation of the shares.

A public offering may be underwritten on a stand-by basis. Historically, most public offerings, and in particular those relating to privatizations, are oversubscribed (about 2 to 4 times).

2. Underwritten Offerings

Whenever an offering is sufficiently large, an underwritten offering can take place in France and/or on an international market. This is particularly the case in the context of privatization transactions. Such transactions, which use the book-billing method, provide the banks leading the syndicate greater flexibility when allocating shares to investors. In the context of an underwritten offering, the price for the offering is set based upon indications of interest received from potential investors; however, the final price determined by the lead managers cannot be less than the price in the public tender offer. During the first privatization which used this technique (Rhône-Poulenc, November 1993), the institutional investors who purchased shares in the underwritten offering paid a price 8% higher than that paid by individuals who purchased shares in the public offering.

3. Bought Deals

The "bought deal" permits the placement of a certain amount (usually large) of securities with certain institutional investors. This type of offering, different from a public offering, can only occur when it involves shares of a listed company being offered at the market price or by techniques explicitly provided for in the general rules of the CBV:

—By "applications" (title 4, chapter III of the general rules of the CBV), the price in this case must be between the best purchase offer and the best sale offer existing at the time of the application (article 4–7–3);
—By option contracts (title 7, chapter II of the general rules of the CBV): these contracts permit the sale or purchase of a given amount of securities at a price quoted on a stock market the day of the contract or the day of its term or at the average of the quoted prices between those two dates.

The seller of securities places the securities through a bank or banks with institutional investors of such seller's choice. Accordingly, the seller transfers the securities first to the bank or banks which have committed to sell them to such institutional investors in France or abroad.

The COB carefully reviews this type of placement in order to ensure that it is not used to advantage unfairly any existing shareholder of the company.

C. Market Activities of Underwriters During Offerings

In France, the banks are the underwriters of securities. The vast majority of French banks provide a full range of banking and securities services such as brokerage, underwriting and investment advisory services including managing on a discretionary basis the portfolios of bank customers. However, banks may not be direct members of the Paris Bourse and have to set up separate subsidiaries which will be members of the Bourse.

The French banks acting as underwriters typically continue to engage in a range of trading activities during a distribution. The underwriters may be active in trading all kinds of securities of the issuer or derivative instruments related to such securities both in the cash market and in the options market. In these markets, the underwriters trade securities in the ordinary course for their own account. In addition, the underwriters continue to make investment decisions for the accounts they manage and their mutual fund management company affiliates continue to make investment decisions on behalf of the mutual funds they manage.

However, pursuant to legal and regulatory requirements to which they are subject and pursuant to their own respective internal policies and conduct of business rules, banks maintain "Chinese wall" procedures to separate certain divisions within their respective organizations. The main purpose of these Chinese walls is to ensure that confidential information held within parts of the respective companies or divisions does not spread inadvertently to other parts of those companies or to affiliated entities.

In addition, under French law, companies are prohibited from purchasing their own shares either directly or through a financial intermediary acting on behalf of the company except in limited circumstances. These circumstances are set forth in article 217–1 and 217–2 of the Companies Act of July 24, 1966, and in COB Regulations No. 90.04. They include purchases made for the purpose of offering shares to employees of the corporation and, for listed companies, purchases made for the purpose of market stabilization. These purchases are limited to 10% of the share capital of the corporation. The company may not own more than 10% of any class of its outstanding shares in capital at any time.

Under COB Regulation No 90.04, such purchases may be only to ensure the

liquidity of the shares or to control excessive fluctuations in their price. The company is required to file a copy of the shareholder's resolution authorizing such transactions with the COB prior to engaging in such transactions, as well as a monthly copy of the register of purchases and sales thereafter.

Under article 9 of COB Regulation No. 90.04, transactions made by a company in its own shares and, during a distribution period, transactions made by financial intermediaries for their own account or on behalf of the underwriting syndicate, for the purpose of ensuring the proper execution of the distribution are presumed to be legitimate when complying with the following requirements: (i) the transactions are performed contrary to the trend of the last quoted price, (ii) the transactions represent a maximum volume of 25% of the total daily transactions recorded over a reference period [16] preceding the transactions, (iii) they are performed only by one intermediary per stock exchange session except during a public offering.

The distribution period begins with the announcement of the distribution and ends one month after the listing of the newly issued shares.

II. The French Securities Market

A. The Equity Market

Securities may be listed on one of France's seven stock exchanges: Paris, Bordeaux, Lille, Lyon, Marseille, Nancy and Nantes which together constitute a single exchange system headed by the same authorities and subject to the same listing requirements. All securities are traded through a single electronic system, CAC.

Trading on the Paris Bourse

Trading on the Paris Bourse begins at 10 a.m. and ends at 5 p.m. (Paris time) each business day.

Securities may be traded on the cash market (marché au comptant) or on the monthly settlement market (règlement mensuel RM). Cash transactions comprise the least actively traded French and foreign equity securities on the official list, all debt securities on the official list and all equity stocks on the second market and hors cote.

The most actively traded French and foreign equity securities on the official list are traded on a monthly settlement basis. All the securities comprising the CAC 40 Index are traded on the monthly settlement market.

Securities on the monthly settlement market are traded in round lots of 5, 10, 25, 50 and 100, set by the Paris Bourse to reflect their limit price. While transactions are firm both in prices and quantity once they have been concluded, the actual cash settlement and delivery of the shares do not take place until the end of the trading month. Investors on the monthly settlement market must meet an initial margin requirement which may be adjusted as necessary.

When investors place orders on the monthly settlement market they may request immediate settlement provided that they have the related cash (for a purchase) or securities (for a sale). Trades on odd lots are settled immediately.

Electronic Trading With CAC

Trading in France takes place on a centralized order driven market through member firms, authorized by the Conseil des Bourses de Valeurs, acting as brokers. Transactions are handled by CAC, an electronic trading system, through terminals installed in member firms' premises and linked to the Paris Bourse central computers. The core of the CAC system is linked upstream to an order routing system and downstream to a computerised system that disseminates key markets data in real time.

Orders entered in the CAC system by the Bourse member firms acting either on their own behalf or as agents for their clients, are automatically ranked by price limit and, within each limit, are queued to reflect the order of entry in the system.

From 9 a.m. to 10 a.m. the market is in its pre-opening phase and orders are entered into the centralized order book, without any transaction taking place.

At 10 a.m., the market opens. Based on the limit orders received, the central computer calculates the opening price at which the largest number of bids and asks orders can be matched. At the same time, the system transforms orders at market price into limit orders at the opening price, with the result that all limit buy orders at higher prices and limit sell orders at lower prices are executed. Limit orders at the opening price are executed to the extent that match orders are available.

From 10 a.m. to 5 p.m., trading takes place on a continuous basis. The execution price is the price limit placed on the matching order. Where price limits are identical, orders are executed on a first entered, first matched basis.

CAC automatically feeds information into the system's electronic data dissemination network. As a result, at any given time, the CAC displays the five best bids and asks (price and volume) as well as, in real time, the five latest transactions completed (time price, number of shares traded).

French securities brokers may also act as principals with respect to clients on the Paris Bourse. However, such prices must be lodged on to the CAC and must be at or within the current market spread at the time of their transmission. After hours principal transactions may also take place at any price within the spread at the previous close, plus or minus 1%. Those transactions must be reported to the SBF prior to the opening of the next trading session. Every morning, prior to the opening, the SBF disseminates through the market data feed message zone the name of the stocks on which after hours transactions have been reported and the number of shares traded.

Finally block trades in specific securities are permitted outside the market spread, subject to certain restrictions (*e.g.* the securities broker effecting the trade must agree to fill all buy orders whose price is higher and all sell orders whose price is lower than such block trade).

The Enforcement Division of the SBF is in charge of seeing that member firms of the Paris Bourse comply with the securities laws and the regulations of the CBV.

B. The MONEP (The Options Market)

The MONEP (Paris Traded Options Market) is located within the Paris Bourse; it is governed and regulated by the Conseil des Bourses de Valeurs, through its general regulation. There are 21 market markers in options on the shares on the MONEP.

The market makers are registered with a professional body, the "Société de Compensation des Marchés Conditionnels" (SCMC) which is affiliated with the SBF and to which the SBF has delegated responsibility for (i) options market administration, (ii) technical clearing of the MONEP, (iii) surveillance and control of operations and members. MONEP members can operate on the markets as brokers and/or as market makers.

Twenty seven series of equity options and two series of options based on the CAC 40 index are traded on the floor of the Paris Bourse, from 10 a.m. to 5 p.m., on a continuous basis by open outcry around different pits., two to four classes of options being listed and traded in each pit. In each pit, several SCMC representatives execute orders

[16] Under article 217–4 of the Companies Act, the reference period consist of five business days for the securities on the monthly settlements market and of 30 business days for securities listed on the immediate settlement market.

from the Public Order Book and are responsible for seeing that traders comply with the market's rules.

In addition, for retail orders, brokerage firms have a direct access to an automated trading system called STAMP (*Système de Transactions Automaiisées du MONEP*) through terminals in their own trading rooms. Orders are keyed into the centralized public order book and the data are displayed and disseminated to users. Such orders are either matched automatically inside the book when they represent the market's best price or routed to SCMC staff for priority execution on the floor if better prices are available there.

MONEP member firms operate through representatives acting in two distinct capacities: (i) As brokers who trade orders received directly from clients or issued for brokerage houses' own account, (ii) as market makers. Since a modification of the General Regulation of the CBV that took place in August 1993, there are three types of market makers:

—The market makers "specialist": a specialist market maker is designated for each class of option. He is the only market maker responsible for quoting and continuously updating a bid/ask price for the series of option allocated to the firm. The bid/ask price offered by the specialist is disseminated by the SCMC on quotation screens.

—The market maker "counterpart to the market": he is required to be present on the floor and may trade within the bid/ask price offered by the specialist. There are various counterparts to the market for the same class of option.

—The market maker acting as "block transaction counterpart". His activity consists in arranging options blocks transactions for institutional clients, typically from the firm's trading room. The transaction is then executed on the market if the price is within the spread displayed.

This change is being implemented gradually on a class of option by class of option basis.

Market makers are required to be present on the floor during trading hours and to quote a bid/ask price to any broker or to the SCMC upon requests. Market makers quotation (bid/ask prices) are entered and disseminated on a real time basis. All trades are immediately time-stamped and entered into the market system in order to be displayed on the floor and disseminated outside the floor.

After hours trading is forbidden.

C. The Regulatory Authorities

A professional body, the Conseil des Bourses de Valeurs (CBV) (Stock Exchange Council) is the market regulatory body. The Conseil des Bourses de Valeurs promulgates regulation dealing with the operation of the French stock exchanges and set forth the conditions for authorization of member firms, for admission and withdrawal from listing, and for take over bids. The CBV rules also set forth a professional code of conduct for Bourse members, their subsidiaries, their manager and their staff. In addition, the Council can take disciplinary action as necessary.

Another professional body, the Société des Bourses Françaises, implements the CBV regulations, monitors the trading system, disseminates data on market conditions, provides a number of listing and issuing services and acts as a clearing house between member firms. The SBF handles day to day administration, surveillance, and development of the market.

The Commission des opérations de bourse (COB), an independent administrative body, is responsible for overall supervision of French securities, options and futures markets. Under the Ordinance of September 28, 1967, setting up the COB, the COB is responsible for seeing to the protection of savings invested in securities and all other investments involving a public offering, to the provision of information to investors and to the proper functioning of markets for securities, listed financial products or negotiable futures contracts.

If the SBF primarily regulates and carries out the surveillance of the market, including by controlling quotation rules, participant's risks or margin calls, the market surveillance carried out by the COB is of a different nature because the COB is entrusted with the broad mission of protecting investors.

The market surveillance carried out by the COB aims at (i) detecting abnormal situations in the functioning of the markets (ii) sorting and treating data that enable the COB to check that its rules are complied with, including those relating to public offers and information of shareholders (iii) detecting securities and futures frauds as well as violations to the business codes of conduct and to regulations of the CBV and the Conseil des Marchés à Terme (Futures Market Council).

The surveillance department of the Enforcement Division of the COB is connected to the various computers of the Paris Bourse, among which the CAC, TOPVAL and REUTER workstations providing the COB with data on a real time basis. Moreover, the COB has set up its own data base directly linked to the Paris Bourse, the MONEP and the MATIF.

On December 14, 1989, the Commission des opérations de bourse and the Securities and Exchange Commission entered into an administrative agreement on cooperation and exchange of information. This Administrative Agreement entered into force on January 31, 1991.

Under this Agreement, the COB and the SEC may exchange transaction information, including the identity of customers, where necessary, in the course of an investigation initiated by either of the Commissions.

D. Laws and Regulations Governing Fraudulent and Manipulative Practices

Provisions relating to fraudulent and manipulative practices are set forth mainly in the Ordinance of September 28, 1967, and in COB Regulation No. 90.04 and No. 90.08.[17] Article 10.1 of the Ordinance of September 1967 makes it a criminal offense for any persons who have access to privileged information on an issuer of securities or on the futures prospects of a security or a negotiable future contract to effect transactions on the market, either directly or through a third party, before the general public was aware of this information. It would also be a criminal offense for such a person to communicate such information to a third party outside the normal course of his professional activities. Under article 10.1, criminal sanctions shall also apply to any persons who have knowingly disseminated to the public, through whatever channels or means, false or deceitful information on an issuer of securities or on the future prospects of a security, a quoted financial product or a negotiable futures contract of such nature as to influence prices. Under article 10.3, similar penalties shall apply to any person who, either directly or indirectly, has knowingly carried out or attempted to carry out a purpose-fully misleading act on a financial market with the aim of impeding the normal functioning of the market. It should be stressed that under article 40 of the Criminal Proceeding Code, any governmental entity who becomes aware of a fact that may constitute a

[17] It could, however, be considered more generally that all regulations taken by the COB aim at preventing fraudulent practices and ensuring investors protection.

criminal offense has to transmit the information to the Public Prosecutor.

The violation of COB Regulation No. 90.08 relating to the use of privileged information is sanctioned by the COB through an administrative proceeding.

COB Regulation No. 90.04 provides that price setting on the market shall result from the general matching of bids and offers in compliance with the Regulation of the Conseil des Bourses de Valeurs or the Counseil du Marché à Terme. Orders transmitted on the market shall not be aimed at hindering or misleading the setting of prices on the market. If the COB so requires in the course of an investigation, any person transmitting orders on the market must be able to publicly explain the reasons for, and the details of, the orders.

Regulation 2.3.11 of the CBV requires the member firms to maintain records of securities transaction effected by them. Such records must be maintained for at least five years from the date thereof. To ensure that the market's rules and business code of conduct are complied with by all participants, member firms must specify, when entering orders into the system, whether these orders come from customers or are being executed for the firm's own account, and whether such orders are the result of program trading. The required transaction information includes (i) the name of the security that is the subject of the transaction, (ii) the date of the transaction, (iii) the price and size of the transaction, (iv) whether the transaction was effected for a customer or a proprietary account, (v) the market on which the transaction is effected, (vi) whether the transaction was a purchase or a sale and (vii) the identity of the account on whose behalf the transaction was effected.

III. Proposed Exemption From Rules 10b–6, 10b–7, 10b–8

A. Reasons for Relief

The application of rules 10b–6, 10b–7 and 10b–8 to the activities of distribution participants and their affiliates outside the United States, as experienced on the occasion of several public offerings in the past few years,[18] often conflicts with market practices in France and impose compliance burdens and costs on French issuers and underwriters and their affiliated purchasers. The application of rules 10b–6, 10b–7 and 10b–8 outside the United States has and would have, inter alia, the following consequences, which jeopardize the success of primary or secondary offering.

1. Distribution participants, including the underwriters and in particular the lead underwriter would be unable to maintain an orderly market by buying and selling affected securities as principles during the offering, within the limits set forth in COB Regulations. Moreover, the affiliates of the distribution participants would be precluded from fulfilling their formal market-making obligations on the MONEP with respect to listed options that are affected securities.

2. The underwriters might not be able to continue certain of their regular contacts with customers such as discussions regarding investment strategies with respect to the rights and shares and might not be permitted to buy and sell affected securities in connection with their customers' trading activities.

3. Distribution participants' risk management activities would be restricted. They would be precluded by rule 10b–6 from hedging in derivatives or other affected securities.

4. Distribution participants' customary proprietary trading activities, involving arbitrage and other trading strategies would be curtailed.

B. Scope of Exemption

We propose that the Commission grant exemptions to the effect that rules 10b–6, 10b–7 and 10b–8 shall not apply to distribution participants, including issuers of qualified French securities (as defined below), and their affiliated purchasers (the Relevant Parties) in connection with transactions in Relevant Securities (as defined below) outside the United States during distributions in the United States of Qualified French Securities (as defined below), subject to the following terms, conditions and limitations:

1. Securities

(a) The security being distributed (a "Qualified French Security") must:

(i) Be issued by (aa) a "foreign private issuer" within the meaning of rule 3b–4 under the Exchange Act incorporated under the laws of France, which issuer (a "French Issuer") has outstanding a component security of the CAC 40 Index[19] (bb) or a subsidiary of a French Issuer; and

(ii) Satisfy one of the following:

(aa) Be a CAC 40 Index component security; or

(bb) Be an equity security of a French Issuer having an average daily trading volume that equals or exceeds the equivalent of FF 30 million (which exceeded US $5 million at June 6, 1994), as published by foreign financial regulatory authorities ("FFRAs")[20] and any US securities exchanges or automated inter-dealer quotation systems during the Reference Period; or

(cc) Be a security that is convertible into, exchangeable for, or is a right to acquire a security of a French Issuer described in subparagraph ii (aa) or (bb) above.

(b) "Relevant Security" means:

(i) A Qualified French Security; or

(ii) A security of the same class and series as, or a right to purchase, a Qualified French Security.

2. Transactions Effected in the United States

All transactions in Relevant Securities effected in the United States shall comply with rules 10b–6, 10b–7 and 10b–8.

3. Transactions Effected in France

(a) All transactions during the Covered Period (as defined below) in Relevant Securities effected in France shall be conducted in compliance with French law. For purposes of this exemption, "Covered Period" means (i) in the case of a rights offering, the period commencing when the

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[18] Elf Acquitaine distributions: June 1991 and February 1994.

Total distributions: October 1991 and June 1992.

Alcatel Alsthom distribution: May 1992.

Rhône-Poulenc distributions: January 1993 and November 1993.

[19] The CAC 40 is a regularly updated market capitalization weighted performance index of CAC 40 French Companies; the shares included in the CAC 40 are selected on the basis of their market capitalization, their trading volume and their sector of activity so that the CAC 40 index covers a diversified range of activities. References to the CAC 40 refer to the composition of the index on the date of this letter; *provided, however,* that any security added to the CAC 40 after the date of this letter also will be treated as a Qualified French Security if its issuer satisfies the requirements in 1.a.i and such security has an aggregate market value that equals or exceeds the equivalent of FF 6 billion (which exceeded US $1 billion at June 6, 1994,) and an average daily trading volume that equals or exceeds the equivalent of FF 30 million (which exceeded US $5 million at June 6, 1994,) as published by FFRAs (as defined in note 2 below) and any US securities exchanges or automated inter-dealer quotation systems during a period (the "Reference Period") that is 20 consecutive business days in Paris within 60 consecutive calendar days prior to the commencement of the Covered Period (as defined in 3.a below).

[20] An FFRA is defined in section 3(a)(51) of the Exchange Act, 5 U.S.C. 78(c)(51), as any (A) foreign securities authority; (B) other governmental body or foreign equivalent of a self-regulatory organization empowered by a foreign government to administer or enforce its laws relating to the regulation of fiduciaries, trusts, commercial lending, insurance, trading in contracts of sale of a commodity for future delivery, or other instruments traded on or subject to the rules of a contract market, board of trade, or foreign equivalent, or other financial activities, or (C) membership organization a function of which is to regulate participation of its members in activities listed above. For purposes of this letter, the Société des Bourses Françaises, is considered to be an FFRA.

subscription price is determined and continuing until the completion of the distribution in the United States, and (ii) in the case of any other offering, the period commencing in Paris three business days before the price is determined in the United States and continuing until the completion of the distribution in the United States; *provided, however,* that the Covered Period shall not commence with respect to any Relevant Party until such person becomes a distribution participant.

(b) All transactions in Relevant Securities during the Covered Period effected in France on a principal basis shall be effected or reported on the trading facilities of the Société des Bourses Françaises.

(c) Disclosure of Trading Activities.[21]

(i) The inside front cover page of the offering materials used in the offer and sale in the United States of a Qualified French Security shall prominently display a statement in substantially the following form, subject to appropriate modification where circumstances require. Such statement shall be in capital letters, printed in bold-face roman type at least as large as ten-point modern type and at least two points leaded:

IN CONNECTION WITH THIS OFFERING, CERTAIN PERSONS MAY ENGAGE IN TRANSACTIONS FOR THEIR OWN ACCOUNTS OR FOR THE ACCOUNTS OF OTHERS IN (IDENTIFY RELEVANT SECURITIES) PURSUANT TO EXEMPTIONS FROM RULES 10b–6, 10b–7 AND 10b–8 UNDER THE SECURITIES EXCHANGE ACT OF 1934. SEE "[IDENTIFY SECTION OF OFFERING MATERIALS THAT DESCRIBES THE TRANSACTIONS TO BE EFFECTED]."

(ii) In addition, there shall be included in the identified section of the offering materials a comprehensive description of the activities that may be undertaken by the Relevant Parties in the Relevant Securities during the distribution in substantially the form of Exhibit A.

(d) Recordkeeping and Reporting.

(i) Each Relevant Party will keep the following information with respect to transactions during the covered Period in Relevant Securities, provided, however, that in the case of a distribution made pursuant to a right offering, such information is only required to be kept during the period or periods (a) commencing at any time during the Covered Period that the rights exercise price does not represent a discount of at least 10% from the current market price of the security underlying the rights and (b) continuing until the end of the Covered Period or until the rights exercise price represents a discount of at least 12 percent from . the current market price of the security underlying the rights;[22]

(aa) Name of the security, date, time of execution and reporting, where available to the Relevant Party, price and volume of each transaction: provided however that no information regarding a customer transaction need be provided unless such transaction has a value of FF 1 500 000 or more;

(bb) The exchange or inter-dealer quotation system on which the transaction was effected;[23]

(cc) An indication whether such transaction was for a proprietary account or the account of a customer, provided however that any transaction effected by an underwriter for a customer account for which it has exercised discretionary authority shall be reported as proprietary trade and;

(dd) The identity of the counterparty only where the counterparty is an underwriter or a selling group member.

(ii) The lead underwriter will communicate the list of the Relevant Parties to the COB;

(iii) The Relevant Parties shall keep all documents prepared pursuant to paragraph 3.d.i for a period of no less than two years;

(iv) Upon the request of the Division made pursuant to the Administrative Agreement executed between the SEC and the COB on December 14, 1989, the COB will require the production and the information referred to in paragraph 3.d.(i) from the Relevant Parties through the lead underwriter. The Relevant Parties will provide this information to the COB in a Comma Delimited ASCII (American Standard Code for Information Interchange) within 10 days of the request by the COB and the COB shall transmit it to the Division within 30 days from the date of the request.

(v) If the Division has inquiries relating to the records provided by such Relevant Parties, it will transmit these inquiries to the COB pursuant to the Administrative Agreement. Representatives of the affected Relevant Party will be made available to respond to the inquiries of the COB.

The proposed exemption to rules 10b–6, 10b–7 and 10b–8 shall also apply unconditionally to all transactions on the SEAQ International and any other securities market in a single country outside France and the United States to which a French issuer has applied for listing the relevant Qualified French Securities if the volume in such relevant Qualified French Security as published by SEAQ International or such other relevant securities markets is less than 10% of the aggregate worldwide trading volume in that security during the Reference Period.

4. General Conditions

(1) For purposes of this exemption a two business day cooling-off period shall apply under rule 10b–6(a)(4)(v), (xi) and (xii) in the United States and in each Significant Market,[24] provided that trading in Relevant Securities in any Significant Market shall be subject to the exemptive relief then available in such markets, if any or the record maintenance and record production requirements contained in the letter regarding Application of cooling-off Periods under rule 10b–6 to Distributions of foreign securities (April 4, 1994) are satisfied by Relevant Parties in such significant market.

(b) The lead underwriter or the global coordinator shall promptly, but in any event before the commencement of the Covered Period, provide a written notice ("Notice") to the Division of the following information: (i) the name of the issuer and the Qualified French Securities; (ii) whether the Qualified French Security is a CAC 40 component security or information with respect to the market capitalization and the average daily trading volume of the Qualified French Securities to be distributed; (iii) the identity of the Significant Markets where the Qualified French Security trades; (iv) if the Notice is for more than one entity, the identity of all underwriters and selling group members relying on these exemptions;

[21] This disclosure requirement shall not apply to distributions effected solely pursuant to Rule 144A under the Securities Act of 1933 (the "Securities Act").

[22] For purposes of this exemption, unless stated otherwise, the market price for a security shall be the closing price at the end of the trading session on the Paris Bourse.

[23] The members of the SBR currently have a monopoly for trading on French securities in France.

[24] A "Significant Market" shall mean (i) (aa) SEAQ International or (bb) any other dealer market outside France and the United States for which price and volume information is published by an FFRA or (ii) any other securities markets in a single country other than France or the United States to which a French Issuer has applied for listing the relevant Qualified French Security and been accepted, if during the Reference Period the volume in either (i) (aa) or (bb) or (ii) in such relevant Qualified French Security, as published by the relevant FRRA(s), in such securities markets (as the case may be), is 10% or more of the aggregate worldwide trading volume in that security published by all FFRAs in (i) and (ii), FFRAs in France, and US securities markets to which such French Issuer has applied for listing such relevant Qualified French Security and been accepted, during the Reference Period.

and (v) a statement that the Relevant Parties are aware of the terms and conditions of these exemptions.

We believe this proposed exemption would make it possible to maintain liquidity for shares of French companies throughout a public offering or private placement in the United States, while minimizing the risk of abuses of the kind at which rules 10b–6, 10b–7 and 10b–8 are aimed.

Thank you for your assistance and the assistance of your staff in this matter.

Sincerely,
Pierre Fleuriot.

Exhibit A

The French underwriters (and their affiliates) will, and the other Underwriters (and their affiliates) may, continue to engage in the transactions and other activities described below, in France and elsewhere outside the United States, in respect of the securities being distributed, securities of the same class and series as the securities being distributed, and securities convertible into, exchangeable for, or giving a right to acquire, the foregoing securities, and derivatives thereof (collectively, the "Relevant Securities"), during the distribution period, in accordance with exemptions obtained from the Securities and Exchange Commission (the "Commission") from the application outside the United States of rules 10b–6, 10b–7 and 10b–8 under the US Securities Exchange Act of 1934. Such exemptions are subject to certain exceptions, limitations and conditions set out in the Commission's exemption, including compliance with French law.

The activities referred to above are (a) buying and selling Relevant Securities for the accounts of such Underwriters (or their affiliates), whether for purposes of risk management in connection with the offering, arbitrage or otherwise, (b) buying and selling Relevant Securities on behalf of customers, (c) advising customers as to the purchase or sale of Relevant Securities, including publication of specific company and industry research reports, (d) engaging in securities lending transactions in Relevant Securities and (e) stabilizing the market (as described below). As a result of these activities, the Underwriters may at any time be short or long in Relevant Securities.

It is general market practice in France for the Underwriters, and the lead Underwriter in particular, to maintain an orderly market in subscription rights and existing shares, and it is expected that the lead Underwriter will take measures to avoid extreme price fluctuations during the distribution period.

The activities referred to above may result in the market prices of the Relevant Securities being different from those that might otherwise have prevailed in the open market if rules 10b–6, 10b–7 and 10b–8 had applied in France and elsewhere outside the United States.

United States Securities and Exchange Commission; Division of Market Regulation

June 7, 1994.

M. Pierre Fleuriot,
Directeur General,
Commission des Operations de Bourse,
39–43 Quai Andre Citroen,
75739 Paris cedex 15,
France

Re: Distributions of Certain French Securities, File No. TP 94–199

Dear Monsieur Fleuriot:

In regard to your letter dated June 7, 1994, as supplemented by conversations with the staff, this response thereto is attached to the enclosed photocopy of your correspondence. By doing this, we avoid having to recite or summarize the facts set forth in your letter. Each defined term in this letter has the same meaning as defined in your letter, unless otherwise noted herein.

Response

On the basis of your representations and the facts presented, the Commission hereby grants exemptions from rules 10b–6, 10b–7, and 10b–8 to distribution participants, as defined in rule 10b–6(c)(6)(ii), including issuers of Qualified French Securities (as defined below), and their affiliated purchasers, as defined in rule 10b–6(c)(6)(i) (collectively, "Relevant Parties"), in connection with transactions in Relevant Securities (as defined below) outside the United States during distributions of Qualified French Securities subject to the following terms, conditions, and limitations:

I. Securities

A. The security being distributed ("Qualified French Security") must:

1. be issued by: (i) a "foreign private issuer" within the meaning of rule 3b–4 under the Exchange Act incorporated under the laws of France, which issuer ("French Issuer") has outstanding a component security of the CAC 40 Index; [1] or (ii) a subsidiary of a French Issuer; and

2. Satisfy one of the following:

i. Be a CAC 40 Index component security; or

ii. Be an equity security of a French Issuer having an average daily trading volume that equals or exceeds the equivalent of FF30 million (which exceeded US$5 million as of June 6, 1994), as published by foreign financial regulatory authorities ("FFRAs") [2] and any U.S. securities exchanges or automated inter-dealer quotation systems during the Reference Period; or

iii. Be a security that is convertible into, exchangeable for, or a right to acquire a security of a French Issuer described in paragraph I.A.2.(i) or (ii) above.

B. "Relevant Security" means:

1. A Qualified French Security; or

2. A security of the same class and series as, or a right to purchase, a Qualified French Security.

II. Transactions Effected in the United States

All transactions in Relevant Securities effected in the United States shall comply with rules 10b–6, 10b–7, and 10b–8.

III. Transactions Effected in France

A. All transactions during the Covered Period (as defined below) in Relevant Securities effected in France shall be conducted in compliance with French law. For purposes of these exemptions, "Covered Period" means: (i) in the case of a rights distribution, the period commencing when the subscription price is determined in the United States and continuing until the completion of the distribution in the United States; and (ii) in the case of any other distribution, the period commencing three business days in Paris before the price is determined in the United States and continuing until the completion of the distribution in the United States; *provided, however,* that the Covered Period shall not commence with respect to any Relevant Party until such person becomes a distribution participant.

B. All transactions in Relevant Securities during the Covered Period effected in France on a principal basis shall be effected or reported on the trading facilities of the Societe des Bourses Francaises.

C. Disclosure of Trading Activities.

1. The inside front cover page of the offering materials used in the offer and sale in the United States of a Qualified French

[1] References to the CAC 40 Index refer to the composition of the index on the date of this letter; *provided, however,* that any security added to the CAC 40 Index after the date of this letter also will be treated as a Qualified French Security if its issuer satisfies the requirements in paragraph I.A.1. and such security has an aggregate market value that equals or exceeds the equivalent of FF6 billion (which exceeded US$1 billion as of June 6, 1994) and an average daily trading volume that equals or exceeds the equivalent of FF30 million (which exceeded US$5 million as of June 6, 1994) as published by "foreign financial regulatory authorities" (as defined below) and any U.S. securities exchanges or automated inter-dealer quotation systems, during a period ("Reference Period") that is 20 consecutive business days in Paris within 60 consecutive calendar days prior to the commencement of the Covered Period as defined in paragraph III.A. below.

[2] An FFRA is defined in Section 3(a)(51) of the Exchange Act, 5 U.S.C. 78(c)(51), as any: (A) foreign securities authority; (B) other governmental body or foreign equivalent of a self-regulatory organization empowered by a foreign government to administer or enforce its laws relating to the regulation of fiduciaries, trusts, commercial lending, insurance, trading in contracts of sale of a commodity for future delivery, or other instruments traded on or subject to the rules of a contract market, board of trade, or foreign equivalent, or other financial activities; or (C) membership organization a function of which is to regulate participation of its members in the activities listed above. For purposes of this letter, the Societe des Bourses Francaises is considered to be an FFRA.

Security shall prominently display a statement in substantially the following form, subject to appropriate modification where circumstances require. Such statement shall be in capital letters, printed in bold-face roman type at least as large as ten-point modern type and at least two points leaded:

IN CONNECTION WITH THIS OFFERING, CERTAIN PERSONS MAY ENGAGE IN TRANSACTIONS FOR THEIR OWN ACCOUNTS OR FOR THE ACCOUNTS OF OTHERS IN (IDENTIFY RELEVANT SECURITIES) PURSUANT TO EXEMPTIONS FROM RULES 10b–6, 10b–7, and 10b–8 UNDER THE SECURITIES EXCHANGE ACT OF 1934. SEE "[IDENTIFY SECTION OF OFFERING MATERIALS THAT DESCRIBES THE TRANSACTIONS TO BE EFFECTED]."

2. In addition, there shall be included in the identified section of the offering materials a comprehensive description of the activities that may be undertaken by the Relevant Parties in the Relevant Securities during the distribution.[3]

D. Recordkeeping and Reporting.

1. Each Relevant Party shall keep and provide to the Commission des Operations de Bourse ("COB"), upon request, the information described in paragraph III.D.2. below with respect to its transactions in Relevant Securities in France; provided, however, that in the case of a distribution made pursuant to rights, such information is only required to be kept and reported to the COB during the period or periods commencing at any time during the Covered Period that the rights exercise price does not represent a discount of at least 10 percent from the then current market price of the security underlying the rights and continuing until: (i) the end of the Covered Period; or (ii) until the rights exercise price represents a discount of at least 12 percent from the then current market price of the security underlying the rights.[4]

2. When required pursuant to paragraph III.D.1. above, the Relevant Parties will provide the following information to the COB in a Comma Delimited ASCII (American Standard Code for Information Interchange) format including a common record layout acceptable to the COB and the Division, with respect to transactions during the Covered Period in Relevant Securities:

i. Name of the security, date, time (of execution and reporting, where available to the Relevant Party), price, and volume of each transaction; *provided, however,* that no information regarding a customer transaction need be provided unless such transaction has a value of FF1,500,000 or more;

ii. The exchange or inter-dealer quotation system on which the transaction was effected, if any;

iii. An indication whether such transaction was for a proprietary account or the account of a customer, *provided that* any transaction effected by a Relevant Party for a customer account for which it has exercised discretionary authority shall be reported as a proprietary trade; and

iv. The identity of a counterparty only where such counterparty is a Relevant Party.

3. The Relevant Parties shall keep all documents produced or prepared pursuant to paragraph III.D.2. for a period of not less than two years.

4. Upon the request of the Division, made pursuant to the Administrative Agreement executed between the SEC and the COB on December 14, 1989, the COB will require the production of the information referred to in paragraph III.D.2. above from the Relevant Parties through the lead underwriter. The Relevant Parties will provide this information to the COB within 10 days of the request by the COB and the COB shall transmit the information to the Division within 30 days from the date of the request.

5. Representatives of a Relevant Party will be made available to respond to inquiries of the COB relating to its records.

IV. Transactions Effected in Significant Markets

A. All transactions in Relevant Securities in a "Significant Market," as defined below, shall be effected in accordance with the requirements of rules 10b–6, 10b–7, and 10b–8, except as permitted by paragraph IV.B. below or by other available exemptions. For purposes of these exemptions, "Significant Market" means: (i) SEAQ International or any other dealer market outside the United States and France for which price and volume information is published by an FFRA; or (ii) any other securities market(s) in a single country other than the United States or France to which a French Issuer has applied for listing the Qualified French Security and been accepted, if during the Reference Period the volume in either (i) or (ii) in such Qualified French Security, as published by the relevant FFRA(s) in such securities market, is 10 percent or more of the aggregate worldwide trading volume in that security published by all FFRAs in (i) and (ii), FFRAs in France, and U.S. securities markets to which such French Issuer has applied for listing such Qualified French Security and been accepted.

B. In the case of a distribution of Qualified French Securities made pursuant to rights ("rights distribution"), the Relevant Parties located in the United Kingdom ("U.K. Relevant Parties"): (a) in connection with the rights distribution, may purchase or solicit the purchase of Relevant Securities in transactions solely in response to orders for the accounts of their customers in the ordinary course of their business in the United Kingdom ("customer facilitation activities"); and (b) may bid for or purchase Relevant Securities as principal in market making transactions through SEAQ International during the rights distribution, in each case subject to the following conditions:

1. During the period from five business days prior to the expiration date of the rights distribution and until the expiration date, inclusive, at any time at which the difference between the rights exercise price and the market price of the security underlying the rights (which for this purpose will be taken to mean the mid-price between the highest bid and lowest offer quoted on SEAQ International for the security underlying the rights) does not represent a discount of at least 10 percent from the then current market price of the security underlying the rights, the U.K. Relevant Parties will effect "passive market making" transactions in the Relevant Securities subject to the terms and conditions of *Letter regarding Distributions of SEAQ and SEAQ International Securities* (July 12, 1993) ("LSE Letter");

2. The U.K. Relevant Parties, in accordance with Item 502(d)(1) of Regulation S–K under the Securities Act, shall include a statement regarding transactions which stabilize or maintain the market price of the Relevant Securities with appropriate modification, to reflect the possibility that the U.K. Relevant Parties may engage in market making, including passive market making, and customer facilitation activities that otherwise would be prohibited by rule 10b–6, and shall include pursuant to rule 408 under the Securities Act in the "Plan of Distribution" or similar section of the prospectus, a brief description of such proposed market making and customer facilitation activities in the Relevant Securities; and

3. The recordkeeping and production requirements set forth by the Commission in the LSE Letter shall apply to all transactions effected by or on behalf of the U.K. Relevant Parties' accounts, or for the accounts of customers in connection with customer facilitation activities during the rights distribution.

V. General Conditions

A. For purposes of these exemptions, a two business day cooling-off period shall apply under Rule 10b–6(a)(4)(v), (xi) and (xii) in the United States and each Significant Market, provided that trading in Relevant Securities in Significant Markets shall be subject to the exemptive relief then available in such market, if any, or the record maintenance and record production requirements contained in *Letter regarding Application of Cooling-Off Periods Under Rule 10b–6 to Distributions of Foreign Securities* (April 4, 1994) are satisfied by Relevant Parties in such Significant Market.

B. The lead underwriter or the global coordinator shall promptly, but in any event before the commencement of the Covered Period, provide a list of the Relevant Parties to the COB and written notice ("Notice") to the Division containing the following information: (i) the name of the issuer and the Qualified French Security; (ii) whether the Qualified French Security is a CAC 40 Index component security or information with respect to the market capitalization and the average daily trading volume of the Qualified French Security to be distributed; (iii) the identity of the Significant Markets where the Qualified French Security trades; (iv) if the Notice is for more than one entity, the identity of all underwriters and selling group members relying on these exemptions;

[3] The staff of the Division of Market Regulation ("Division") and the Division of Corporation Finance have reviewed Exhibit A attached to your request letter and believe that the disclosure contained therein would satisfy the requirement of this subparagraph.

[4] For purposes of these exemptions, unless stated otherwise, the market price for a security shall be the closing price at the end of the trading session on the Paris Bourse.

[5] and (v) a statement that the Relevant Parties are aware of the terms and conditions of these exemptions.

C. Any person who fails to comply with the conditions of the exemptions, including a failure to provide requested information, would not be permitted to rely on the exemptions in future distributions. Upon a showing of good cause, however, the Commission or the Division may determine that it is not necessary under the circumstances that the exemptions be denied.

The foregoing exemptions from rules 10b–6, 10b–7, and 10b–8 are based solely on your representations and the facts presented, and are strictly limited to the application of those rules to the proposed transactions. Any different facts or representations might require a different response. Responsibility for compliance with any other applicable provisions of the federal securities laws must rest with the Relevant Parties. The Division expresses no view with respect to any other questions that the proposed transactions may raise, including, but not limited to, the adequacy of disclosure concerning, and the applicability of any other federal or state laws to, the proposed transactions.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Robert L.D. Colby,

Deputy Director.

[FR Doc. 94–14738 Filed 6–16–94; 8:45 am]

BILLING CODE 8010–01–P

[Release No. 34–34198; International Series Release No. 672; File No. SR–Amex–94–19]

Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change and Amendment No. 1 to Proposed Rule Change by the American Stock Exchange, Inc. Relating to the Listing and Trading of Options on the Nikkei Stock Index 300

June 10, 1994.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on May 31, 1994, the American Stock Exchange, Inc. ("Amex" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Amex. On June 10, 1994, the Amex filed Amendment No. 1 to the proposed rule change.[3] The Commission is publishing this notice to solicit comments on the proposed rule change and Amendment No. 1 from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is proposing to trade standardized options on the Nikkei Stock Index 300 ("Index"). In addition, the Amex proposes to amend Amex Rule 904C(b) to provide for a position limit for the Index of 50,000 contracts on the same side of the market, provided that no more than 30,000 of such contracts are in series in the nearest expiration month.

The text of the proposed rule change is available at the Office of the Secretary, the Amex, and at the Commission.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Amex included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Amex has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

The Exchange is proposing to trade standardized options on the Index. The Index is comprised of 30 stocks which are representative of the first section of the Tokyo Stock Exchange ("TSE").

The Index was designed and is maintained by Nihon Keizai Shimbun, Inc. ("Nihon"). The Index's component securities were selected for their high market capitalizations and high degree of liquidity, and are representative of the relative distribution of industries within the broader Japanese equity market.

The median capitalization of the companies in the Index on March 31, 1994, was 340.1 billion yen (US $3.3 billion at the exchange rate of 102.75 yen per dollar prevailing on March 31, 1994). The average market capitalization of these companies was US $7.5 billion on the same date and using the same rate of exchange. The individual market capitalizations of these companies ranged from a low of US $875 million to a high of US $76.5 billion on March 31, 1994. The largest stock accounted for 3.41 percent of the total weighting of the Index, while the smallest accounted for 0.04 percent.

The Index is a capitalization-weighted index and is calculated by multiplying the price of each component security (in Japanese yen) by its number of shares outstanding, adding those sums and dividing by the current Index divisor. The Index divisor was determined initially to yield a benchmark value of 100 on October 1, 1982. The Index's closing value on April 13, 1994, was 296.35. The Index multiplier is 100, and, for valuation purposes, one Index unit (1.0) is assigned a fixed value of one U.S. dollar.

The Index will be maintained by Nihon. To maintain the continuity of the Index, the divisor will be adjusted to reflect certain events relating to the component securities. These events include, but are not limited to, changes in the number of shares outstanding, spinoffs, certain rights issuances, and mergers and acquisitions. The composition of the Index will be reviewed periodically by Nihon.

The proposed options on the Index are to be European-style (*i.e.*, exercises are permitted at expiration only), and cash-settled. Trading hours for the Index options will be 9 a.m. to 4:15 p.m. (New York time). Options on the Index will expire on the Saturday following the third Friday of the expiration month ("Expiration Friday"). The last trading day in an option series normally will be the business day immediately preceding Expiration Friday of each expiration month (normally a Thursday) and trading in expiring options will cease at the close of trading on such day. The exercise settlement value for all of the Index's expiring options will be the special opening quotation, which is calculated based upon the opening price of each of the component securities on the TSE on the last business day prior to expiration. If a stock fails to open for

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[5] Supplemental Notices shall be provided for underwriters and selling group members identified after a Notice has been filed.

[1] 15 U.S.C. section 78s(b)(1) (1988).

[2] 17 CFR § 240.19b–4 (1993).

[3] In Amendment No. 1, the Amex amended its proposal to provide that: (1) The exercise settlement value for all of the Nikkei Stock Index 300 expiring option contracts will be the special opening quotation, which is calculated based upon the opening prices of each of the component securities on the Tokyo Stock Exchange on the last business day prior to expiration; (2) the position and exercise limits for Nikkei Stock Index 300 option contracts in the series with the nearest expiration month will be 30,000 contracts; (3) the trading unit for Nikkei Stock Index 300 options is the Index value multiplied by $100; (4) for valuation purposes, one Nikkei Stock Index 300 unit (1.0) is assigned a fixed value of one U.S. dollar; and (5) the Tokyo Stock Exchange has recently requested that a new comprehensive surveillance sharing agreement be entered into for options on the Nikkei Stock Index 300, which agreement will cover the sharing of surveillance information regarding the index's component securities. See Letter from Claire P. McGrath, Managing Director and Special Counsel for Derivative Securities, Amex, to Michael Walinskas, Branch Chief, Derivatives Regulation, Division of Market Regulation, Commission, dated June 10, 1994.

trading, the last available price of the stock will be used to calculate the Index's settlement value. When an option expiration is moved in accordance with an Exchange holiday, the last trading day for the expiring Index options will be Wednesday, and the exercise settlement value of the Index options will be determined at the opening of the regular Thursday trading session on the TSE, even if the TSE is open on Friday. If the TSE will be closed on the Friday before expiration but the Amex is not, the last trading day for expiring Index options will be on Wednesday.

The Exchange plans to list options series with expirations in the three near-term calendar months and in the three additional calendar months in the March cycle. In addition, longer-term options series having up to 36 months to expiration may be traded. In lieu of such long-term options on a full-value Index level, the Exchange may list long-term, reduced-value put and call options based on one-tenth (1/10th) of the Index's full value. The current and closing Index value of any such reduced-value long-term option will be rounded to the nearest one-hundredth (1/100th) after the initial computation. In either event, the interval between expiration months for either a full-value or reduced-value long-term option will not be less than six months.

Amex Rules 900C through 980C will apply to the trading of standardized and long-term option contracts based on the Index. These rules cover issues such as sales practices, margin requirements, exercise prices, position and exercise limits, and floor trading procedures. Surveillance procedures currently used to monitor trading in each of the Exchange's other index options also will be used to monitor trading in options on the Index. The Exchange represents that the TSE has requested that a new comprehensive surveillance sharing agreement be executed with respect to options on the Index. This agreement will cover the sharing of surveillance information regarding the Index's component securities.

The Exchange believes that the Index is a Stock Index Option under Amex Rule 901C(a) and a Broad Stock Index Group under Amex Rule 900C(b)(1). With respect to Amex Rule 903C(b), the Exchange proposes to list near-the-money (*i.e.*, Within ten points above or below the current index value) option series on the Index at 2½ point strike (exercise) price intervals when the value of the Index is below 200 points. In addition, the Exchange proposes to establish, pursuant to Amex Rule 904C(b), a position limit of 50,000 contracts on the same side of the market, provided no more than 30,000 of such contracts are in series in the nearest expiration month.

In anticipation of substantial customer activity in the options on this Index (including institutional activity), the Exchange seeks to have the ability to utilize its Auto-Ex system for orders in the Index options of up to 50 contracts. Auto-Ex is the Exchange's automated execution system which provides for the automatic execution of market and marketable limit orders at the best bid or offer at the time the order is entered. The Exchange believes that the ability to use Auto-Ex for orders of up to 50 contracts will provide customers with deep, liquid markets, as well as expeditious executions.

The Exchange believes that the proposed rule change is consistent with section 6(b) of the Act in general, and furthers the objectives of section 6(b)(5) in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanism of a free and open market and a national market system.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Amex does not believe that the proposed rule change will impose any burden on competition.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period: (i) As the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding, or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve such proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC. Copies of such filing also will be available for inspection and copying at the principal office of the Amex. All submissions should refer to File No. SR–Amex–94–19 and should be submitted by July 8, 1994.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[4]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 94–14739 Filed 6–16–94; 8:45 am]

BILLING CODE 8010–01–M

[Release No. 34–34200; File No. SR–MSTC–94–08]

Self-Regulatory Organizations; Midwest Securities Trust Company; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating to Reorganization Processing

June 10, 1994.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] notice is hereby given that on May 5, 1994, the Midwest Securities Trust Company ("MSTC") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by MSTC. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[4] 17 CFR § 200.30–3(a)(12) (1993).

[1] 15 U.S.C. section 78s (b)(1) (1988).

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change adds to Article IV of MSTC's rules an interpretation which describes the Reorganization Processing System.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, MSTC included statements concerning the purpose of and basis for the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. MSTC has prepared summaries, set forth in sections A, B, and C below, or the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

The purpose of the rule filing is to set forth in MSTC's rules the fact that MSTC may provide reorganization notices by computer facility. The computer facility that MSTC developed for the purpose of providing reorganization notices is a user-friendly, real-time computer system that allows participants, through the use of intuitive, data-driven displays, to view offer information on-line. It will allow MSTC participants to inquire as to various offer criteria, including offer type(s), target CUSIP(s), MSTC offer status, and offer date(s). Participants will be able to tailor their inquiries to only those offers in which they have a depository position. They may also view the location of a position within their MSTC account(s) for a chosen CUSIP. In addition, participants will be able to inquire as to a CUSIP's reorganization history.

Rule 4 of Article IV of MSTC's rules describes MSTC's activities with respect to reorganizations, and sections 3 and 4 of Rule 2 of Article IV describe MSTC's responsibilities with respect to reorganization information disseminated by MSTC. Pursuant to these rules, MSTC currently provides daily notification of newly announced and updated corporate reorganization offers to its participants through manually produced, hard-copy notices. MSTC produces these notices, which include pertinent offer information, for a variety of offer types including, but not limited to, mergers, reverse splits, tenders and exchanges, expiring rights and warrants, put options on corporate and municipal bonds, and expiring convertible securities.

Each current notice includes a disclaimer to the effect that MSTC does not guarantee the correctness or completeness of the information provided. This liability standard has been used for over twenty years and was part of MSTC's written procedures when MSTC applied for and received permanent registration as a clearing agency. The proposed interpretation sets forth language that limits MSTC's liability with respect to the information provided by computer. The liability standard is substantially the same as the standard for the hard copy notices.

The proposed rule change is consistent with section 17A of the Act in that it will facilitate the prompt and accurate clearance and settlement of securities transactions.

B. Self-Regulatory Organization's Statement on Burden on Competition

MSTC does not believe that the proposed rule change will impose any burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants, or Others

Written comments were not and are not intended to be solicited with respect to the proposed rule change, and none have been received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

MSTC requests that the proposed rule change become effective upon filing pursuant to 19(b)(3)(A)(iii)[2] of the Act and subparagraph (e)(4) of rule 19b–4[3] thereunder. The foregoing rule change effects a change in an existing service that does not adversely affect the safeguarding of securities or funds in the custody or control of MSTC or for which MSTC is responsible and does not significantly affect the respective rights or obligations of MSTC or persons using the service. At any time within sixty days of the filing of such rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. section 552, will be available for inspection and copying in the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC 20549. Copies of such filing will also be available for inspection and copying at the principal office of the above-referenced self-regulatory organization.

All submissions should refer to File No. SR–MSTC–94–08 and should be submitted by July 8, 1994.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.[4]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 94–14784 Filed 6–16–94; 8:45 am]

BILLING CODE 8010–01–M

[2] 15 U.S.C. section 78s(b)(3)(A)(iii) (1988).

[3] 17 CFR § 240.19b–4(e)(4) (1993).

[Release No. 34–34193; File No. SR–NSCC–94–08]

Self-Regulatory Organizations; National Securities Clearing Corporation; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Modifying NSCC's Correction Fees

June 10, 1994.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934,[1] notice is hereby given that on June 1, 1994, the National Securities Clearing Corporation ("NSCC") filed with the Securities and Exchange Commission ("Commission") the proposed rule change (File No. SR–NSCC–94–08) as described in Items I, II, and III below, which Items have been prepared by primarily NSCC. The Commission is publishing this notice to solicit comments on the proposed rule changes from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change modifies NSCC's fee structure as it relates to

[4] 17 CFR § 200.30–3(a)(12) (1993).

[1] 15 U.S.C. section 78s(b)(1) (1988).

correction fees for the processing of municipal securities transactions. The text of the rule change is set forth at Exhibit A.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, NSCC included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. NSCC has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

The purpose of the rule change is to modify NSCC's fee structure as it relates to correction fees for the processing of municipal securities transactions to reflect the fact that correction capabilities have been accelerated in conformity with comparison capabilities. In August of 1993, NSCC accelerated the comparison processing for municipal securities transactions to the date after trade date ("T+1"). Previously NSCC had charged participants for supplemental input on or after T+2. Because correction processing can now be initiated on T+1, the NSCC fee structure is being modified in order to charge participants for supplemental input on or after T+1. Although the acceleration of municipal bond comparison occurred in August of 1993, this fee change will be effective for supplemental comparison processing as of June 1, 1994.

The proposed rule change provides for the equitable allocation of dues, fees, and charges among participants. Therefore, NSCC believes that it is consistent with the requirements of the Act, particularly section 17A(b)(3)(D) of the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

NSCC believes that the proposed rule changes will not have any impact or impose a burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

NSCC has neither solicited nor received any written comments.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to section 19(b)(3)(A)(ii) of the Act[2] and subparagraph (e)(2) of Rule 19b–4 thereunder because it establishes a due, fee, or other charge imposed by NSCC.[3] At any time within sixty days of the filing of such rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC 20549. Copies of such filing will also be available for inspection and copying at the principal office of NSCC. All submissions should refer to File No. SR–NSCC–94–08 and should be submitted by July 8, 1994.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.[4]

Margaret H. McFarland,

Deputy Secretary.

Exhibit A

The text of the proposed rule change is as follows: Italicized text indicates additions. Bracketed text indicates deletions.

3. *Amex and OTC Corporate Bond and UIT* [Bond System] Correction Fees[5]:

* * * * *

4. Municipal Bond System Correction Fees:

a. All supplemental input after T (Advisory, As Of, Demand As Of, Withhold) except for Demand As Of Advisories and Trades Deleted.

(1) T+1—$.40 to the submitter
(2) T+1—$.60 to the submitter
(3) after T+2—$1.00 to the submitter

b. Trades Deleted:

(1) T+1—$.40 to both sides
(2) T+2—$.60 to both sides
(3) after T+2—$1.00 to both sides

5[4]. OTC Equity and Bond System Correction Fees:

* * * * *

[FR Doc. 94–14733 Filed 6–16–94; 8:45 am]

BILLING CODE 8010–01–M

[Rel. No. IC–20350; 812–8834]

American AAdvantage Funds, et al.; Notice of Application

June 10, 1994.

AGENCY: Securities and Exchange Commission ("SEC").

ACTION: Notice of application for exemption under the Investment Company Act of 1940 (the "Act").

APPLICANTS: American AAdvantage Funds, and future portfolios thereof (the "Trust"), and AMR Investment Services, Inc. ("AMR").

RELEVANT ACT SECTIONS: Order requested under section 6(c) for an exemption from sections 18(f)(1), 18(g), and 18(i) of the Act.

SUMMARY OF APPLICATION: Applicants seek an amendment to a prior order that permits applicants to issue two classes of shares representing interests in the same portfolio of securities (the "Prior Order").[1] The requested amendment would permit applicants to issue an unlimited number of classes of shares. Applicants request that any relief granted pursuant to the application also apply to any future open-end management investment companies that are advised by AMR or an entity controlling, controlled by, or under common control (within the meaning of section 2(a)(9) of the Act) with AMR and that issue and sell classes of shares on a basis identical in all material respects to that described in the application.

FILING DATE: The application was filed on February 8, 1994, and amended on March 11, 1994, May 11, 1994, and June 7, 1994.

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[2] 15 U.S.C. section 78s(b)(3)(A)(ii) (1988).

[3] 17 CFR § 240.19b–4(e)(4) (1993).

[4] 17 CFR § 200.30–3(a)(12) (1993).

[5] The abbreviations Amex, OTC, and UIT refer respectively to: the American Stock Exchange, Inc., over-the-counter, and unit investment trust.

[1] Investment Company Act Release Nos. 18298 (Sept. 6, 1991) (notice) and 18346 (Oct. 7, 1991) (order).

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the SEC orders a hearing. Interested persons may request a hearing by writing to the SEC's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on July 6, 1994, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the SEC's Secretary.

ADDRESSES: Secretary, SEC, 450 Fifth St., NW., Washington, DC 20549. Applicants, 4333 Amon Carter Boulevard, Fort Worth, Texas 76155.

FOR FURTHER INFORMATION CONTACT: Marc Duffy, Staff Attorney, (202) 942–0565, or C. David Messman, Branch Chief, (202) 942–0564 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee at the SEC's Public Reference Branch.

APPLICANTS' REPRESENTATIONS: 1. The Trust is registered under the Act as an open-end management investment company. The Trust currently offers shares representing interests in seven investment portfolios (together with future investment portfolios, the "Funds"); the American AAdvantage Money Market Fund, the American AAdvantage Municipal Money Market Fund; and the American AAdvantage U.S. Treasury Money Market Fund (the "Money Market Funds"); the American AAdvantage Balanced Fund (the "Balanced Fund"); the American AAdvantage Equity Fund (the "Equity Fund"); the American AAdvantage International Equity Fund (the "International Equity Fund"); and the American AAdvantage Limited-Term Income Fund (the "Limited-Term Income Fund" and, collectively with the Balanced Fund, the Equity Fund, and International Equity Fund, the "Non-Money Market Funds").

2. AMR is the manager of each Fund, the sole investment adviser of the Money Market Funds, and the sole active investment adviser to the Limited-Term Income Fund. AMR is a wholly-owned subsidiary of AMR Corporation, the parent company of American Airlines, Inc. The assets of each of the Non-Money Market Funds, other than the Limited-Term Income Fund, are allocated by AMR among certain investment advisers designated for each Fund.

3. Applicants seek to amend the Prior Order to permit the Funds to offer an unlimited number of classes of shares in their existing and future investment portfolios. These new classes will be offered (a) in connection with a plan adopted pursuant to rule 12b–1 under the Act (a "Distribution Plan"), (b) in connection with a non-rule 12b–1 shareholder services plan (a "Shareholder Services Plan"), (c) in connection with the allocation of certain expenses, as described below, that are directly attributable only to certain classes, and/or (d) without any Distribution Plan or Shareholder Services Plan. The Distribution Plan and the Shareholder Services Plan are sometimes collectively referred to as the "Plans."

4. Shares of the Funds presently are offered with no front-end sales charge. Pursuant to the terms of the Prior Order, the Money Market Funds currently offer and sell two classes of shares designated as Mileage Class shares and Institutional Class shares. Mileage Class shares are presently offered and sold only to natural persons and certain grantor trusts. Institutional Class shares of the Money Market Funds and shares of the Non-Money Market Funds are presently offered and sold primarily to institutions.

5. Shares of each existing Fund are distributed directly by the Trust. In the future, some or all classes of the Funds may be distributed through one or more principal underwriters. Under the current self-distribution arrangement, distribution activities are carried out primarily by officers of the Trust. The Mileage Class of each of the Money Market Funds has adopted a rule 12b–1 plan, which provides that each Mileage Class will pay .25% of its average daily net assets to AMR as compensation for distribution services.

6. Currently, each shareholder of the Non-Money Market Funds is required to enter into a shareholder services agreement with AMR (a "Shareholder Services Agreement"). Under this agreement, AMR provides or oversees on behalf of the shareholder's account certain administrative and management services (other than investment advisory and portfolio allocation services) for which each shareholder (and not the Fund) pays an annualized fee directly to AMR. This fee currently equals 0.30% of a shareholder's assets invested in each Fund.

7. If applicants' proposed multiple class distribution system ("Multiple Class System") is approved by the SEC, and subject to shareholder approval, the Non-Money Market Funds will no longer have Shareholder Services Agreements. After implementation of the Multiple Class System, the Non-Money Market Funds will have internalized fees as described below. Certain classes of the Funds, however, may establish an externalized account maintenance fee for low balance accounts. It is presently expected that any account maintenance fee charged will not exceed an annual fee of approximately $25. The fee will be a direct charge against the shares held in the account and will be collected by redeeming a sufficient number of full and/or fractional shares.

8. With respect to each new class of shares created, the Funds could enter into a Distribution Plan agreement and/or a Shareholder Services Plan agreement with AMR and/or other groups, organizations or institutions ("Organizations") concerning the provision of certain services to shareholders of a particular class.

9. Because many of the services contemplated under a Distribution Plan will be distribution related, such Plan will be adopted pursuant to rule 12b–1 under the Act. A Shareholder Services Plan will be adopted and operated in accordance with the procedures set forth in rule 12b–1 (b) through (f) as if the expenditures made thereunder were subject to rule 12b–1, although the shares offered in connection with such a Plan need not be accorded the voting rights specified in rule 12b–1. Under a Shareholder Services Plan, fees will be paid by a Fund to one or more Organizations for shareholder services provided with respect to the shares. Organizations may charge other fees directly to class shareholders who are the beneficial owners of shares in connection with class shareholder accounts.

10. With respect to each new class, a Fund could pay an Organization either directly or indirectly pursuant to a Distribution Plan or Shareholder Services Plan for its services and assistance in accordance with the terms of its particular Plan agreement ("Plan Payments") and the expense of such payments will be borne entirely by the beneficial owners of the class of the Fund to which each Plan agreement relates. Plan Payments paid to an Organization pursuant to a Distribution Plan agreement currently are not expected to exceed .75% of the average daily net asset value of the shares of the class subject to that particular Distribution Plan agreement. Similarly, Plan Payments paid to an Organization

pursuant to a Shareholder Services Plan agreement are currently not expected to exceed .30% of the average daily net value of the shares of the class subject to that particular Shareholder Services Plan agreement.

11. If any class of a Fund's shares are distributed by a member of the National Association of Securities Dealers, Inc. ("NASD"), with respect to each class of shares such Fund shall comply with Article III, section 26 of the Rules of Fair Practice of the NASD as it relates to the maximum amount of asset-based sales charges that may be imposed by an investment company.

12. Applicants anticipate that shares of one new class will be offered to tax-exempt employee benefit and retirement plans of AMR Corporation and its affiliates (the "AMR Class"). Other new classes, as well as the existing Institutional Class and Mileage Class, will be offered to institutional investors (other than such benefit plans) and to natural persons (the "Unaffiliated Classes"). The offerees of AMR Class shares, on the one hand, and of the Unaffiliated Classes, on the other hand, will not overlap. Offerees of the AMR Class shares will consist of tax-exempt employee benefit and retirement plans of AMR Corporation and its affiliates for the benefit of employees, under which the assets are held in trust by a trustee and employees have limited pre-retirement access to the assets. Applicants propose to describe, in a separate prospectus, the expenses, performance data and net asset value of the AMR Class shares only to investors eligible to purchase AMR Class shares and not to investors eligible to purchase shares of the Unaffiliated Classes. Only those limited "inside" investors described above will be eligible to purchase AMR Class shares. Persons to whom the Unaffiliated Classes will be offered will be ineligible to purchase AMR Class shares since such investors do not fall within the scope of AMR Class offerees as defined above.

13. In addition, because shares of each class will be marketed to different types of investors, the method of soliciting sales of such shares will vary. A separate prospectus will be used to offer AMR Class shares and will be tailored to the needs of such investors regarding purchase procedures and cost information.

14. The shares in different classes within a Fund might have different exchange privileges. Any exchange privilege connected to any of the Funds' shares will be limited to exchanges among Funds that are part of the same "group of investment companies," as defined in rule 11a–3 under the Act. All exchanges will be conducted in accordance with the provisions of rule 11a–3. In addition, applicants anticipate that shares of each Fund will be exchangeable for shares of other classes within the same Fund to the extent that the shareholder will have been eligible to purchase the shares acquired in the exchange.

15. The expenses of the Trust that cannot be attributed directly to any one Fund ("Trust Expenses") generally will be allocated to each Fund based on the relative net assets of those Funds. Certain expenses that may be attributable to a particular Fund, but not a particular class ("Fund Expenses") will be allocated to each class based on the daily net assets of the class. Finally, certain expenses may be attributable to a particular class of shares of a Fund ("Class Expenses"). Class Expenses will be charged directly to the net assets of the particular class and thus will be borne on a *pro rata* basis by the outstanding shares of such class.

16. Class Expenses may include: (a) Plan Payments relating to a class of shares, (b) transfer agent fees identified as being attributable to a specific class of shares, (c) stationery, printing, postage, and delivery expenses related to preparing and distributing materials such as shareholder reports, prospectuses, and proxy statements to current shareholders of a specific class, (d) Blue Sky registration fees incurred by a class of shares, (e) SEC registration fees incurred by a class of shares, (f) expenses of Administrative Services Agreements and other administrative personnel and services as required to support the shareholders of a specific class, (g) trustees' fees or expenses incurred as a result of issues relating to one class of shares, (h) accounting expenses relating solely to one class of shares, (i) auditors' fees, litigation expenses, and legal fees and expenses relating to a class of shares, and (j) expenses incurred in connection with shareholders meetings as a result of issues relating to one class of shares. Any other expense will be allocated as a Class Expense only if such allocation is approved by a further SEC exemptive order.

17. AMR may choose to waive or reimburse Class Expenses on certain classes of the Fund on a voluntary, temporary basis. Class Expenses are by their nature specific to a given class and obviously expected to vary from one class to another. Applicants believe that it is acceptable and consistent with shareholder expectations to reimburse or waive Class Expenses at different levels for different classes of the same Fund.

18. In addition, AMR may waive or reimburse Trust Expenses and/or Fund Expenses (with or without a waiver or reimbursement of Class Expenses), but only if the same proportionate amount of Trust Expenses and/or Fund Expenses are waived or reimbursed for each class of a Fund. Thus, any Trust Expenses that are waived or reimbursed will be credited to each class of a Fund according to the relative net assets of the classes. Similarly, any Fund Expenses that are waived or reimbursed will be credited to each class of that Fund according to the relative net assets of the classes. Trust Expenses and Fund Expenses apply equally to all classes of a given Fund. Accordingly, it may not be appropriate to waive or reimburse Trust Expenses or Fund Expenses at different levels for different classes of the same Fund.

Applicants' Legal Analysis

1. Applicants request an amendment to the Prior Order exempting them from the provisions of sections 18(f)(1), 18(g), and 18(i) of the Act to the extent that the proposed issuance and sale of an unlimited number of classes of shares representing interests in the same Funds might be deemed to (a) result in a "senior security" within the meaning of section 18(g) and thus be prohibited by section 18(f)(1), and (b) violate the equal voting provisions of section 18(i).

2. The proposed Multi-Class Arrangement does not involve borrowings and does not affect the Funds' existing assets or reserves. In addition, the proposed arrangement will not increase the speculative character of the shares in a Fund, since all shares will participate in all of a Fund's appreciation, income, and expenses in the manner described above.

3. Applicants believe that the proposed allocation of expenses and voting rights under the Multi-Class System is equitable and will not discriminate against any group of shareholders. Investors purchasing shares offered in connection with a Plan and/or bearing Class Expenses will bear the costs associated with the related services and have exclusive shareholder voting rights with respect to matters affecting the applicable Plan. Conversely, investors purchasing shares that are not covered by a plan or not bearing Class Expenses will not be burdened with such expenses or enjoy such voting rights.

4. Accordingly, applicants assert that the requested amendment is appropriate in the public interest and is consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act.

Applicants' Conditions

Applicants agree that the amended order granting the requested relief shall be subject to the following conditions:

1. Each class of shares of a Fund will represent interests in the same portfolio of investments, and be identical in all respects, except as set forth below. The only differences between the classes of shares of a Fund will relate solely to one or more of the following: (a) Expenses assessed to a class pursuant to a Plan, if any, with respect to such class; (b) the impact of Class Expenses, which are limited to any or all of the following: (i) Transfer agent fees identified as being attributable to a specific class of shares, (ii) stationery, printing, postage, and delivery expenses related to preparing and distributing materials such as shareholder reports, prospectuses, and proxy statements to current shareholders of a specific class, (iii) Blue Sky registration fees incurred by a class of shares, (iv) SEC registration fees incurred by a class of shares, (v) expenses of Administrative Services Agreements and other administrative personnel and services as required to support the shareholders of a specific class, (vi) Trustees' fees or expenses incurred as a result of issues relating to one class of shares, (vii) accounting expenses relating solely to one class of shares, (viii) auditors' fees, litigation expenses, and legal fees and expenses relating to a class of shares, and (ix) expenses incurred in connection with shareholders meetings as a result of issues relating to one class of shares; (c) the fact that the classes will vote separately with respect to matters relating to the Fund's Distribution Plan, if any, or any other matters appropriately limited to such class(es); (d) the different exchange privileges of the class of shares, if any; and (e) the designation of each class of shares of a Fund. Any additional incremental expenses not specifically identified above that are subsequently identified and determined to be properly applied to one class of shares shall not be so applied unless and until approved by the SEC.

2. The Board of Trustees (the "Board"), including a majority of the Trustees who are not interested persons of the Trust ("Independent Trustees") will have approved the Multiple Class System with respect to a particular Fund prior to the implementation of the system by that Fund. The minutes of the meetings of the Board of the Trust regarding the deliberations of the Trustees with respect to the approvals necessary to implement the Multiple Class System will reflect in detail the reasons for the determination by the Board that the proposed Multiple Class System is in the best interests of each Fund and its shareholders.

3. The initial determination of the Class Expenses that will be allocated to a particular class and any subsequent changes thereto will be reviewed and approved by a vote of the Board of Trustees of the Trust, including a majority of the Independent Trustees. Any person authorized to direct the allocation and disposition of monies paid or payable by a Fund to meet Class Expenses shall provide the Board and the Trustees shall review, at least quarterly, a written report of the amounts so expended and the purposes for which such expenditures were made.

4. If any class is subject to a Shareholder Services Plan, the Plan will be adopted and operated in accordance with the procedures set forth in rule 12b–1 (b) through (f) as if the expenditure made thereunder were subject to rule 12b–1, except that shareholders need not enjoy the voting rights specified in rule 12b–1.

5. On an ongoing basis, the Board of the Trust, pursuant to its fiduciary responsibilities under the Act and otherwise, will monitor each Fund, as applicable, for the existence of any material conflicts among the interests of the classes of its shares, if there is more than one class. The Board, including a majority of the Independent Trustees, shall take such actions as is reasonably necessary to eliminate any such conflicts that may develop. AMR and each Fund's manager investment adviser(s) and distributor, if any, will be responsible for reporting any potential or existing conflicts to the Board. If such a conflict arises, AMR, and the investment adviser(s) and distributor, if any, at their own expense, will take such actions as are necessary to remedy such conflict, including establishing a new registered management investment company, if necessary.

6. The Board of each Fund will receive quarterly and annual statements concerning the amounts expended under the Plans complying with paragraph (b)(3)(ii) of rule 12b–1, as it may be amended from time to time. In the statements, only expenditures properly attributable to the sale or servicing of a particular class of shares will be used to justify any fee for services charged to that class. Expenditures not related to the sale or servicing of a particular class will not be presented to the Board to justify any fee attributable to that class. The statements, including the allocations upon which they are based, will be subject to the review and approval of the Independent Trustees in the exercise of their fiduciary duties.

7. Dividends and other distributions paid by a Fund with respect to each class of its shares, to the extent any dividends and other distributions are paid, will be declared and paid on the same day and at the same time, and will be determined in the same manner and will be in the same amount, except that the amount of the dividends and other distributions declared and paid by a particular class may be different from that of another class because Plan Payments made by a class under a Plan and other Class Expenses will be borne exclusively by that class.

8. The methodology and procedures for calculating the net asset value and dividends and other distributions of the classes and the proper allocation of expenses among the classes have been reviewed by an expert (the "Expert") who has rendered a report to the Board of the Trust, which has been provided to the staff of the SEC, stating that such methodology and procedures are adequate to ensure that such calculations and allocations would be made in an appropriate manner. On an ongoing basis, the Expert, or an appropriate substitute Expert, will monitor the manner in which the calculations and allocations are being made and, based upon such review, will render at least annually a report to the Funds that the calculations and allocations are being made properly. The reports of the Expert will be filed as part of the periodic reports filed with the SEC pursuant to sections 30(a) and 30(b)(1) of the Act. The work papers of the Expert with respect to such reports, following request by the Funds which the Funds agree to make, will be available for inspection by the SEC staff upon written request to the Funds for such work papers by a senior member of the Division of Investment Management or a Regional office of the SEC, limited to the Director, an Associate Director, the Chief Accountant, the Chief Financial Analyst, Assistant Director, and any Regional Administrators or Associate or Assistant Administrators. The initial report of the Expert is a "Special Purpose" report on "policies and procedures placed in operation" in accordance with Statements on Auditing Standards ("SAS") No. 70, "Reports on the Processing of Transactions by Service Organizations" of the American Institute of Certified Public Accountants ("AICPA"). Ongoing reports will be reports on "policies and procedures placed in operation and tests of operating effectiveness" prepared in

accordance with SAS No. 70 of the AICPA, as it may be amended from time to time, or in similar auditing standards as may be adopted by the AICPA from time to time.

9. Applicants have adequate facilities in place to ensure implementation of the methodology and procedures for calculating the net asset value and dividends and other distributions of the classes of shares and the proper allocation of expenses among the classes of shares and this representation has been concurred with by the Expert in the initial report referred to in condition 8 above and will be concurred with by the Expert, or an appropriate substitute Expert, on an ongoing basis at least annually in the ongoing reports referred to in condition 8 above. Applicants will take immediate corrective action if the Expert or appropriate substitute Expert, does not so concur in the ongoing reports.

10. If any class of shares is distributed by a principal underwriter, the prospectus of such Fund will contain a statement to the effect that a salesperson and any other person entitled to receive compensation for selling or servicing shares of a Fund may receive different compensation with respect to one particular class of shares over another in the Fund.

11. If any class of shares is distributed by a principal underwriter, the Trust will adopt compliance standards as to when each class of shares may appropriately be sold to particular investors. Applicants will require all persons selling shares of a Fund to agree to conform to such standards.

12. The conditions pursuant to which the amended exemptive order is granted and the duties and responsibilities of the Board of the Trust with respect to the Multiple Class System will be set forth in guidelines which will be furnished to the Trustees.

13. Each Fund will disclose the respective expenses, performance data, distribution arrangements, services, fees, sales loads, and exchange privileges applicable to each class of shares, other than AMR Class shares, in every prospectus, regardless of whether all classes of shares are offered through each prospectus. AMR Class shares will be offered solely pursuant to a separate prospectus. The prospectus for the AMR class shares will disclose the existence of the Funds' other classes, and the prospectus for the Funds' other classes will disclose the existence of the AMR Class shares and will identify the investors eligible to purchase AMR Class shares. Each Fund will disclose the respective expenses and performance data applicable to all classes of shares in every shareholder report. The shareholder reports will contain, in the statement of assets and liabilities and statement of operations, information related to the Fund as a whole generally and not on a per class basis. Each Fund's per share data, however, will be prepared on a per class basis with respect to all classes of shares of such Fund. To the extent any advertisement or sales literature describes the expenses or performance data applicable to any class of shares, it will also disclose the respective expenses and/or performance data applicable to all classes of shares, except AMR Class shares. Advertising materials reflecting the expenses or performance data for AMR Class shares will be available only to those persons eligible to purchase such shares. The information provided by applicants for publication in any newspaper or similar listing of a Fund's net asset value and public offering price will present each class of shares separately. The Funds need not provide such information with respect to the AMR Class shares; however, to the extent that a Fund chooses to do so, the net asset value or public offering price of AMR Class shares also will be presented separately.

14. Applicants acknowledge that the grant of the amended exemptive order requested by this application will not imply SEC approval of, authorization of, or acquiescence in any particular level of payments that any Fund may make pursuant to a Plan in reliance on the amended exemptive order.

For the Commission, by the Division of Investment Management under delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 94–14734 Filed 6–16–94; 8:45 am]

BILLING CODE 8010–01–M

Issuer Delisting; Notice of Application to Withdraw from Listing and Registration; (EastGroup Properties, Shares of Beneficial Interest, $1.00 Par Value) File No. 1–7094

June 10, 1994.

EastGroup Properties ("Company") has filed an application with the Securities and Exchange Commission ("Commission"), pursuant to section 12(d) of the Securities Exchange Act of 1934 ("Act") and Rule 12d2–2(d) promulgated thereunder, to withdraw the above specified security from listing and registration on the American Stock Exchange, Inc. ("Amex").

The reasons alleged in the application for withdrawing these securities from listing and registration include the following:

According to the Company, in addition to being listed on the Amex, its Shares of Beneficial Interest are listed on the New York Stock Exchange, Inc. ("NYSE"). The Company's Shares of Beneficial Interest commenced trading on the NYSE at the opening of business on May 3, 1994, and concurrently therewith such securities were suspended from trading on the Amex.

In making the decision to withdraw its Share of Beneficial Interest from listing on the Amex, the Company considered the direct and indirect costs and expenses attendant on maintaining the dual listing of its Shares of Beneficial Interest on the NYSE and on the Amex. The Company does not see any particular advantage in the dual trading of its Shares of Beneficial Interest and believes that dual listing would fragment the market for its Shares of Beneficial Interest.

Any interested person may, on or before July 1, 1994 submit by letter to the Secretary of the Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549, facts bearing upon whether the application has been made in accordance with the rules of the exchanges and what terms, if any, should be imposed by the Commission for the protection of investors. The Commission, based on the information submitted to it, will issue an order granting the application after the date mentioned above, unless the Commission determines to order a hearing on the matter.

For the commission, by the Division of Market Regulation, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 94–14740 Filed 6–16–94; 8:45 am]

BILLING CODE 8010–01–M

[Rel. No. IC–20351; 812–8762]

MIMLIC Asset Allocation Fund, Inc., et al.; Notice of Application

June 10, 1994.

AGENCY: Securities and Exchange Commission ("SEC").

ACTION: Notice of application for exemption under the Investment Company Act of 1940 (the "Act").

APPLICANTS: MIMLIC Asset Allocation Fund, Inc., MIMLIC Fixed Income Securities Fund, Inc., MIMLIC Investors Fund I, Inc., MIMLIC Mortgage Securities Income Fund, Inc., MIMLIC Money Market Fund, Inc. (collectively, the "Applicant Funds"), MIMLIC Asset

Management Company (the "Adviser"), and MIMLIC Sales Corporation (the "Distributor"). Applicants also seek relief on behalf of registered, open-end management investment companies (collectively, with the Applicant Funds, the "Funds") for which the Adviser, or any person controlled by or under common control with the Adviser, hereafter may serve as investment adviser, or for which the Distributor, or any person controlled by or under common control with the Distributor, hereafter may serve as distributor of such Fund's shares.

RELEVANT ACT SECTIONS: Exemption requested under section 6(c) from sections 2(a) (32), 2(a) (35), 18(f), 18(g), 18(i), 22(c), and 22(d) of the Act, and rule 22c–1 thereunder.

SUMMARY OF APPLICATION: Applicants seek a conditional order to permit the Funds to create multiple classes of shares and to assess and, under certain circumstances, waive a contingent deferred sales charge ("CDSC") upon the redemption of certain shares.

FILING DATES: The application was filed on January 10, 1994, and amended on April 6, 1994 and June 2, 1994. In a letter to the SEC, counsel to applicants agreed to file an amendment during the notice period to make certain changes to its application. This notice reflects the changes to be made to the application by such further amendment.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the SEC orders a hearing. Interested persons may request a hearing by writing to the SEC's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on July 5, 1994, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the SEC's Secretary.

ADDRESSES: Secretary, SEC, 450 5th Street, NW., Washington, DC 20549. Applicants, 400 Robert Street North, St. Paul Minnesota 55101.

FOR FURTHER INFORMATION CONTACT: James J. Dwyer, Staff Attorney, at (202) 942–0581, or C. David Messman, Branch Chief, at (202) 942–0564 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee at the SEC's Public Reference Branch.

Applicants' Representations

1. Each Applicant Fund is a Minnesota corporation registered under the Act as an open-end management investment company. Except for MIMLIC Money Market Fund, Inc.[1] the Applicant Funds currently offer shares to the public at net asset value plus a front-end sales charge ("FESC"). The shares currently also are subject to ongoing distribution and service fees pursuant to a plan adopted under rule 12b–1 (the "Plan").[2] For shares of the Asset Allocation Fund, the Plan Fees currently are up to .35% of that Fund's average daily net assets; for shares of each of the other Funds, the Plan Fees are up to .30% of each Fund's average daily net assets.

2. The Adviser, a registered investment adviser, serves as each Applicant Fund's investment adviser. The Distributor, a registered broker-dealer, serves as principal underwriter of the shares of each Applicant Fund.

3. Applicants seek relief to permit the Funds to offer multiple classes of shares that would differ only as set forth in condition 1 below. The additional classes may be subject to a FESC, a CDSC, a combination of both, or neither, and also may be subject to Plan Fees. The Funds will not impose FESCs, CDSCs, or Plan Fees in excess of amounts permitted by article III, section 26 of the Rules of Fair Practice of the National Association of Securities Dealers, Inc. (the "NASD"), as they may be amended from time to time.

4. Under the requested order, the Applicant Funds' currently outstanding shares will be designated "Class A" shares. Applicants contemplate selling a new class of shares ("Class B shares") at net asset value without the imposition of a FESC at the time of purchase. Under the applicable rule 12b–1 plan, Class B shareholders initially will pay a shareholder services fee at an annual rate of up to .25%, and a distribution fee at an annual rate of up to .75%, of average daily net assets attributable to Class B shares. The Class B shares would be subject to a CDSC, as further described below. Class B shares would not be issued in connection with investments of $1,000,000 or more, but rather such investors would be permitted to invest in Class A shares, which would not be subject to a CDSC.

5. Applicants contemplate that the Class B shares purchased by a shareholder automatically will convert to Class A shares of the same Fund after a certain holding period. Class B shares acquired through the reinvestment of dividends and distributions will be considered held in a separate sub-account. Each time any Class B shares purchased by a shareholder converts to Class A shares, a *pro rata* share of the Class B shares in the sub-account also will convert to Class A shares. Applicants may suspend such conversion if an expert's opinion or Internal Revenue Service ruling that such conversion does not constitute a taxable event under Federal income tax law is not available. The conversion feature would benefit long-term Class B shareholders by relieving them of most of the burden of distribution expenses after the Distributor has been compensated.

6. Each service rendered to a specific class of shares will augment or replace, and not be duplicative of, any other service rendered to the class, or to the Fund. Expenses specific to a particular class of shares may be calculated and charged to the respective class. All other expenses incurred by a Fund will be allocated between the various classes based on the percentage of net assets of the class at the beginning of the day after adjusting for the prior day's capital share activity. Because of the differing class expenses and Plan Fees, the net income attributable to and the dividends payable on one class of shares of a Fund may be higher or lower than those of the other classes of shares of the same Fund. To the extent that a Fund has undistributed net income, the net asset value of the various classes of shares of the Fund may differ.

7. Applicants contemplate that any class of shares of a Fund may be exchanged for shares of the corresponding class of other Funds. Exchanges also are permitted into money market Funds managed by the Adviser. All exchanges will comply with rule 11a–3 under the Act.

8. Applicants also seek exemptive relief to permit the Funds to impose a

[1] MIMLIC Money Market Fund, Inc. (the "Money Market Fund") is a no-load fund that currently offers Class A shares to the public at net asset value. Applicants intend that the Money Market Fund and any other Funds that are "money market" Funds, as defined in rule 2a–7 under the Act, will continue to issue shares at net asset value without the imposition of a FESC or CDSC, but that the Money Market Fund may offer multiple classes of shares with variations in distribution or service fees and in class expenses.

[2] Applicants anticipate that all shareholder servicing fees will be imposed under a rule 12b–1 plan. Nevertheless, applicants may subsequently decide to impose a non-rule 12b–1 shareholder servicing fee. Accordingly, the term "Plans," as used herein, collectively refers to any rule 12b–1 plans and any non-rule 12b–1 shareholder services plans adopted in accordance with condition 16 below. The term "Plan Fees" refers to any fees charged pursuant to any of the Plans.

CDSC on redemptions of Class B shares, and possibly other future classes of shares. The period during which the CDSC will apply (the "CDSC period") and the CDSC percentage will vary with the amount of the investment, and is expected to vary in the future depending on any Plan Fees, if any, imposed by a Fund with respect to the shares subject to the CDSC. The CDSC only would be imposed on shares issued on or after the date that the requested order is granted. In addition, any amendments to the CDSC will apply only when they are reflected in an amended and supplemented prospectus, and no such amendments adversely would affect shares issued prior to the effective date of such amendment.

9. The applicable CDSC will be calculated on the lesser of the net asset value at the time the shares were issued or redeemed. No CDSC will be imposed on amounts representing capital appreciation, shares or amounts representing shares purchased through the reinvestment of dividends or capital gains distributions, or shares held for longer than the CDSC period. It will be assumed that redemptions will be made first of shares not subject to a CDSC in the order purchased, and then of shares subject to a CDSC in the order purchased. If a shareholder owns more than one class of shares and does not specify which shares are to be redeemed, shares not subject to a CDSC with the highest Plan Fees will be redeemed in full prior to any redemptions of shares not subject to a CDSC with lower Plan Fees.

10. Applicants intend to waive the CDSC on redemptions of shares (a) resulting from the exercise of a Fund's right to liquidate a shareholder's account whose aggregate net asset value is less than the effective minimum size set forth in the Fund's then-current prospectus, and (b) in the event of the death or disability of a shareholder within the meaning of section 72(m)(7) of the Internal Revenue Code of 1986, as amended, provided that the shareholder held the shares at the time of death or initial determination of disability, and provided that the shareholder owned the shares as an individual or as a joint tenant with the right of survivorship or as a tenant-in-common.

Applicants' Legal Analysis

1. Applicants request an exemptive order to the extent that the proposed issuance and sale of various classes of shares representing interests in the same Fund might be deemed: (a) To result in a "senior security" within the meaning of section 18(g); (b) prohibited by section 18(f)(1); and (c) to violate the equal voting provisions of section 18(i).

2. Applicants believe that the proposed multi-class arrangement will better enable the Funds to meet the competitive demands of today's financial services industry. Under the multi-class arrangement, an investor will be able to choose the method of purchasing shares that is most beneficial given the amount of his or her purchase, the length of time the investor expects to hold his or her shares, and other relevant circumstances. The proposed arrangement would permit the Funds to facilitate both the distribution of their securities and provide investors with a broader choice as to the method of purchasing shares without assuming excessive accounting and bookkeeping costs or unnecessary investment risks.

3. Applicants further believe that the proposed allocation of expenses and voting rights relating to the Plans in the manner described in the application is equitable and would not discriminate against any group of shareholders. In addition, such arrangements should not give rise to any conflicts of interest because the rights and privileges of each class of shares are substantially identical.

4. Applicants submit that the proposed multi-class arrangement does not present any concerns that section 18 was designed to ameliorate. The multi-class arrangement does not involve borrowings, does not affect a Fund's existing assets or reserves, and does not involve a complex capital structure. The multi-class arrangement will not increase the speculative character of the shares of the Funds. No class of shares will have preference or priority over any other class of shares in a Fund with respect to particular assets, and no class of shares will be protected by any reserve or other account.

5. Applicants submit that the requested exemption to permit the Funds to implement the proposed CDSC is appropriate in the public interest, and is consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. The proposed CDSC arrangements will provide shareholders the option of having greater investment dollars working for them from the time of their purchase than if a sales load had been imposed at such time.

Applicants' Conditions

Applicants agree that any order granting the requested relief shall be subject to the following conditions:

1. Each class of shares will represent interests in the same portfolio of investments of a Fund and be identical in all respects, except as set forth below. The only differences among various classes of shares of the same Fund will relate solely to: (a) The designation of each class of shares of the Fund; (b) expenses assessed to a class as a result of a Plan providing for Plan Fees; (c) different expenses which the board of directors of a Fund may in the future determine to allocate to a specific class, which will be limited to: (i) Transfer agency fees as identified by the transfer agent as being attributable to a specific class; (ii) printing and postage expenses related to preparing and distributing materials such as shareholder reports, prospectuses, and proxies to current shareholders; (iii) Blue Sky registration fees incurred by a class of shares; (iv) SEC registration fees incurred by a class of shares; (v) the expenses of administrative personnel and services as required to support the shareholders of a specific class; (vi) litigation or other legal expenses relating solely to one class of shares; and (vii) directors' fees incurred as a result of issues relating to one class of shares; (d) voting rights on matters exclusively affecting one class of shares (*e.g.*, the adoption, amendment, or termination of a Plan) in accordance with the procedures set forth in rule 12b–1, except as provided in condition 15 below; (e) the different exchange privileges of the various classes of shares as described in the prospectuses (and as more fully described in the statements of additional information) of the Funds; and (f) classes that impose a Plan Fee may convert to another Class. Any additional incremental expenses not specifically identified above that are subsequently identified and determined to be properly allocated to one class of shares shall not be so allocated until approved by the SEC pursuant to an amended order.

2. The directors of each of the Funds, including a majority of the independent directors, shall have approved the multi-class distribution system prior to the implementation thereof by a particular Fund. The minutes of the meetings of the directors of each of the Funds regarding the deliberations of the directors with respect to the approvals necessary to implement the multi-class distribution system will reflect in detail the reasons for determining that the proposed multi-class distribution system is in the best interest of both the Fund and its shareholders.

3. The initial determination of the class expenses, if any, that will be allocated to a particular class of a Fund and any subsequent changes thereto will be reviewed and approved by a vote of the directors of the affected Fund,

including a majority of the independent directors. Any person authorized to direct the allocation and disposition of monies paid or payable by a Fund to meet class expenses shall provide to the directors, and the directors shall review, at least quarterly, a written report of the amounts so expended and the purpose for which the expenditures were made.

4. On an ongoing basis, the directors of the Funds, pursuant to their fiduciary responsibilities under the Act and otherwise, will monitor each Fund for the existence of any material conflicts among the interests of the various classes of shares. The directors, including a majority of the independent directors, shall take such action as is reasonably necessary to eliminate any such conflicts that may develop. The Adviser and the Distributor will be responsible for reporting any potential or existing conflicts to the directors. If a conflict arises, the Adviser and the Distributor at their own costs will remedy such conflict up to and including establishing a new registered management investment company.

5. The directors of the Funds will receive quarterly and annual statements concerning distribution and shareholder servicing expenditures complying with paragraph (b)(3)(ii) of rule 12b–1, as it may be amended from time to time. In the statements, only expenditures properly attributable to the sale or servicing of a particular class of shares will be used to justify any Plan Fee charged to that class. Expenditures not related to the sale or servicing of a particular class will not be presented to the directors to justify any Plan Fee attributable to that class. The statements, including the allocations upon which they are based, will be subject to the review and approval of the independent directors in the exercise of their fiduciary duties.

6. Dividends paid by a Fund with respect to each class of shares, to the extent any dividends are paid, will be calculated in the same manner, at the same time, on the same day, and will be in the same amount, except that fee payments made under the Plan relating to a particular class will be borne exclusively by each such class and except that any class expenses will be borne by the applicable class of shares.

7. The methodology and procedures for calculating the net asset value and dividends/distributions of the various classes and the proper allocation of income and expenses among the various classes has been reviewed by an expert (the "Expert"). The Expert has rendered a report, which has been provided to the staff of the SEC, stating that such methodology and procedures are adequate to ensure that such calculations and allocations will be made in an appropriate manner. On an ongoing basis, the Expert, or an appropriate substitute Expert, will monitor the manner in which the calculations and allocations are being made and, based upon such review, they will render at least annually a report to the Funds that the calculations and allocations are being made properly. The reports of the Expert shall be filed as part of the periodic reports filed with the SEC pursuant to section 30(a) and 30(b)(1) of the Act. The work papers of the Expert with respect to such reports, following request by the Funds which the Funds agree to make, will be available for inspection by the SEC staff upon the written request for such work papers by a senior member of the Division of Investment Management or of a Regional Office of the SEC, limited to the Director, an Associate Director, the Chief Accountant, the Chief Financial Analyst, an Assistant Director, and any Regional Administrators or Associate and Assistant Administrators. The initial report of the Expert is a "report on policies and procedures placed in operation" and the ongoing reports will be "reports on policies and procedures placed in operation and tests of operating effectiveness" as defined and described in SAS No. 70 of the AICPA, as it may be amended from time to time, or in similar auditing standards as may be adopted by the AICPA from time to time.

8. Applicants have adequate facilities in place to ensure implementation of the methodology and procedures for calculating the net asset value and dividends/distributions among the various classes of shares and the proper allocation of income and expenses among such classes of shares and this representation has been concurred with by the Expert in its initial report referred to in condition 7 above and will be concurred with by the Expert, or an appropriate substitute Expert, on an ongoing basis at least annually in the ongoing reports referred to in condition 7 above. Applicants agree to take immediate corrective action if the Expert, or an appropriate substitute Expert, does not so concur in the ongoing reports.

9. The prospectuses of the Funds will contain a statement to the effect that a salesperson and any other person entitled to receive compensation for selling or servicing Fund shares may receive different levels of compensation for selling one particular class of shares over another in a Fund.

10. The Distributor will adopt compliance standards as to when shares of a particular class may appropriately be sold to particular investors. Applicants will require all persons selling shares of the Funds to agree to conform to these standards.

11. The conditions pursuant to which the exemptive order is granted and the duties and responsibilities of the directors of the Funds with respect to the multi-class distribution system will be set forth in guidelines which will be furnished to the directors.

12. Each Fund prospectus (regardless of whether all classes of shares of such Fund are offered through such prospectus) will disclose the respective expenses, performance data, distribution arrangements, services, Plan Fees, FESC, CDSC, exchange privileges, and conversion features applicable to each class of shares. The shareholder reports of each Fund will disclose the respective expenses and performance data applicable to each class of shares in every shareholder report. The shareholder reports will contain, in the statement of assets and liabilities and statement of operations, information related to the Fund as a whole generally and not on a per class basis. Each Fund's per share data, however, will be prepared on a per class basis with respect to all classes of shares of such Fund. To the extent any advertisement or sales literature describes the expenses or performance data applicable to any class of shares, it will disclose the expenses and/or performance data applicable to all classes. The information provided by applicants for publication in any newspaper or similar listing of the Funds' net asset values and public offering prices will separately present each class of shares.

13. Applicants acknowledge that the grant of the exemptive order requested by this application will not imply SEC approval, authorization, or acquiescence in any particular level of payments that the Funds may make pursuant to any Plans in reliance on the exemptive order.

14. Any class of shares with a conversion feature ("Purchase Class") will convert into another class ("Target Class") of shares on the basis of the relative net asset values of the two classes, without the imposition of any sales load, fee, or other charge. After conversion, the converted shares will be subject to an asset-based sales charge and/or service fee (as those terms are defined in article III, section 26 of the NASD's Rules of Fair Practice), if any, that in the aggregate are lower than the asset-based sales charge and service fee

to which they were subject prior to the conversion.

15. If a Fund implements any amendment to its rule 12b–1 plan (or, if presented to shareholders, adopts or implements any amendments of a non-rule 12b–1 shareholder services plan) that would increase materially the amount that may be borne by the Target Class shares under the Plan, existing Purchase Class shares will stop converting into Target Class unless the Purchase Class shareholders, voting separately as a class, approve the proposal. The directors shall take such action as is necessary to ensure that existing Purchase Class shares are exchanged or converted into a new class of shares ("New Target Class"), identical in all material respects to Target Class as it existed prior to implementation of the proposal, no later than such shares previously were scheduled to convert into Target Class shares. If deemed advisable by the directors to implement the foregoing, such action may include the exchange of all existing Purchase Class shares for a new class ("New Purchase Class"), identical to existing Purchase Class shares in all material respects except that New Purchase Class will convert into New Target Class. New Target Class or New Purchase Class may be formed without further exemptive relief. Exchanges or conversions described in this condition shall be effected in any manner that the directors reasonably believe will not be subject to federal taxation. In accordance with condition 4, any additional cost associated with the creation, exchange, or conversion of New Target Class or New Purchase Class shall be borne solely by the Adviser and the Distributor. Purchase Class shares sold after the implementation of the proposal may convert into Target Class shares subject to the higher maximum payment, provided that the material features of the Plan of the Target Class and the relationship of such Plan to the Purchase Class shares are disclosed in an effective registration statement.

16. The shareholder services plan will be adopted and operated in accordance with the procedures set forth in rule 12b–1 (b) through (f) as if the expenditures made thereunder were subject to rule 12b–1, except that shareholders need not enjoy the voting rights specified in rule 12b–1.

17. Applicants will comply with the provisions of proposed rule 6c–10 under the Act, Investment Company Act Release No. 16619 (Nov. 2, 1988), as such rule is currently proposed and as it may be reproposed, adopted or amended.

For the SEC, by the Division of Investment Management, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 94–14735 Filed 6–16–94; 8:45 am]

BILLING CODE 8010–01–M

[Release No. 35–26064]

Filings Under the Public Utility Holding Company Act of 1935 ("Act")

June 10, 1994.

Notice is hereby given that the following filing(s) has/have been made with the Commission pursuant to provisions of the Act and rules promulgated thereunder. All interested persons are referred to the application(s) and/or declaration(s) for complete statements of the proposed transaction(s) summarized below. The application(s) and/or declaration(s) and any amendments thereto is/are available for public inspection through the Commission's Office of Public Reference.

Interested persons wishing to comment or request a hearing on the application(s) and/or declaration(s) should submit their views in writing by July 5, 1994, to the Secretary, Securities and Exchange Commission, Washington, DC 20549, and serve a copy on the relevant applicant(s) and/or declarant(s) at the address(es) specified below. Proof of service (by affidavit or, in case of an attorney at law, by certificate) should be filed with the request. Any request for hearing shall identify specifically the issues of fact or law that are disputed. A person who so requests will be notified of any hearing, if ordered, and will receive a copy of any notice or order issued in the matter. After said date, the application(s) and/or declaration(s), as filed or as amended, may be granted and/or permitted to become effective.

American Electric Power Company Inc., et al. (70–7022)

American Electric Power Company, Inc. ("AEP"), a registered holding company, and AEP Generating Company ("Generating"), an electric public utility subsidiary of AEP, both of 1 Riverside Plaza, Columbus, Ohio 43215, have filed a post-effective amendment to their application-declaration filed under Sections 9(a), 10, 12(b) and 12(d) of the Act and Rules 44 and 45 thereunder.

By order dated August 17, 1984 (HCAR No. 23399), Generating acquired a ½ undivided interest in the Rockport Generating Station ("Plant") with Indiana & Michigan Electric Company, now Indiana Michigan Power Company ("I&M"), also a subsidiary of AEP, including responsibility for 50% of the costs associated with acquiring certain air and water pollution control devices ("Project").

By order dated October 4, 1984 (HCAR No. 23445) ("October 1984 Order"), Generating was authorized to enter into an Agreement of Sale ("Agreement") with the City of Rockport, Indiana ("City") providing for the construction and installation of the Project by the City, and the issuance by the City of pollution control revenue bonds ("Series 1984 A bonds") to finance Generating's share of the Project. The October 1984 Order authorized the issuance of the Series 1984 A Bonds in a principal amount of $150 million. In addition, the October 1984 Order reserved jurisdiction "with respect to the fees and commissions to be incurred by [Generating] and AEP in connection with this transaction, and the terms of sale under the Agreement."

By order dated September 6, 1985 (HCAR No. 23821) ("1985 Order"), Generating was authorized to enter into a First Amendment to Agreement of Sale ("1985 Agreement") with the City providing for the issuance and sale of three additional series of pollution control bonds (collectively, "Series 1985 Bonds"), each in the principal amount of $55 million with a maturity of September 1, 2014. One series of the Series 1985 Bonds was issued with a variable interest rate ("Variable Rate Bonds") the rate of which was based upon an index and not to exceed 12% per annum, determined weekly and payable monthly. A second series of the Series 1985 Bonds was issued with the interest payable semi-annually at a rate which will be adjusted every five years based upon an index ("Adjustable Bonds"). A third series of the Series 1985 Bonds was issued with the interest rate fixed at 9⅜% per annum, payable semi-annually ("Fixed Rate Bonds"), and these Fixed Rate Bonds were issued subject to optional redemption following an initial period not to exceed ten years. The proceeds of the Series 1985 Bonds were used to cover a portion of the cost of construction of the Project and to refund the outstanding short-term Series 1984 A Bonds in the principal amount of $150 million. The 1985 Order included no reservation of jurisdiction.

AEP and Generating now propose that Generating entire into an agreement with the City whereby the City will issue and sell up to $55 million of a series of refunding bonds ("Refunding Bonds") the net proceeds from the sale of which will be used to provide for the

payment of principal required for the refunding prior to their stated maturity of $55 million principal amount of the Fixed Rate Bonds. The Refunding Bonds will be issued under and secured by the existing indenture ("Indenture") between the City and the Lincoln National Bank and Trust Company, as trustee ("Trustee") and a fifth supplemental indenture ("Fifth Supplemental Indenture") to be execute pursuant to Commission authorization under this post-effective amendment. Pursuant to the Indenture and the Fifth Supplemental Indenture, the proceeds of the sale of the Refunding Fixed Rate Bonds will be deposited with the Trustee and applied by the Trustee, together with other funds supplied by Generating, to the redemption of the Series 1985 A Bonds at a price of 102% of the principal amount thereof.

It is stated that the Refunding Fixed Rate Bonds will bear interest semi-annually and mature at a date or dates not more than 40 years from the date of their issuance. The Refunding Fixed Rate Bonds may be subject to mandatory or optional redemption under circumstances and terms specified at the time of pricing, and, if it is deemed advisable, may also include a sinking fund provision. In addition, the Refunding Fixed Rate Bonds may not, if it is deemed advisable, be redeemable at the option of the City in whole or in part at any time for a period to be determined at the time of pricing the Refunding Fixed Rate Bonds.

Generating has been advised that, depending on maturity and other factors, the annual interest rate on obligations, interest on which is so excludable from gross income, historically has been, and can be expected at the time of issuance of the Refunding Fixed Rate Bonds to be, 1½% to 2½% or more lower than the rates of obligations of like terms and comparable quality, interest on which is fully subject to Federal income tax. In any event, on series or Refunding Fixed Rate Bonds will be issued at rates in excess of those generally obtained at the time of pricing for sales of substantially similar tax-exempt bonds (having the same maturity, issued by entities of comparable credit quality and having similar terms, conditions and features). As of June 1, 1994, Generating anticipated that the interest rate for the Refunding Fixed Rate Bonds would be 7.25% without any credit enhancement and 6.75% with bond insurance.

Generating will not agree, without further Commission authorization, to the issuance of any Refunding Fixed Rate Bond by the City (i) if the stated maturity of any such Bond shall be more than forth (40) years, (ii) if the rate of interest to be borne by any such Bond shall exceed 8% per annum, (iii) if the discount from the initial public offering price of any such Bond shall exceed 5% of the principal amount thereof, or (iv) if the initial public offering price shall be less than 95% of the principal amount thereof.

Generating also proposes to provide credit enhancement for the Refunding Bonds in the form of a letter of credit, surety bond or bond insurance and pay any related fees. As a supplement or alternative to a letter of credit, surety bond or bond insurance, AEP proposes to guarantee the Refunding Bonds. Any letter of credit would not exceed $55 million and would be for a term ranging from one to five years and would be renewable. Drawings under the letter of credit would bear interest at no more than 1% above the bank's prime rate. Generating may pay an annual fee which would not exceed 1.25% of the face amount of the letter of credit.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 94–14736 Filed 6–16–94; 8:45 am]

BILLING CODE 8010–01–M

[Rel. No. IC–20349; File No. 811–3242]

The Wright Managed Money Market Trust: Notice of Application For Deregistration June 10, 1994

AGENCY: Securities and Exchange Commission ("SEC").

ACTION: Notice of Application for Deregistration under the Investment Company Act of 1940 ("Act").

APPLICANT: The Wright Managed Money Market Trust.

RELEVANT ACT SECTION: Section 8(f).

SUMMARY OF APPLICATION: Applicant requests an order declaring that it has ceased to be an investment company.

FILING DATE: The application was filed on May 27, 1994.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the SEC orders a hearing. Interested persons may request a hearing by writing to the SEC's Secretary and serving applicant with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on July 5, 1994, and should be accompanied by proof of service on applicant, in the form of an affidavit, or for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons may request notification of a hearing by writing to the SEC's Secretary.

ADDRESSES: Secretary, SEC, 450 Fifth Street, NW., Washington, DC 20549. Applicant, 24 Federal Street, Boston, MA 02110.

FOR FURTHER INFORMATION CONTACT: Bradley W. Paulson, Staff Attorney, at (202) 942–0147 or C. David Messman, Branch Chief, at (202) 942–0564 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application is available for a fee from the SEC's Public Reference Branch.

Applicant's Representations

1. Applicant, a Massachusetts business trust, registered as an open-end, diversified management investment company on August 12, 1981, by filing a notification of registration on Form N–8A pursuant to section 8(a) of the Act. On the same date, applicant filed a registration statement on Form N–1A under the Securities Act of 1933 and pursuant to section 8(b) of the Act. The registration statement was declared effective on March 12, 1982. Applicant's public offering commenced soon thereafter.

2. On January 19, 1994, the board of trustees of applicant, including a majority of trustees who were not interested persons of applicant, approved a plan of reorganization (the "Plan"). The Plan provided that applicant would transfer all its assets and stated liabilities to the Wright Managed U.S. Treasury Money Market Fund ("Treasury Fund"), a series of The Wright Managed Income Trust (a Massachusetts business trust), in exchange for shares of Treasury Fund. Pursuant to rule 17a–8, applicant's trustees determined that the sale of applicant's assets to Treasury Fund was in the best interests of applicant's shareholders, and that the interests of the existing shareholders would not be diluted as a result.[1]

3. Preliminary copies of proxy materials to solicit shareholder approval

[1] Applicant and Treasury Fund may be deemed to be affiliated persons of each other by reason of having a common investment adviser. Although purchases and sales between affiliated persons generally are prohibited by section 17(a) of the Act, rule 17a–8 provides an exemption for certain purchases and sales among investment companies that are affiliated persons of each other solely by reason of having a common investment adviser, common directors, and/or common officers.

of the reorganization were filed with the SEC on January 28, 1994. Definitive proxy materials were distributed to applicant's shareholders of record as of February 28, 1994, and filed with the SEC on March 10, 1994. At a meeting of shareholders of applicant held on March 28, 1994, applicant's shareholders approved the Plan.

4. On March 31, 1994, the reorganization was consummated. Applicant transferred all its assets to Treasury Fund in exchange for shares of beneficial interest in Treasury Fund and the assumption by Treasury Fund of the stated liabilities of applicant. The exchanges were made at net asset value determined as of the close of business on March 30, 1994. As of such date, applicant had an aggregate net asset value of $16,978,270.79. Each of applicant's shareholders received shares of Treasury Fund that represented the same aggregate net asset value as the shares of applicant owned by such shareholder immediately before the reorganization.

5. Applicant and Treasury Fund assumed their own expenses in connection with the reorganization. Applicant incurred legal, accounting, and printing and mailing expenses in the approximate amounts of $12,200, $2,500, and $1,300, respectively. Treasury Fund incurred reorganization expenses for legal and accounting services of $12,200 and $2,500, respectively.

6. As of the date of the application, applicant had no shareholders, assets, or liabilities. Applicant is not a party to any litigation or administrative proceeding. Applicant is not presently engaged in, nor does it propose to engage in, any business activities other than those necessary for the winding up of its affairs.

7. Applicant was terminated as a business trust under the laws of the Commonwealth of Massachusetts as of May 20, 1994.

For the SEC, by the Division of Investment Management, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 94–14737 Filed 6–16–94; 8:45 am]

BILLING CODE 8010–01–M

SMALL BUSINESS ADMINISTRATION

[Declaration of Disaster Loan Area #2724]

South Dakota (And Contiguous Counties in Wyoming); Declaration of Disaster Loan Area

Lawrence County and the contiguous counties of Butte, Meade, and Pennington in South Dakota, and Crook and Weston Counties in Wyoming constitute a disaster area as a result of damages caused by a landslide which was the result of heavy rains which occurred April 25–27, 1994 in the Town of Lead. Applications of loans for physical damage as a result of this disaster may be filed until the close of business on August 8, 1994, and for economic injury until the close of business on March 8, 1995 at the address listed below: U.S. Small Business Administration, Disaster Area 1 Office, 360 Rainbow Blvd. South, 3rd floor, Niagara Falls, NY 14303, or other locally announced locations.

The interest rates are:

	Percent
For physical damage:	
Homeowners with credit available elsewhere	7.125
Homeowners without credit available elsewhere	3.625
Businesses with credit available elsewhere	7.125
Businesses and non-profit organizations without credit available elsewhere	4.000
Others (including non-profit organizations) with credit available elsewhere	7.125
For economic injury:	
Businesses and small agricultural cooperatives without credit available elsewhere	4.000

The numbers assigned to this disaster for physical damage are 272409 for South Dakota and 272509 for Wyoming. For economic injury the numbers are 827800 for South Dakota and 827900 for Wyoming.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008)

Dated: June 8, 1994.

Erskine B. Bowles,

Administrator.

[FR Doc. 94–14797 Filed 6–16–94; 8:45 am]

BILLING CODE 8025–01–M

Action Subject to Intergovernmental Review

AGENCY: Small Business Administration.

ACTION: Notice of Action Subject to Intergovernmental Review Under Executive Order 12372.

SUMMARY: This notice provides for public awareness of SBA's intention to refund twenty-two existing Small Business Development Centers (SBDCs) on October 1, 1994. Currently there are 56 SBDCs operating in the SBDC program. The following SBDCs are intended to be refunded, subject to the availability of funds: Alabama, Alaska, Connecticut, Delaware, Iowa, Kentucky, Louisiana, Maryland, Massachusetts, Michigan, Mississippi, Missouri, New York, Ohio, Puerto Rico, Dallas, Houston, Lubbock, San Antonio, Vermont, Virgin Islands, and West Virginia. This notice also provides a description of the SBDC program by setting forth a condensed version of the program announcement which has been furnished to each of the SBDCs to be refunded. This publication is being made to provide the State single points of contact, designated pursuant to Executive Order 12372, and other interested State and local entities, the opportunity to comment on the proposed refunding in accord with the Executive Order and SBA's regulations found at 13 CFR Part 135.

EFFECTIVE DATE: September 15, 1994.

ADDRESSES: Comments should be addressed to Ms. Johnnie L. Albertson, Associate Administrator for SBDC Program, U.S. Small Business Administration, 409 Third Street SW., Fifth Floor, Washington, DC 20416.

FOR FURTHER INFORMATION CONTACT: Same as above.

Action Subject to Intergovernmental Review

SBA is bound by the provisions of Executive Order 12372, "Intergovernmental Review of Federal Programs." SBA has promulgated regulations spelling out its obligations under that Executive Order. See 13 CFR Part 135, effective September 30, 1983.

In accord with these regulations, specifically 135.4, SBA is publishing this notice to provide public awareness of the pending application of twenty-two existing Small Business Development Centers (SBDCs) for refunding. Also published herewith is an annotated program announcement describing the SBDC program in detail.

This notice is being published three months in advance of the expected date of refunding these SBDCs. Relevant information identifying these SBDCs and providing their mailing address is provided below. In addition to this publication, a copy of this notice is being simultaneously furnished to the affected State single point of contact which has been established under the Executive Order.

The State single points of contact and other interested State and local entities are expected to advise the relevant SBDC of their comments regarding the proposed refunding in writing as soon as possible. The SBDC proposal cannot be inconsistent with any area-wide plan providing assistance to small business, if there is one, which has been adopted by an agency recognized by the State government as authorized to do so. Copies of such written comments should also be furnished to Ms. Johnnie L. Albertson, Associate Administrator for SBDC Program, U.S. Small Business Administration, 409 Third Street, SW., Fifth Floor, Washington, DC 20416. Comments will be accepted by the relevant SBDC and SBA for a period of 90 days from the date of publication of this notice. The relevant SBDC will make every effort to accommodate these comments during the 90-day period. If the comments cannot be accommodated by the relevant SBDC, SBA will, prior to refunding the SBDC, either attain accommodation of any comments or furnish an explanation of why accommodation cannot be attained to the commentor prior to refunding the SBDC.

Description of the SBDC Program

The SBDC operates under the general management and oversight of SBA, but with recognition that a partnership exists between the Agency and the SBDC for the delivery of assistance to the small business community. SBDC services shall be provided pursuant to a negotiated Cooperative Agreement with full participation of both parties.

SBDCs operate on the basis of a state plan to provide assistance within a state or designated geographical area. The initial plan must have the written approval of the Governor. As a condition to any financial award made to an applicant, non-Federal funds must be provided from sources other than the Federal Government. SBDCs operate under the provisions of P.L. 96–302, as amended by P.L. 98–395, a Notice of Award (Cooperative Agreement) issued by SBA, and the provisions of this Program Announcement.

Purpose and Scope

The SBDC Program is designed to provide quality assistance to small businesses in order to promote growth, expansion, innovation, increased productivity and management improvement. To accomplish these objectives, SBDCs link resources of the Federal, State, and local governments with the resources of the educational system and the private sector to meet the specialized and complex needs of the small business community. SBDCs also coordinate with other SBA programs of business development and utilize the expertise of these affiliated resources to expand services and avoid duplication of effort.

Program Objectives

The overall objective of the SBDC Program is to leverage Federal dollars and resources with those of the state, academic community and private sector to:

(a) strengthen the small business community;

(b) contribute to the economic growth of the communities served;

(c) make assistance available to more small businesses than is now possible with present Federal resources;

(d) create a broader based delivery system to the small business community.

SBDC Program Organization

SBDCs are organized to provide maximum services to the local small business community. The lead SBDC receives financial assistance from the SBA to operate a statewide SBDC Program. In states where more than one organization receives SBA financial assistance to operate an SBDC, each lead SBDC is responsible for Program operations throughout a specific regional area to be served by the SBDC. The lead SBDC is responsible for establishing a network of SBDC subcenters to offer service coverage to the small business community. The SBDC network is managed and directed by a full-time Director. SBDCs must ensure that at least 80 percent of Federal funds provided are used to provide services to small businesses. To the extent possible, SBDCs provide services by enlisting volunteer and other low cost resources on a statewide basis.

SBDC Services

The specific types of services to be offered are developed in coordination with the SBA district office which has jurisdiction over a given SBDC. SBDCs emphasize the provision of indepth, high-quality assistance to small business owners or prospective small business owners in complex areas that require specialized expertise. These areas may include, but are not limited to: management, marketing, financing, accounting. strategic planning, regulation and taxation, capital formation, procurement assistance, human resource management, production, operations, economic and business data analysis, engineering, technology transfer, innovation and research, new product development, product analysis, plant layout and design, agri-business, computer application, business law information, and referral (any legal services beyond basic legal information, and referral require the endorsement and technical assistance services are made available to small businesses located in rural areas.

The degree to which SBDC resources are directed towards specific areas of assistance is determined by local community needs, SBA priorities and SBDC Program objectives and agreed upon by the SBA district office and the SBDC.

The SBDC must offer quality training to improve the skills and knowledge of existing and prospective small business owners. As a general guideline, SBDCs should emphasize the provision of training in specialized areas other than basic small business management subjects. SBDCs should also emphasize training designed to reach particular audiences such as members of SBA priority and special emphasis groups.

SBDC Program Requirements

The SBDC is responsible to the SBA for ensuring that all programmatic and financial requirements imposed upon them by statute or agreement are met. The SBDC must assure that quality assistance and training in management and technical areas are provided to the State small business community through the State SBDC network. As a condition of this agreement, the SBDC must perform, but not be limited to, the following activities:

(a) the SBDC ensures that services are provided as close as possible to small business population centers. This is accomplished through the establishment of SBDC subcenters.

(b) the SBDC ensures that lists of local and regional private consultants are maintained at the lead SBDC and each SBDC subcenter. The SBDC utilizes and provides compensation to qualified small business vendors such as private management consultants, private consulting engineers, and private testing laboratories.

(c) the SBDC is responsible for the development and expansion of resources within the State, particularly the development of new resources to assist small businesses that are not presently associated with the SBA district office.

(d) the SBDC ensures that working relationships and open communications exist within the financial and investment communities, and with legal associations, private consultants, as well as small business groups and associations to help address the needs of the small business community.

(e) the SBDC ensures that assistance is provided to SBA special emphasis groups throughout the SBDC network. This assistance shall be provided to veterans, women, exporters, the handicapped, and minorities as well as any other groups designated a priority by SBA. Services provided to special emphasis groups shall be performed as part of the Cooperative Agreement.

Advance Understandings

The Lead SBDC and all SBDC subcenters shall operate on a forty (40) hour week basis, or during the normal business hours of the State or Host Organization, throughout the calendar year.

The amount of time allowed the Lead SBDC and subcenters for staff vacations and holidays shall conform to the policy of the Host organization.

Dated: June 8, 1994.

Erskine B. Bowles,

Administrator.

Addresses of Relevant SBDC State Directors

Mr. Robert McKinley, Region Director, Univ. of Texas at San Antonio, 1222 North Main Street, San Antonio, TX 78212, (210) 558–2450

Mr. John P. O'Connor, State Director, University of Connecticut, Box U–41, Room 422, Storrs, CT 06269–2041, (203) 486–4135

Mr. Ronald Manning, State Director, Iowa State University, 137 Lynn Avenue, Ames, IA 50010, (515) 292–6351

Ms. Liz Klimback, Region Director, Dallas Community College, 1402 Corinth Street, Dallas, TX 75212, (214) 565–5833

Mr. John Ciccarelli, State Director, University of Massachusetts, School of Management, Amherst, MA 01003, (413) 545–6301

Mr. Raleigh Byars, State Director, University of Mississippi, Old Chemistry Building, University, MS 38677, (601) 232–5001

Mr. James L. King, State Director, State University of New York, SUNY Plaza, S–523, Albany, NY 12246, (518) 443–5398

Mr. Jose Romaguera, Director, University of Puerto Rico, Box 5253—College Station, Mayaguez, PR 00681, (809) 834–3590

Mr. Clinton Tymes, State Director, University of Delaware, Suite 005—Purnell Hall, Newark, DE 19711, (302) 831–2747

Ms. Janet Holloway, State Director, University of Kentucky, 225 Business & Economics Bldg., Lexington, KY 40506–0034, (606) 257–7668

Mr. Woodrow McCutchen, State Director, Department of Economic and Employment Development, 217 East Redwood St., 9th Floor, Baltimore, MD 21202, (410) 333–6995

Mr. Robert Stevens, Acting State Director, Wayne State University, 2727 Second Avenue, Detroit, MI 48201, (313) 964–1798

Mr. Max Summers, State Director, University of Missouri, Suite 300, University Place, Columbia, MO 65211, (314) 882–0344

Ms. Holly Schick, State Director, Ohio Department of Development, 77 South High Street, Columbus, OH 43226–1001, (614) 466–2711

Dr. Elizabeth Gatewood, Region Director, University of Houston, 1100 Louisiana, Suite 500, Houston, TX 77002, (713) 752–8444

Mr. Donald L. Kelpinski, State Director, Vermont Technical College, P.O. Box 422, Randolph Center, VT 05060, (802) 728–9101

Ms. Hazel Kroesser, State Director, Governor's Office of Community and Industrial Development, 1115 Virginia Street, East Charleston, WV 25310, (304) 558–2960

Mr. Craig Bean, Region Director, Texas Tech University, 2579 South Loop 289, Suite 114, Lubbock, TX 79423–1637, (806) 745–3973

Mr. Chester Williams, Director, University of the Virgin Islands, 8000 Nisky Center, Suite 202, St. Thomas, US V. Islands 00802, (809) 776–3206

[FR Doc. 94–14831 Filed 6–16–94; 8:45 am]

BILLING CODE 8025–01–M

Hartford Connecticut District Advisory Council; Public Meeting

The U.S. Small Business Administration Hartford District Advisory Council will hold a public meeting at 8:30 a.m. on Monday, July 18, 1994, at 2 Science Park, New Haven, Connecticut 06511 to discuss such matters as may be presented by members, staff of the U.S. Small Business Administration, or others present.

For further information, write or call Ms. JoAnn Van Vechten, District Director, U.S. Small Business Administration, 330 Main Street, Hartford, Connecticut 06106, (203) 240–4670.

Dated: June 13, 1994.

Dorothy A. Overal,

Acting Assistant Administrator, Office of Advisory Councils.

[FR Doc. 94–14830 Filed 6–16–94; 8:45 am]

BILLING CODE 8025–01–M

DEPARTMENT OF TRANSPORTATION

Aviation Proceedings; Agreements Filed During the Week Ended June 10, 1994

The following Agreements were filed with the Department of Transportation under the provisions of 49 U.S.C 412 and 414. Answers may be filed within 21 days of date of filing.

Docket Number: 49594.

Date filed: June 7, 1994.

Parties: Members of the International Air Transport Association.

Subject: COMP Telex Mail vote 687, Rounding Units for Namibia/Lesotho/Swaziland.

Proposed Effective Date: July 1, 1994.

Docket Number: 49595.

Date filed: June 7, 1994.

Parties: Members of the International Air Transport Association.

Subject: CSC/Reso/063 dated April 11, 1994, Expedited Resos Only, R–1—600AA, R–2— 600AB, R–3— 600B(II), R–4—670A.

Proposed Effective Date: Expedited July 1, 1994.

Docket Number: 49596.

Date filed: June 7, 1994.

Parties: Members of the International Air Transport Association.

Subject: CSC/Reso/063 dated April 11, 1994, Non-Expedited Resos, r–1—600b, r–4—660, r–7—686, r–10—1673, r–2—606, r–5—670, r–8—1600b, r–11—1682, r–3—619, r–6—671, r–9—1600r.

Proposed Effective Date: October 1, 1994.

Phyllis T. Kaylor,

Chief, Documentary Services Division.

[FR Doc. 94–14786 Filed 6–16–94; 8:45 am]

BILLING CODE 4910–62–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Tax on Certain Imported Substances (Dimethyl Terephthalate); Notice of Determination

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice.

SUMMARY: This notice announces a determination, under Notice 89–61, that the list of taxable substances in section

4672(a)(3) will be modified to include dimethyl terephthalate.

EFFECTIVE DATE: This modification is effective April 1, 1992.

FOR FURTHER INFORMATION CONTACT: Tyrone J. Montague, Office of Assistant Chief Counsel (Passthroughs and Special Industries), (202) 622–3130 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

Under section 4672(a), an importer or exporter of any substance may request that the Secretary determine whether such substance should be listed as a taxable substance. The Secretary shall add such substance to the list of taxable substances in section 4672(a)(3) if the Secretary determines that taxable chemicals constitute more than 50 percent of the weight, or more than 50 percent of the value, of the materials used to produce such substance. This determination is to be made on the basis of the predominant method of production. Notice 89–61, 1989–1 C.B. 717, sets forth the rules relating to the determination process.

Determination

On June 10, 1994, the Secretary determined that dimethyl terephthalate should be added to the list of taxable substances in section 4672(a)(3), effective April 1, 1992.

The rate of tax prescribed for dimethyl terephthalate, under section 4671(b)(3), is $3.23 per ton. This is based upon a conversion factor for xylene of 0.547 and a conversion factor for methane of 0.165.

The petitioner is Cape Industries, a manufacturer and exporter of this substance. No material comments were received on this petition. The following information is the basis for the determination.

HTS number: 2917.37.00.00
CAS number: 120–61–6

Dimethyl terephthalate is derived from the taxable chemicals xylene and methane. Dimethyl terephthalate is a solid produced predominantly by oxidation of xylene followed by esterification with methanol.

The stoichiometric material consumption formula for dimethyl terephthalate is:

C_8H_{10} (xylene)+2 CH_4 (methane)+4 O_2 (oxygen) →
$C_{10}H_{10}O_4$ (dimethyl terephthalate)+4 H_2O (water)

Dimethyl terephthalate has been determined to be a taxable substance because a review of its stoichiometric material consumption formula shows that, based on the predominant method of production, taxable chemicals constitute 51.8 percent by weight of the materials used in its production.

Dale D. Goode,

Federal Register Liaison Officer Assistant Chief Counsel (Corporate).

[FR Doc. 94–14704 Filed 6–16–94; 8:45 am]

BILLING CODE 4830–01–U

Tax on Certain Imported Substances (Glycerine, et al.); Notice of Determinations

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice.

SUMMARY: This notice announces determinations, under Notice 89–61, that the list of taxable substances in section 4672(a)(3) will be modified to include glycerine and phenol.

EFFECTIVE DATE: This modification is effective January 1, 1991.

FOR FURTHER INFORMATION CONTACT: Tyrone J. Montague, Office of Assistant Chief Counsel (Passthroughs and Special Industries), (202) 622–3130 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

Under section 4672(a), an importer or exporter of any substance may request that the Secretary determine whether such substance should be listed as a taxable substance. The Secretary shall add such substance to the list of taxable substances in section 4672(a)(3) if the Secretary determines that taxable chemicals constitute more than 50 percent of the weight, or more than 50 percent of the value, of the materials used to produce such substance. This determination is to be made on the basis of the predominant method of production. Notice 89–61, 1989–1 C.B. 717, sets forth the rules relating to the determination process.

Determination

On June 10, 1994, the Secretary determined that glycerine and phenol should be added to the list of taxable substances in section 4672(a)(3), effective January 1, 1991.

The rate of tax prescribed for glycerine, under section 4671(b)(3), is $9.52 per ton. This is based upon a conversion factor for propylene of 0.67, a conversion factor for chlorine of 2.16, and a conversion factor for sodium hydroxide of 1.54.

The rate of tax prescribed for phenol, under section 4671(b)(3), is $6.33 per ton. This is based upon a conversion factor for benzene of 0.9 and a conversion factor for propylene of 0.4.

The petitioner is Dow Chemical Company, a manufacturer and exporter of these substances. No material comments were received on these petitions. The following information is the basis for the determinations.

Glycerine

HTS number: 1520.90.00.00

CAS number: 56–81–5

Glycerine is derived from the taxable chemicals propylene, chlorine, and sodium hydroxide. Glycerine is a liquid produced predominantly by the reaction of epichlorohydrin with an aqueous caustic carbonate solution, followed by the removal of water, sodium chloride, and other impurities by mechanical means, chemical extraction, and distillation.

The stoichiometric material consumption formula for glycerine substance is:

C_3H_6 (propylene) + 2 Cl_2 (chlorine) + 2 NaOH (sodium hydroxide) + H_2O (water) → $C_3H_8O_3$ (glycerine) + 2 NaCl (sodium chloride) + 2 HCl (hydrogen chloride)

Glycerine has been determined to be a taxable substance because a review of its stoichiometric material consumption formula shows that, based on the predominant method of production, taxable chemicals constitute 93.5 percent by weight of the materials used in its production.

Phenol

HTS number: 2907.11.00.00

CAS number: 108–95–2

Phenol is derived from the taxable chemicals benzene and propylene. Phenol is a solid produced predominantly based on cumene peroxidation.

The stoichiometric material consumption formula for phenol is:

C_6H_6 (benzene) + C_3H_6 (propylene) + O_2 (oxygen) → C_6H_6O (phenol) + C_{36} (acetone)

Phenol has been determined to be a taxable substance because a review of its stoichiometric material consumption formula shows that, based on the predominant method of production, taxable chemicals constitute 78.9 percent by weight of the materials used in its production.

Dale D. Goode,

Federal Register Liaison Officer, Assistant Chief Counsel (Corporate).

[FR Doc. 94–14702 Filed 6–16–94; 8:45 am]

BILLING CODE 4830–01–U

Tax on Certain Imported Substances (Tetrahydrofuran, et al.); Notice of Determinations

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice.

SUMMARY: This notice announces determinations, under Notice 89–61, that the list of taxable substances in section 4672(a)(3) will be modified to include tetrahydrofuran and 1,4 butanediol.

EFFECTIVE DATE: This modification is effective October 1, 1994.

FOR FURTHER INFORMATION CONTACT: Tyrone J. Montague, Office of Assistant Chief Counsel (Passthroughs and Special Industries), (202) 622–3130 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

Under section 4672(a), an importer or exporter of any substance may request that the Secretary determine whether such substance should be listed as a taxable substance. The Secretary shall add such substance to the list of taxable substances in section 4672(a)(3) if the Secretary determines that taxable chemicals constitute more than 50 percent of the weight, or more than 50 percent of the value, of the materials used to produce such substance. This determination is to be made on the basis of the predominant method of production. Notice 89–61, 1989–1 C.B. 717, sets forth the rules relating to the determination process.

Determination

On June 10, 1994, the Secretary determined that tetrahydrofuran and 1,4 butanediol should be added to the list of taxable substances in section 4672(a)(3), effective October 1, 1994. However, if these substances are produced from acetylene derived from coal they are not taxable substances.

The rate of tax prescribed for tetrahydrofuran, under section 4671(b)(3), is $5.28 per ton unless it is produced from acetylene derived from coal. This is based upon a conversion factor for acetylene of 0.40 and a conversion factor for methane of 0.97.

The rate of tax prescribed for 1,4 butanediol, under section 4671(b)(3), is $4.20 per ton unless it is produced from acetylene derived from coal. This is based upon a conversion factor for methane of 0.77 and a conversion factor for acetylene of 0.32.

The petitioner is E. I. DuPont de Nemours and Company, a manufacturer and exporter of these substances. No material comments were received on these petitions. The following information is the basis for the determinations.

Tetrahyrofuran

HTS number: 2932.11.00.00
CAS number: 109–99–9

Tetrahyrofuran is derived from the taxable chemicals methane and acetylene. Tetrahyrofuran is a liquid produced predominantly by the reaction of acetylene (derived from methane in natural gas) with formaldehyde made by air oxidation and dehydrogenation of methanol (derived from methane in natural gas) producing the intermediate butynediol which is in turn reacted with hydrogen (derived from methane in natural gas) to produce 1,4 butanediol. The 1,4 butanediol is ring closed using an acid catalyst to produce tetrahydrofuran.

The stoichiometric material consumption formula for tetrahyrofuran is:

C_2H_2 (acetylene) + 3 CH_4 (methane) + 0.5 O_2 (oxygen) + 2 H_2O (water) → C_4H_8O (tetrahydrofuran) + 5 H_2 (hydrogen) + CO_2 (carbon dioxide)

Tetrahyrofuran has been determined to be a taxable substance because a review of its stoichiometric material consumption formula shows that, based on the predominant method of production, taxable chemicals constitute 58.7 percent by weight of the materials used in its production.

1,4 butanediol

HTS number: 2905.39.10.00
CAS number: 110–63–4

1,4 butanediol is derived from the taxable chemicals methane and acetylene. 1,4 butanediol is a liquid produced predominantly by the reaction of acetylene (derived from methane in natural gas) with formaldehyde made by air oxidation and dehydrogenation of methanol (derived from methane in natural gas) producing the intermediate butynediol which is in turn reacted with hydrogen (derived from methane in natural gas) to produce 1,4 butanediol.

The stoichiometric material consumption formula for 1,4 butanediol is:

3 CH_4 (methane) + C_2H_2 (acetylene) + 3 H_2O (water) + 0.5 O_2 (oxygen) → $C_4H_{10}O_2$ (1,4 butanediol) + 5 H_2 (hydrogen) + CO_2 (carbon dioxide)

1,4 butanediol has been determined to be a taxable substance because a review of its stoichiometric material consumption formula shows that, based on the predominant method of production, taxable chemicals constitute 51.3 percent by weight of the materials used in its production.

Dale D. Goode,

Federal Register Liaison Officer, Assistant Chief Counsel (Corporate).

[FR Doc. 94–14703 Filed 6–16–94; 8:45 am]

BILLING CODE 4830–01–U

DEPARTMENT OF VETERANS AFFAIRS

Mental Health and Behavioral Sciences Service (111C)

Notice of Fund Availability Under the VA Homeless Providers Grant and Per Diem Program

AGENCY: Veterans Health Administration, VA.

ACTION: Notice.

SUMMARY: The Department of Veterans Affairs is announcing the availability of funds for applications for assistance under VA's Homeless Providers Grant and Per Diem program. This Notice contains information concerning the program, application process and amount of funding available.

DATES: An original completed grant application for assistance under the VA Homeless Providers Grant and Per Diem Program must be received in Mental Health and Behavioral Sciences Service in Washington, DC by 5:30 pm Eastern Time on July 22, 1994. Applications may not be sent by facsimile (FAX). In the interest of fairness to all competing applicants this deadline is firm as to date and hour, and VA will treat as ineligible for consideration any application that is received after the deadline. Applicants should take this practice into account and make early submission of their material to avoid any risk of loss of eligibility brought about by unanticipated delays or other delivery-related problems.

FOR A COPY OF THE APPLICATION PACKAGE, CONTACT: For a copy of the application package contact Mental Health and Behavioral Sciences Service (111C), Department of Veterans Affairs, 810 Vermont Ave., NW., Washington, DC 20420; (202) 535–7313. For a document relating to the VA Homeless Providers Grant and Per Diem Program see the interim final rule, 38 CFR § 17.700, published in the **Federal Register** on June 1, 1994. Funds made available through this Notice are subject to those regulations.

ADDRESSES: An original completed grant application must be submitted to the following address: Mental Health and Behavioral Sciences Service (111C), Department of Veterans Affairs, 810

Vermont Ave., NW., Washington, DC 20420, Attention: Lynn Bailey. Applications must be received in Mental Health and Behavioral Sciences Service by the application deadline.

FOR FURTHER INFORMATION CONTACT: Lynn H. Bailey, Program Manager, VA Homeless Providers Grant and Per Diem Program, Mental Health and Behavioral Sciences Service (111C), Department of Veterans Affairs, 810 Vermont Ave., NW., Washington, DC 20420; (202) 535–7313 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: This Notice announces the availability of funds for assistance under VA's Homeless Providers Grant and Per Diem program. This is a new program authorized by Pub. L. 102–590, the Homeless Veterans Comprehensive Service Programs Act of 1992. Funding was appropriated by the Department's appropriations act for fiscal year 1994 (Pub. L. 103–124, approved October 28, 1993). Funding applied for under this Notice may be used for: (1) Expansion, remodeling or alteration of existing buildings; (2) acquisition of buildings, and acquisition and rehabilitation of buildings; (3) new construction; (4) procurement of vans; and (5) per diem payments, or in-kind assistance through VA in lieu of per diem payments, for eligible applicants who established supportive housing or supportive services programs after November 10, 1992. Applicants may apply for more than one type of assistance.

Applicants may not receive assistance to replace funds provided by any State or local government to assist homeless persons. For existing projects, VA will fund only the portion of the project that will expand the program. A proposal for an existing project that seeks to shift its focus by changing the population to be served or the precise mix of services to be offered is not eligible for consideration. Not more than 25 percent of services available in projects funded through this grant program may be provided to clients who are not receiving those services as veterans.

Authority. VA's Homeless Providers Grant and Per Diem Program is authorized by sections 3 and 4 of Public Law 102–590, the Homeless Veterans Comprehensive Service Programs Act of 1992; 38 U.S.C. 7721 note. An interim final rule for the program, 38 CFR § 17.700, was published in the **Federal Register** on June 1, 1994. The funds made available under this Notice are subject to the requirements of those regulations.

Allocation. A total of approximately $5.5 million is available for this program.

Application Requirements. The specific grant application requirements will be specified in the application package. The package includes all required forms and certifications. Conditional selections will be made based on criteria described in the application. Applicants who are conditionally selected will be notified of the additional information needed to confirm or clarify information provided in the application. Applicants will then have one month to submit such information. If an applicant is unable to meet any conditions for grant award within the specified timeframe, VA reserves the right to not award funds and to use the funds available for other components of the grant and per diem program. Application requirements for per diem payments are specified in the interim final rule, 38 CFR §§ 17.715–17.723.

Approved: June 13, 1994.

Jesse Brown,

Secretary of Veterans Affairs.

[FR Doc. 94–14722 Filed 6–16–94; 8:45 am]

BILLING CODE 8320–01–M

Sunshine Act Meetings

Federal Register
Vol. 59, No. 116
Friday, June 17, 1994

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice of Agency Meeting

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that at 10:27 a.m. on Tuesday, June 14, 1994, the Board of Directors of the Federal Deposit Insurance Corporation met in closed session to consider matters relating to the Corporation's corporate and supervisory activities.

In calling the meeting, the Board determined, on motion of Director Jonathan L. Fiechter (Acting Director, Office of Thrift Supervision), seconded by Director Eugene A. Ludwig (Comptroller of the Currency), concurred in by Acting Chairman Andrew C. Hove, Jr., that Corporation business required its consideration of the matters on less than seven days' notice to the public; that no earlier notice of the meeting was practicable; that the public interest did not require consideration of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting by authority of subsections (c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), (c)(9)(B), and (c)(10) of the "Government in the Sunshine Act" (5 U.S.C. 552b(c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), (c)(9)(B), and (c)(10)).

The meeting was held in the Board Room of the FDIC Building located at 550 17th Street, NW., Washington, DC.

Dated: June 14, 1994.

Federal Deposit Insurance Corporation.

Patti C. Fox,

Acting Deputy Executive Secretary.

[FR Doc. 94-14972 Filed 6-15-94; 2:53 am]

BILLING CODE 6714-01-M

FEDERAL ENERGY REGULATORY COMMISSION

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: June 13, 1994, 59 FR 30384.

PREVIOUSLY ANNOUNCED TIME AND DATE OF MEETING: June 15, 1994, 10:00 a.m.

CHANGE IN THE MEETING: The following Docket No. has been Item CAG-2 on the Agenda scheduled for June 15, 1994:

Item No., Docket No., and Company

CAG-2—RP94-96-000, Consolidated Natural Gas Company

Lois D. Cashell,

Secretary.

[FR Doc. 94-14929 Filed 6-15-94 1:05 pm]

BILLING CODE 6717-01-M

BOARD OF GOVERNORS OF THE FEDERAL RESERVE SYSTEM

TIME AND DATE: 10:00 a.m., Wednesday, June 22, 1994.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets, NW., Washington, DC 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.
2. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452-3204. You may call (202) 452-3207, beginning at approximately 5 p.m. two business days before this meeting, for a recorded announcement of bank and bank holding company applications scheduled for the meeting.

Dated: June 14, 1994.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 94-14902 Filed 6-15-94; 8:45 am]

BILLING CODE 6210-01-P

NATIONAL CREDIT UNION ADMINISTRATION

TIME AND DATE: 11:00 a.m., Thursday, June 23, 1994.

PLACE: Board Room, 7th Floor, Room 7047, 1775 Duke Street, Alexandria, Virginia 22314-3428.

STATUS: Open.

BOARD BRIEFING:

1. Insurance Fund Report.

MATTERS TO BE CONSIDERED:

1. Approval of Minutes of Previous Open Meeting.
2. Final Rule: Amendments to Parts 701.6 and 741.11, NCUA's Rules and Regulations, NCUA's Fiscal Year and NCUSIF's Insurance Year to Calendar Year.
3. Proposed Rule: Amendments to Part 708, NCUA's Rules and Regulations, Mergers of Federally Insured Credit Unions.

RECESS: 11:30 a.m.

TIME AND DATE: 11:45 a.m., Thursday, June 23, 1994.

PLACE: Board Room, 7th Floor, Room 7047, 1775 Duke Street, Alexandria, Virginia 22314-3428.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Approval of Minutes of Previous Closed Meetings.
2. Administrative Action under Part 747, NCUA's Rules and Regulations. Closed pursuant to exemptions (6) and (8).
3. Appeal of Determination under Part 709, NCUA's Rules and Regulations. Closed pursuant to exemptions (6) and (8).
4. Administrative Action under Section 206 of the Federal Credit Union Act. Closed pursuant to exemptions (8), (9)(A)(ii), and (9)(B).
5. Administrative Action under Section 208 of the Federal Credit Union Act. Closed pursuant to exemptions (8); (9)(A)(ii), and (9)(B).
6. Midsession Budget Review. Closed pursuant to exemptions (2), (6), and (9)(B).

FOR MORE INFORMATION CONTACT: Becky Baker, Secretary of the Board, Telephone (703) 518-6304.

Becky Baker,

Secretary of the Board.

[FR Doc. 94-14958 Filed 6-15-94; 2:32 pm]

BILLING CODE 7535-01-M

SECURITIES AND EXCHANGE COMMISSION

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Pub. L. 94-409, that the Securities and Exchange Commission will hold the following meeting during the week of June 20, 1994.

A closed meeting will be held on Tuesday, June 21, 1994, at 3:00 p.m.

Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the closed meeting. Certain staff members who have an interest in the matters may also be present.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c) (4), (8), (9)(A) and (10) and 17 CFR 200.402(a) (4), (8), (9)(i) and (10), permit consideration of the scheduled matters at a closed meeting.

Commissioner Roberts, as duty officer, voted to consider the items listed for the closed meeting in a closed session.

The subject matter of the closed meeting scheduled for Tuesday, June 21, 1994, at 3:00 p.m., will be:

Institution of administrative proceedings of an enforcement nature.

Settlement of administrative proceedings of an enforcement nature.

Report of investigation.

At times, changes in Commission priorities require alterations in the scheduling of meeting items. For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact: Brian Lane (202) 942–0600.

Dated: June 14, 1994.

Jonathan G. Katz,

Secretary.

[FR Doc. 94–14928 Filed 6–15–04; 1:05 pm]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: [59 FR 30097, June 10, 1994].

STATUS: Closed meeting.

PLACE: 450 Fifth Street, NW., Washington, DC.

DATE PREVIOUSLY ANNOUNCED: June 10, 1994.

CHANGE IN THE MEETING: Additional Item.

The following item was considered at a closed meeting held on Tuesday, June 14, 1994, at 2:00 p.m.

Personnel matter.

Commissioner Roberts, as duty officer, determined that Commission business required the above change and that no earlier notice thereof was possible.

At times, changes in Commission priorities require alterations in the scheduling of meeting items. For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact: John Ramsay at (202) 942–0700.

Dated: June 14, 1994.

Jonathan G. Katz,

Secretary.

[FR Doc. 94–14977 Filed 6–15–94; 3:41 pm]

BILLING CODE 8010–01–M

Corrections

Federal Register
Vol. 59, No. 116
Friday, June 17, 1994

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Council for the Elimination of Tuberculosis; Meeting

Correction

In notice document 94-13377 appearing on page 28553 in the issue of Thursday, June 2, 1994, make the following correction:

In the second column, in the first full paragraph, in the fifth line, "energy testing" should read "anergy testing".

BILLING CODE 1505-01-D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts412, 413, 482, 485, and 489

[BPD-802-P]
RIN 0938-AG46

Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 1995 Rates

Correction

In proposed rule document 94-12516 beginning on page 27708 in the issue of Friday, May 27, 1994, make the following corrections:

1. On page 27771, in the 1st column, in the 23rd line, "was" should read "will be".

2. On page 27819, in Table 6B, in the fourth and fifth columns, remove "Pre" and "481".

3. On page 27896, remove the table and footnotes that appear at the bottom of the page.

4. On page 27897, remove lines one and two at the top of the page.

BILLING CODE 1505-01-D

Federal Register

Friday
June 17, 1994

Part II

Environmental Protection Agency

40 CFR Parts 9 and 89

Determination of Significance for Nonroad Sources and Emission Standards for New Nonroad Compression-Ignition Engine At or Above 37 Kilowatts; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9 and 89

[FRL–4893–8]

RIN 2060–AD54

Control of Air Pollution; Determination of Significance for Nonroad Sources and Emission Standards for New Nonroad Compression-Ignition Engines At or Above 37 Kilowatts

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: Section 213 of the Clean Air Act (CAA) as amended requires the Environmental Protection Agency (EPA) to make a determination of the significance of the contribution of nonroad sources to nonattainment of the National Ambient Air Quality Standards (NAAQS) for ozone and carbon monoxide (CO) in more than one nonattainment area. If the Agency makes a positive determination of significance, it must then promulgate regulations that will result in reductions in emissions from nonroad sources. In today's action, EPA is finalizing the determination of significance of emissions from nonroad engines. EPA is also promulgating standards for carbon monoxide (CO), hydrocarbon (HC), particulate matter (PM), oxides of nitrogen (NO_X) and smoke emissions from large nonroad compression-ignition (CI) engines at or above 37 kilowatts (kW) in power, with exclusions for certain types of engines. The NO_X standard is expected to reduce average per unit NO_X emissions from affected engines by 27 percent before the year 2010, with a 37 percent reduction by the year 2025.

EFFECTIVE DATE: This regulation is effective July 18, 1994. The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of July 18, 1994. The information collection requirements contained in 40 CFR 89.114–96 through 89.120–96, 89.122–96 through 89.127–96, 89.129–96, 89.203–96 through 89.207–96, 89.209–96 through 89.211–96, 89.304–96 through 89.331–96, and 89.404–96 through 89.424–96 have not been approved by the Office of Management and Budget (OMB) and are not effective until OMB has approved them. A technical amendment will be published in the **Federal Register** when OMB has approved the information collection requirements.

ADDRESSES: Materials relevant to this final rule are contained in Docket No. A–91–24 and A–91–18, located at the Air Docket, 401 M Street SW., Washington, DC 20460, and may be reviewed in room M–1500 from 8 a.m. until noon and from 1:30 p.m until 3:30 p.m. Monday through Friday. As provided in 40 CFR part 2, a reasonable fee may be charged by EPA for photocopying docket materials.

FOR FURTHER INFORMATION CONTACT: Linda Hormes, Office of Mobile Sources, Certification Division, (313) 668–4502.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The preamble, regulatory language and regulatory support document are available electronically on the Technology Transfer Network (TTN). TTN is an electronic bulletin board system (BBS) operated by EPA's Office of Air Quality Planning and Standards. Users are able to access and download TTN files on their first call. After logging onto TTN BBS, to navigate through the BBS to the files of interest, the user must enter the appropriate command at each of a series of menus. The steps required to access information on this rulemaking are listed below. The service is free of charge, except for the cost of the phone call.

TTN BBS: 919–541–5742 (1200–14400 bps, no parity, 8 data bits, 1 stop bit)
Voice Helpline: 919–541–5384
Internet address: TELNET ttnbbs.rtpnc.epa.gov
Off-line: Mondays from 8:00 AM to 12:00 Noon ET

1. Technology Transfer Network Top Menu <T> GATEWAY TO TTN TECHNICAL AREAS (Bulletin Boards) Command: T
2. TTN Technical Information Areas <M> OMS—Mobile Sources Information Command: M
3. OMS BBS === MAIN MENU <K> Rulemaking & Reporting Command: K
4. Rulemaking Packages <6> Non-Road Command: 6
5. NON-Road Rulemaking Area File area #2 . . . Non-Road Engines Command: 2<CR>
6. Non-Road Engines

At this stage, the system will list all available nonroad engine files. To download a file, select a transfer protocol which will match the terminal software on your own computer, then set your own software to receive the file using that same protocol.

If unfamiliar with handling compressed (i.e. ZIP'ed) files, go to the TTN top menu, System Utilities (Command: 1) for information and the necessary program to download in order to unZIP the files of interest after downloading to your computer. After getting the files you want onto your computer, you can quit the TTN BBS with the <G>oodbye command.

I. Table of Contents

II. Legal Authority and Background

Authority for the actions in this notice is granted to EPA by sections 202, 203, 204, 205, 206, 207, 208, 209, 213, 215, 216, and 301 of the Clean Air Act as amended (42 U.S.C. 7521, 7522, 7523, 7524, 7525, 7541, 7542, 7543, 7547, 7549, 7550, 7601(a)).

On November 15, 1990, the Clean Air Act Amendments of 1990 (CAAA) were enacted in order to broaden and strengthen the CAA. While the CAA had long specifically authorized EPA regulation of on-highway vehicle and engine emissions, the 1990 amendments extended EPA's authority to regulate nonroad vehicles and engines. Specifically, revised section 213 directs EPA to: (1) Conduct a study of emissions from nonroad engines and vehicles; (2) determine whether emissions of CO, NO_X, and volatile

organic compounds (VOCs) from nonroad engines and vehicles are significant contributors to ozone or CO in more than one area which has failed to attain the NAAQS for ozone or CO; and (3) regulate those categories or classes of new nonroad engines and vehicles that contribute to such air pollution if nonroad emissions are determined to be significant. EPA may also regulate other emissions from new nonroad engines or vehicles if the Agency determines that they contribute to air pollution which may reasonably be anticipated to endanger public health or welfare. Finally, EPA is to regulate emissions from new locomotives by 1995.

The Nonroad Engine and Vehicle Emission Study required by section 213(a)(1) was completed in November 1991.[1] The purpose of this final rule is to implement section 213(a) (2), (3), (4), and (5) by determining that emissions from nonroad engines and vehicles are significant contributors to ozone and CO nonattainment and by promulgating regulations containing standards applicable to emissions from certain nonroad engines and vehicles.

III. Determination of Significance

Section 213(a)(2) of the CAA provides that after notice and public comment, EPA is to determine, based on the Nonroad Engine and Vehicle Emission Study (hereafter called the Nonroad Study), whether nonroad emissions are significant contributors to ozone or CO in more than one nonattainment area. Based on the results of the Nonroad Study and consideration of the public comments discussed below, EPA is finalizing its proposed affirmative significance determination in today's rulemaking.

The majority of commenters did not address EPA's proposed determination of significance. Of those who did, most were in opposition, including organizations representing equipment manufacturers and users. Expressing support for the determination were some engine manufacturers, state and local organizations and environmental groups. A summary of comments is found in the Response to Comments document contained in the docket for this rule. Major comments are discussed below, accompanied by EPA's response.

1. Use of the EKMA Model

Several commenters stated that EPA had not adequately demonstrated a significant contribution to ozone or CO nonattainment from nonroad engines or vehicles, as directed by the Act. These commenters argued that EPA had shown only the nonroad contribution to ozone precursor and CO emission inventories, and not the nonroad contribution to ozone formation or ozone and CO nonattainment. Some commenters questioned EPA's use of the Empirical Kinetic Modeling Approach (EKMA model) as the basis for its air quality analysis, and they suggested that EPA should have used a grid-based air quality model.

However, the Agency did conduct photochemical modeling. Using the EKMA model, the Agency analyzed the effects of nonroad engine emission controls on ozone concentrations. The results of this analysis, presented in more detail in the Notice of Proposed Rulemaking (NPRM) (ref. 58 FR 28809, May 17, 1993), showed that by eliminating nonroad engines in the studied areas, ozone levels would drop between four and 13 parts per billion (ppb) below current levels. This amounts to levels roughly three to eight percent lower than current levels in the 16 ozone nonattainment areas included in the analysis.

The EKMA model has been used by the Agency for a number of years. Although the decision to use this model was driven to some extent by time and resource constraints, the Agency maintains its position that this model is valid and appropriate for the nonroad analysis. The Agency may utilize grid-based air quality modeling in future analyses.

Furthermore, the Agency has traditionally based regulatory decisions on pollutant emission levels and the potential for their reduction. Because of the wide variability inherent in photochemical modeling (source emission levels, emission transport, and meteorological effects including ambient temperatures, cloud cover, sunlight intensity, wind patterns, and so forth), the Agency has typically relied on estimates of potential reductions in source emission inventories as the basis for regulatory analyses. These emission reduction estimates and the well established VOC/NO_X link with tropospheric ozone formation, in conjunction with ozone monitors showing unacceptably high ambient ozone levels, have formed the basis of the Agency's regulatory approach toward ozone control for many years. In addition, as discussed in the NPRM, the Senate Committee Report, in discussing the significance of the contribution of nonroad emissions to ozone problems, specifically discussed the percentage of nationwide NO_X and VOC emissions attributed to nonroad engines. Thus, the Senate clearly understood the relationship between emissions of NO_X and VOCs to the creation of ozone.

The NPRM discussed in detail the Nonroad Study's findings regarding the contribution from nonroad sources of summertime VOCs and NO_X. These findings clearly show that emissions from nonroad engines are a major source of VOCs and NO_X, as well as CO in most, if not all of the nonattainment areas studied. Given the clear link between VOCs and NO_X and the formation of ozone, there can be no question that emissions from nonroad engines are significant contributors to ozone formation in at least two ozone nonattainment areas. Therefore, the Agency has met the CAA mandate to "determine * * * whether emissions * * * from new and existing nonroad engines or nonroad vehicles * * * are significant contributors to ozone or carbon monoxide concentrations in more than one area which has failed to attain the national ambient air quality standards * * *"

2. NO_X Transport

Some commenters asserted that EPA failed to properly consider both the transport of ozone precursor emissions and the natural decay of NO_X concentrations, NO_X having a lifetime of only six to ten hours according to one commenter. One commenter suggested EPA had erroneously assumed that ozone precursors emitted in rural areas are transported toward, and never away from, urban areas. Some commenters suggested that equipment operated primarily in rural areas should be exempted from regulation since these areas do not have air quality problems. Another commenter argued that reducing NO_X can increase ozone, therefore EPA must first show that NO_X reductions will result in reduced ozone nonattainment before promulgating regulations.

Those commenters suggesting the Agency had erroneously assumed that NO_X always will be transported toward, rather than away from, the urban core, may have misunderstood the Agency's assumption. The Agency assumed only that pollution transport *can* occur toward the urban core, thereby contributing to high source emission inventories. It is obvious that different days will produce different transport patterns, and that the potential for rural NO_X and/or rural ozone to be transported toward the urban core exists.

As for the Agency's failure to account for the short lifetime of NO_X and its subsequent low likelihood of long-range

[1] The Nonroad Study is available in the docket for this rulemaking. It is also available through the National Technical Information Service, referenced as document PB 92-126960.

transport, the commenters failed to recognize NO_X sinks. A NO_X "sink" is a molecular compound which stores NO_X (NO and NO_2) for potential later release. Therefore, the NO_X itself may disappear, but it disappears into NO_X sinks, sometimes referred to as NOy, and can then be re-released at a later time. Examples of NO_X sinks include the nitrate radical (NO_3), which forms at night in the presence of ozone and nitrogen dioxide (NO_2) and then quickly photolyzes in the morning,[2] and nitrous acid (HONO), probably formed from NO_2 and water, which is a major source of the hydroxyl radical (OH), a primary constituent for tropospheric ozone formation.[3] Another NO_X sink is peroxyacetyl nitrate (PAN), which transports NO_X over relatively large distances through the atmosphere. The rate of PAN decomposition significantly increases with temperature, so that it can be formed in colder regions, transported, and then decomposed to deliver NO_2 to warmer regions. Another NO_X sink, methyl peroxynitrate (CH_3OONO_2) can last as many as two days in the upper troposphere and then quickly disassociate under surface level temperature conditions, thereby providing a source of NO_2.[4]

Regarding comments that EPA is required to show that NO_X reductions will not lead to actual ozone increases, the Agency disagrees. Most studies indicate that reductions of both VOC and NO_X will lead to reductions of ozone, except under specific circumstances.[5] The photochemical modeling of alternative emission control strategies contained in the ROMNET report[6] offers additional support: ROMNET found that reductions in both VOC and NO_X emissions beyond the minimum requirements of the CAA and across the northeastern U.S. would be required to bring the major East Coast cities into attainment of the ozone standard. In addition, a National Academy of Sciences Study[7] states that, "* * * ozone in rural areas of the eastern U.S. is limited by the availability of NO_X rather than hydrocarbons, and that reductions in NO_X probably will be necessary to reduce rural ozone values." This same study also states that, "Control of NO_X * * *, although it is predicted to lead to an increase in ozone in some places, such as downtown Los Angeles and New York City * * * will probably be necessary in addition to or instead of VOC control to alleviate the ozone problem in many cities and regions." Even under those circumstances where a NO_X decrease can result in an ozone increase, the ozone increase occurs only until a "ridgeline" is reached, after which further NO_X control results in reduced ozone concentrations. In areas with relatively high VOC/NO_X ratios, typical of suburban and rural areas, decreasing NO_X concentrations at constant VOC concentrations is very effective in ozone reduction.[8]

3. Defining Significance

Some commenters argued that EPA cannot make a significance determination without first defining a standard upon which to base that determination, the claim being that without first defining what is significant, any level of contribution could conceivably be deemed as significant. Some commenters argued that the legislative history found in a Senate report stating, "Emissions from off-road and non-road engines and vehicles now make up a *significant* portion of pollution * * * [E]missions inventories from EPA estimate that farm and construction equipment emit 3.7 percent of CO nationwide, four percent of nationwide NO_X, and 1.3 percent of total hydrocarbons * * *,"[9] does not provide guidance on significance, as the NPRM stated.

The Agency disagrees with the contention that a specific numerical standard for significance must be determined prior to considering whether nonroad emissions are significant. When Congress mandated that EPA determine the significance of nonroad emissions, Congress could have given EPA a specific numerical mandate for determining whether such emissions are significant contributors. Instead, Congress gave EPA wide discretion to determine whether the emissions of NO_X, VOCs and CO from nonroad engines and vehicles are significant contributors to ozone or CO concentrations. In any case, any reasonable indicator of significance would conclude that emissions from nonroad engines and vehicles were indeed significant contributors. As presented in the NPRM and discussed above, the Agency's photochemical modeling showed that without nonroad sources, the ozone levels of 16 of the 19 analyzed nonattainment areas would decrease from three to eight percent from their current levels and differences in excess of five percent were indicated in eight of the 16 areas. Additionally, NO_X emission levels from nonroad sources were found to be exceeded by only one other source: the generation of electrical power. Nonroad VOC emission levels were found to be exceeded by only two other sources: light-duty highway vehicles and solvent evaporation. Nonroad CO emission levels were found to be exceeded by only two other sources: light-duty highway vehicles and residential fuel use. In addition, emissions from nonroad engines and vehicles accounted for over ten percent of the inventory of:

(1) VOCs in 12 to 14 of the 19 nonattainment areas studied in the nonroad study;

(2) NO_X in 16 to 19 of the areas studied; and

(3) CO in six to seven of the areas studied.

As pointed out in the NPRM, in numerous nonattainment areas, other sources are regulated that have lower emissions than the total from nonroad engines in the area. Therefore, it is reasonable to conclude that the higher contributions from nonroad sources in those areas are also significant enough to justify the regulation of NO_X, VOC and CO emissions from nonroad engines and vehicles.

4. Operation in Rural Areas

Some commenters stated that some equipment covered by the proposed regulations operates primarily (almost 80 percent based on number of units) in areas already meeting federal clean air requirements; therefore, these commenters concluded that such equipment should not be regulated.

The Agency believes that these pieces of equipment can reasonably be expected to contribute to ozone nonattainment. Also, the Agency has determined that it should not regulate engines only in urban nonattainment areas. Most commenters made strong

[2] Finlayson-Pitts, B.J., and J.N. Pitts, Jr., "Atmospheric Chemistry of Tropospheric Ozone Formation: Scientific and Regulatory Implications," *Air & Waste*, Vol. 43, August 1993, p. 1091.

[3] *Rethinking the Ozone Problem in Urban and Regional Air Pollution*, National Research Council, 1991.

[4] *Rethinking the Ozone Problem in Urban and Regional Air Pollution*, National Research Council, 1991.

[5] *Rethinking the Ozone Problem in Urban and Regional Air Pollution*, National Research Council, 1991.

B.J. Finalyson-Pitts and J.N. Pitts, Jr., "Atmospheric Chemistry of Tropospheric Ozone Formation: Scientific and Regulatory Implications," *Air and Waste*, Vol. 43, August 1993.

[6] U.S. Environmental Protection Agency, "Regional Oxidant Modeling for Northeast Transport (ROMNET), EPA–450/4–91–002a, Research Triangle Park, NC: Office of Air Quality Planning and Standards, June 1991.

[7] *Rethinking the Ozone Problem in Urban and Regional Air Pollution*, National Research Council, 1991, pp. 363 and 377.

[8] B.J. Finlayson-Pitts and J.N. Pitts, Jr., "Atmospheric Chemistry of Tropospheric Ozone Formation: Scientific and Regulatory Implications," *Air and Waste*, Vol. 43, August 1993.

[9] S.R. Rept. No. 101–228, p. 104 (emphasis added).

arguments substantiating the need for national uniformity of treatment for all equipment incorporating regulated engines regardless of the intended geographic area of equipment use. Moreover, Title II of the Act generally requires national regulation of mobile sources, given the inherent ability of such sources to move from one area to another. Also, as discussed, nonroad sources have been clearly shown to contribute significantly to pollution in several nonattainment areas.

5. Significance Determination for Classes and Categories of Nonroad Engines

Some commenters stated that various subcategories of nonroad equipment (e.g., farm equipment, mining equipment) individually represent only a small contribution to national pollutant inventories and to nonattainment and that a significance determination should be made for each specific subcategory of nonroad engine, not for nonroad engines as a whole.

These comments have misinterpreted the clear language of section 213(a). Paragraphs one and two of section 213(a) make it clear that EPA's determination of significance should be based on whether emissions from all new and existing nonroad engines are significant contributors to ozone or CO concentrations. There is no indication that the significance determination should be based on contributions from various subcategories of nonroad engines or vehicles. By contrast, if the Administrator makes an affirmative decision regarding significance, then section 213(a)(3) requires the Administrator to promulgate regulations for those classes and categories of nonroad engines and vehicles "which in the Administrator's judgment cause, or contribute to, such air pollution." This mandate does not include any reference to a determination of significance for classes and categories. Thus, the Agency believes that Congress did not intend a showing of significant contribution to be required for regulation of classes or categories of nonroad engines and vehicles.

This interpretation is echoed by the language in section 213(a)(4) which allows the Agency to regulate new nonroad engine emissions that were not referred to in the Nonroad Study. Under this paragraph, if the Agency determines that any such emissions significantly contribute to air pollution which may reasonably be anticipated to endanger the public health or welfare, the Agency may promulgate regulations applicable to those classes or categories of new nonroad engines and vehicles which in the Administrator's judgment cause or contribute to such air pollution. Once again, there is a reference to significant contribution regarding the initial determination on emissions from all nonroad engines or vehicles, but there is no such reference to significance in the subsequent language regarding regulation of classes or categories of engines and vehicles. Therefore, it seems clear that Congress intended that a showing of significance is not required for regulation of classes or categories of nonroad engines and vehicles.

One commenter suggested that EPA had misinterpreted the statute's requirements based on a perceived inconsistency between that interpretation and the Agency's proposed consent decree settling several lawsuits.[10] This commenter stated that, in the proposed consent decree, EPA had implicitly acknowledged its obligation to make the significance determination for each category or class of products it intends to regulate by specifically reserving its "right" to determine that large gasoline and/or small diesel nonroad engines do not cause or contribute to air pollution within the meaning of section 213(a)(3). Such a reservation, this commenter argued, would be meaningless if EPA were permitted, as proposed in the NPRM, to regulate any category or class of nonroad engine or nonroad vehicle regardless of its contribution to ozone or CO concentrations in nonattainment areas.

The Agency disagrees with the assertion that there is an inconsistency between the Agency's proposed consent decree and the NPRM. In fact, the consent decree does not discuss any determination of "significant contribution" for classes or categories of nonroad engines. The decree only discusses "contribution". The Agency assumes this comment is meant to suggest that prior to regulating, EPA must first show that each equipment type (agricultural, construction, mining, and so forth) contributes significantly to nonattainment. As discussed above, the Agency interprets the Act to provide for regulation of any classes or categories of nonroad engines and vehicles that can be shown to cause or contribute to air pollution. The NPRM discussed the contribution to air pollution of the engine size and type being regulated today. The Agency reserves the right to use other class or category types in future nonroad emissions regulations.

[10] *Sierra Club* v. *Browner*, Civ. No. 93–0197 NHJ (D.D.C. 1993).

6. Equipment Distribution/Use of Consolidated Metropolitan Statistical Areas (CMSA)

Some commenters stated that EPA's use of CMSAs to define the urban areas was inappropriate. These commenters asserted that since many CMSAs encompass an area roughly equivalent to a 100 mile diameter, much of the CMSA is rural. Consequently, EPA has assumed a uniform distribution of nonroad equipment resulting in as many farm tractors in downtown New York City as in the surrounding countryside, according to comments.

Comments that EPA assumed a uniform distribution of equipment within areas evaluated in the Nonroad Study, thereby resulting in an equal number of farm tractors in both downtown New York City and the surrounding countryside, are incorrect. The equipment population distributions used in the Nonroad Study were derived from estimates of activity levels within specific counties of each CMSA. A county, such as that containing Manhattan, would presumably show an activity index for agricultural equipment presumably at or near zero. Therefore, the agricultural equipment population estimate for Manhattan would also be at or near zero.[11]

7. Support of the Agency's Determination of Significance

Some commenters supported the Agency's proposed significance determination. One engine manufacturer supported grouping the 80-plus types of nonroad equipment together instead of evaluating and regulating each type of equipment separately. This commenter also stated that it is not cost effective to build parallel regulated/unregulated engine families for the U.S. market to support regulated and unregulated applications.

A State commented that it is particularly important that any EPA regulation control emissions from construction and farm equipment, as those emissions cannot be controlled by state or local agencies. It cited its own estimates that agricultural equipment contributes over 90 tons per day of NO_x in the State of California. Much of these emissions occur in the San Joaquin valley and are a primary contributor to the nonattainment status of that overwhelmingly agricultural area.

In addition, a major city agreed with the Agency's significance

[11] The methodology is documented in the Energy and Environmental Analysis final report entitled "Methodology to Estimate Nonroad Equipment Populations by Nonattainment Areas," available for review in Docket #A–91–24, Item No. II–A–3.

determination, stating that further reductions in VOC, CO, and NO_x were essential to achieving attainment. A regional association of states also supported the Agency's determination of significance, stating that engines subject to the proposed standards are responsible for approximately 11 percent of all NO_x emitted in its region, making control of emissions from these sources critical to their efforts to meet the statutory requirements of the CAA. An environmental association stated that without significant reductions from nonroad engines, states will not be able to develop long-term plans for the attainment and maintenance of ambient air quality standards.

IV. Definition of Nonroad Engine

CAA section 216(10) defines the term "nonroad engine" as "an internal combustion engine (including the fuel system) that is not used in a motor vehicle or a vehicle used solely for competition, or that is not subject to standards promulgated under section 111 or 202." Section 111(a)(3) of the CAA notes, however, that "Nothing in Title II of this Act relating to nonroad engines shall be construed to apply to stationary internal combustion engines."

1. Original Proposed Definition of Nonroad Engine

In the May 17, 1993 NPRM, EPA proposed that the engines encompassed by the statutory definition of nonroad engine included internal combustion engines meeting one of the following criteria:

(1) Any internal combustion engine (including the fuel system) of any size which is used to propel any vehicle if the engine is not otherwise excluded from this definition (see below). This includes any internal combustion engine which serves a dual function (that is, to both propel a vehicle and operate a device while stationary), such as a mobile crane;

(2) Any internal combustion engine which is located in (or on) a nonroad vehicle and which is an integral part of the nonroad vehicle at the time of the nonroad vehicle's manufacture and which is not otherwise excluded from this definition (see below); or

(3) Any internal combustion engine or combination of internal combustion engines arranged to function together, regardless of application, with a combined output of less than 175 hp, unless otherwise excluded from this definition (see below).

Several specific exclusions were included in the proposed definition of nonroad engines. An internal combustion engine would not be considered a nonroad engine if:

(1) The engine is used to propel a motor vehicle or a vehicle used solely for competition;

(2) The engine is regulated under section 111 or section 202 of the Act, regardless of size; or

(3) The engine is located on a trailer or other platform attached to (not an integral part of) a nonroad vehicle or is otherwise not an integral part of a nonroad vehicle and the engine has an output greater than or equal to 175 hp.

EPA received numerous comments in response to this NPRM definition. The vast majority of commenters opposed all or part of the proposed definition.

The primary reason cited by commenters for their opposition to the proposed definition relates to the use of a horsepower (hp) cut-off point as the means for determining which internal combustion engines are classified as nonroad engines. The commenters asserted that the use of a horsepower cut-off point would allow engines used in mobile applications to be regulated as stationary sources, and would allow stationary engines to be regulated as mobile sources, solely on the basis of engine size. The commenters noted that this would result in identical sources being regulated in a different manner based solely on engine power. Commenters further indicated that the use of a horsepower cut-off point is arbitrary and not reflective of the realities of portable or transportable equipment, which can be and are moved from one area to another and, therefore, should be classified as nonroad regardless of horsepower.

According to these commenters, an engine should be classified on the basis of its use as mobile or stationary, rather than on its horsepower. In other words, the determination as to whether an engine is a nonroad engine should depend on whether the engine is either used in equipment that is mobile (that is, self-propelled, portable or transportable), or in equipment that is in fact used in a stationary manner at a particular location for an extended period of time.

Industry commenters indicated that to do otherwise could result in costly and unnecessary administrative burdens for manufacturers. According to these commenters, such administrative burdens would result from engines and equipment that would be wrongly subjected to a myriad of different mobile and stationary source regulations in states and local air quality management districts. The commenters also indicated that regulation by a multitude of regulatory agencies could result in restricting the geographic operating range of certain engines and equipment.

In addition, commenters indicated that it would be contrary to the intent of the Act. In support of this position, these commenters noted that Congress did not establish a horsepower cut-off point in the Act for distinguishing between nonroad and stationary engines, and did not require that nonroad vehicles be self-propelled to fall within the nonroad definition.

The comments from state and local air pollution control agencies also opposed the use of a horsepower cut-off point for determining whether internal combustion engines would be classified as nonroad engines. Local air pollution control agencies noted that they are currently regulating stationary engines under 175 hp and would lose the authority to continue regulating these engines under the proposed nonroad definition.

For a detailed discussion of the comments regarding the nonroad definition initially proposed see the Response to Comments in the docket.

2. Revised Definition of Nonroad Engine

In response to the comments received regarding the nonroad definition proposed in the May 17, 1993 NPRM, EPA revised the nonroad engine definition. The revised definition was published in the **Federal Register** on October 4, 1993 (58 FR 51595). The comment period was reopened until October 25, 1993, so that interested parties could provide comments on the following revised definition of nonroad engine:

(1) Except as discussed in (2) below, a nonroad engine is any internal combustion engine:

(i) In or on a piece of equipment that is self-propelled or serves a dual purpose by both propelling itself and performing another function (such as a mobile crane); or

(ii) In or on a piece of equipment that is intended to be propelled while performing its function (such as lawn mowers and string trimmers); or

(iii) That, by itself or in or on a piece of equipment, is portable or transportable, meaning designed to be and capable of being carried or moved from one location to another. Indicia of transportability include, but are not limited to, wheels, skids, carrying handles, dolly, trailer, platform or mounting.

(2) An internal combustion engine is not a nonroad engine if:

(i) The engine is used to propel a motor vehicle or a vehicle used solely for competition; or

(ii) The engine is regulated under section 111 or section 202 of the Act; or

(iii) The engine otherwise included in (1)(iii) remains or will remain at a location for more than 12 consecutive months, or a shorter period of time where such period is representative of normal annual source operation at a stationary source that resides at a fixed location for more than 12 months (e.g., seasonal operations such as canning facilities.) A location is any site at a building, structure, facility, or installation. Any engine (or engines) that replaces an engine at a location and that is intended to perform the same or similar function as the engine replaced will be included in calculating the consecutive time period.

A portable generator engine which functions as a permanent back-up generator and which is replaced by a different engine (or engines) that performs the same function would be an example of engines covered by (2)(iii). In such a case, the cumulative residence time of both generators, including the time between removal of the original engine and installation of the replacement, would be counted toward the consecutive residence time period.

EPA intended the revised definition of nonroad engines to address concerns expressed by the commenters in response to the definition originally proposed. Under the revised definition, an internal combustion engine would be a nonroad engine if it is used in equipment that is self-propelled or intended to be propelled while performing its function, or if it is portable or transportable. The revised definition specifically distinguishes between nonroad engines and stationary internal combustion engines on the basis of engine mobility and residence time, rather than on horsepower size.

EPA intended that stationary internal combustion engines be all internal combustion engines regulated by a federal New Source Performance Standard promulgated under section 111 of the Act and all internal combustion engines that are neither nonroad engines nor engines used to propel a motor vehicle or a vehicle used solely for competition. Moreover, the revised definition specifically states that portable and transportable engines remaining in a particular location for over 12 months are not nonroad engines (this excludes engines in self-propelled equipment and equipment intended to be propelled while performing its intended function), thus ensuring that engines that are actually used in a stationary manner are considered stationary engines.

The revised nonroad engine definition excluded from nonroad regulation those engines that are used for normal annual source operations at fixed stationary sources that only operate on a seasonal basis, such as canneries. This provision is designed to ensure that engines that operate as integral parts of these stationary sources are considered stationary.

The revised nonroad engine definition also included a provision that if an engine is replaced by another engine within the 12 month period, the replacement engine should be considered in calculating the consecutive time period. This provision is designed to ensure that where an internal combustion engine is necessary for the operation of a stationary facility, the replacement of one particular engine with another would not prevent the engines from being included as part of the stationary facility.

EPA included as a prohibited act any attempt to circumvent the residence time exclusion of a portable or transportable engine in (2)(iii) by means of removing the engine from its location for a period and then returning it to that same location. In such cases, the time between removal of the engine and its return to service (or replacement) would be counted towards the time period specified in (2)(iii).

3. Final Definition of Nonroad Engine

The majority of comments received on the revised definition supported the usage-based definition, as opposed to the initially proposed power-based definition. Still, most commenters requested that EPA make two modifications to the revised nonroad engine definition.

The first modification requested by the commenters relates to section (2)(ii) of the revised definition which stated that an engine is not a nonroad engine if it is regulated under section 111 or section 202 of the CAA. The commenters expressed concern that this portion of the definition would allow states to promulgate state regulations under the authority of section 111, creating a loophole in the state preemption framework, whereby states would be able to regulate preempted engines. They contended that this would result in dual standards for an engine, as both stationary and nonroad.

The second modification requested by the commenters relates to the application of the 12 month residence time limitation to seasonal operations. While most commenters agreed with the proposal to use a 12 month residence time limit to distinguish between mobile and stationary use of portable or transportable engines, several commenters opposed the proposal to consider residence time based on "seasonal" use. These commenters asserted that excluding an undefined group of engines for an indeterminate period of time, between one and 365 days, is neither reasonable nor enforceable. Moreover, the same commenters requested that EPA clarify that the 12 month residence time applies only to those portable and transportable engines which are integral parts of fixed stationary sources.

One commenter opposed the 12 month time limit on the grounds that it could create a regulatory vacuum which would result in some engines escaping all nonroad engine and stationary engine regulations. In support of the revised nonroad engine definition, another commenter stated that the equipment used on a military installation should be designed so emissions are reduced by the engine manufacturer and not by the end user. The commenter requested that EPA clarify the term "location" in a manner that would permit a "location" to exist within a stationary source.

The comments from a State agency supported the elimination of the horsepower criteria for nonroad engines, but expressed concern that the new definition would cause it to lose permitting authority for engines it was currently regulating as stationary engines. The commenter suggested that those states with permitting programs be allowed to maintain permitting authority over those engines which they had previously determined to be stationary.

One local air pollution agency disagreed with EPA's conclusion that portable engines are nonroad engines. In support of its position, the agency cited title V of the CAA as evidence that Congress recognized that some stationary sources were moveable. If EPA were to adopt a definition based on residence time, the agency requested that three months, rather than a year, be the cutoff point beyond which an engine would no longer be considered nonroad.

The Agency believes that the revised nonroad definition eliminates the potential for the arbitrary classification of internal combustion engines as nonroad or stationary sources based on engine size. Rather, as noted by the commenters, the revised definition is based on the use of the engine, which is a more appropriate and reliable indicator of its classification.

EPA has considered the modification requested by some commenters regarding that portion of the definition that provides an internal combustion

engine is not a nonroad engine if it is regulated under CAA section 111. The Agency has amended the revised definition to provide that an internal combustion engine is not a nonroad engine if "The engine is regulated by a federal New Source Performance Standard promulgated under section 111 of the Act." Thus, under provision (2)(ii), national emission standards for an internal combustion engine must be promulgated before it is classified as a stationary engine.

Contrary to the comments, EPA believes that it is appropriate to exclude from the nonroad definition engines that remain at sources that only operate on a seasonal basis. Although such sources, such as canning facilities, may operate for less than 12 months in any one year, they operate regularly for a similar time period year after year. Operations for a seasonal source generally occur at the same location, rather than traveling between different states or regions. Engines that are located at a seasonal source during the full annual operations period of that source should be considered a part of that source. They are clearly integral parts of these facilities. Moreover, as such sources produce emissions that can be calculated on a regular basis, a local air quality agency or other authority should be able to reasonably enforce stationary source regulations. As a result, the Agency has maintained the seasonal source exclusion. However, as requested by several commenters, EPA has revised the language for the exclusion to make it clearer. EPA believes that a seasonal source is a stationary source because it functions at only one location for its full annual operating period, even if that period is less than 12 months. EPA has specified in the final regulations that a seasonal source must remain at a single location on a permanent basis (that is, at least two years) and must operate approximately three months or more each year. EPA also clarified that an engine located at a seasonal source is an engine that remains at the source for the full annual operating period of the source. This should eliminate any confusion as to whether certain sources are considered to be seasonal sources.

EPA also disagrees with commenters who believe that only engines "fixed" in place for more than 12 months should be excluded from the nonroad definition. An internal combustion engine can be stationary without being "affixed" to the ground or other structures. To require otherwise could result in the improper classification of internal combustion engines. For example, an engine that is not bolted or otherwise attached to a structure but remains at one location for five years would be classified under the commenters' proposition as a nonroad engine, even though it operates in a stationary manner, as evidenced by its remaining at the same location for an extended period of time. Therefore, the Agency has decided that the fact that an engine is not "affixed" to the ground or other structure does not necessarily identify the internal combustion engine as a nonroad engine.

The Agency also believes that 12 months is the appropriate time limit for determining whether an internal combustion engine which is either portable or transportable is to be classified as a stationary engine. Generally, engines that remain at one site for more than 12 months will stay at that site either permanently or for an extended period of time. In such cases, local or state air quality agencies should be able to regulate the applicable engines as stationary sources, since the emissions impact is occurring over a period of time which is likely to have a measurable impact on an area's air quality.

The term "location" has been defined so as to permit a "location" to exist within a facility. Section (2)(iii) of the revised definition defines "location" as "any single site at a building, structure, facility or installation." This definition of "location" provides more precision in classifying an engine as nonroad if the engine is actually intended to be used in a mobile manner within a stationary source. In other words, an engine would be considered nonroad if it moves to different sites within a stationary source.

EPA does not agree with the assertion made by one commenter that title V of the CAA evidences Congress' recognition that some stationary sources are moveable. Title V of the CAA deals with the permitting of stationary sources and not with the determination as to which internal combustion engines are nonroad engines and which are stationary engines.

4. Nonroad Engines Manufactured Prior to the Effective Date of This Definition

In the initial NPRM, EPA noted that it interprets the exclusion in CAA section 302(z) to apply only to those internal combustion engines that are manufactured after the effective date of these regulations. EPA stated that this interpretation avoids a regulatory gap for engines manufactured between the promulgation of the CAA and the date that these regulations are promulgated. EPA received several comments opposing this interpretation. These commenters claimed that the language in section 302(z) applied to all nonroad engines at the time of the passage of the 1990 CAAA, even though that term had not yet been defined with any reasonable clarity. In addition, commenters asserted that nonroad engines are generally preempted from regulation by states under title II of the Act.

EPA continues to believe that internal combustion engines manufactured prior to the effective date of these regulations should not be considered preempted nonroad engines. First, EPA believes that until the regulations finalizing the definition of nonroad engine (as well as the regulations determining the scope of the term "new" as applied to nonroad engines) were complete, no state or other entity could be assured whether such engines would be defined as nonroad engines or as stationary internal combustion engines and the extent to which state regulations of such engines was preempted. Congress clearly intended EPA to determine which internal combustion engines should be defined as nonroad engines and which should be stationary internal combustion engines.[12] As has been discussed above, the final definition of nonroad engine promulgated today is substantially revised from the definition originally proposed. Moreover, as the comments reveal, numerous other definitions of nonroad engine have been suggested to the Agency, many of which are either significantly broader or significantly narrower than EPA's final definition. EPA believes that if the exclusionary language of section 302(z) were applied before EPA's definition of nonroad engine became final, states would have been frustrated from regulating any internal combustion engines manufactured during that time, given the uncertain nature of such engines. For example, a state would not know whether to include regulations of engines in its New Source Review program, or whether such engines should be regulated in a separate in-use operation program. Further, until the initial regulations regarding nonroad engines were finalized, states could not determine the extent to which their regulation of such engines would be preempted, and thus were hampered from going forward with specific programs to regulate such engines. EPA believes that Congress did not intend states to be prevented from regulating these engines before EPA defined what they were. In particular, EPA believes that permits for internal combustion

[12] See Report of House of Representatives Committee on Energy and Commerce, Rept. 101-490, at 272 (May 17, 1990).

engines issued prior to July 18, 1994, are not precluded under section 209 and 302(z) if the permits apply to internal combustion engines manufactured before July 18, 1994, even if those engines are of a type that has been defined by EPA to be nonroad engines.

Moreover, even to the extent such engines are defined to be nonroad engines in this final rule, such engines were not preempted from state regulations under section 209 prior to the effective date of these regulations. The two sections of the Act preempting state regulation of nonroad engines, section 209(e)(1) and section 209(a) (as incorporated by section 213(d)), refer to "nonroad engines subject to regulation under this Act" or to engines "subject to this part." EPA believes that, until EPA promulgated final regulations defining nonroad engines and subjecting such engines to regulation, these engines were not preempted from state regulation under the Act, nor were they subject to any regulation under title II of the Act.

Finally, some of the comments regarding the definition of nonroad engines and the issue of grandfathering examined whether grandfathering subjects an engine to dual regulation (i.e., regulation both by the state as a stationary source and by EPA as a nonroad engine). There is no such risk in this instance because EPA has not subjected any engines manufactured before the effective date of this regulation to regulation as new nonroad engines. Such engines, if they are regulated at all, are regulated under title I programs.

Moreover, it should be noted that the vast majority of these engines are no longer new nonroad engines. Thus, even if they are viewed as preempted nonroad engines, they are subject to in-use regulation by states.

As discussed below in section VI. U. (definition of new), states are not precluded from regulating the use of nonroad engines. Nothing in section 209 of the CAA prohibits local pollution control districts from regulating the operation of nonroad engines, such as the hours of usage, sulfur limits in fuel (state fuel restrictions may in some cases be precluded under section 211), daily mass emission limits, and title I operating permits. In addition, local districts can impose a permitting fee consistent with the costs incurred for various operational expenditures, such as monitoring usage and administrative functions. EPA believes that utilization of this option will assist local districts in achieving their targeted emission levels.

Moreover, states are not prevented from requiring retrofitting of nonroad engines, as long as such requirements do not amount to a standard relating back to the original design of the engine by the original engine manufacturer. As discussed below, EPA believes modest retrofit requirements may be required after a reasonable amount of time, such as at the time of reregistration or rebuilding. Moreover, after a sufficient time has passed after an engine ceases to be new, for example, after the end of the useful life of the engine, a state may institute more significant retrofit requirements. As the court stated in *Allway Taxi* v. *City of New York*, 340 F. Supp. 1120, 1124 (S.D.N.Y.), *aff'd*, 468 F. 2d 624 (2d Cir. 1972), section 209 "was made not to hamstring localities in their fight against air pollution but to prevent the burden on interstate commerce which would result if, instead of uniform standards, every state and locality were left free to impose different standards for exhaust emission control devices for the manufacture and sale of new cars." The Act does not intend preemption of regulations, like regulation of the use of nonroad engines or modest retrofit requirements after an engine is no longer new, that "would cause only minimal interference with interstate commerce, since they would be directed at intrastate activities and the burden of compliance would be on individual owners and not on manufacturers and distributors." *Id.*

EPA has added an interpretive rule in the form of an appendix to these regulations summarizing its views on these issues (see Appendix I to subpart A of part 89: Internal combustion engines manufactured prior to the effective date of the nonroad engine definition). This interpretive rule does not supersede, alter, replace, or change the scope of these regulations. The appendix is intended to be interpretive guidance and is not final agency action subject to judicial review.

Based on comments received from several of California's local air quality districts, the Agency is concerned about the impact of the nonroad definition on the unique situation that exists in these areas, that is, the current local regulation of certain engines as stationary sources which, as a result of the nonroad definition, will become nonroad engines subject to emission standards promulgated only by EPA. According to the commenters, classification of these engines as nonroad by EPA may negatively affect the ability of local districts to achieve targeted emission reduction levels. To some extent, the grandfathering in of certain engines, discussed above, addresses this concern by ensuring that engines regulated prior to the effective date of this rulemaking continue to be regulated in the same manner. Nevertheless, this may not, in all situations, allay concerns regarding the overall impact that classification of these engines as nonroad will have on an area. The Agency believes, however, that any additional concerns that may exist following the effective date of this rule can be addressed by local air quality districts through their regulation of nonroad engine operations.

5. Equating Nonroad Engines With Nonroad Vehicles and Equipment

EPA received one comment on the October 4, 1993 notice that opposed the revised definition of the term "nonroad engine" because, according to the commenter, the definition equated nonroad engines with nonroad equipment. This comment states that, by defining nonroad engines in terms of their use "in or on a piece of equipment," EPA exceeded its authority because, according to the commenter, the CAA only authorizes EPA to regulate nonroad engines and vehicles, not nonroad equipment. This comment argues that EPA does not have equal authority over off-highway mobile cranes, which are nonroad vehicles, and lawnmowers and string trimmers, which are nonvehicular nonroad equipment. This comment asks EPA to acknowledge that it lacks authority to regulate nonroad equipment.

First, EPA disagrees with the commenter's contention that the nonroad engine definition "equates" nonroad engines with nonroad equipment. The nonroad engine definition is written to include only engines, and cannot be read to include equipment. The definition clearly refers only to "engines used in" certain applications, not to the applications themselves. Moreover, this definition has been promulgated pursuant to numerous comments received by the Agency, discussed above, that assert that the most appropriate definition of nonroad engine is one that refers to the use or application of the engine.

EPA also notes that this rulemaking does not promulgate any standards for nonroad equipment, only for nonroad engines. The only restriction on nonroad equipment manufacturers in this rulemaking is a prohibition on the use of uncertified nonroad engines manufactured after the applicable implementation dates. This prohibition is necessary to enforce the engine-based standards and is authorized under the Clean Air Act.

In addition, EPA does not agree that it lacks authority to regulate nonroad equipment or particular applications of nonroad engines. CAA section 213, as well as section 301(a), provide EPA with authority to regulate both nonroad equipment and particular applications of nonroad engines, as well as nonroad engines and nonroad vehicles.

Congress used the terms "nonroad engine," "equipment," and "vehicle" interchangeably (see, e.g., S. Rep., Legislative History of the 1990 Amendments to the Clean Air Act, Committee on Environment and Public Works to accompany S. 1630, December 20, 1989, at 104–105). It is EPA's belief that Congress intended nonroad vehicles and engines to be inclusive terms covering all manner and types of equipment not defined as motor vehicles, vehicles for competition, or stationary sources (see, e.g., H. Rep., Legislative History of the 1990 Amendments to the Clean Air Act, Committee on Energy and Commerce to accompany H.R. 3030, May 17, 1990, at 310). There is no evidence that Congress intended to limit the reach of its nonroad mandate to self-propelled vehicles; on the contrary, it appears that Congress used the term vehicle to include any carrier for the engine.

Section 213 and the rest of the CAA provide EPA with authority to regulate nonroad equipment and particular applications of nonroad engines in nonroad equipment. The Act provides equal authority to regulate off-highway mobile cranes, which are nonroad vehicles, and lawnmowers, which are nonroad equipment.

Moreover, the interpretation of EPA's authority suggested by the commenter would undermine the environmental and public health benefits of the nonroad emission reduction program by creating a gaping loophole. EPA can find no evidence that Congress intended the regulation of certain nonroad engines, vehicles, and equipment that cause or contribute to air pollution, but not the regulation of others.

Finally, there is a practical interrelationship between an engine and the equipment that houses it or is powered by it. Equipment or vehicle characteristics may have a significant impact on the emissions associated with the operation of the engine. The nonroad engine definition relies to a great extent on this interrelationship between an engine and a piece of equipment to determine whether an engine is a mobile or stationary source. In the future development of the nonroad program, EPA may determine that it is most effective to test and certify a nonroad engine integrally with its related equipment, rather than separately. Additionally, it may become necessary and appropriate to regulate aspects of equipment to control fuel spillage, evaporative emissions, or refueling emissions. EPA believes that the CAA provides authority for such regulation. EPA does not believe Congress, in giving EPA the authority to regulate all nonroad engines, intended to create an artificial barrier between the engine and the equipment that houses it. Therefore, if EPA determines in future rulemakings that the most effective way to control emissions from nonroad engines is to regulate directly the nonroad equipment housing the engines, EPA shall do so using its authority under the Clean Air Act.

V. Requirements of the Final Rule

This section provides a general overview of the major elements of the final rule. A general discussion of comments submitted to EPA during the public comment periods is presented in section VI.

A. Applicability

The regulations of today's action apply to all new nonroad CI engines at or above 37 kW with certain exemptions and exclusions. Hereafter the engines included in this rule will be referred to as "large nonroad CI engines."

The vast majority of large nonroad CI engines currently being used and manufactured are diesel-fueled engines. The use of alternative fuels by nonroad engines will not be necessary to meet the emission standards. However, these regulations apply to large nonroad CI engines regardless of the fuel that is used (for example, diesel, compressed natural gas (CNG), rapeseed, methanol, ethanol, and blends). Provisions have been included which allow manufacturers to apply for Administrator approval of alternative test procedures if fuel other than diesel is to be used.

B. Standards

EPA is adopting the proposed NO_x emission and smoke standards for all large nonroad CI engines at or above 37 kW produced on or after the implementation dates presented below. Furthermore, EPA is adopting standards for HC, CO, and PM emissions for engines at or above 130 kW, consistent with those standards adopted by California in sections 2420–2427, chapter 11, title 13 of the California Code of Regulations, "California Regulation for New 1996 and Later Heavy-duty Off-road Diesel Cycle Engines."

All standards and units have been converted to metric in the final rule (discussed in more detail in section VI.A.). For ease of use, the tables below and in section V.C. show the English units parenthetically. The metric units, however, are the units used in the regulations and thus all affected parties must follow these units in complying with the standards promulgated today.

Net Power kW(Hp)	HC g/kW-hr (g/bH p-hr)	CO g/kW-hr (g/bH p-hr)	NO_x g/kW-hr (g/bH p-hr)	PM g/kW-hr (g/bH p-hr)	Smoke A/L/P[1] (Percent)
≥130 (≥175)	1.3 (1.0)	11.4 (8.5)	9.2 (6.9)	0.54 (0.4)	20/15/50
≥75 to =130 (≥100 to <175)	.....	.....	9.2 (6.9)	.....	20/15/50
≥37 to <75 (≥50 to <100)	.....	.....	9.2 (6.9)	.....	20/15/50

[1] Smoke Opacity Standards are reported in terms of percent opacity during an acceleration mode, a lug mode and the peak opacity on either the acceleration or lug modes.

In addition, EPA is prepared to propose and adopt additional standards for HC, CO, and PM emissions for engines from 37 kW to less than 130 kW consistent with those to be adopted by the European Community (EEC) and the United Nations Economic Commission for Europe (ECE) as soon as these groups finalize their requirements for HC, CO, and PM emissions. The European standards are currently projected to be as follows:

Net Power kW (Hp)	HC g/kW-hr (g/bHp-hr)	CO g/kW-hr (g/bHp-hr)	PM g/kW-hr (g/bHp-hr)
≥130	[1] 1.3	5.0	[1] 0.54
(≥175)	(1.0)	(3.7)	(0.40)
≥75 to <130	1.3	5.0	0.70
(≥100 to <175)	(1.0)	(3.7)	(0.52)
≥37 to <75	1.3	6.5	0.85
(≥50 to <100)	(1.0)	(4.8)	(0.63)

[1] Consistent with the current California standards.

Note that the adopted CO standard for engines at or above 130 kW may be changed from 11.5 g/kW-hr to 5.0 g/kW-hr when the European rules are final. This would ensure consistency between EPA and the more stringent European standard. This is also compatible with California since engines certified to the lower European CO standard would clearly be below the California CO standard.

C. Implementation Dates

All engines produced by an engine manufacturer on or after January 1 of the implementation year specified below by power category must be certified by the engine manufacturer according to the requirements in effect for that year. No nonroad vehicle or equipment manufacturer may install in its vehicles or equipment nonroad engines manufactured after January 1 of the implementation year specified below unless such engines are certified engines. EPA expects nonroad vehicle and equipment manufacturers to begin installing certified engines as soon as they become available from engine manufacturers, although EPA understands that some transition period may be necessary for vehicle and equipment manufacturers to deplete their inventory.

Early certification is allowed one year prior to the applicable implementation date for engines participating in the averaging, banking, and trading (ABT) program for NO_X.

Engine size, kW (Hp)	Implementation date
≥130 to ≤560 (≥175 to ≤750).	January 1, 1996.
≥75 to <130 (≥100 to <175).	January 1, 1997.
≥37 to <75 (≥50 to <100).	January 1, 1998.
>560 (>750)	January 1, 2000.

D. Certification and Test Procedures

1. Engine Family Selection

EPA is adopting the engine family definition as proposed. EPA had expressed some concern in its proposal that, should it adopt HC, CO and PM emission standards in the final rule, it was uncertain whether manufacturers should be allowed to include engines with different numbers of cylinders or cylinder orientations in the same engine family. EPA argued that it was uncertain whether deterioration of HC, CO and PM emission performance would proceed at different rates in-use for engines with different numbers of cylinders. One commenter expressed a strong desire to be able to consolidate engine families as much as practicable. The commenter also reminded EPA of the substantial enforcement liability program in this rule that would provide adequate incentive to ensure a manufacturer makes reasonable use of the engine family flexibilities.

The Agency is aware that additional built-in safeguards such as the manufacturers' burden to define engine families in such a way as to ensure all engine configurations have similar emission characteristics, and the manufacturers' recall liability if all engine configurations are not as durable as expected. The Agency has no additional data at this time to address its original concern. However, the Agency does believe that the enforcement provisions in this rule will provide incentive to manufacturers to ensure that their engines are properly grouped so that they can be appropriately represented by the selected test engines.

2. Exhaust Emission Test Procedures

The smoke test procedures are adopted as they were proposed.

The gaseous emission 8-mode test procedures are finalized as proposed with minor revisions. These procedures apply to HC and CO emissions as well as NO_X.

For PM emission measurement, EPA is adopting the California test procedures finalized in Sections 2420–2427, Title 13 of the California Code of Regulations, "California Regulation for New 1996 and Later Heavy-duty Off-road Diesel Cycle Engines," as amended by California Air Resources Board Resolution 92–2, described in CARB mailout #93–42 dated September 1, 1993. These procedures are incorporated by reference in the regulations.

Manufacturers of engines that are not able to operate properly over the 8-mode or smoke test cycles (such as engines with constant speed governors) may petition the Administrator prior to certification to allow use of an alternative test procedure. Upon adequate demonstration of need, the Administrator may allow use of alternative procedures. If an engine is unable to be operated over the smoke test procedure, the manufacturer must submit an alternative test plan to the Administrator for approval in advance of any testing performed for certification purposes. Use of alternative test procedures to demonstrate exhaust emission compliance is discussed in Section VI.H.

3. Certification Test Fuel

EPA is adopting the certification test fuel specifications as proposed. This is because the most common diesel fuel available to nonroad engines will have a higher sulfur content than that required for highway CI engines. Furthermore, to ensure that no commercially available fuel is inadvertently excluded by this rule, EPA has broadened the band of fuel sulfur content to include all fuels ranging from greater than .05 percent to .5 percent fuel sulfur. However, as a provision of harmonizing with California emission standards, and explained below, EPA will allow engine manufacturers the option to use test fuel specified by California, which contains lower sulfur content.

California's particulate standard is predicated on the use of low sulfur fuel, which is the State-wide fuel standard for both nonroad and highway engines. Therefore, the particulate standard EPA is adopting is likewise predicated on the use of low sulfur fuel. However, EPA cannot require testing on a fuel that is not widely available. To compensate for the effect of sulfur on particulate emissions, EPA is permitting two options for demonstrating compliance with those standards. First, EPA will allow testing on the low sulfur

California-specified test fuel for compliance with all emission standards because sulfur content does not impact HC, CO or NO_X emissions. Second, when testing is conducted with the higher sulfur federal certification fuel, the particulate measurement may be adjusted by using the following equation to reflect the effects of higher sulfur content of the fuel on particulate emissions:

$PM_{adj} = PM - [BSFC * 0.0917 * (FSF - USLF_{CA})]$

Where:

PM_{adj} = adjusted measured PM level [g/Kw-hr]
PM = measured weighted PM level [g/Kw-hr]
BSFC = measured brake specific fuel consumption [G/Kw-hr]
FSF = fuel sulfur weight fraction
$USLF_{CA}$ = upper sulfur level weight fraction of California specification.[13]

This adjustment only applies to engines with no exhaust gas aftertreatment. No adjustment is provided for engines with exhaust gas aftertreatment.

The test fuel option selected by the manufacturer will not affect enforcement testing for the HC, CO, NO_X and smoke standards. EPA may select either fuel, without constraints, for confirmatory or other compliance testing for all of the standards, except particulate. For particulate testing, EPA's options are constrained somewhat by the manufacturer's choice of test fuel. If a manufacturer chooses to test using low sulfur California test fuel, EPA would not use higher sulfur, with the associated adjustment factor, for official enforcement of the particulate standard. However, if a manufacturer chooses to test using the higher sulfur fuel, EPA will presume the manufacturer accepts the validity of the adjustment factor, in which case EPA could choose to do a particulate enforcement test using either the higher sulfur fuel with adjustment or the low sulfur fuel without adjustment. This issue is discussed further in section VI. I. below.

4. Certification Test Engine Selection

EPA has revised the proposed certification test engine selection criteria. The selection of an engine configuration within an engine family will be based on the most fuel injected per stroke of an injector at maximum power.

5. Labeling of Engines From Each Engine Family

EPA is adopting the proposed requirement to label each engine; some minor modifications have been made to the proposal.

6. Definition of "New"

EPA has added a definition of "new" as it pertains to nonroad engines, vehicles and equipment.

7. Other Requirements

EPA is adopting as proposed:

(a) The requirement to obtain a federal certificate for each engine family every model year;

(b) The recordkeeping and reporting requirements;

(c) Provisions for EPA confirmatory testing with minor technical revisions; and

(d) The averaging, banking and trading provisions.

8. Fees

As discussed in the NPRM for this rulemaking, EPA is authorized under section 217 of the CAA to establish fees to recover compliance program costs associated with sections 206 and 207. EPA will propose to establish fees for today's nonroad compliance program at some future time, after associated costs are determined.

E. Enforcement

1. Prohibited Acts

EPA is adopting provisions that will prohibit introducing engines into commerce in the U.S. which are not covered by a certificate of conformity issued by EPA. Additionally it will be a prohibited act to use a regulated but uncertified nonroad engine in nonroad vehicles or equipment.

2. Selective Enforcement Auditing (SEA)

With the exception of some revisions described below, the SEA program is being adopted as proposed. The large nonroad CI engine SEA program is an emission compliance program for new production nonroad engines and is authorized by CAA section 213. With this action EPA may issue a SEA test order for any engine family for which EPA has issued a certificate of conformity.

3. Emission Defect Warranty

EPA is adopting emission design and defect warranty requirements as proposed. Nonroad engine manufacturers will be required to warrant emission related components for a period of five years or 3,000 hours from the date of purchase by the ultimate purchaser. This warranty will help ensure the manufacturing of a durable emission system and will require the manufacturer to cover all repairs and replacements involving emission related components, at no cost to the ultimate purchaser, during the warranty period.

4. Tampering Prohibitions

EPA is adopting as proposed prohibitions against tampering with nonroad engines. Nonroad tampering provisions will help ensure that in-use engines remain in certified configurations and continue to comply with emission standards. All persons, will be prohibited from removing or rendering inoperative any device or element of design installed on or in a nonroad engine. The manufacturing, sale and installation of a part or component intended for use with a nonroad engine, where a principal effect of the part or component is to bypass, defeat, or render inoperative a device or element of design of the nonroad engine will also be prohibited.

5. Importation Restrictions

EPA is implementing the proposed restrictions on the importation of nonconforming nonroad engines. Today's action will permit independent commercial importers (ICIs) who hold valid certificates of conformity issued by EPA to import nonconforming nonroad engines. Under this program, the ICI must certify the engine to applicable U.S. regulations via the certification process before an engine is imported. ICIs will be responsible for assuring that subsequent to importation, the nonroad engines are properly modified and/or tested to comply with EPA's emission and other requirements over their useful lives. The ICIs will also be responsible for recalls, maintenance instructions, emission warranties, engine emission labeling, and maintaining adequate records in the same manner as an engine manufacturer.

Today's action also provides certain exceptions to the restrictions on importing nonconforming nonroad engines. These exceptions are similar to the existing regulations on importing nonconforming motor vehicles and motor vehicle engines and include

[13] Should European requirements be finalized using a different fuel sulfur level but maintaining the same PM emission standards as those adopted in this rule and allowing no adjustment for fuel sulfur content, EPA will consider revising its regulations to replace the upper sulfur level weight fractions from the California specification (that is, $USLF_{CA}$) with the upper sulfur level weight fraction from the final European test fuel specification (that is, $USLF_{eu}$).

exemptions for repairs and alterations, testing, precertification, display, national security, hardship, nonroad engines greater than 20 original production years old, and certain nonroad engines proven to be identical, in all material respects, to their corresponding U.S. versions. These exceptions also include the exclusion of nonconforming engines used solely for competition.

6. In-Use Enforcement

EPA is adopting the proposed regulations subjecting nonroad engine manufacturers to the requirements of section 207 of the CAA. Under the adopted regulations EPA has the authority to recall engines which do not comply with emission standards in-use. As proposed, the in-use testing liability period will be up to seven years or 6,000 hours, which ever occurs first. The actual repair period for which a manufacturer must remedy nonconformities would not be limited by actual years or hours, thus any resulting recall will apply to all engines of the recall family, regardless of the years or hours of an individual engine.

In-use compliance with emission standards will be determined based on test results using the same test procedure as that used in certification. EPA is modeling its large nonroad CI engine recall program after section 207 of the CAA and therefore the Administrator may require manufacturers to recall applicable engines if a substantial number of properly maintained and used engines are found to be out of conformity with the regulations issued under section 213 of the CAA.

7. Defect Reporting

EPA is adopting the proposed emission defect reporting regulations which require manufacturers to report to EPA emission-related defects that affect a given class or category of engines. The emission defect reporting regulations also specify procedural and reporting requirements for manufacturers that initiate voluntary emission recalls.

8. Exemptions

EPA is adopting the proposed regulations which allow manufacturers and other persons, where appropriate, to request exemptions from regulation for certain purposes. These purposes include testing, display, national security, export, and for manufacturer-owned and precertification nonroad engines.

VI. Public Participation and Discussion of Comments

EPA held a public hearing on June 25, 1993 at which testimony was given by 14 individuals, including representatives from equipment and engine manufacturers and states. The public comment period was open until July 27, 1993. EPA received over 80 written comments during this time. In addition, meetings were requested by two organizations and held during the comment period. As mentioned previously, the public comment period was reopened from October 4, 1993 through October 25, 1993. During this period, EPA received additional comments which were given further consideration in developing the final rule. The discussion of major comments and EPA's responses are divided into general categories. More detailed Agency responses to comments may be found in the "Response to Comments" document in the docket for this rulemaking.

In addition, a related rule concerning preemption of state nonroad regulations was proposed at 56 FR 45866, September 6, 1991. A public hearing was conducted on September 20, 1991. Many industries presented comments through an association or individually. Represented at the hearing and in written comments are the following: engine manufacturers; manufacturers and dealers of various types of equipment including agricultural, construction, mining, utility, and lawn and garden; manufacturers of emission controls; railroads; manufacturers of industrial trucks; the San Diego Country Air Pollution Control District; and the State of California. EPA considered these comments in promulgating this final rule.

A. Conversion of Standards and Measures to Metric Units

EPA's proposed regulation presented standards and measures in non-metric units, with metric units given parenthetically. Comments were received requesting that, for purposes of harmonization with Europe, EPA present all standards and measures in metric units, forgoing the non-metric units altogether. EPA has the authority to do so under the Metric Conversion Act of 1975 and Executive Order of July 25, 1991. Therefore, EPA is adopting metric units in the final rule.

In the final rule, the metric power equivalents (kilowatts (kW)) given for horsepower units in two cases are different from the proposed equivalents. The 131 kW category in the NPRM is now 130 kW, and the 559 kW category is now 560 kW. EPA was requested to adopt the 130 and 560 kW categories because they are in harmony with categories currently being developed by the European Community. An engine manufacturers' association stated that so doing would not include or exclude any engines that would not otherwise have been included or excluded in EPA's proposed rule. EPA agrees that a one kW change will not significantly affect the engine family implementation schedule.

The units in the tables of standards and implementation dates in this preamble show the non-metric equivalents. The regulatory language is exclusively metric.

B. Emission Standards

1. HC, CO, and PM Emission Standards

EPA proposed NO_x and smoke standards and did not propose standards for HC, CO, and PM. Since NO_x emission was demonstrated in the draft Regulatory Support Document to be largely unaffected by transient operation, EPA is confident that an emission standard based on the adopted steady-state 8-mode test procedures for NO_x will result in a sizable in-use emission reduction. Likewise for smoke, the adopted on-highway smoke test procedures have both transient and steady-state operating modes, giving EPA confidence that the necessary technologies will be applied to meet the smoke standards which will result in actual in-use emission reduction.

However, in its proposed rule, the Agency reasoned that sufficient data and analyses had not been generated to adequately demonstrate that the 8-mode test procedures are representative of potential transient operation occurring in actual use. Since HC, CO, and PM emissions typically increase during transient operation, the Agency was not confident that standards for these three pollutants on the adopted steady-state 8-mode test procedures would result in real emission reduction in actual use and, thus, proposed not to regulate them. However, EPA did request comment on the appropriateness of adopting standards for these pollutants. In particular, EPA requested comment on whether it should adopt California's standards for these pollutants.

State and local agencies, environmental groups, health agency officials, and engine industry representatives all requested that standards for HC, CO, and PM be included in the rule. The industry argued that, while adequate data may not have been generated to establish an emission reduction benefit of the additional standards, adoption of the

additional standards is critical to worldwide marketing strategies which require regulatory harmony between the U.S. and foreign government entities. The industry commenters claim, in this context, that by harmonizing with the California standards and the projected European standards presented in Section V.B., EPA would actually reduce the cost to an engine manufacturer which would not be compelled to build a different version of its engine for U.S. consumption than would be built for the rest of the world. Arguments were presented that in any case there would be no harm in regulating these additional pollutant emissions and there might be some consequential emission control or at least a capping effect on HC, CO, and PM emissions.

EPA is committed to providing regulatory harmonization when it can be done without compromising U.S. environmental goals. Since HC, CO, and PM emissions are typically higher during transient operation, EPA maintains its position that there is too much uncertainty about the ability of the existing steady state test procedures to accurately predict those emissions from in-use nonroad engines. Therefore, EPA believes it is technically incorrect to claim emission reduction benefits for HC, CO, and PM emissions as measured by the test procedure being adopted. However, at the same time, EPA believes that adopting these standards will not compromise U.S. nationally uniform environmental goals.

In reaching the decision to regulate HC, CO, and PM, EPA had to consider any additional costs which might be imposed, and queried the industry during the public comment period. Engine manufacturers responded that these additional standards would not result in added cost, or that any added costs would be offset by the efficiency gained by having harmonized standards. On the basis of these comments, EPA is concluding that adopting HC, CO, and PM standards will not result in increased cost burden.

EPA is not incorporating HC, CO, and PM into the averaging, banking and trading option. The flexibility provided by this option is desirable for NO_x compliance, where there are quantifiable environmental benefits to be gained. However, because HC, CO and PM standards have been promulgated solely for harmonization with California and Europe (neither of which allow ABT), and because the benefits for HC, CO, and PM are not similarly quantifiable, ABT is not appropriate for HC, CO, and PM. Moreover, the burden to the Agency and to industry of tracking and enforcing ABT for HC, CO, and PM would defeat the Agency's intent to minimize such burdens to the degree that the Agency would reconsider its decision to adopt those standards at all, an option the Agency is not willing to choose.

2. Smoke Standards

One commenter questioned EPA's authority to regulate smoke emissions, stating that EPA did not demonstrate as required in CAA section 213(a)(4) that smoke significantly contributes to air pollution that may reasonably be anticipated to endanger public health or welfare. EPA made a finding in the NPRM that smoke significantly contributes to air pollution, based on smoke's impact on visibility. As evidence of smoke's significant contribution to air pollution, EPA specifically cited in its draft Regulatory Support Document the agreement to reduce smoke from the Navajo Generating Station to improve visibility in the Grand Canyon. EPA discussed in the NPRM why smoke may reasonably be anticipated to endanger both public health and welfare. EPA stated that "there are indications that visible smoke may have an adverse effect on health" (58 FR 28809, 28845). The particles that make up smoke, about 2.5 microns in diameter, are of a size that reflects and refracts light. These particles are sufficiently small to be inhaled into the lower lung cavities, thus posing a potential health threat to the inhaler. See, for example, volume 329 of the New England Journal of Medicine (December 9, 1993, p. 1753) for a discussion of the association between particulate air pollution and mortality rates. EPA also cited damage through soiling of urban buildings, homes, cars and other property. EPA has met the statutory mandate of CAA section 213(a)(4) for smoke, and stands by its assessments presented in the NPRM and RSD for this rulemaking. Hence, EPA is retaining the smoke standards as proposed.

C. Lower Emission Standards

Environmentalists and states requested that EPA commit to a second phase of emission standards for new large nonroad CI engines on an "aggressive" timeline. They are satisfied with the level of the standard only on an interim basis and want to quickly move to a more stringent standard. One commenter expressed concern that, without specifying a deadline for promulgating a second phase of emission standards in this rule, manufacturers will be slow to cooperate with EPA in developing the new test procedures.

Engine manufacturers have asked for assurances that they will have from five to eight years of "regulatory stability" before more stringent standards are promulgated, in order to amortize their investment in the current standards.

EPA believes that more stringent emission standards should not be promulgated until the existing test cycle has been verified to be representative, or until a more representative test cycle has been developed. EPA is currently working with engine manufacturers to evaluate actual in-use operating conditions and the test procedures adopted in this rule. These data will be used to determine the necessary modifications to the test procedures to ensure that more stringent emission standards in the future result in actual in-use emission reductions.

EPA has every intention of moving forward to determine the most appropriate test procedures to use in future regulation of the engines covered in this rule. EPA has found that coordination with industry on clearly technical projects such as this is most beneficial since it allows the Agency to receive early input as procedures are being developed. Such early feedback creates an atmosphere of consensus-building and allows the Agency to promulgate rules that are more equitable, efficient and effective. At this point, however, EPA cannot make assurances that it will provide engine manufacturers "five to eight years of regulatory stability," and neither can it commit to promulgating more stringent standards on an "aggressive" timeline.

D. Exemptions

The American Mining Congress and other commenters in the mining industry requested that surface mining equipment be exempted from regulation since, according to the commenters, mining equipment operates well outside nonattainment areas. One commenter within the mining industry suggested that regulation of mining equipment should be on a case-by-case basis. In other words, if the mining equipment at a site is shown to contribute to ozone or CO nonattainment, the equipment at that site should be subject to regulation. As an alternative, these commenters suggested horsepower cutoffs ranging from 500 to 750 horsepower, above which nonroad equipment would be exempted from compliance. These commenters also took exception to EPA's inclusion of mining equipment in the construction equipment category, stating that mining equipment is larger and more specialized than construction

equipment. Further, they stated that while construction equipment may be used at a mine site, mining equipment is never used on a typical urban construction site. These commenters also questioned EPA's application of the proposed regulations to mining equipment since emissions from such equipment were not included in the analysis contained in the Nonroad Study.

The Agency sees no justifiable reason for exempting from regulation all mining equipment or mining equipment above certain horsepower cutoffs. The Agency is obliged to regulate all classes or categories of new nonroad engines that cause or contribute (without reference to significance) to ozone or CO pollution in more than one nonattainment area. The Agency believes that such equipment, even if operating outside nonattainment areas, is capable of contributing to ozone nonattainment and, therefore, the Agency cannot justify an exemption of mining equipment.

Regarding whether mining equipment is being inappropriately included in the construction equipment category, the Agency believes that mining equipment should not be treated as a separate class of equipment. There is acknowledged crossover of equipment used on construction and mining sites. For example, excavators, off-highway trucks, crushing equipment, rubber tired loaders and dozers, and crawler tractors are types of equipment commonly used by both mining and construction industries. While some equipment may currently be used only at mining sites, there is no way to predict future equipment use with certainty. Given the high degree of similarity between construction equipment and equipment used in mines, EPA believes that it is justified in treating equipment used in mining as a subcategory of construction equipment. EPA is not required, in determining classes and categories of nonroad engines or vehicles, to subdivide such engines into small subcategories of engines, each of which may have less of an impact on nonattainment than the broader category in which they are included.

Moreover, it should be noted that the American Mining Congress specifically stated in its comments in the recent EPA rulemaking on preemption of state standards for nonroad engines and vehicles that surface mining equipment should be considered "construction equipment" in the context of that rulemaking (EPA Docket No. A–91–18). In addition, EPA held a meeting with the American Mining Congress on July 22, 1993, and asked for specific information to support their request for exemption from the proposed regulations. Such information requests included specific dollar figures for the technology needed to comply, a component level breakdown of costs, annual equipment sales and horsepower ranges of mining equipment and other information specifically targeted toward the impacts of mining equipment on ozone and CO nonattainment.[14] As of October 25, 1993, the close of this rulemaking's second comment period, the Agency had not received this information.

Regarding the comment that mining equipment operates well outside of nonattainment areas, the American Mining Congress submitted as part of its public comment a report from the TRC Environmental Corporation which states that 40 mine sites are located in ozone nonattainment areas.[15] Moreover, EPA is not required to make determinations of nonroad contributions to air pollution on a site by site basis, or to regulate on a site by site basis; CAA section 213 requires a national program based on an aggregate significance determination.

Commenters suggested the Agency use varying horsepower cutoffs above which nonroad engines should not be regulated. The main rationale given by commenters was that the technology improvements and/or design changes to these larger engines would be too costly. EPA has received very little data directly addressing the actual costs anticipated for these changes, and no information was provided detailing the specific unique high cost technologies that these engines would need, even after the specific request by EPA discussed above. As discussed in section VII, EPA agrees that the cost of compliance for engines over 560 kW (750 horsepower) would be more than the average cost per engine estimated in this rule. EPA uses the net present value of the retail price increase per engine reported in this rule to estimate the cost of this regulation to society, not to predict the cost of any particular engine covered by this rule. While the Agency did not do a cost breakout by engine size, EPA's assessment of the limited cost data submitted by one manufacturer of engines greater than 560 kW suggests that the retail price of these larger engines could increase by approximately $100 per 75 kW due to this regulation. Therefore, in absolute terms, the cost is greater for larger engines. However, in relative terms, the price increase for larger engines only represents about one percent of the total cost of the equipment in which the engine is used. On average, this represents a slightly lower percentage price increase than for smaller engines covered by this rule. EPA has determined that this level of increase for extremely high cost machinery is reasonable.

EPA also received several comments stating that certain farm equipment, skid steer loaders in particular, should be exempted from regulation because they do not significantly contribute to ozone nonattainment. As discussed above, EPA is not required to make a significance determination for every category of nonroad engine it intends to regulate. The significance determination applies only to the initial determination regarding emissions from all nonroad engines and vehicles. Once that determination is made, the Agency shall promulgate regulations for all classes and categories that contribute (without reference to significance) to nonattainment in more than one area. The Nonroad Study clearly shows that farm equipment air pollution causes or contributes to nonattainment in several of the nonattainment areas studied.

With regard to specific subcategories of farm equipment, EPA is not required to make determinations regarding every subcategory of equipment that it intends to regulate. The Senate, in fact, instructed EPA not to disaggregate the universe of nonroad engines into small subcategories.[16] Therefore, given EPA's finding regarding farm equipment, skid steer loaders and other subcategories of farm equipment will not be exempted from the regulations promulgated in this notice.

E. Particulate Matter Test Procedures

EPA is adopting by reference the PM test procedures adopted by California in Sections 2420–2427, Chapter 11, title 13 of the California Code of Regulations, "California Regulation for New 1996 and Later Heavy-Duty Off-Road Diesel Cycle Engines." California developed its test procedures by combining portions of the June 2 and June 30, 1992 versions of the test procedures being developed by the International Standards Organization as ISO–8178 test procedures recommended practices.

In determining the PM test procedures to adopt in the final rule, EPA

[14] A complete breakdown of the information requested, as well as a summary of the meeting, is contained in Docket #A–91–24, Item No. IV–E–01.

[15] "Analysis of Nonroad Engine Emissions in the Mining Industry," TRC Environmental Corporation, July 1993, p. 1.

[16] Senate Report 101–228, p. 104. The Senate provisions regarding nonroad engines were ultimately rejected in favor of the House of Representatives' provisions, but the language in the Report indicates the intent of Congress in determining the breadth of categories.

considered the need for harmonization and enforceability. EPA determined that the California PM test procedures meet these two needs. First, this procedure ensures harmonization with the State of California, allowing manufacturers to design one engine for both the California and federal markets. The California procedures include the full range of the ISO–8178 recommended practices as published in June 1992, providing wide latitude for the conditions and methods used for PM measurement. EPA is not concerned with allowing the engine manufacturers to use the full latitude of ISO–8178 for certification testing because, as previously discussed, no PM emission reduction benefits are being claimed, and EPA has the ability to perform in-use compliance testing over the entire range of the ISO–8178 procedures.

EPA is confident that its ability to perform compliance testing using any procedure within the boundaries of ISO–8178 will ensure that engine manufacturers use good judgment in selecting their specific PM test procedures. At the same time, EPA recognizes the potential burden of liability for emission compliance over the entire range of conditions specified in ISO–8178. This burden results from an engine manufacturer's responsibility to comply with emission standards under any test conditions specified by the test procedures. Historically, when a range of test conditions exist, manufacturers choose to test with the conditions which are worst-case for emissions performance. To the extent that a manufacturer is unable to determine with certainty the worst-case conditions, it may be necessary to perform a number of emission tests which bracket the range of test condition combinations within the ISO–8178 procedures to ensure that the worst-case emissions are accounted for. Thus the burden to the manufacturer is increased testing dictated by the level of risk that a particular engine family would fail EPA testing (compliance or in-use) due to an unaccounted-for test condition specified in ISO–8178. However, EPA believes that the overriding concern expressed in the comments for harmonization outweighs the potential burden of liability to comply with a broad test procedure. Furthermore, the Agency does not have an alternative test procedure option that would ensure harmonization at this time.

EPA is satisfied that the adopted PM test procedures are implementable and enforceable. The Agency is prepared to review any proposals from the nonroad manufacturing industry to modify any portions of the PM test procedures that would narrow the scope of test conditions while maintaining the integrity of the procedures. EPA is not prepared to make its own proposal to tighten the test procedure specifications at this time as it might negatively impact harmonization for an emittant for which EPA is claiming no emission benefit in this rule.

EPA considered adopting a modified version of its current on-highway engine test procedures for particulate contained in 40 CFR part 86, subpart N. This would address the flexibility issues regarding the ISO–8178 procedure, because subpart N has tighter measurement tolerances and specific methodologies and procedures for emission measurement. However, EPA did not have an effective means to address the various needs of the different manufacturers (that originally led to the broad range of options in ISO–8178) in the time frame of this rule without adversely affecting some manufacturers more than others. Additionally, this approach presented some risk that the test procedures developed from EPA's current regulations would contain some elements not in harmony with California and Europe. Since EPA believes the California PM test procedures will meet its needs and ensure harmony, development of its own procedures based on subpart N was determined less desirable at this time.

Finally, EPA considered, but rejected, adoption of the most recent United Nation draft version of ISO–8178. This draft represents the most current development of these test procedures and is compatible with current European plans. However, the United Nation's draft version of ISO–8178 must still go through a review process that could result in a number of additional changes and will likely take one to two years before being adopted. If EPA adopted the draft United Nations version, the Agency could eventually find itself to be in harmony with neither the California version nor the final adopted European version of ISO–8178.

F. Smoke Test Procedures

Commenters requested that EPA revise the on-highway smoke procedures in 40 CFR 86, Subpart I, which were proposed for this rule. The same revisions were requested under a separate EPA action that specifically focuses on technical clarification on the subpart I procedures. Since part 89 regulations directly reference the part 86 subpart I procedures, EPA will not consider these comments in this rule. Any revisions adopted under the separate EPA action of technical amendments to part 86 subpart I procedures will likewise apply to engines certified under part 89.

Manufacturers point out that this test was specifically designed for on-highway truck engines and is less applicable to nonroad engine usage, but agree that this test is the best available at this time. In their comments, engine manufacturers agreed to use the on-highway smoke test procedures until more representative and globally harmonized smoke test procedures can be developed.

EPA is working closely with Europe and other government agencies as well as with voluntary standard-setting organizations to develop new smoke test procedures. These procedures are not sufficiently developed at this time to reference or adopt.

EPA is willing to use cooperatively developed and harmonized smoke test procedures that it determines meet its needs to control in-use smoke emissions. A mechanism has been provided in this rule to allow the use of such procedures via the alternative test procedures approval process. With this process, the manufacturer requests EPA approval to use the alternative test procedures in advance of certification. EPA has authority to grant such a request if the procedures are determined to be equivalent or better than the promulgated procedures.

In the absence of a "world-wide" smoke procedure, EPA is confident the adopted procedures will reduce smoke emissions and will ensure harmonization with California. California has pointed out it has modified its test procedures somewhat by allowing the use of an in-line smokemeter. EPA has included provisions by which a manufacturer may use alternative measuring equipment upon demonstration that it correlates with the current opacity meter.

G. Use of the On-highway Federal Test Procedure (FTP)

EPA has decided not to allow use of the on-highway FTP for any aspect of nonroad engine certification. Based on data received during the comment period and discussed in the Response to Comments document, the ability of the on-highway test cycle to predict nonroad NO_x emissions for some types of engines is uncertain. In addition, even those commenters in support of the on-highway FTP option stated that they would likely make minimal use of it. These reasons form the basis of EPA's decision not to adopt this option.

H. Alternate Test Procedures for Constant Speed Engines

A number of engine manufacturers requested that EPA allow use of an alternate test procedure for engines that use constant speed governors. These engines are typically used on applications such as generator sets that must be capable of holding one precise speed during operation. Commenters have stated that these engines are not properly represented by, and may not be capable of operating over, the 8-mode test procedures. Commenters recommended that EPA allow use of the ISO 8178–D2 test procedures (2-mode) for constant speed engines.

EPA has a mechanism in the regulations that would allow this request for alternate test procedures to be made with full technical justification. Insufficient data were presented for EPA to determine the need and appropriateness of adopting the specific ISO 8178–D2 test procedures for constant speed engines in this final rule. However, there may be adequate technical justification for such an alternate test procedure. EPA has made available in the regulations provisions by which an engine manufacturer may propose to the Administrator the use of an alternate test procedure with adequate demonstration. This would be the appropriate mechanism for manufacturers of constant speed engines should they determine that the 8-mode test procedures are unrepresentative for their engines.

I. Certification Test Fuel

EPA is adopting test fuel requirements which allow an engine manufacturer to submit data either using a test fuel that falls within the specification in the proposed regulations, modified to expand the fuel sulfur range to greater than .05 percent to .5 percent fuel sulfur, or a lower sulfur test fuel that is consistent with the test fuel to be used in California. EPA retains the right to perform confirmatory or in-use enforcement testing using either test fuel.

EPA modified the fuel sulfur concentration range of its proposed test fuel based on concerns that the range specified may inadvertently preclude the use of a fuel that could be available for use now or in the future. For example, the current proposal in Europe specifies a test fuel with sulfur content ranging from .1 percent to .2 percent. Should the final European requirements specify such a fuel in the future, EPA's proposal would not have allowed use of this fuel. As this is not EPA's intent, the Agency chose to broaden the range of fuel sulfur content specified in Table 4 to Appendix A of Subpart D in Part 89 of today's regulation.

EPA proposed that all nonroad engines be certified using test fuel with a sulfur content of 0.2 to 0.5 percent sulfur by weight. EPA reasoned that although federal on-highway and California state-wide sulfur specifications will be .03 to .05 percent sulfur by weight, some diesel fuel producers will continue to provide fuel with a higher sulfur content for 49-state nonroad use. EPA believes some producers will decide not to incur the cost of purchasing and operating hydrotreating equipment necessary for sulfur removal in the absence of a requirement to provide low sulfur fuel for the federal nonroad segment of the market. Therefore, it is likely that the fuel available to the majority of nonroad engines will be higher sulfur fuel.

Manufacturers requested to certify on low sulfur fuel because it will save them the cost of performing an extra test (that is, one on high sulfur fuel for the federal rule and one on low sulfur fuel for California). They argued that because the sulfur content of the fuel does not influence the production of NO_X emission and smoke, they should be allowed to use low sulfur fuel for certification testing.

EPA believes that using fuel specifications of commercially available fuel for certification testing is an important demonstration of emission performance of in-use nonroad engines. EPA acknowledges that, in this case, the sulfur content of the test fuel will not impact either NO_X or smoke emissions. However, EPA has agreed to adopt PM standards for the purposes of harmonization with California and Europe. It is generally accepted that fuel sulfur has a noticeable impact on PM emissions. The impact of fuel sulfur on PM, NO_X and smoke emissions is discussed further in the Response to Comments document. Since fuel sulfur does have an impact on PM emissions, PM emissions in the federal fleet will be higher in actual use than in the California fleet where the only available fuel will have low sulfur content. While this rationale would argue against allowing use of low sulfur certification fuel, at the same time, it is likely that the engines certified on low sulfur fuel will have no higher PM emission in actual use than would have resulted had EPA promulgated only NO_X and smoke emission standards. Because harmonization, rather than emission benefits, is the driving factor behind EPA's decision to impose the PM standard, EPA sees no need to increase the testing burden by requiring a different certification fuel specification to demonstrate compliance with the PM standard.

For these reasons, EPA will, at this time, allow engine manufacturers the option to use low sulfur test fuel as specified in the regulatory language and consistent with California regulations. EPA may not continue to allow this option in future regulations where emission benefits for PM reduction are claimed, unless EPA is satisfied that the low sulfur test fuel is the fuel generally used by the regulated engines. Manufacturers using the higher sulfur test fuel may normalize the PM emission results with the equation discussed in section V.D.3.

J. Certification Test Engine Selection

EPA proposed that the test engine selected to represent an engine family be a "worst case emitter." This proposal allowed each manufacturer to use its best technical judgment based on unique understanding of the specific engine design it is certifying. The flexibility of such a methodology could result in the most cost effective and most accurate selections, because the selection would be tailored to the specific engine family being considered.

Engine manufacturers were not comfortable taking on the uncertainty of choosing their own "worst case" test engine, pointing out that "worst case" is ambiguous. For example, what is worst case for NO_X may not be worst case for smoke.

EPA is aware of this tendency for "worst case" to be emission specific. For that reason, in the past, the federal on-highway rules and CARB's rule have specified that the engine selected for certification testing must be the one that injects the most fuel per stroke of an injector at maximum power. This approach generally results in the selection of the least efficient design within the engine family. While this approach is more prescriptive than the proposal, it generally results in more consistency and is more likely to assure the selection of worst case for at least some of the emittants. It gives manufacturers a more defined program and creates less administrative burden than the proposed method which required manufacturers and EPA to make determinations and evaluations for each engine family.

For the reasons discussed above, EPA is adopting this more traditional engine selection criteria—most fuel per stroke of an injector at maximum power—in the final rule.

K. Miscellaneous Certification Issues

1. Engine Labeling

Comments were received requesting that EPA modify some of the proposed engine labeling requirements to be consistent with California regulations. Some of the modifications requested were wording changes. Others involved deleting or changing labeling requirements. EPA's response to these requests is included in the Response to Comments document. One request for a modification had the potential for a more significant impact on industry. This request was to add a provision requiring "supplemental labels" to be installed by the equipment manufacturer should the original engine label be obscured after engine installation. EPA believes this provision would impose an additional burden on the equipment manufacturers (in the form of label costs and recordkeeping to ensure the correct label was placed on the equipment) and that no significant benefit would be gained. Thus, EPA is not requiring the use of supplemental labels, but will not prohibit equipment manufacturers from using such labels, provided the labels meet the labeling requirements set forth in the regulation.

2. Requiring Yearly Certification, Accepting California and European Certificates

Comments were received requesting that EPA not require yearly certification in cases where no changes to the engine family were made. EPA is retaining this requirement. It believes that the burden imposed on manufacturers in cases where no changes are made is minimal (no additional testing required and only the resubmission of paperwork from the previous year), and that yearly certification ensures continuity and equitable treatment among manufacturers.

A commenter also requested that EPA accept certification by California or Europe in lieu of federal certification for reasons of economy. EPA's on-highway certification program requires that every vehicle sold in the United States be covered by a federal certificate of conformity. On-highway manufacturers are permitted to "carry across" emission data from testing performed to demonstrate compliance with California regulations to satisfy federal requirements. This is possible because the test procedures are identical. For the nonroad certification program, EPA envisions that similar certification and carryover/carry across policies will be in effect, which will allow manufacturers to use the test data from a test performed for European or California certification to satisfy federal requirements as long as the manufacturer provides evidence that the procedures used comply with the federal regulations. It is EPA's responsibility to assure compliance with federal regulations. Manufacturers should be assured, however, that the consistency and quality of the California certification program is such that engine families certified by California will very likely receive federal certification. At this time, European regulations are not final, so EPA cannot yet officially harmonize its requirements with Europe. Therefore, EPA is finalizing its proposal to require an annual federal certificate for each engine family.

3. Technical Certification Test Procedure Revisions

Comments were provided on subparts D and E of the regulatory language, dealing with certification test equipment and test procedures. In some cases, the comments were corrections of typographical errors or inconsistencies within the regulatory language. In other cases, EPA was requested to modify technical aspects of its proposed procedure. EPA adopted some, but not all of, the requested changes. These are discussed in the Response to Comments Document.

L. Implementation Dates

EPA is adopting the implementation schedule as proposed.

Environmental and state organizations commented that EPA should shorten the total implementation period, stating that staggering implementation up to the year 2000 would delay important emissions benefits. On the other hand, engine manufacturers asked for one to two years additional time, citing costs and facility constraints. Equipment manufacturers also asked for one year to eighteen months to implement necessary equipment changes.

In addressing state and environmental concerns, EPA considered a number of factors in its phase-in schedule determination. First, the category of engines to be regulated in 1996 represents about 30 percent of the total population. This first group includes engines similar to existing on-highway engines which can directly utilize the on-highway emission control strategies and will produce a substantial early benefit. The other three categories of engines belong to a manufacturing segment of the nonroad industry that has, for the most part, not previously been subject to EPA emission standards. Manufacturers of these categories of engines have neither the facilities in place to collect required information nor staff with experience in the certification process. Further, the phase-in schedule was designed to allow time for the technical development which will be needed for the category of smaller-sized engines to comply with the standards. Finally, over 95 percent of the total engine population to be regulated will be in compliance by the 1998 model year. The final category (in the year 2000, engines at or above 560 kW) represents a small percentage of the yearly sales population.

EPA believes that engine and equipment manufacturers have been provided enough flexibility in this rule (through such features as ABT for NO_x and staggered schedules) to allow enough lead time for them to make any necessary changes or modifications by the implementation date. Engine manufacturers have stated that they intend to use the flexibilities of this rule to minimize the impact of these regulations on their equipment manufacturer customers. EPA designed the phase-in schedule so that smaller engines, which will be more difficult to control to the adopted NO_x standard, and equipment using these engines, which may require the most modification due to tighter packaging constraints, have an additional one to two years for development before regulation. Furthermore, early banking allows manufacturers to selectively forego modifying specific models by collecting credits one year in advance of implementation from engines that have been made to comply with the NO_x standards before the implementation date of the standard. Finally, ABT provides to manufacturers of that small percentage of engines requiring extensive modification the ongoing option to avoid situations where high cost or tight time constraints make modifications unreasonable. Therefore, EPA is retaining the implementation schedule as proposed. No additional time is being granted to engine, vehicle or equipment manufacturers. However, EPA will allow vehicle and equipment manufacturers a reasonable amount of time after the implementation dates for the different engine categories so that the equipment and vehicle manufacturers can clear their inventory of unregulated engines.

M. In-use Enforcement

EPA proposed an in-use recall program which included testing of in-use engines. EPA believes that a critical element in the success of its nonroad program is assuring that manufacturers build engines that continue to meet emission standards beyond the certification and production stages.

Under the adopted regulations, EPA has the authority to recall engines which do not comply with emission standards in-use. As proposed, the in-use testing liability period will be up to seven years or 6,000 hours, whichever occurs first. This represents 70 to 75 percent of the nonroad engine average expected useful life. The repair period for which a manufacturer must remedy nonconformities would not be limited by actual years or hours; thus any resulting recall may be required to be applied to all engines of the recall family, regardless of the years or hours of an individual engine. In-use compliance with emission standards will be determined based on test results using the same test procedure as that used in certification.

One commenter expressed concern that EPA's recall program carefully select in-use engines which have been properly maintained and used and that are representative of engines in-use. EPA acknowledges the concern of this commenter. The Agency conducts its on-highway recall program with careful attention to compliance with the requirements of the CAA concerning proper maintenance and use, and will continue to do so for the nonroad program, although differences between uses for on-highway and nonroad equipment may require certain deviations from the on-highway program. EPA is modeling its large nonroad CI engine recall program after section 207 of the CAA and therefore the Administrator may require manufacturers to recall applicable engines if a substantial number of properly maintained and used engines are found to be out of conformity with the regulations issued under section 213 of the CAA.

The recall regulations adopted today provide procedures and requirements for manufacturers of engines for which a determination of nonconformity has been made. Such requirements include notification to be sent to engine owners, the manufacturer's remedial plan and EPA approval of the plan, and procedures to be followed in the event that the manufacturer requests a public hearing to contest the Administrator's finding of nonconformity.

N. Useful Life

EPA is adopting the definition of useful life as proposed with additional conditions. The useful life of engines covered by this rule is ten years or 8,000 hours, whichever comes first. Further, the useful life ends when the engine is scrapped or rebuilt. EPA is adding a provision allowing the manufacturer to apply to the Administrator for a shorter useful life period for engines that are subject to severe service in seasonal equipment or that are designed specifically for lower useful life hours to match equipment life.

Engine useful life defines the period of time a manufacturer is liable for the emissions that the engine emits. In-use surveillance emission testing may be conducted at any time by EPA to determine if an engine family, after some time in use, is still meeting emission standards. EPA is adopting an in-use testing and recall program based on testing for a period of seven years or 6,000 hours, representing 70 to 75 percent of the average expected useful life for nonroad engines. Therefore, while the manufacturer's liability for its engines covers the full useful life, evaluation of an engine family's in-use compliance will be based on those engines within the engine family that have attained 70 to 75 percent or less of their expected useful life. This not only allows EPA to find more properly maintained and used engines, but also allows for variation in the durability of different engine configurations within the same engine family without selecting engines that are at the end of their useful life.

While generally agreeing with the ten year/8,000 hour useful life for most engines, manufacturers expressed their concern that some engine families are expected to have a useful life less than 8,000 hours. These engines are designed to be used in severe conditions, often in seasonal equipment, or equipment with a short useful life. Manufacturers are concerned that, should all engines be assumed to last for 8,000 hours, in-use testing of these severe application engines at 6,000 hours (that is, 75 percent of the useful life) would unfairly penalize severe application engines that could in fact be outside of their designed shorter useful life. EPA understands that such a situation could exist, and thus is providing means for the manufacturer to petition the Administrator for an alternative useful life as stated previously. Solid engineering data should accompany the request so that a reliable engineering judgment can be made.

Two commenters requested that EPA adopt a shorter useful life period for engine families with individual cylinder displacement below a specified volume. It appears that this suggestion was intended to provide a straightforward method to administer useful life at the time of certification. However, EPA is not aware of a supportable technical rationale that would suggest there is correlation between cylinder volume and useful life, or that engines with smaller cylinder volumes wear out faster than engines with larger cylinder volumes. Smaller engines are also installed in smaller equipment and the relative work expectation is no greater than larger engines in larger equipment. Most engines covered by this rule are built to operate at full load/rated speed most of the time. Therefore, in relative terms, engines are generally equally stressed during their lifetime regardless of their size or power. For these reasons, EPA does not believe it is appropriate to define a shorter useful life for all engines under a specified cylinder volume. EPA has provided a means for a manufacturer to provide evidence that would allow severe service engines to be held to a shorter useful life.

O. Locomotive Engines

EPA proposed to exclude engines used to propel locomotives from this rulemaking, as regulation of such engines is being undertaken separately. EPA did not, however, exclude other engines operated on locomotives from this rulemaking. EPA requested comment as to whether such other engines ("auxiliary engines") should be regulated in this or the later locomotives action.

EPA received several comments on this issue. The commenters all noted that auxiliary engines are appropriately regulated under section 213(a)(5) as "engines used in locomotives." EPA agrees with this determination and is promulgating a definition of "engines used in locomotives" that corresponds to this determination. While there was general agreement with the regulatory authority under which auxiliary engines used on locomotives can be regulated, comments were received both agreeing and disagreeing with EPA's proposal that the auxiliary engines should be regulated in today's rulemaking action. EPA believes that the statutory mandate of section 213(a)(5) allows EPA to regulate auxiliary engines in this rulemaking. Moreover, the standard under which such engines are to be regulated is virtually identical to the standard under section 213(a)(3). EPA also received comments indicating that auxiliary engines are similar in design and performance to other nonroad engines regulated in this rulemaking, and that such engines should therefore be regulated in this rulemaking.

Therefore, EPA is including auxiliary large CI engines operated on locomotives in this rulemaking. This issue is discussed further in the Response to Comments in the docket.

P. Vehicle and Equipment Manufacturer Requirements

EPA is finalizing the requirement that nonroad vehicle and equipment manufacturers and importers use certified nonroad engines. EPA believes that the most effective way to ensure that certified engines are used in nonroad vehicles and equipment is to require such engines to be used.

In the May 17, 1993 NPRM, EPA stated that CAA section 213 provides authority to require nonroad vehicle and equipment manufacturers to use certified nonroad engines. However, EPA did not propose such a requirement. Instead, EPA requested comment on how it might assure that only certified nonroad engines be used in nonroad vehicles and equipment. EPA received comments on this issue from a State and an environmental association. Both comments requested that nonroad vehicle and equipment manufacturers be required to use certified nonroad engines. One comment agreed that EPA has authority under CAA section 213 to establish such a requirement, and the other pointed out that the entire program would be undercut without such a requirement.

In the October 4, 1993 notice, EPA proposed requiring nonroad vehicle and equipment manufacturers and importers to use certified nonroad engines. EPA received 12 comments on this issue, frem six companies, four industry associations, one State, and one environmental association.

Two commenters opposed the establishment of this requirement. One company argued that failure to require use of certified engines would not undercut the program because engine inventories are already kept to a minimum as their purchase is a significant investment. An association argued that without a technical support document and regulatory language, it could not comment meaningfully.

EPA disagrees that industry inventory control practices can take the place of a requirement that certified nonroad engines be used in nonroad vehicles and equipment. Without a requirement that certified engines be used, nonroad vehicle and equipment manufacturers would be free to use uncertified engines, thus undermining the environmental and public health benefits of the nonroad large CI engine emission reduction program. EPA is not requiring vehicle or equipment manufacturers to be responsible for certification or performance of nonroad engines; that is the responsibility of the engine manufacturer. The final regulations merely prohibit nonroad vehicle and equipment manufacturers from using uncertified nonroad engines in their nonroad vehicles and equipment. Violation of this prohibition would be a violation of CAA section 203(a), and would subject nonroad vehicle and equipment manufacturers to sanctions under sections 204 and 205. EPA does not agree that the October 4, 1993 notice was so lacking in specificity as to require reproposal. In fact, this prohibition was clearly discussed in the October 4 notice. EPA does not find regulatory language regarding prohibited acts to have been required in the October 4 notice because such language would have only restated the requirement that nonroad vehicle and equipment manufacturers must use certified nonroad engines. That requirement was clearly spelled out in the notice.

Several commenters agreed with the requirement. Of the two companies that supported the requirement, one stated that the responsibility of vehicle and equipment manufacturers should be limited to assuring that engines have emission compliance labels, and that engine manufacturers should be responsible for certification, testing, audits, warranty, and recall. A State that supported the requirement said it is the only way to ensure that certified engines are used. An environmental association said the requirement should improve the enforceability of the rule. EPA agrees with these comments. The nonroad vehicle and equipment manufacturer is responsible only for assuring that certified engines are used.

Several commenters neither agreed nor disagreed with the requirement but raised questions regarding it. Several commenters asked about the use of noncertified engines built prior to the implementation dates of this regulation. Several commenters requested implementation dates for vehicles and equipment, to provide sufficient lead time for engine manufacturers to produce certified engines for vehicle and equipment manufacturers to use. Two commenters stated that an implementation date for engine manufacturers was sufficient.

EPA is not establishing separate implementation dates for nonroad vehicle and equipment manufacturers. However, EPA recognizes that certified engines are not likely to be available in the numbers needed by nonroad vehicle and equipment manufacturers on the implementation date, and that vehicle and equipment manufacturers will continue to use noncertified engines built prior to the implementation date until noncertified engine inventories are used up and certified engines are available. As long as vehicle and equipment manufacturers do not inventory engines outside of normal business practices (that is, as long as they do not stockpile noncertified engines), vehicle and equipment manufacturers will be considered to be in compliance.

Another question raised by several commenters regards products intended for export. Commenters asked whether engine manufacturers can continue to produce noncertified engines for export, and whether noncertified engines may be imported for use in nonroad vehicles and equipment intended for export. One commenter requested an exemption from liability for engine and equipment manufacturers if nonroad vehicles or equipment sold for export are used in the U.S.

This regulation does not prohibit import of noncertified engines for use in nonroad vehicles and equipment intended for export. As originally proposed, the exemption for repair and alteration in 40 CFR 89.611–96(b)(1) will allow the import under bond of noncertified engines for use in vehicles and equipment intended for export. Further, this regulation does not prohibit the manufacture of noncertified engines intended for export. Manufacture of noncertified engines intended for export is allowed under the conditions specified in 40 CFR 89.909–96(a), as originally proposed. EPA is not providing a blanket exemption from liability for nonroad manufacturers whose products, intended for export, are used in the U.S. Such manufacturers may, in fact, be liable for sanctions. Each case must be determined on its own merits.

Q. Alternative Fuels

The Agency proposed that the use of alternative fuels would not be necessary to comply with the emission standards, but allowed any manufacturer wanting to use alternative fuels to petition the Administrator for approval of alternative test procedures appropriate for that fuel.

Two commenters addressed alternative fuels. One argued that alternative-fueled CI engines should be exempt from regulation because of increased costs and increased competition with non-CI alternative-fueled engines. The other commenter stated that EPA should include all natural gas engines in this regulation, establish better test procedures as soon as possible, and allow these engines to certify to the same standards.

EPA will adopt as proposed its provisions to include alternative fuel CI engines. No data were provided to

support any of the statements made by commenters. EPA still believes that including alternative fuel engines is appropriate. Any additional cost for these engines to certify is small and comparable to that of diesel fueled engines. EPA reserves the right to adjust standards when necessary, such as adjusting the HC standard to its non-methane equivalent, for certain alternative fuels.

R. Selective Enforcement Auditing

EPA received a number of comments on its proposed Selective Enforcement Auditing (SEA) program for large nonroad CI engines. The proposed nonroad SEA program was designed to be similar to the existing on-highway program for heavy-duty motor vehicle engines, with some modifications to accommodate differences between the two industries.

Comments indicate that industry understands EPA's need for the SEA program, but concern was expressed regarding EPA's proposed changes from the on-highway program to adapt to the large nonroad CI engine industry.

EPA proposed to determine annual limits for the number of SEAs a manufacturer would receive. Each passing audit counts as one toward a manufacturer's annual limit. EPA's on-highway light-duty vehicle (LDV), light-duty truck (LDT) and heavy-duty engine (HDE) programs determine annual limits by dividing a manufacturer's projected annual production by 300,000 for LDV and LDT manufacturers and 30,000 for HDE manufacturers, then rounding to the nearest whole number. If the calculated production factor is less than one, the figure is set at one for that manufacturer.

To compensate for differences between the on-highway and nonroad industries, EPA proposed that nonroad engine manufacturers' annual limits would be determined by first calculating two annual limit factors, the production factor and the family factor. These factors respectively represent the maximum number of audits based on yearly annual sales and on the number of engine families produced in that model year.

The production factor was derived from the annual limits currently used in the on-highway SEA programs and the relative contributions of emissions from on-highway and nonroad sources. EPA proposed that the production factor should be the projected annual nonroad engine sales of each manufacturer divided by 9,500 and rounded to the nearest whole number. If the calculated production factor is less than one, the figure is set at one for that manufacturer.

The family factor was proposed as an alternative method to compensate for situations where manufacturers may have low production but a large number of engine families. EPA proposed that the family factor would be determined by dividing the number of engine families certified by the manufacturer in a given model year by five and rounding to the nearest whole number.

EPA proposed to use whichever value is higher of either the production factor or the family factor as the annual limit of SEAs for a manufacturer.

Manufacturers commented that EPA was putting a larger SEA burden on nonroad manufacturers than on on-highway manufacturers. They recommended eliminating the family factor and that annual limits be determined, as in the on-highway HDE SEA program, by dividing by 30,000 and rounding to the nearest whole number.

Annual limits were also discussed at the public hearing for this rule on June 30, 1993. At that time EPA expressed concern that if a manufacturer were assigned an annual limit of one, and that manufacturer passed an SEA early in the model year, the incentive to maintain close control over emissions may decrease or the desire to establish very low emission limits to maximize credits in an averaging program might increase the risk of noncompliance. Similarly, the manufacturer could modify its production to increase emissions with the knowledge that no more SEAs would likely be assigned during that model year.

EPA has decided to revise its proposed production factor method for determining annual limits. As commented upon, EPA's proposed production factor analysis did not take into consideration projected emission reductions for large nonroad CI engines. EPA estimated that the emission contribution for large nonroad CI engines is approximately half of the contribution for on-highway sources. However, EPA estimates that NO_x emissions from nonroad engines will decrease by approximately 37 percent by the year 2025 or when a complete fleet turnover occurs. Therefore, EPA reevaluated its production factor analysis and determined that the production factor divisor should be 16,000.

EPA has decided to retain the family factor method for determining annual limits. This method was proposed to help compensate for the expected low annual production per engine family and for the possible multitude of engine families with relatively few SEAs per manufacturer to check compliance. EPA estimates that the average annual production per engine family for large nonroad CI engines, even with the expanded engine family definition, will be less than one tenth and less than one twentieth the average production of on-highway HDE and combined LDV/LDT engine families respectively. Consequently, EPA believes the family factor in combination with the production factor is necessary to assign annual limits to large nonroad CI engine manufacturers.

As in the on-highway program, a goal of the nonroad SEA program is to encourage manufacturers to perform self-auditing. Some manufacturers commented that EPA should develop specific guidelines for counting self-auditing against manufacturers' annual limits. Additionally, it was suggested that EPA should count audits conducted by CARB toward annual limits.

EPA recognizes the time, effort and cost manufacturers expend on self-audit testing and considers the quality, scope and effectiveness of such programs when assigning audits to a manufacturer. However, EPA's on-highway HDE SEA program has had audit failures even when a manufacturer's self-auditing showed that engines were in compliance with standards. Consequently, EPA believes that spot checks of manufacturer's self-audit programs by SEAs are necessary.

The criteria governing the assignment of audits are too numerous and interconnected to make specific guidelines relating self auditing to annual limits useful. For instance, a manufacturer with a comprehensive self-audit program who is reluctant to remedy deficiencies and fails SEAs warrants continued attention by EPA just as a manufacturer with a minimal program is likely to receive few SEAs if it routinely designs and produces engines well below emission standards. Likewise, manufacturers who set unusually low FELs in averaging programs will be subject to extra scrutiny.

Substantial consideration will be given to assembly line testing required by CARB on engine families sold nationwide when the CARB test protocols (for example, sampling plan) are as stringent as EPA's. While EPA will not reduce its annual limits based on CARB audits, it will work together with CARB to exchange emission test data and consequently more efficiently assess compliance with applicable standards.

Manufacturers will be notified of SEAs by means of a test order. EPA proposed that the test order would specify the engine family to be audited, or EPA could specify an engine

configuration or range of configurations from a family to be audited. Manufacturers commented that, by auditing engine families, EPA could be significantly increasing the SEA burden on manufacturers. However, as indicated in the NPRM, EPA planned to consider requests by manufacturers to exclude particular engines or configurations from test samples for reasons such as urgent customer orders or to minimize test cell set-up time. EPA still plans to consider those requests.

EPA proposed that imported engines could be selected at ports of entry or storage locations in the U.S. SEA engines are typically selected from the point of final engine assembly or from a storage or shipping facility. Manufacturers commented that selecting foreign-produced engines at ports should be an option but not a requirement. Comments also indicated that port selections could significantly increase the manufacturers' SEA costs.

However, as indicated in the NPRM, manufacturers could designate selection locations to minimize disruption and shipping costs. EPA would not likely select engines for SEAs that are only imported installed in equipment; instead, SEAs of those engines would usually occur during foreign trips by SEA staff.

The total number of engines tested in an SEA will be dictated by the number of engines required to reach the statistically acceptable pass/fail decision within the sampling plan applied. As in the on-highway program, these sampling plans were designed to meet a 40 percent Acceptable Quality Level (AQL).

EPA proposed to use the same sampling plans used for the on-highway HDE SEA program with two revisions. The proposed revisions were to include a sampling plan (Plan AA) for lower production engines and to permit the use of the on-highway sampling plan A on families with projected production between 20 and 99 engines. Plan AA was proposed as an option for families with projected annual production between 20 and 50 engines and to permit an audit pass decision in as few as three tests with a maximum of 20 tests.

Manufacturers requested that EPA provide further flexibility in the use of sampling plans. It was requested that EPA make each sampling plan available for manufacturers regardless of the audited engine's projected annual production. It was also requested that EPA permit the use of CARB's low-volume sampling plan which permits a pass decision in as few as two tests and has a maximum test sample of ten engines.

EPA is not adopting CARB's low-volume sampling plan for the SEA program. EPA believes this sampling plan's consumer risk is too great to justify its use in a federal emission compliance program. However, EPA may consider requests by manufacturers to terminate testing early during SEAs of low production families when the audit results are significantly and consistently below each applicable standard or FEL, and selection of additional engines would be difficult or cause a delay in shipment of customer-ordered engines, or the manufacturer's test facility does not have sufficient capacity to expeditiously conclude the SEA.

As proposed, failure of an SEA may result in suspension or revocation of the certificate of conformity for that engine family. To have the certificate reinstated subsequent to a suspension, or reissued subsequent to a revocation, the manufacturer must demonstrate, by showing passing data that improvements, modifications, or replacement have brought the family into compliance. The regulations include hearing provisions which allow the manufacturer to challenge EPA's suspension or revocation decision based on application of the sampling plans or the manner in which tests were conducted.

S. Averaging, Banking and Trading (ABT)

1. Inclusion of ABT

EPA proposed ABT for NO_x emissions from large nonroad CI engines. This market-based incentive program is designed to provide manufacturers with flexibility in meeting the NO_x standard while achieving a target level of environmental benefits.

Many commenters supported the inclusion of ABT. Others opposed the program. One commenter believes that the program would be overly complex, difficult to enforce, and would decrease the effectiveness of the standard by increasing the overall emissions.

EPA disagrees. The target level of environmental benefits was proposed with ABT in mind. In EPA's opinion, and as discussed in the NPRM, the flexibilities afforded by ABT are appropriate to achieve the 9.2 g/kW-hr NO_x average emission standard and the resultant target 37 percent reduction in fleet emissions upon fleet turnover. EPA is confident that the target level of environmental benefits will be achieved by this regulation.

2. Participation of California-certified Engines in ABT

EPA proposed that engines sold in California and subject to California emissions standards would not be included in the federal ABT program. EPA also proposed that engines sold in California but preempted from California regulation or not subject to California emission standards (primarily construction and farm equipment below 130 kW (175 hp)) be eligible to participate in ABT.

One commenter preferred to have a 50-state credit exchange program which would include all engines shipped to all 50 states regardless of the state regulations. Other commenters believed that the engines subject to state regulations should be excluded from participation in the program. Also, one commenter preferred that all engines sent to California not be included in the federal ABT program and recommended the compromise of having a California-only averaging set.

EPA believes that to maintain the effectiveness of the separate California and national emission standards, any engines both sold in California and subject to California regulations (or both subject to regulations and sold in other states that adopt California's regulations under section 209(e)(2)(B)) should not be allowed to participate in the federal ABT program. Although a 50-state scenario would reduce the tracking burden on manufacturers, reduced tracking burden is not a sufficient reason in EPA's opinion to include California engines. Because California does not allow ABT, all engines both sold in the California market and subject to California regulations will be at or below the NO_x standard finalized by EPA today. Therefore, including these engines in the national average could cause the average emissions of engines in the other 49 states to exceed the standard. Finally, engines sold in California but not subject to California emission regulations are subject to federal regulations and, thus, may participate in ABT.

3. Power Ratings for Credit Calculations

EPA proposed to calculate credits by taking the difference between the standard and the FEL, times the sales volume of engines participating in the program, times the power rating. The power rating was proposed to be the largest power rating within an engine family for those families using credits, and the smallest rating within an engine family for families generating credits.

Some commenters claimed that the proposed method for determining the

power rating for credit calculations translates into a significant (greater than 50 percent) reduction in the number of credits generated and an increase in the number of credits used. They recommended that families be divided into subfamilies, and the most environmentally-safe power rating be drawn from each subfamily for credit calculations. An engine family would have to consist of a broad range of power ratings to realize either a 50 percent reduction in credit generation or a 50 percent increase in credit use. EPA stated in the NPRM that it would not allow multi-configuration engine families to be arbitrarily divided into multiple engine families to maximize credit generation or minimize credit usage.

However, in those specific cases where such a broad range of power ratings occur in one family, a manufacturer would likely be able to demonstrate, consistent with § 89.116–96(d) of the regulations, that the expected useful life emission characteristics of some configurations within a broad engine family warrant a separate engine family designation. This would mitigate the credit reduction caused by extremely broad engine families while maintaining EPA's intent that subcategories not be established for the sole purpose of maximizing credits.

4. Discounting of Credits

EPA's proposed ABT program did not include a discount on credits. The proposal did specify a first in, first out (FIFO) accounting system for credits used in averaging (see § 89.204–96(b)); this effectively extends FIFO to banking and trading because in order to ultimately use banked or traded credits, they must be averaged.

Some commenters approved of the absence of a discount on banked or traded credits. One commenter disapproved because discounting, which is included in the on-highway heavy duty averaging program, is viewed as ensuring that a tangible environmental benefit will accrue from a banking program. This commenter would prefer a reduction in available banked credits through discounting or the use of a last in, first out (LIFO) accounting system to mitigate this effect over time.

EPA determined that a discount was appropriate for the on-highway heavy duty ABT program.[17] The rationale for the credit discount was two-fold. First, additional environmental benefits were desired from banking and trading over and above the benefits produced from the averaging program already in place when banking and trading were added. Credit discounting was determined to be an appropriate method of providing a tangible environmental benefit, so that both manufacturers and the public would share the benefits created by the addition of banking and trading. Second, EPA believed that the amount of the discount would not be a disincentive toward participation in the program. Although a credit discount may be appropriate for the on-highway heavy duty ABT program, where banking and trading were promulgated separately from averaging, EPA is not promulgating a credit discount for today's action. The level of environmental benefits, the level of the emission standard, and the banking and trading components of the ABT program were determined in conjunction with one another. Therefore, a credit discount for today's action is not necessary.

One commenter requested that if EPA was not requiring discounting, the Agency should require the use of LIFO as a means to minimize the value of early banking and of banking in general. Under a FIFO accounting system, older banked credits must be used in the current year's average before credits generated in the current year. This potentially allows manufacturers to bank all the current year's credits, which will have a three year potential credit life, if manufacturers are able to use previously-banked credits or purchased credits to offset those engines with FELs above the standard. This encourages manufacturers to achieve more emissions reductions earlier, which may be beneficial for the environment. Mandating a LIFO accounting system may discourage early emission reductions and was not proposed by the Agency.

5. Allowing Early Banking of Emission Credits

Some commenters supported EPA's proposal to allow manufacturers to bank credits one year in advance of the implementation date in order to provide incentives to introduce clean technology a year early. One commenter suggested allowing early banking starting in 1995 regardless of the phase-in implementation date. One commenter believed that early banking should be excluded in order to prevent the generation of windfall credits.

The Agency believes that incentives should be provided for manufacturers to make early use of clean technology. This consideration outweighs the Agency's concerns regarding the minimal number of credits that may be generated a year in advance by the small percentage of engines which already meet the upcoming standard. EPA presented an analysis in the NPRM demonstrating that credits from this small percentage of engines did not represent significant windfall credits.

Although EPA supports early banking incentives for the introduction of clean technology, EPA does not support allowing early banking starting in 1995 regardless of the phase-in implementation date. EPA proposed the phase-in implementation dates because many manufacturers had informed EPA that additional leadtime is necessary for particular sizes of engines. Although it would be beneficial to the environment to have clean engines introduced earlier, EPA is not allowing early banking beyond one year because the larger number of engine families and the extended years of early banking would increase the potential of windfall credits.

6. Early Banking Credit Generation Level

EPA proposed to allow manufacturers to generate credits one model year prior to the implementation date of the standards. EPA proposed that engines banking early must have NO_x emissions below 9.2 g/kW-hr and could generate credits up to the 9.2 g/kW-hr according to § 89.207–96 and bank these credits for future use.

One commenter opposed the idea of early banking. However, several commenters disagreed on the credit generation level. Some commenters recommended that, to create an incentive for manufacturers to meet the standards early, they should be allowed to generate credits up to 11.9 g/kW-hr. Another commenter opposed the credit generation level of 11.9 g/kW-hr.

EPA believes that it is inappropriate to establish a credit generation level above 9.2 g/kW-hr due to the possibility of windfall credits. EPA did not receive data to indicate that emission credits granted to industry at the 11.9 g/kW-hr level would be, overall, less than or equal to the environmental benefits gained by the early banking program. Therefore, manufacturers participating in early banking may only generate credits up to 9.2 g/kW-hr.

7. Liability and Noncompliance

Several commenters were concerned about the enforcement of the ABT program. One commenter wanted assurance that strict penalties were in place for exceeding FELs and other commenters wanted assurance that adequate compliance demonstration methodologies were in place.

[17] 55 FR 30584, 30592–30593 (July 26, 1990).

EPA has substantial experience in enforcement of vehicle and engine emissions from the on-highway ABT program. This experience will be carried forward to the nonroad program. EPA will ensure that manufacturers are held responsible for meeting the FELs that they set, that the FELs are carefully monitored by means of the SEA program, and that overall compliance is effectively monitored. Further, manufacturers will not be allowed to use credits to remedy FEL exceedances detected by EPA enforcement.

8. Disclosure of Credit Information

Due to the connection between credit information and confidential sales information, EPA regulations concerning the release of confidential business information have restricted the public's opportunity to review manufacturers' submission of credit generation and usage. EPA is currently discussing with the participating manufacturers in the on-highway ABT program the possibility of implementing a means of allowing the public to access enough information to make general assessments about the effectiveness of the ABT program on a regular basis. The Engine Manufacturers Association concurs that it is important to provide an ongoing opportunity for the public to evaluate the overall progress of the program. EPA and EMA expect to finalize an agreement in the near future on the periodic release of credit data in a format that would be useful to the public.

T. Nonroad Equipment Definition

EPA is finalizing the following definition for the term nonroad equipment: "Nonroad equipment means equipment that is powered by nonroad engines." This definition follows Congress' format for defining "nonroad vehicles." EPA believes this definition will clarify use of the term nonroad equipment.

Defining the term nonroad equipment is a logical outgrowth of this rulemaking, is in keeping with the intent of Congress, and clarifies EPA's use of the term. EPA also notes that the definition of the term "nonroad vehicle" has been revised to match the statutory definition; instead of defining nonroad vehicles as vehicles propelled by nonroad engines, they are defined as vehicles powered by nonroad engines.

U. Definition of New

In the September 6, 1991 NPRM proposing regulations under section 209(e) of the CAA regarding preemption of state nonroad regulations, EPA proposed a definition of "new nonroad engine" and "new nonroad vehicle." In that NPRM, EPA defined "new nonroad engine" and "new nonroad vehicle" to mean a nonroad engine or a nonroad vehicle the equitable or legal title to which has never been transferred to an ultimate purchaser. EPA did not provide a definition of "new" in its May 17, 1993 NPRM because EPA expected that the definition of "new" promulgated in the context of the section 209(e) rulemaking would control how "new" would be defined in this rule. However, EPA has not yet promulgated its section 209(e) regulations. Therefore, EPA is finalizing a definition of "new" in this rulemaking relying in part on the definition proposed in the September 6, 1991 NPRM and the comments received in response to that NPRM.

Ultimate purchaser was proposed to be defined as the first person who in good faith purchases such a new nonroad vehicle or nonroad engine for purposes other than resale. Additionally, with respect to imported nonroad engines, EPA proposed to define "new" nonroad engine to be a nonroad engine manufactured after the effective date of a regulation issued under section 213 which would be applicable to such engine had it been manufactured for importation into the United States. These definitions also applied to "new locomotives" and "new engines used in locomotives."

Comments on EPA's proposed definition of "new" were several. First, CARB, the San Diego Air Pollution Control Board (SDAPCB), and the Manufacturers of Emissions Controls Association (MECA) supported EPA's definition. CARB asked that EPA clarify which regulatory activities states may perform; for example, whether states may require in-use testing and impose add-on or retrofit requirements. On the other hand, many commenters, including U.S. Representative Terry Bruce, the Equipment Manufacturers Institute (EMI), the Engine Manufacturers Association (EMA), and the Portable Power Equipment Manufacturers Association (PPEMA), opposed EPA's proposed definition and proposed that "new" should mean manufactured after either the effective date of the Clean Air Act Amendments, November 15, 1990, or after federal regulations take effect. These commenters believe that Congress intended an "absolute" preemption. That is, the nonroad engines and vehicles in the preempted categories manufactured after November 15, 1990 would never be subject to any kind of state emission regulation. EMA commented that if EPA does not accept the latter definition, it should expand its proposed definition so that engines remain "new" until they have exceeded their useful life.

Commenters in the railroad industry also supported a definition of "new" as "manufactured after November 1990" and stated further that the railroad industry has traditionally been preempted from state regulation, such as in the area of safety. The same commenters indicated that they believe that state control of locomotive emissions or state enforcement of federal standards would interfere with interstate commerce. Railroad commenters also stated that any standards for rebuilt or remanufactured engines or locomotives should be uniform federal standards—not state standards. Furthermore, if remanufactured engines were rebuilt to comply with such federal standards, they should be considered "new".

Commenters also opposed the proposed definition regarding imported vehicles and engines because the definition of "new" was different depending upon whether the nonroad engine was produced domestically or abroad.

These proposed definitions for "new nonroad vehicles" and "new nonroad engines" parallel the definitions of "new motor vehicles" and "new motor vehicle engines" in section 216 of the Clean Air Act. The definition of "new" proposed for imported nonroad engines was intended to address nonconforming engines which may become subject to federal emission requirements at the time the engine or vehicle is imported into the United States. The Agency has decided to delete this definition of "new" for imported engines. EPA agrees with the commenters that imports and domestic products should generally be treated alike for regulatory purposes. Today's rule treats domestic and imported nonroad engines the same way for purposes of determining whether they are new.

This final rule establishes for the purpose of these federal regulations, a definition of "new" as it applies to all domestically manufactured and imported "new nonroad engines," "new nonroad vehicles," and "new nonroad equipment."[18] New nonroad engines, vehicles, and equipment are defined as engines, vehicles, and equipment the equitable or legal title to which has not been transferred to an ultimate purchaser. The ultimate purchaser is

[18] This final rule does not provide a final definition of "new" for the purposes of determining the scope of preemption of state nonroad regulations under section 209(e). EPA shall finalize its definition of "new" as applied to preemption of state regulations in a later rulemaking.

defined as the first person who in good faith purchases such engine, vehicle, or equipment for purposes other than resale. For some engines, vehicles, or equipment the passage of title in the United States may not formally occur or manufacturers may retain title and lease the engines or equipment. In these cases, a domestic or imported nonroad engine, nonroad vehicle, or nonroad equipment will retain its status as "new" until such engine or vehicle is "placed into service." An engine, vehicle, or equipment is considered "placed into service" when the engine, vehicle, or equipment is used for its functional purposes. EPA believes that the definition of new should include the "placed into service" addition to the motor vehicle definition of new found in section 216 of the Act because of the nature of the nonroad market. Nonroad engines, nonroad vehicles and nonroad equipment are often leased and maintained by the manufacturer well into the useful life of the nonroad equipment. A piece of equipment, the title of which has passed to the ultimate purchaser, should not be treated differently than a piece of equipment which is being used but has not yet passed to an ultimate purchaser.

The Agency believes that this definition of "new" comports with the language, intent and structure of the Clean Air Act and is a permissible construction of the statute. Contrary to the assertion of some commenters, EPA's definition of "new" is consistent with the dictionary definition of the word as "having existed or been made but a short time." Webster's Ninth New Collegiate Dictionary, 1990. Generally speaking, manufactured products are sold soon after they are made and are considered new until they are sold or used. The commenters' definition of new—anything manufactured after the Clean Air Act Amendments' enactment or an applicable regulation's promulgation—would mean, by contrast, that any engine manufactured after a certain date would be new forever. This is certainly not the plain meaning of "new." Congress could have stated that the federal preemption applied to certain equipment manufactured after a certain date, but Congress did not do so. Elsewhere in title II, Congress specified that a provision only applied to products manufactured after a certain date (see, section 218 requiring a ban on engines manufactured after the 1992 model year that require leaded gasoline) or first introduced into commerce after a certain date (see, section 211(f) regarding prohibition on fuels that are not substantially similar to fuels used to certify vehicles as meeting emission standards). The lack of such a date here further supports that Congress intended "new" to mean newly manufactured and not yet sold.

The legislative record also shows Congressional intent that "new" should refer to newly manufactured products. In his colloquy with Senator Wilson explaining the final version of section 209(e), Senator Chafee notes that "because the preemption is limited to new engine standards only, States can continue to require existing *and in-use* nonroad engines to reduce emissions * * *" [Emphasis added] 136 Cong. Rec. S17237 (October 26, 1990). This language is echoed by similar language from Senator Baucus in his report to the Senate on the conference bill. 136 Cong. Rec. S16976 (October 27, 1990). If Congress intended the definition of new nonroad engines or equipment, and as a result the preemption, to apply to an engine for its entire life, then it would appear that there would be no distinction between new and in-use nonroad engines, as an engine manufactured after a certain date would always be new. Yet the statements of Senator Chafee and Senator Baucus clearly contemplate such a distinction.

The Agency's definition of new is also consistent with the way the Act approaches motor vehicle emission control. As noted earlier, section 216 defines new in the context of motor vehicles as "a motor vehicle the equitable or legal title to which has never been transferred to an ultimate purchaser." The Act applies federal emissions standards to "new" vehicles. These federal standards are enforced through certification, assembly line, and recall testing. States, on the other hand, have a role in motor vehicle emission control through inspection/maintenance programs and are not restricted from controlling used vehicles. The section 209(a) prohibition of state regulation of motor vehicles addresses only "new" motor vehicles and engines and prohibits state regulation that occurs before sale, titling, or registration of the vehicle.[19]

The Clean Air Act Amendments of 1990 take a parallel approach to nonroad standards and enforcement. Section 213 provides EPA with authority to set standards for "new" engines and provides for federal enforcement of such standards in the same manner as motor vehicle enforcement. Furthermore, nothing on the face of section 209(e) or section 213 indicates that Congress intended "new" to be interpreted differently in the nonroad and motor vehicle contexts.[20] Given that the preemption provisions for new motor vehicles and new nonroad engines appear in the same section of the Clean Air Act, it is reasonable to believe that Congress did not intend for the word "new" to be defined differently within the same section without stating this intent explicitly.[21]

There is not a compelling policy or factual justification for defining new differently in the nonroad and motor vehicle contexts. State regulation of nonroad engines does not generally present any greater degree of disruption of the movement of products, engines or equipment between states than does regulation of motor vehicles. The comments provide little if any justification, in terms of relevant distinctions between motor vehicles and nonroad engines, to justify such a significant departure from EPA's established practice for regulating mobile sources.

The Agency's definition of new is also consistent with case law. In *Allway Taxi, Inc.* v. *City of New York*,[22] the court held that where the exercise of local police power serves the purpose of a federal act—the Clean Air Act in that case—the preemptive effect of the act should be narrowly construed. In keeping with that principle, EPA believes that the definition of "new" should be construed narrowly in order

[19] Section 209(a) provides, in part, ". . . No State shall require certification, inspection, or any other approval relating to the control of emissions from any new motor vehicle or new motor vehicle engine as condition precedent to the initial retail sale, titling (if any), or registration of such motor vehicle, motor vehicle engine, or equipment."

[20] Much of the argument below discusses the definition of "new" as applied to section 209 of the statute. However, these arguments are equally valid for the purposes of defining "new" under section 213, especially given the integrated nature of Part A of Title II, the legislative and statutory history, and practical necessity. For example, consistent definitions of new under sections 209 and 213 are likely to ensure that there are no unintended gaps in regulation or unintended dual regulation. Also, the statutory definition of "new motor vehicle" and "new motor vehicle engine" are applicable equally to federal regulations and preemption of state regulations. EPA generally sees no logical reason to treat nonroad engines differently. However, see the discussion in footnote 21.

[21] EPA recognizes that regulation of locomotives presents unique circumstances, including questions regarding interstate commerce, that require special attention. EPA therefore believes that the definition of "new" as used in "new locomotive" and "new engine used in a locomotive" may need to be treated differently for the purposes of determining preemption of state regulation under section 209(e) than it is treated for the purpose of federal regulation under section 213(a). This issue will be addressed in a later rulemaking.

[22] *Allway Taxi, Inc.* v. *City of New York*, 340 F. Supp. 1120 (S.D.N.Y.), *aff'd*, 468 F.2d 624 (2d Cir. 1972).

to protect states' rights, particularly in an area such as public health in which states traditionally exercise control. California's nonroad regulations will serve the purpose of the federal act by improving air quality.

In *Allway Taxi*, the court discussed the federal preemption of new motor vehicles and interpreted the meaning of new motor vehicle as defined in Section 216 of the Act. The court noted that this definition "reveals a clear congressional intent to preclude states and localities from setting their own exhaust emission control standards only with respect to the manufacture and distribution of new automobiles."[23] The court stated further that the narrow purpose in the definition is reinforced by prohibiting states and localities from setting emission standards before the initial sale or registration of an automobile. Congress specifically declared that section 209 did not preempt states from regulation of the use or movement of motor vehicles after they have reached their ultimate purchasers.[24]

EPA believes that the further a state requirement is removed in time from the manufacture and distribution of new engines, the less interstate commerce is likely to be burdened. Furthermore, the legality of particular regulatory controls that a state may impose on nonroad vehicles or engines that are no longer new will depend upon the burden that such controls place on interstate commerce. In fact, the court in *Allway Taxi* stated that a state or locality is not free to impose its own emission control measures the moment after a new car is bought and registered. "That would be an obvious circumvention of the Clean Air Act and would defeat the congressional purpose of preventing obstruction to interstate commerce."[25] The court further stated that federal preemption does not, however, preclude a state from imposing its own exhaust emission control standards upon the resale or reregistration of the automobile. Furthermore, states are not precluded from setting standards for licensing of vehicles for commercial use. These types of regulations, which are more removed, "would cause only minimal interference with interstate commerce, since they would be directed primarily to intrastate activities and the burden of compliance would be on individual owners and in-state users and not on manufacturers and distributors."[26]

[23] *Id.* at 1124.
[24] *Id.*
[25] *Id.*
[26] *Id.*

EPA expects that the principles articulated in *Allway Taxi* will be applied by the courts to any State adoption of in-use controls. For example, manufacturers have voiced a concern that California would attempt to impose in-use emission control measures that would apply immediately after a new vehicle or engine were purchased. As the *Allway Taxi* court said, such standards applied to almost-new vehicles would be an attempt to circumvent section 209 preemption and would obstruct interstate commerce.[27]

It should be noted that section 209(e)(2) of the Act does not prevent California or other states from regulating nonroad engines and vehicles in use.[28] EPA believes that the requirements of section 209(e)(2) apply only to new nonroad engines and vehicles. The requirements of section 209(e)(2) are only required for nonroad engines and vehicles the regulation of which has been preempted. The language of section 209(e)(2) does not state any clear preemption, either for new or in use vehicles. The only clear preemption of state regulation of nonroad engines occurs in section 209(e)(1) and section 209(a).[29] Both of these subsections are limited to new engines and vehicles. Given the general legal presumption against reading a preemption more broadly than explicitly required, as discussed in *Allway Taxi*, a preemption of state regulation of nonroad engines and vehicles in use should not be readily implied.

Another indication that section 209(e)(2) was not intended to apply to most in-use regulations of nonroad engines is the fact that neither the Senate nor the House version of the 1990 Act amendments would have preempted state regulation of anything but new nonroad engines. Neither version would have expressly preempted regulation in use. It would be unusual for a bill to come out of conference with a broader preemption than existed in either house and without any mention in the legislative history that such broader preemption had been mandated. In fact, both Senators Chafee and Baucus believed that the scope of the preemption had been narrowed from the House bill, not widened.[30]

In fact, as the legislative history indicates, it appears that Congress intended the preemption provisions of section 209, as applied to nonroad engines, to be analogous to the preemption provisions as applied to motor vehicles, except that California cannot request any waiver of the Federal preemption of state regulation of new small farm and construction equipment and locomotives.

Further indication that section 209(e)(2) was not intended to apply to in-use regulations is the fact that, if the subsection were applied to in-use regulations, then California would be the only government (local, state or federal) that could directly set regulations for nonroad engines in use. EPA's mandate under section 213 applies only to new engines. Therefore, EPA will not promulgate standards for in-use regulation of nonroad engines under section 213, beyond in-use regulations normally associated with new certified engines (*e.g.* in-use testing and recall requirements under section 207). States other than California would not be able to regulate nonroad engines in use (*e.g.* operation controls under section 209(d)) until California regulates them and could only regulate them in a manner identical to California's regulations. Nothing in the legislative history indicates such a dramatic departure from the current ability of states and local authorities to regulate emissions of mobile sources in use.

[27] *Id.* EPA expects the reasoning and policy outlined above in the *Allway Taxi* discussion to apply to locomotives although its implementation is dependent upon the ultimate definition of new locomotive.

[28] In-use testing and recall programs of the type set forth in section 207 ensure compliance with standards required to be met by manufacturers at the time of certification of the engine. Because these in-use standards relate to the original manufacture of the engine and place the burden of compliance upon the manufacturer, they are deemed to be standards affecting a new motor vehicle or a new nonroad engine and thus require a waiver under the criteria of section 209(b) or 209(e)(2) respectively.

[29] Section 209(a) applies to nonroad vehicles because of the language of section 213(d) of the Act, which specifically requires that EPA's standards regulating nonroad engines and vehicles be subject to sections 206, 207, 208 and 209 of the Act, with such modifications of the applicable regulations as the Administrator deems appropriate. Thus, Congress clearly anticipated that all of section 209 would be applicable to nonroad engines. Subsections (a) through (d) of section 209 do not specifically reference nonroad engines, nor do sections 206, 207 or 208. However, the language of section 213(d) clearly is intended to apply such provisions to nonroad engines. Further indication of Congress' intent is the language of the last sentence of section 209(e)(1), which states that subsection 209(b) does not apply for purposes of subsection (e)(1). (Section 209(b) provides the procedure under which California can receive a waiver of section 209(a) preemption for motor vehicles.) This sentence would not have been necessary unless subsection 209(a) through (d) otherwise applied.

[30] Both Senators declare that state preemption is limited to new locomotives and new small farm and construction equipment. Both mention that states may still regulate other new nonroad equipment, presumably after receiving EPA approval. Finally, each declare that states also fully retain existing authority to regulate emissions from all types of existing or in-use nonroad engines by specifying fuel quality specifications, operational modes or characteristics or measures that limit the use of nonroad engines or equipment.

Therefore, if section 209(e)(2) is determined to apply to in-use regulations, the entire United States regulatory scheme for regulation of nonroad engines in use would be dependent on the actions of one state, California. Congress could not have meant to grant such plenary power to a single state.

This is especially true given the location-specific nature of in-use regulations. In-use regulations, such as time of use or place of use restrictions (*e.g.* high occupancy vehicle lanes) are typically very site specific. An in-use regulation suitable for California, or in part of California, may have little or no relevance or practicality to the type of in-use regulation suitable for another area. Such regulations which primarily effect local users are more appropriately controlled and implemented by local and state governments.

Moreover, section 209(d) of the Act clearly limits the preemption of state regulation in use. It states that "nothing in this part shall preclude or deny to any other State or political subdivision thereof the right otherwise to control, regulate, or restrict the use, operation or movement of registered or licensed motor vehicles." As was stated above, section 209 as a whole applies equally to nonroad engines. Thus, section 209(d) should be interpreted to mean that, unless state regulation of use of nonroad engines is specifically preempted, section 209 should not be interpreted to grant any implicit preemption, except within the framework of *Allway Taxi*.

Given the language of section 209 and the lack of any express preemption, the legislative history of these provisions, and the general presumption against providing broad preemption where such preemption is not made explicit, EPA believes that it is clear that section 209(e)(2) does not apply to in use regulation of nonroad engines.

While EPA recognizes the important principle of narrowly construing the preemptive effect of the Act as explained in *Allway Taxi*, EPA also notes that certain state regulations that may be characterized as "in-use" regulations may be preempted because they are effectively regulations on the design of new engines rather than on the use of "in-use" engines. Industry has expressed concern that states might impose retrofit requirements on nonroad engines and vehicles as soon as they are introduced into commerce, or when such engines are being rebuilt, or at a date after which nonroad engines are typically rebuilt.[31] EPA recognizes that CARB does not envision a retrofit requirement and that, because of the nature of the nonroad market, it is unlikely that other states would adopt such a requirement.[32] However, given EPA's definition of new and the scope of the definition within this rulemaking, this issue could arise when other states plan their in-use emission strategy. In such a case, EPA believes that a retrofit requirement mandating a retrofit of a nonroad engine immediately after the engine is no longer new is adverse to the Congressional intent of section 209(e) and the principles laid out in *Allway Taxi*. Therefore, in this scenario, such a retrofit requirement would be deemed an in-use emission standard relating back to the original design of the new engine by the original engine manufacturer (OEM) and would be subject to the waiver criteria of section 209(e)(2). Within this same scenario, only California could adopt such a requirement and other states could only adopt California's requirement if California subsequently was granted a waiver. However, after a reasonable amount of time has passed and the engine is no longer new (most likely when an engine is being rebuilt), modest retrofit requirements would most likely not be deemed to significantly affect the OEM and thus such requirements would not be subject to subsection 209(e)(2). In this second scenario, the modest retrofit requirements would still be subject to challenge in court under the *Allway Taxi* criteria.[33]

Therefore, the Agency has determined that nonroad engines and nonroad vehicles will be "new" for purposes of the Act until the equitable or legal title passes to the ultimate purchaser, or if title passage does not occur, then the engine or vehicle will be new until placed into service.

V. Definition of Locomotive

The September 6, 1991 NPRM to the California nonroad preemption regulation defined locomotive as a self-propelled piece of on-track equipment (other than equipment designed for operation both on highways and rails, specialized maintenance equipment, and other similar equipment) designed for moving other equipment or carrying freight or passenger traffic or both. As with the definition of "new," EPA did not propose a definition of locomotive in its May 17th NPRM, but is finalizing a definition is this rulemaking, relying in part on the definition proposed in the September 6, 1991 NPRM and the comments received in response to that NPRM. The comments discussed below are contained in Docket # A–91–18.

EMA noted a difference between the NPRM definition and the definition given in the Locomotive Inspection Act (LIA) upon which the EPA definition was based, but did not recommend EPA use the LIA definition in the definition EMA provided. The only difference between the EPA definition and the LIA definition is that the LIA definition of locomotive includes a piece of equipment without propelling motors but with one or more control stands. This item was not included by EPA since if it has no propelling motors it will not be of concern for purposes of engine emissions regulations. It is noted that neither the Association of American Railroads (AAR) nor any railroad companies that commented on the NPRM, such as Union Pacific and Southern Pacific, had any specific comments on the definition of locomotive.

EMA provided definitions for "locomotive" and "locomotive engine".[34] Under this definition, the regulation of any engine mounted on a locomotive (such as an engine driving a crane or winch) would be preempted. The dictionary definition of "locomotive" is a "self-propelled vehicle, usually diesel or electric, that travels on rails and moves railroad cars."[35] EMA's definition of locomotive engine goes beyond the specific purpose of locomotion to include any other engine that might be placed on a

[31] See Oral Statement of the Engine Manufacturers Association, Docket entry IV-F–7, which states "The ultimate purchaser must have the assurance that the engine * * * she might purchase, and which properly meets EPA requirements * * * is 'good' until that engine is ready to be rebuilt. No state should be allowed to impose retrofit standards on engines which otherwise conform to EPA requirements."

[32] See Letter from Mr. Cackette, CARB to Mr. Mandel, EMA, dated July 20, 1993, Docket entry IV–I–55.

[33] EPA's definition of "new" does not present a problem for engines or equipment that do not sell relatively quickly (*e.g.*, within a year of being made) in California. If California's regulation set standards applicable to "new" engines, *i.e.* as of the date title passed, regardless of when the engine was produced, then an engine manufactured in 1990 but not sold until 1994 would be subject to 1994 emission standards. This problem is avoided since California's Utility Engine Rule ties the date of manufacture to the standard, therefore a 1990 engine would be subject to a 1990 standard and a 1994 engine subject to a 1994 standard.

[34] EMA recommended the following definitions: "Locomotive" means a self-propelled piece of on-track railroad equipment (other than equipment designed for operation both on-highway and on-track) and "Locomotive engine" means an engine included in a locomotive. See Statement of Engine Manufacturers Association, Docket entry IV-G–19.

[35] Websters II, New Riverside University Dictionary, 1988.

locomotive. EPA believes that the term "locomotive engine" is limited to the engine used to propel the locomotive and other railroad cars. However, EPA does believe that the term "engines used in locomotives," as found in section 209(e)(1)(B), can be defined to include other engines which are mounted on a locomotive regardless of whether they are used for purposes of self-propulsion. EPA notes that under this definitional framework the "locomotive" is only that piece of on-track equipment which is self-propelling and is designed for moving other cars containing equipment, freight, or passengers. "Engines used in locomotives" thus includes an engine placed in the locomotive to propel the train and also includes other engines mounted on the locomotive for auxiliary power generation for the train, but does not include engines mounted on the train elsewhere than the locomotive. An engine providing power for a crane or winch, for example, would only be considered preempted from state regulation (if it otherwise met the requirements for "new") as "an engine used in [a] locomotive" if such engine were mounted on the locomotive. EPA believes these definitions reflect the intent of Congress to reduce the burden on interstate commerce for the railroad industry, and address EMA's concerns regarding auxiliary engines.[36]

EPA has stricken the word "carrying" from the definition of locomotive. This was done to avoid implying that any persons or property that were moved by the engine had to be located directly on the locomotive. The word "moving" in the definition is all that is needed to give the correct meaning.

For the final rule, EPA has decided that a "locomotive" means a self-propelled piece of on-track equipment (other than equipment designed for operation both on highways and rails, specialized maintenance equipment, and other similar equipment) designed for moving other equipment, freight or passenger traffic. EPA has also decided that the term "engines used in locomotives" means either an engine placed in the locomotive to move other equipment, freight , or passenger traffic, or an engine mounted on the locomotive to provide auxiliary power.

VII. Cost Analysis

EPA has adjusted its estimate of the average annual cost of this rule upward from approximately $29 million to $70 million. EPA has decided to make the adjustment after analyzing new information provided by commenters with respect to the engine modifications required to meet the adopted emission standards and updated cost information provided confidentially by manufacturers. Based on EPA's revised analysis (see the final version of the Regulatory Support Document in the docket), the Agency has adjusted the present value of the per engine increase in retail price of a 1996 model year engine upward from approximately $110 per engine to approximately $220 per engine (in 1992 dollars).

To maintain acceptable performance throughout the engine speed band, some manufacturers commented that they will choose to use waste-gate technology in lieu of smoke limiters on some of their engine models. These manufacturers stated that, for their engine designs, applying a smoke limiter to control smoke could cause a performance discontinuity that could present a safety concern under certain operating conditions. While the cost of waste-gate technology was not accounted for in EPA's proposed cost impact, the Agency believes it is reasonable for manufacturers to use a costlier solution in those cases where there is a potential performance or safety impact. EPA estimates that half of the turbocharged engines could be fitted with this technology. That represents approximately 30 percent of all engines covered by this rule with a parallel 30 percent reduction in use of smoke limiter technology. Based on average per piece cost figures submitted by manufacturers, EPA has calculated that the addition of waste-gate technology in the technology mix would result in a per engine weighted hardware cost increase of approximately $35 per engine, while the weighted cost due to use of smoke limiter technology will be revised to $3 per engine.

EPA also assumed in its estimate of hardware cost that there would be little or no cost involved with upgrading fuel pumps to increased injection pressures (as opposed to changing pump type, rotary to in-line, in-line to unit injector). During the comment period, manufacturers provided concrete evidence that there is a significant cost increment to increasing injection pressures. Based on manufacturers' data an average weighted cost of $73 per engine will be assessed to account for modifications that will allow in-line fuel pumps and unit fuel injection systems to accommodate incremental increases in injection pressure.

Manufacturers also provided information on additional hardware costs. Electronic control systems and low sac fuel injectors were two strategies mentioned. While electronic control will reduce NO_x emission, EPA maintains that is not the most cost effective method to meet the requirements of this rule. A number of marketing and performance reasons unrelated to emission performance, such as fuel economy and versatility, make such strategies attractive to manufacturers. These reasons in and of themselves may cause manufacturers to convert a portion of their fleets to electronic controls. Because EPA's cost estimate is based on the necessary cost to meet this rule and to maintain current performance and fuel economy characteristics, the extra cost incurred by a manufacturer to install electronic control will not be added to EPA cost estimates.

Similarly, manufacturers requested that EPA include the cost of low sac injectors. Low sac injectors are an effective HC control strategy. However, EPA's proposal did not contain HC standards, and the HC standard adopted in the final rule can be expected to do no better than cap the current HC levels. Furthermore, EPA requested that manufacturers provide information on the cost ramifications of adopting additional standards. Industry comments have stated that EPA's adoption of the HC standard will not increase the cost of this rule.

EPA believes it has adequately accounted for costs of low sac injectors in its fuel system cost estimates and will not report a separate cost line to account for the limited usage of low sac injectors caused by this rulemaking. A percentage of the engine production volume by the 1996 model year will be using low sac injectors whether regulations are in place or not. An additional percentage of regulated engines that undergo fuel system modifications will incorporate low sac injectors at that time. Manufacturers that intend to do this have reported fuel system modification costs that include the low sac injector costs. These costs are already included in the EPA hardware cost estimate under the "Fuel System Improvements" section of the RSD.

Several manufacturers suggested that their engine model prices would increase more than the proposed EPA per engine retail price increase. It should be noted that the EPA present value per engine retail price estimate is a relative estimate aggregated across engines on a sales-weighted basis. Thus the estimate cannot be directly translated into the price increase a consumer should expect to pay for a particular piece of equipment. For engines greater than 130 kW, the disaggregated data generally indicate

[36] See Letter from Glenn Keller, EMA to Joanne Goldhand, EPA, Docket entry IV–I–54.

that an engine purchaser can expect a price increase of approximately $100 per 75 kW, which represents less than one percent of the equipment price in most cases. Price increases for engines between 37 kW and 130 kW will generally increase between zero to two percent of the equipment price. These are general estimates and there will be exceptions that do not show in EPA's reported aggregate value. In any event, relative industry level estimates calculated for regulatory analysis purposes would not be expected to match the retail price of a particular engine design. However, based on all data available (including confidential manufacturers' submissions), EPA believes that its final adjusted estimate reported in the rulemaking is accurate in the aggregate and is consistent with accepted regulatory costing methodology.

Some comments suggested that the proposed rule would cause a significant increase in fuel consumption. EPA maintains that the impact of this rule on fleet average fuel consumption will be minimal. EPA's experience with on-highway engines is that fuel consumption decreases when the various technologies to control emissions are added. From 1988 to 1991, fuel consumption decreased one percent, while NO_X and smoke decreased about 40 percent for the average on-highway engine. Specific power also increased four percent. EPA's on-highway findings are consistent with an analysis presented by Caterpillar at the American Petroleum Institute Off-Highway Forum in September, 1993 in Milwaukee, Wisconsin (see the RSD for details of this analysis).

EPA's estimate of hardware costs accounts for those additional costs needed to control fuel consumption beyond what is necessary to reduce NO_X emission levels to meet the standard. These methods to both reduce NO_X emissions and maintain current fuel consumption and performance have been used for a number of years in the on-highway fleet.

Since fuel economy and power are important criteria for the consumers of these engines, most manufacturers commented that they are going to add hardware to their engines in an effort to maintain current levels of performance. Some manufacturers commented that while they would do their best to fully maintain the baseline fuel economy levels, selected engine models would incur a small fuel economy penalty despite their efforts. While a small number of engine families may not be capable, for either technical or cost reasons, to fully retain current fuel consumption and power levels, EPA's past experience with the on-highway program has shown that most engine models will be able to attain the emission standards without compromising fuel consumption or power. One manufacturer stated that it expected fuel efficiency to increase over time as manufacturers optimize their engine designs. EPA has strong evidence from its historical database suggesting that is the case.

EPA maintains that the impact of this rule on equipment in which regulated engines are installed will be minimal. EPA has accounted for the cost of applying the range of engine technologies required to maintain engine efficiency so that equipment modifications will not be required. Furthermore, the added program flexibilities, such as the later implementation date for lower power engines and the implementation of the ABT program, provide means for manufacturers to minimize any negative impacts. Based on EPA's analysis in the RSD and further discussed in the Response to Comments document in the docket, EPA believes that the adopted rules provide the means to avoid equipment modifications in all but the most severe cases. These cases will not affect the aggregate cost analysis presented in this rule.

Comments received with respect to equipment impacts centered around the need to redesign the engine cooling system and increase maintenance to offset an expected loss in engine efficiency. A number of commenters disagreed with EPA's assessment of no impact on equipment.

EPA provided analysis in the draft RSD supporting minimal loss in engine efficiency. Manufacturers did not provide data demonstrating efficiency losses and did not refute the data provided by EPA. Four equipment manufacturers and their association did provide average cost figures. These cost figures were based on anticipated equipment modifications and increased maintenance due to engine efficiency loss estimates that were not supported with data. Furthermore, projections and costs for equipment modification and maintenance were highly aggregated and thus provided insufficient resolution to establish the need for the projected equipment changes. Requests from EPA for additional data from specific manufacturers were not responded to with sufficient detail. Based on the information available to EPA (and discussed further in the Response to Comments in the docket), the Agency concludes that equipment modifications will rarely be needed to accommodate certified engines.

VIII. Environmental Benefits

National Ambient Air Quality Standards (NAAQS) have been set for criteria pollutants which adversely affect human health, vegetation, materials, and visibility. Three criteria pollutants (nitrogen dioxide (NO_2), ozone (O_3), and particles smaller than 10 microns (PM_{10})), are impacted by NO_X emissions. EPA has determined the standards set in this rule will reduce NO_X emissions and help nonattainment areas come into compliance with the NAAQS for ozone. The following provides a summary of the reduction expected of NO_X emissions. The underlying analysis is described in greater detail in the Regulatory Support Document.

The Agency believes the adopted standards should reduce average per-unit NO_X emission from large nonroad CI engines by 27 percent before the year 2010, with a fleet-wide 37 percent reduction once a complete fleet turnover occurs or by the year 2025. This will result in annual nationwide reductions of roughly 800,000 tons of NO_X by the year 2010 and over 1,200,000 tons of NO_X by the year 2025. Based on EPA projections of future emission levels, these reductions represent four percent of total nationwide annual NO_X emissions expected in 2010.[37]

IX. Cost Effectiveness

In evaluating various pollution control options, EPA considers the cost effectiveness of the control. The cost effectiveness of a pollution control measure is typically expressed as the cost per ton of pollutant emissions reduced. Other things being equal, Agency guidance directs that the regulatory option selected should, for a given level of effectiveness, cost less per ton of emissions reduced.

A. Cost Per Ton of NO_X Reduction

EPA has revised its cost effectiveness estimate of the NO_X standard upward to $188 per ton of NO_X removed from the exhaust of the affected engines. This figure is based on the ratio of the present value of the stream of projected costs to the present value of the stream of projected emission reduction benefits, and it reflects the revised cost estimates presented in section VII.

[37] U.S. Environmental Protection Agency, *National Air Pollutant Emission Estimates: 1940–1990*, EPA–450/4–91–026, November, 1991, p. 46.

B. Comparison to Cost Effectiveness of Other Emission Control Strategies

The cost-effectiveness of the nonroad NO_X standards may be compared to other CAA measures that reduce NO_X emissions. title I of the 1990 CAAA requires certain areas to provide for reductions in VOC and NO_X emissions as necessary to attain the NAAQS for ozone. Title I specifically outlines provisions for the application of reasonably available control technology (RACT) and new source review (NSR) for major NO_X emitters. In addition, EPA anticipates that more stringent reductions in NO_X emissions will be necessary in certain areas. Such reductions will be identified through dispersion modeling analyses required under title I. The cost-effectiveness of these measures is generally estimated to be in the range of $100 to $5,000 per ton of NO_X reduced.[38]

In addition to applying NO_X control technologies to meet requirements under CAA title I, many point sources will also be required to meet NO_X emission rate limits set forth in other programs, including those established under CAA title IV, which addresses acid deposition (that is, acid rain). EPA anticipates that the cost of complying with regulations required under section 407 of the CAA (Nitrogen Oxides Emission Reduction Program), which proposes nationwide limits applicable to NO_X emission from coal-fired power plants, will be between $200 and $250 per ton.

The cost effectiveness of controlling NO_X emissions from on-highway mobile sources has also been estimated. The 1998 heavy-duty highway engine NO_X standard is estimated to cost between $210 and $260 per ton of NO_X reduced, and the recently promulgated on-board diagnostics regulation is estimated to cost $1974 per ton of NO_X reduced from malfunctioning in-use light-duty vehicles.

In summary, the revised cost effectiveness of the NO_X standard included in this rule remains favorable relative to the cost effectiveness of several other NO_X control measures required under the Clean Air Act. To the extent that cost effective nationwide controls are applied to large nonroad CI engines, the need to apply in the future more expensive additional controls to mobile and stationary sources that also contribute to acid deposition, as well as ozone nonattainment, nutrient loading, visibility, and PM nonattainment may be reduced.

[38] U.S. Environmental Protection Agency, The Clean Air Act Section 183(d) Guidance on Cost-Effectiveness, EPA–450/2–91–008, November 1991

X. Administrative Requirements

A. Administrative Designation and Regulatory Analysis

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether the regulatory action is "significant" and therefore subject to OMB review and the requirements of the Executive Order. The Order defines "significant regulatory action" as one that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition jobs, the environment, public health or safety, or state, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Pursuant to the terms of Executive Order 12866, it has been determined that this rule is a "significant regulatory action" because it may adversely affect in a material way that sector of the economy involved with the production of nonroad large CI engines and nonroad vehicles and equipment using those engines, previously unregulated by EPA. As such, this action was submitted to OMB for review. Changes made in response to OMB suggestions or recommendations will be documented in the public record.

B. Paperwork Reduction Act

The information collection requirements pertaining to certification and ABT in this rule have been submitted for approval to the Office of Management and Budget (OMB) under the *Paperwork Reduction Act*, 44 U.S.C. 3501 *et seq.* An Information Collection Request document has been prepared by EPA (ICR No. 1684.01) and a copy may be obtained from Sandy Farmer, Information Policy Branch, EPA/OPPE/ORME, 401 M Street SW., Washington, DC 20460 (Mail Code 2136) or by calling (202) 260–2740. These requirements are not effective until OMB approves them and a technical amendment to that effect is published in the **Federal Register.**

This collection of information has an estimated reporting burden averaging 5,800 hours annually for a typical engine manufacturer. However, the hours spent annually on information collection activities by a given manufacturer depends upon manufacturer-specific variables, such as the number of engine families, production changes, emissions defects, and so forth. This estimate includes time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Chief, Information Policy Branch; EPA/OPPE/ORME; 401 M Street SW., (Mail Code 2136); Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, marked "Attention: EPA Desk Officer."

All other information collection requirements in this rule have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* and have been assigned the following control numbers:

EPA ICR No.	Type of information	OMB control No.
ICR No. 11	Selective Enforcement Auditing.	2060–0064
ICR No. 282	Emission Defect Reporting.	2060–0048
ICR No. 10	Importation of Nonconforming Vehicles.	2060–0095
ICR No. 12	Exclusions ...	2060–0124
ICR No. 95	Exemptions .	2060–0007

C. Impact on Small Entities

The Regulatory Flexibility Act of 1980 requires federal agencies to identify potentially adverse impacts of federal regulations upon small entities. In instances where significant impacts are possible on a substantial number of these entities, agencies are required to perform a Regulatory Flexibility Analysis (RFA).

EPA has determined that this rule will not have a significant effect on a substantial number of small entities. This regulation will affect manufacturers of large nonroad CI engines, a group that does not contain a substantial number of small entities. Manufacturers will be able to take advantage of the flexibility afforded by the averaging, banking, and trading program.

Therefore, as required under section 605 of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, I certify that this regulation does not have a significant impact on a substantial number of small entities.

List of Subjects

40 CFR Part 9

Reporting and recordkeeping requirements.

40 CFR Part 89

Environmental protection, Administrative practice and procedure, Air pollution control, Confidential business information, Imports, Incorporation by reference, Labeling, Nonroad source pollution, Reporting and recordkeeping requirements.

Dated: May 31, 1994.

Carol M. Browner,

Administrator.

For the reasons set out in the preamble title 40, chapter I of the Code of Federal Regulations is amended as follows:

PART 9—[AMENDED]

1. The authority citation for part 9 continues to read as follows:

Authority: 7 U.S.C. 135 *et seq.*, 136–136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601–2671; 21 U.S.C. 331j, 346a, 348; 31 U.S.C. 9701; 33 U.S.C. 1251 *et seq.*, 1311, 1313d, 1314, 1321, 1326, 1330, 1334, 1345(d) and (e), 1361; E.O. 11735, 38 FR 21243, 3 CFR, 1971–1975 Comp p. 973; 42 U.S.C. 241, 242b, 243, 246, 300f, 300g, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–1, 300j–2, 300j–3,300j–4, 300j–9, 1857 *et. seq.*, 6901–6992k, 7401–7671q, 7542, 9601–9657, 11023, 11048.

2. Section 9.1 is amended by adding a new heading and entries to the table in numerical order to read as follows:

§ 9.1 OMB approvals under the Paperwork Reduction Act.

* * * * *

40 CFR citations	OMB control No.
Control of Emissions From New and In-Use Nonroad Engines	
89.611	2060–0007
89.905	
89.906	
89.801	2060–0048
89.803	
85.1903 through 85.1906	
85.1908	
85.1909	
89.505 through 89.509	2060–0064
89.511	
89.512	
89.603 through 89.605	2060–0095
89.607 through 89.612	
89.903	2060–0124
89.1	
89.2	

* * * * *

3. Part 89 is added to read as follows:

PART 89—CONTROL OF EMISSIONS FROM NEW AND IN-USE NONROAD ENGINES

Subpart A—General

Sec.

Authority: Sections 202, 203, 204, 205, 206, 207, 208, 209, 213, 215, 216, and 301(a) of the Clean Air Act, as amended (42 U.S.C. 7521, 7522, 7523, 7524, 7525, 7541, 7542, 7543, 7547, 7549, 7550, and 7601(a)).

Subpart A—General

§ 89.1 Applicability.

(a) This part applies to nonroad compression-ignition engines that have a gross power output at or above 37 kilowatts (kW) and that are used for any purpose.

(b) The following nonroad engines are not subject to the provisions of this part:

(1) Engines used in aircraft as defined in § 87.1(a) of this chapter;

(2) Engines used in underground mining or engines used in underground mining equipment and regulated by the Mining Safety and Health Administration (MSHA) in 30 CFR parts 7, 31, 32, 36, 56, 57, 70, and 75;

(3) Engines used to propel a locomotive; and

(4) Engines used in marine vessels as defined in the General Provisions of the United States Code, 1 U.S.C. 3 (1992).

§ 89.2 Definitions.

The following definitions apply to part 89. All terms not defined herein have the meaning given them in the Act.

Act means the Clean Air Act, as amended, 42 U.S.C. 7401 *et.seq.*

Adjustable parameter means any device, system, or element of design which is physically capable of being adjusted (including those which are difficult to access) and which, if adjusted, may affect emissions or engine performance during emission testing.

Administrator means the Administrator of the Environmental Protection Agency or his or her authorized representative.

Auxiliary emission control device (AECD) means any element of design that senses temperature, vehicle speed, engine RPM, transmission gear, or any other parameter for the purpose of activating, modulating, delaying, or deactivating the operation of any part of the emission control system.

Certification means, with respect to new nonroad engines, obtaining a certificate of conformity for an engine family complying with the nonroad engine emission standards and requirements specified in this part.

Emission control system means any device, system, or element of design which controls or reduces the emission of substances from an engine.

Engine, as used in this part, refers to nonroad engine.

Engine manufacturer means any person engaged in the manufacturing or assembling of new nonroad engines or importing such engines for resale, or who acts for and is under the control of any such person in connection with the distribution of such engines. Engine manufacturer does not include any dealer with respect to new nonroad engines received by such person in commerce.

Engine used in a locomotive means either an engine placed in the locomotive to move other equipment, freight, or passenger traffic, or an engine mounted on the locomotive to provide auxiliary power.

EPA enforcement officer means any officer or employee of the Environmental Protection Agency so designated in writing by the Administrator (or by his or her designee).

Family emission limit (FEL) means an emission level that is declared by the manufacturer to serve in lieu of an emission standard for certification purposes and for the averaging, banking, and trading program. A FEL must be expressed to the same number of decimal places as the applicable emission standard.

Gross power means the power measured at the crankshaft or its equivalent, the engine being equipped only with the standard accessories (such as oil pumps, coolant pumps, and so forth) necessary for its operation on the test bed. Alternators must be used, if necessary, to run the engine. Fans, air conditioners, and other accessories may be used at the discretion of the manufacturer, but no power adjustments for these accessories may be made.

Identification number means a specification (for example, model number/serial number combination) which allows a particular nonroad engine to be distinguished from other similar engines.

Locomotive means a self-propelled piece of on-track equipment (other than equipment designed for operation both on highways and rails, specialized maintenance equipment, and other similar equipment) designed for moving other equipment, freight or passenger traffic.

Model year (MY) means the manufacturer's annual new model production period which includes January 1 of the calendar year, ends no later than December 31 of the calendar year, and does not begin earlier than January 2 of the previous calendar year. Where a manufacturer has no annual new model production period, model year means calendar year.

New, for the purposes of this part, means a domestic or imported nonroad engine, nonroad vehicle, or nonroad equipment the equitable or legal title to which has never been transferred to an ultimate purchaser. Where the equitable or legal title to the engine, vehicle, or equipment is not transferred to an ultimate purchaser until after the engine, vehicle or equipment is placed into service, then the engine, vehicle, or equipment will no longer be new after it is placed into service. A nonroad engine, vehicle, or equipment is placed into service when it is used for its functional purposes.

Nonroad compression-ignition engine means a nonroad engine which utilizes the compression-ignition combustion cycle.

Nonroad engine means:

(1) Except as discussed in paragraph (2) of this definition, a nonroad engine is any internal combustion engine:

(i) in or on a piece of equipment that is self-propelled or serves a dual purpose by both propelling itself and performing another function (such as garden tractors, off-highway mobile cranes and bulldozers); or

(ii) in or on a piece of equipment that is intended to be propelled while performing its function (such as lawnmowers and string trimmers); or

(iii) that, by itself or in or on a piece of equipment, is portable or transportable, meaning designed to be and capable of being carried or moved from one location to another. Indicia of transportability include, but are not limited to, wheels, skids, carrying handles, dolly, trailer, or platform.

(2) An internal combustion engine is not a nonroad engine if:

(i) the engine is used to propel a motor vehicle or a vehicle used solely for competition, or is subject to standards promulgated under section 202 of the Act; or

(ii) the engine is regulated by a federal New Source Performance Standard promulgated under section 111 of the Act; or

(iii) the engine otherwise included in paragraph (1)(iii) of this definition remains or will remain at a location for more than 12 consecutive months or a shorter period of time for an engine located at a seasonal source. A location is any single site at a building, structure, facility, or installation. Any engine (or engines) that replaces an engine at a location and that is intended to perform the same or similar function as the engine replaced will be included in calculating the consecutive time period. An engine located at a seasonal source is an engine that remains at a seasonal source during the full annual operating period of the seasonal source. A seasonal source is a stationary source that remains in a single location on a permanent basis (i.e., at least two years) and that operates at that single location approximately three months (or more) each year. This paragraph does not apply to an engine after the engine is removed from the location.

Nonroad equipment means equipment that is powered by nonroad engines.

Nonroad vehicle means a vehicle that is powered by a nonroad engine as defined in this section and that is not a motor vehicle or a vehicle used solely for competition.

Nonroad vehicle or nonroad equipment manufacturer means any person engaged in the manufacturing or assembling of new nonroad vehicles or equipment or importing such vehicles or equipment for resale, or who acts for and is under the control of any such person in connection with the distribution of such vehicles or equipment. A nonroad vehicle or equipment manufacturer does not include any dealer with respect to new nonroad vehicles or equipment received by such person in commerce.

Opacity means the fraction of a beam of light, expressed in percent, which fails to penetrate a plume of smoke.

Operating hours means:

(1) For engine storage areas or facilities, all times during which personnel other than custodial personnel are at work in the vicinity of the storage area or facility and have access to it.

(2) For all other areas or facilities, all times during which an assembly line is in operation or all times during which testing, maintenance, service accumulation, production or compilation of records, or any other procedure or activity related to certification testing, to translation of designs from the test stage to the production stage, or to engine manufacture or assembly is being carried out in a facility.

Presentation of credentials means the display of the document designating a person as an EPA enforcement officer or EPA authorized representative.

Test fleet means the engine or group of engines that a manufacturer uses during certification to determine compliance with emission standards.

Ultimate purchaser means, with respect to any new nonroad engine, new nonroad vehicle, or new nonroad equipment, the first person who in good faith purchases such new nonroad engine, nonroad vehicle, or nonroad equipment for purposes other than resale.

Used solely for competition means exhibiting features that are not easily removed and that would render its use other than in competition unsafe, impractical, or highly unlikely.

§ 89.3 Acronyms and abbreviations.

The following acronyms and abbreviations apply to part 89.

AECD	Auxiliary emission control device.
ASME	American Society of Mechanical Engineers.
ASTM	American Society for Testing and Materials.
CAA	Clean Air Act.
CAAA	Clean Air Act Amendments of 1990.
CI	Compression-ignition.
CO	Carbon monoxide.
CO_2	Carbon dioxide.
EPA	Environmental Protection Agency.
FEL	Family emission limit.
FTP	Federal Test Procedure.
g/kW-hr	Grams per kilowatt hour.
HC	Hydrocarbons.
ICI	Independent Commercial Importer.
kW	Kilowatt.
NIST	National Institute for Standards and Testing.

NTIS	National Technical Information Service.
NO	Nitric oxide.
NO_2	Nitrogen dioxide.
NO_X	Oxides of nitrogen.
O_2	Oxygen.
OEM	Original equipment manufacturer.
SAE	Society of Automotive Engineers.
SEA	Selective Enforcement Auditing.
SI	Spark-ignition.
U.S.C.	United States Code.
VOC	Volatile organic compounds.

§ 89.4 Section numbering.

(a) Sections are numbered sequentially by subpart.

(b) Where two different standards or requirements are concurrently applicable, the model year of applicability is indicated by the number following the main section number. The two digits following the hyphen designate the first model year for which a section is effective.

Example: Section 89.304–96 applies to the 1996 and subsequent model years until superseded. If a § 89.304–98 is promulgated, it would take effect beginning with the 1998 model year; § 89.304–96 would apply to model years 1996 through 1997. Therefore, in calendar year 1997, a manufacturer may be certifying both 1997 and 1998 model year engines, requiring the use of different requirements concurrently.

Note: Model year 2000 and later will appear sequentially with 1999 and earlier based on the order of the last two digits of the year, not in calendar year order; that is, § 89.304–03 will appear before § 89.304–99.

(c) A section without the model year designation is applicable to all model years as designated in the applicability section for the subpart or part or in the text of the section.

§ 89.5 Table and figure numbering; position.

(a) Tables for each subpart appear in an appendix at the end of the subpart. Tables are numbered consecutively by order of appearance in the appendix. The table title will indicate the model year (if applicable) and the topic.

(b) Figures for each subpart appear in an appendix at the end of the subpart. Figures are numbered consecutively by order of appearance in the appendix. The figure title will indicate the model year (if applicable) and the topic.

§ 89.6 Reference materials.

(a) *Incorporation by reference.* The documents in paragraph (b) of this section have been incorporated by reference. The incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be inspected at US EPA, OAR, 401 M Street SW., Washington, DC 20460, or at the Office of the Federal Register, 800 N. Capitol Street NW., Suite 700, Washington, DC.

(b) The following paragraphs and tables set forth the material that has been incorporated by reference in this part.

(1) *ASTM material.* The following table sets forth material from the American Society for Testing and Materials which has been incorporated by reference. The first column lists the number and name of the material. The second column lists the section(s) of this part, other than § 89.6, in which the matter is referenced. The second column is presented for information only and may not be all inclusive. Copies of these materials may be obtained from American Society for Testing and Materials, 1916 Race St., Philadelphia, PA 19103.

Document number and name	40 CFR part 89 reference
ASTM D86–90:	
Standard Test Method for Distillation of Petroleum Products	Appendix A to Subpart D.
ASTM D93–90:	
Standard Test Methods for Flash Point by Pensky-Martens Closed Tester	Appendix A to Subpart D.
ASTM D129–91:	
Standard Test Method for Sulfur in Petroleum Products (General Bomb Method)	Appendix A to Subpart D.
ASTM D287–92:	
Standard Test Method for API Gravity of Crude Petroleum and Petroleum Products (Hydrometer Method)	Appendix A to Subpart D.
ASTM D445–88:	
Standard Test Method for Kinematic Viscosity of Transparent and Opaque Liquids (and the Calculation of Dynamic Viscosity).	Appendix A to Subpart D.
ASTM D613–86:	
Standard Test Method for Ignition Quality of Diesel Fuels by the Cetane Method	Appendix A to Subpart D.
ASTM D1319–89:	
Standard Test Method for Hydrocarbon Types in Liquid Petroleum Products by Fluorescent Indicator Adsorption.	Appendix A to Subpart D.
ASTM D2622–92:	
Standard Test Method for Sulfur in Petroleum Products by X-ray Spectrometry	Appendix A to Subpart D.
ASTM E29–90:	
Standard Practice for Using Significant Digits in Test Data to Determine Conformance with Specifications	89.207–96; 89.509–96.

(2) *SAE material.* The following table sets forth material from the Society of Automotive Engineers which has been incorporated by reference. The first column lists the number and name of the material. The second column lists the section(s) of this part, other than § 89.6, in which the matter is referenced. The second column is presented for information only and may not be all inclusive. Copies of these materials may be obtained from Society of Automotive Engineers International, 400 Commonwealth Dr., Warrendale, PA 15096–0001.

Document number and name	40 CFR part 89 reference
SAE J244 June 83:	
Recommended Practice for Measurement of Intake Air or Exhaust Gas Flow of Diesel Engines	89.416–96
SAE J1937 November 89:	
Recommended Practice for Engine Testing with Low Temperature Charge Air Cooler Systems in a Dynamometer Test Cell	89.327–96

Document number and name	40 CFR part 89 reference
SAE Paper 770141: Optimization of a Flame Ionization Detector for Determination of Hydrocarbon in Diluted Automotive Exhausts, Glenn D. Reschke	89.319–96

(3) *California Air Resources Board Test Procedure.* The following table sets forth material from the Title 13, California Code of Regulations, Sections 2420–2427, as amended by California Air Resources Board Resolution 92–2 and published in California Air Resources Board mail out #93–42, September 1, 1993) which has been incorporated by reference. The first column lists the number and name of the material. The second column lists the section(s) of this part, other than § 89.6, in which the matter is referenced. The second column is presented for information only and may not be all inclusive. Copies of these materials may be obtained from California Air Resources Board, Haagen-Smit Laboratory, 9528 Telstar Avenue, El Monte, CA 91731–2990.

Document number and name	40 CFR part 89 reference
California Regulations for New 1996 and Later Heavy-Duty Off-Road Diesel Cycle Engines	89.112–96 89.119–96 89.508–96

§ 89.7 Treatment of confidential information.

(a) Any manufacturer may assert that some or all of the information submitted pursuant to this part is entitled to confidential treatment as provided by part 2, subpart B of this chapter.

(b) Any claim of confidentiality must accompany the information at the time it is submitted to EPA.

(c) To assert that information submitted pursuant to this part is confidential, a manufacturer must indicate clearly the items of information claimed confidential by marking, circling, bracketing, stamping, or otherwise specifying the confidential information. Furthermore, EPA requests, but does not require, that the submitter also provide a second copy of its submittal from which all confidential information has been deleted. If a need arises to publicly release nonconfidential information, EPA will assume that the submitter has accurately deleted the confidential information from this second copy.

(d) If a claim is made that some or all of the information submitted pursuant to this part is entitled to confidential treatment, the information covered by that confidentiality claim will be disclosed by the Administrator only to the extent and by means of the procedures set forth in part 2, subpart B of this chapter.

(e) Information provided without a claim of confidentiality at the time of submission may be made available to the public by EPA without further notice to the submitter, in accordance with § 2.204(c)(2)(i)(A) of this chapter.

Appendix A to Subpart A—Internal Combustion Engines Manufactured Prior to July 18, 1994

This appendix sets forth the Environmental Protection Agency's (EPA's) interpretation of the Clean Air Act regarding the status of certain internal combustion engines manufactured before July 18, 1994, (the effective date of the final rulemaking promulgating EPA's definition of nonroad engine). This interpretation does not alter, replace, supersede, or change the scope of subpart A. It is not final agency action subject to judicial review.

1. EPA interprets the Clean Air Act as not precluding state regulation of internal combustion engines manufactured prior to July 18, 1994, except that state regulation of such engines that are used in motor vehicles or vehicles used solely for competition is precluded. EPA believes that the language of Clean Air Act section 302(z) generally excluding emissions resulting directly from nonroad engines and nonroad vehicles from the definition of stationary source could not be applied until after the definition of nonroad engine was specified in final regulations promulgated by EPA. EPA believes that if the exclusionary language of section 302(z) were applied before EPA's definition of nonroad engine became final, states would have been frustrated from regulating internal combustion engines manufactured during that time, given the uncertain nature of the definition of such engines. EPA believes that Congress did not intend states to be prevented from regulating these engines before a final EPA definition was promulgated. EPA does not believe that Congress intended the exclusionary language of section 302(z) regarding nonroad engines and vehicles to be applied retroactively to engines, vehicles, and equipment regulated pursuant to a permit issued before the date that the terms nonroad engine and nonroad vehicle were defined.

2. EPA further believes that internal combustion engines manufactured prior to July 18, 1994 are not preempted, under Clean Air Act section 209, from state regulation. The two sections of the Act preempting state regulation of nonroad engines, section 209(e)(1) and section 209(a) (as incorporated by section 213(d)), refer to "nonroad engines subject to regulation under this Act" or to engines "subject to this part" (i.e., part A of title II of the Act). EPA believes that, until EPA promulgated final regulations defining nonroad engines and subjecting such engines to regulation, these engines were not preempted from state regulation under the Act, as the engines were not yet defined as nonroad engines, nor were they subject to any regulation under title II of the Act. In the regulations with an effective date of July 18, 1994, EPA has issued final rules defining nonroad engines and, thus, subjecting nonroad engines to regulation under part A of title II of the Act. Accordingly, EPA believes that pursuant to Clean Air Act section 209, state regulation of new nonroad engines is preempted for engines manufactured on or after that date, and is not preempted as to engines manufactured before that date.

3. Moreover, EPA believes that states are not precluded under section 209 from regulating the use and operation of nonroad engines, such as regulations on hours of usage, daily mass emission limits, or sulfur limits on fuel; nor are permits regulating such operations precluded once the engine is placed into service or once the equitable or legal title to the engine or vehicle is transferred to an ultimate purchaser, as long as no certification, inspection, or other approval related to the control on emissions is required as a condition precedent to the initial retail sale, titling, or registration of the engine or equipment. EPA believes that states are not prevented by section 209 from requiring retrofitting of nonroad engines in certain circumstances once a reasonable time has passed after the engine is no longer new, as long as the requirements do not amount to a standard relating back to the original manufacturer. Therefore, EPA believes that modest retrofit requirements may be required after a reasonable amount of time (e.g., at the time of reregistration or rebuilding) and more significant retrofit requirements may be

required after a more significant period of time (e.g., after the end of the useful life of the engine).

Subpart B—Emission Standards and Certification Provisions

§ 89.101–96 Applicability.

The requirements of subpart B are applicable to all new nonroad compression-ignition engines subject to the provisions of subpart A of part 89, pursuant to the schedule delineated in § 89.102–96.

§ 89.102–96 Effective dates, optional inclusion.

(a) This subpart applies to all engines described in § 89.101–96 with the following gross power output and manufactured after the following dates:

(1) Greater than or equal to 37 kW but less than 75 kW and manufactured on or after January 1, 1998;

(2) Greater than or equal to 75 kW but less than 130 kW and manufactured on or after January 1, 1997;

(3) Greater than or equal to 130 kW but less than or equal to 560 kW and manufactured on or after January 1, 1996;

(4) Greater than 560 kW and manufactured on or after January 1, 2000.

(b) A manufacturer can optionally certify engines manufactured up to one calendar year prior to the effective date of mandatory certification to earn emission credits under the averaging, banking, and trading program. Such optionally certified engines are subject to all provisions relating to mandatory certification and enforcement described in this part.

§ 89.103–96 Definitions.

The definitions in subpart A of part 89 apply to this subpart. All terms not defined herein or in subpart A have the meaning given them in the Act.

§ 89.104–96 Useful life, recall, and warranty periods.

(a) The useful life is a period of 8,000 hours of operation or ten years of use, whichever first occurs.

(b) Engines are subject to recall testing for a period of 6,000 hours of operation or seven years of use, whichever first occurs. However, in a recall, engines in the subject class or category must be recalled regardless of actual years or hours of operation.

(c) Warranties imposed by the Clean Air Act are for 3,000 hours of operation or five years of use, whichever first occurs.

(d) Manufacturers may apply to the Administrator for approval for a shorter useful life period for engines that are subject to severe service in seasonal equipment, or are designed specifically for lower useful life hours to match equipment life. Such an application must be made prior to certification.

§ 89.105–96 Certificate of conformity.

Every manufacturer of a new nonroad compression-ignition engine must obtain a certificate of conformity covering the engine family, as described in § 89.116–96. The certificate of conformity must be obtained from the Administrator prior to selling, offering for sale, introducing into commerce, or importing into the United States the new nonroad compression-ignition engine for each model year.

§ 89.106–96 Prohibited controls.

(a) An engine may not be equipped with an emission control system for the purpose of complying with emission standards if such system will cause or contribute to an unreasonable risk to public health, welfare, or safety in its operation or function.

(b) An engine with an emission control system may not emit any noxious or toxic substance which would not be emitted in the operation of such engine in the absence of such system except as specifically permitted by regulation.

§ 89.107–96 Defeat devices.

(a) An engine may not be equipped with a defeat device.

(b) For purposes of this section, "defeat device" means any device, system, or element of design which senses operation outside normal emission test conditions and reduces emission control effectiveness.

(1) Defeat device includes any auxiliary emission control device (AECD) that reduces the effectiveness of the emission control system under conditions which may reasonably be expected to be encountered in normal operation and use unless such conditions are included in the test procedure.

(2) Defeat device does not include such items which either operate only during engine starting or are necessary to protect the engine (or equipment in which it is installed) against damage or accident during its operation.

§ 89.108–96 Adjustable parameters, requirements.

(a) Nonroad engines equipped with adjustable parameters must comply with all requirements of this subpart for any adjustment in the physically adjustable range.

(b) An operating parameter is not considered adjustable if it is permanently sealed or otherwise not normally accessible using ordinary tools.

(c) The Administrator may require that adjustable parameters be set to any specification within its adjustable range for certification, selective enforcement audit, or in-use testing to determine compliance with the requirements of this subpart.

§ 89.109–96 Maintenance instructions.

The manufacturer must furnish or cause to be furnished to the ultimate purchaser of each new nonroad engine written instructions for the maintenance needed to assure proper functioning of the emission control system.

§ 89.110–96 Emission control information label.

(a) The manufacturer must affix at the time of manufacture a permanent and legible label identifying each nonroad engine. The label must meet the following requirements:

(1) Be attached in such a manner that it cannot be removed without destroying or defacing the label;

(2) Be durable and readable for the entire engine life;

(3) Be secured to an engine part necessary for normal engine operation and not normally requiring replacement during engine life;

(4) Be written in English; and

(5) Be located so as to be readily visible to the average person after the engine is installed in the equipment. A supplemental label meeting all the requirements of this section may be attached to a location other than the engine, in cases where the required label must be obscured after the engine is installed in the equipment.

(b) The label must contain the following information:

(1) The heading "Important Engine Information;"

(2) The full corporate name and trademark of the manufacturer;

(3) EPA standardized engine family designation;

(4) Engine displacement;

(5) Advertised power;

(6) Engine tuneup specifications and adjustments. These should indicate the proper transmission position during tuneup, and accessories (for example, air conditioner), if any, that should be in operation;

(7) Fuel requirements;

(8) Date of manufacture (month and year). The manufacturer may, in lieu of including the date of manufacture on the engine label, maintain a record of the engine manufacture dates. The manufacturer shall provide the date of manufacture records to the Administrator upon request;

(9) Family emission limits (FELs) if applicable; and

(10) The statement: "This engine conforms to [model year] U.S. EPA regulations large nonroad compression-ignition engines."

(c) Other information concerning proper maintenance and use or indicating compliance or noncompliance with other standards may be indicated on the label.

(d) Each engine must have a legible unique engine identification number permanently affixed to or engraved on the engine.

§ 89.111–96 Averaging, banking, and trading of exhaust emissions.

Regulations regarding the availability of an averaging, banking, and trading program along with applicable record-keeping requirements are found in subpart C of this part. Participation in the averaging, banking, and trading program is optional.

§ 89.112–96 Oxides of nitrogen, carbon monoxide, hydrocarbon, and particulate matter exhaust emission standards.

(a) Nonroad engines to which this subpart is applicable must meet the following exhaust emission standards:

(1) Exhaust emissions of oxides of nitrogen shall not exceed 9.2 grams per kilowatt hour (g/kW-hr).

(2) Exhaust emissions of carbon monoxide shall not exceed 11.4 g/kW-hr for engines at and above 130 kW.

(3) Exhaust emissions of hydrocarbon shall not exceed 1.3 g/kW-hr for engines at and above 130 kW.

(4) Exhaust emissions of particulate matter shall not exceed 0.54 g/kW-hr for engines at and above 130 kW.

(b) Exhaust emission of oxides of nitrogen, carbon monoxide, and hydrocarbon is measured using the procedures set forth in subpart E of this part.

(c) Exhaust emission of particulate matter is measured using the California Regulations for New 1996 and Later Heavy-Duty Off-Road Diesel Cycle Engines. This procedure is incorporated by reference. See § 89.6.

(d) In lieu of the standard specified in paragraph (a)(1) of this section, manufacturers may elect to include engine families in the averaging, banking, and trading program, the provisions of which are specified in subpart C of this part. The manufacturer must set a family emission limit (FEL) not to exceed 14.6 grams per kilowatt hour. This FEL serves as the standard for that family.

§ 89.113–96 Smoke emission standard.

(a) Exhaust opacity from compression-ignition nonroad engines for which this subpart is applicable must not exceed:

(1) 20 percent during the acceleration mode;

(2) 15 percent during the lugging mode; and

(3) 50 percent during the peaks in either the acceleration or lugging modes.

(b) Opacity levels are to be measured and calculated as set forth in part 86, subpart I.

§ 89.114–96 Special test procedures.

(a) *Use of special test procedures by EPA.* The Administrator may, on the basis of written application by a manufacturer, establish special test procedures other than those set forth in this part, for any nonroad engine that the Administrator determines is not susceptible to satisfactory testing under the specified test procedures set forth in subpart E of this part or part 86, subpart I.

(b) *Use of alternate test procedures by manufacturer.*

(1) A manufacturer may elect to use an alternate test procedure provided that it yields equivalent results to the specified procedures, its use is approved in advance by the Administrator, and the basis for equivalent results with the specified test procedures is fully described in the manufacturer's application.

(2) The Administrator may reject data generated under alternate test procedures which do not correlate with data generated under the specified procedures.

§ 89.115–96 Application for certificate.

(a) For each engine family that complies with all applicable standards and requirements, the engine manufacturer must submit to the Administrator a completed application for a certificate of conformity.

(b) The application must be approved and signed by the authorized representative of the manufacturer.

(c) The application will be updated and corrected by amendment as provided for in § 89.123–96 to accurately reflect the manufacturer's production.

(d) *Required content.* Each application must include the following information:

(1) A description of the basic engine design including, but not limited to, the engine family specifications, the provisions of which are contained in § 89.116–96;

(2) An explanation of how the emission control system operates, including a detailed description of all emission control system components, each auxiliary emission control device (AECD), and all fuel system components to be installed on any production or test engine(s);

(3) Proposed test fleet selection and the rationale for the test fleet selection;

(4) Special or alternate test procedures, if applicable;

(5) The description of the operating cycle and the period of operation necessary to accumulate service hours on test engines and stabilize emission levels;

(6) A description of all adjustable operating parameters (including, but not limited to, injection timing and fuel rate), including the following:

(i) The nominal or recommended setting and the associated production tolerances;

(ii) The intended physically adjustable range;

(iii) The limits or stops used to establish adjustable ranges;

(iv) Production tolerances of the limits or stops used to establish each physically adjustable range; and

(v) Information relating to why the physical limits or stops used to establish the physically adjustable range of each parameter, or any other means used to inhibit adjustment, are effective in preventing adjustment of parameters to settings outside the manufacturer's intended physically adjustable ranges on in-use engines;

(7) For families participating in the averaging, banking, and trading program, the information specified in subpart C of this part;

(8) A description of the test equipment and fuel proposed to be used;

(9) All test data obtained by the manufacturer on each test engine;

(10) An unconditional statement certifying that all engines in the engine family comply with all requirements of this part and the Clean Air Act.

(b) At the Administrator's request, the manufacturer must supply such additional information as may be required to evaluate the application including, but not limited to, projected nonroad engine production.

§ 89.116–96 Engine families.

(a) A manufacturer's product line is divided into engine families that are comprised of engines expected to have similar emission characteristics throughout their useful life periods.

(b) The following characteristics distinguish engine families:

(1) Fuel;

(2) Cooling medium;

(3) Method of air aspiration;

(4) Method of exhaust aftertreatment (for example, catalytic converter or particulate trap);

(5) Combustion chamber design;

(6) Bore;

(7) Stroke;

(8) Number of cylinders, (engines with aftertreatment devices only); and

(9) Cylinder arrangement (engines with aftertreatment devices only).

(c) Upon a showing by the manufacturer that the useful life period emission characteristics are expected to be similar, engines differing in one or more of the characteristics in paragraph (b) of this section may be grouped in the same engine family.

(d) Upon a showing by the manufacturer that the expected useful life period emission characteristics will be different, engines identical in all the characteristics of paragraph (b) of this section may be divided into separate engine families.

§ 89.117–96 Test fleet selection.

(a) The manufacturer must select for testing, from each engine family, the engine with the most fuel injected per stroke of an injector at maximum power.

(b) Each engine in the test fleet must be constructed to be representative of production engines.

(c) After review of the manufacturer's test fleet, the Administrator may select from the available fleet one additional test engine from each engine family.

§ 89.118–96 Service accumulation.

(a)(1) Each test engine in the test fleet must be operated with all emission control systems operating properly for a period sufficient to stabilize emissions.

(2) A manufacturer may elect to consider as stabilized emission levels from engines with no more than 125 hours of service.

(b) No maintenance, other than recommended lubrication and filter changes, may be performed during service accumulation without the Administrator's approval.

(c) Service accumulation should be performed in a manner using good engineering judgment to ensure that emissions are representative of in-use engines.

(d) The manufacturer must maintain, and provide to the Administrator if requested, records stating the rationale for selecting the service accumulation period and records describing the method used to accumulate service hours on the test engine(s).

§ 89.119–96 Emission tests.

(a) *Manufacturer testing.* (1) Upon completion of service accumulation, the manufacturer must test each test engine using the specified test procedures, except as provided in § 89.114–96. The procedures to be used are set forth in:

(i) Subpart E of this part;

(ii) The California Regulations for New 1996 and Later Heavy-Duty Off-Road Diesel Cycle Engines. This procedure has been incorporated by reference. See § 89.6; and

(iii) Part 86, subpart I of this chapter.

(2) Each test engine must be configured to be representative of actual in-use operation. The Administrator may specify the adjustment of any adjustable parameter. All test results must be reported to the Administrator.

(b) *Confirmatory testing.* The Administrator may conduct confirmatory testing or other testing on any test engine. The manufacturer must deliver test engines as directed by the Administrator. When the Administrator conducts confirmatory testing or other testing, those test results are used to determine compliance with emission standards.

(c) *Use of carryover test data.* In lieu of testing to certify an engine family for a given model year, the manufacturer may submit, with the Administrator's approval, emission test data used to certify that engine family in previous years. This "carryover" data is only allowable if the submitted test data show that the test engine would comply with the emission standard(s) for the model year for which certification is being sought.

(d) *Test fuels.* EPA may use the fuel specified in either Table 4 or Table 5 of appendix A to subpart D of this part in confirmatory testing or other testing on any test engine. Emission test results based on use of Table 5 fuel will be used to confirm compliance with HC, CO, NO_x, PM, and smoke standards. Emission test results based on Table 4 fuel will be used to confirm compliance with HC, CO, NO_x, and smoke standards; when a manufacturer uses the fuel specified in Table 4 of appendix A to subpart D of this part for its certification testing, EPA has the option to use the PM emission result, corrected using the PM correction factor specified in § 89.425–96, to confirm compliance with the PM standard.

§ 89.120–96 Compliance with emission standards.

(a) If all test engines representing an engine family have emissions less than or equal to each emission standard, that family complies with the emission standards.

(b) If any test engine representing an engine family has emissions greater than each emission standard, that family will be deemed not in compliance with the emission standard(s).

(c) If aftertreatment is employed by an engine family, then a deterioration factor must be determined and applied.

(d) For engine families included in the averaging, banking, and trading program, the families' emission limits (FELs) are used in lieu of the applicable federal emission standard.

§ 89.121–96 Certificate of conformity effective dates.

The certificate of conformity is valid from the date of issuance by EPA until 31 December of the model year or calendar year for which it is issued.

§ 89.122–96 Certification.

(a) If, after a review of the manufacturer's application, request for certificate, information obtained from any inspection, and such other information as the Administrator may require, the Administrator determines that the application is complete and that the engine family meets the requirements of this part and the Clean Air Act, the Administrator shall issue a certificate of conformity.

(b) If, after a review of the information described in paragraph (a) of this section, the Administrator determines that the requirements of this part and the Clean Air Act have not been met, the Administrator will deny certification. The Administrator must give a written explanation when certification is denied. The manufacturer may request a hearing on a denial.

§ 89.123–96 Amending the application and certificate of conformity.

(a) The manufacturer of nonroad compression-ignition engines must notify the Administrator when changes to information required to be described in the application for certification are to be made to a product line covered by a certificate of conformity. This notification must include a request to amend the application or the existing certificate of conformity. Except as provided in paragraph (e) of this section, the manufacturer shall not make said changes or produce said engines prior to receiving approval from EPA.

(b) A manufacturer's request to amend the application or the existing certificate of conformity shall include the following information:

(1) A full description of the change to be made in production or of the engine to be added;

(2) Engineering evaluations or data showing that engines as modified or added will comply with all applicable emission standards; and

(3) A determination whether the manufacturer's original test fleet selection is still appropriate, and if the original test fleet selection is determined not to be appropriate, proposed test fleet selection(s) representing the engines changed or added which would have been required if the engines had been included in the original application for certification.

(c) The Administrator may require the manufacturer to perform tests on the engine representing the engine to be added or changed.

(d) *Decision by Administrator.* (1) Based on the description of the proposed amendment and data derived from such testing as the Administrator may require or conduct, the Administrator will determine whether the proposed change or addition would still be covered by the certificate of conformity then in effect.

(2) If the Administrator determines that the change or new engine(s) meets the requirements of this subpart and the Act, the appropriate certificate of conformity is amended.

(3) If the Administrator determines that the changed or new engine(s) does not meet the requirements of this subpart and the Act, the certificate of conformity will not be amended. The Administrator shall provide a written explanation to the manufacturer of the decision not to amend the certificate. The manufacturer may request a hearing on a denial.

(e) A manufacturer may make changes in or additions to production engines concurrently with notifying the Administrator as required by paragraph (a) of this section, if the manufacturer complies with the following requirements:

(1) In addition to the information required in paragraph (b) of this section, the manufacturer must supply supporting documentation, test data, and engineering evaluations as appropriate to demonstrate that all affected engines will still meet applicable emission standards.

(2) If, after a review, the Administrator determines additional testing is required, the manufacturer must provide required test data within 30 days or cease production of the affected engines.

(3) If the Administrator determines that the affected engines do not meet applicable requirements, the Administrator will notify the manufacturer to cease production of the affected engines and to recall and correct at no expense to the owner all affected engines previously produced.

(4) Election to produce engines under this paragraph will be deemed to be a consent to recall all engines which the Administrator determines do not meet applicable standards and to cause such nonconformity to be remedied at no expense to the owner.

§ 89.124–96 Record retention, maintenance, and submission.

(a) The manufacturer of any nonroad compression-ignition engine must maintain the following adequately organized records:

(1) Copies of all applications filed with the Administrator.

(2) A detailed history of each test engine used for certification including the following:

(i) A description of the test engine's construction, including a general description of the origin and buildup of the engine, steps taken to ensure that it is representative of production engines, description of components specially built for the test engine, and the origin and description of all emission-related components;

(ii) A description of the method used for service accumulation, including date(s) and the number of hours accumulated;

(iii) A description of all maintenance, including modifications, parts changes, and other servicing performed, and the date(s) and reason(s) for such maintenance;

(iv) A description of all emission tests performed (except tests performed by the EPA directly) including routine and standard test documentation, as specified in subpart E of this part, date(s) and the purpose of each test;

(v) A description of all tests performed to diagnose engine or emission control performance, giving the date and time of each and the reason(s) for the test; and

(vi) A description of any significant event(s) affecting the engine during the period covered by the history of the test engine but not described by an entry under one of the previous paragraphs of this section.

(b) Routine emission test data, such as those reporting test cell temperature and relative humidity at start and finish of test and raw emission results from each mode or test phase, must be retained for a period of one year after issuance of all certificates of conformity to which they relate. All other information specified in paragraph (a) of this section must be retained for a period of eight years after issuance of all certificates of conformity to which they relate.

(c) Records may be kept in any format and on any media, provided that at the Administrator's request, organized, written records in English are promptly supplied by the manufacturer.

(d) The manufacturer must supply, at the Administrator's request, copies of any engine maintenance instructions or explanations issued by the manufacturer.

§ 89.125–96 Production engines, annual report.

(a) Upon the Administrator's request, the manufacturer must supply a reasonable number of production engines for testing and evaluation. These engines must be representative of typical production and must be supplied for testing at such time and place and for such reasonable periods as the Administrator may require.

(b) The manufacturer must annually, within 30 days after the end of the model year, notify the Administrator of the number of engines produced by engine family, by gross power, by displacement, by fuel system, or by other categories as the Administrator may require.

§ 89.126–96 Denial, revocation of certificate of conformity.

(a) If, after review of the manufacturer's application, request for certification, information obtained from any inspection, and any other information the Administrator may require, the Administrator determines that one or more test engines do not meet applicable standards (or family emission limits, as appropriate), then the Administrator will notify the manufacturer in writing, setting forth the basis for this determination.

(b) Notwithstanding the fact that engines described in the application may comply with all other requirements of this subpart, the Administrator may deny the issuance of, suspend, or revoke a previously issued certificate of conformity if the Administrator finds any one of the following infractions to be substantial:

(1) The manufacturer submits false or incomplete information;

(2) The manufacturer denies an EPA enforcement officer or EPA authorized representative the opportunity to conduct authorized inspections;

(3) The manufacturer fails to supply requested information or amend its application to include all engines being produced;

(4) The manufacturer renders inaccurate any test data which it submits or otherwise circumvents the intent of the Act or this part;

(5) The manufacturer denies an EPA enforcement officer or EPA authorized representative reasonable assistance (as defined in § 89.129–96(e)).

(c) If a manufacturer knowingly commits an infraction specified in

paragraph (b)(1) or (b)(4) of this section, knowingly commits any other fraudulent act which results in the issuance of a certificate of conformity, or fails to comply with the conditions specified in §§ 89.203–96(f), 89.206–96(d), 89.209–96(c) or 89.210–96(g), the Administrator may deem such certificate void ab initio.

(d) When the Administrator denies, suspends, revokes, or voids ab initio a certificate of conformity the manufacturer will be provided a written determination. The manufacturer may request a hearing under § 89.127–96 on the Administrator's decision.

(e) Any suspension or revocation of a certificate of conformity shall extend no further than to forbid the introduction into commerce of engines previously covered by the certification which are still in the hands of the manufacturer, except in cases of such fraud or other misconduct that makes the certification invalid ab initio.

§ 89.127–96 Request for hearing.

(a) A manufacturer may request a hearing on the Administrator's denial, suspension, voiding ab initio or revocation of a certificate of conformity.

(b) The manufacturer's request must be filed within 30 days of the Administrator's decision, be in writing, and set forth the manufacturer's objections to the Administrator's decision and data to support the objections.

(c) If, after review of the request and supporting data, the Administrator finds that the request raises a substantial and factual issue, the Administrator will grant the manufacturer's request for a hearing.

§ 89.128–96 Hearing procedures.

(a)(1) After granting a request for a hearing the Administrator shall designate a Presiding Officer for the hearing.

(2) The hearing will be held as soon as practicable at a time and place determined by the Administrator or by the Presiding Officer.

(3) The Administrator may, at his or her discretion, direct that all argument and presentation of evidence be concluded within a specified period established by the Administrator. Said period may be no less than 30 days from the date that the first written offer of a hearing is made to the manufacturer. To expedite proceedings, the Administrator may direct that the decision of the Presiding Officer (who may, but need not, be the Administrator) shall be the final EPA decision.

(b)(1) Upon appointment pursuant to paragraph (a) of this section, the Presiding Officer will establish a hearing file. The file shall consist of the following:

(i) The determination issued by the Administrator under § 89.126–96(d);

(ii) The request for a hearing and the supporting data submitted therewith;

(iii) All documents relating to the request for certification and all documents submitted therewith; and

(iv) Correspondence and other data material to the hearing.

(2) The hearing file will be available for inspection by the applicant at the office of the Presiding Officer.

(c) An applicant may appear in person or may be represented by counsel or by any other duly authorized representative.

(d)(1) The Presiding Officer, upon the request of any party or at his or her discretion, may arrange for a prehearing conference at a time and place he/she specifies. Such prehearing conference will consider the following:

(i) Simplification of the issues;

(ii) Stipulations, admissions of fact, and the introduction of documents;

(iii) Limitation of the number of expert witnesses;

(iv) Possibility of agreement disposing of any or all of the issues in dispute; and

(v) Such other matters as may aid in the disposition of the hearing, including such additional tests as may be agreed upon by the parties.

(2) The results of the conference shall be reduced to writing by the Presiding Officer and made part of the record.

(e)(1) Hearings shall be conducted by the Presiding Officer in an informal but orderly and expeditious manner. The parties may offer oral or written evidence, subject to the exclusion by the Presiding Officer of irrelevant, immaterial, and repetitious evidence.

(2) Witnesses will not be required to testify under oath. However, the Presiding Officer shall call to the attention of witnesses that their statements may be subject to the provisions of 18 U.S.C. 1001 which imposes penalties for knowingly making false statements or representations or using false documents in any matter within the jurisdiction of any department or agency of the United States.

(3) Any witness may be examined or cross-examined by the Presiding Officer, the parties, or their representatives.

(4) Hearings shall be reported verbatim. Copies of transcripts of proceedings may be purchased by the applicant from the reporter.

(5) All written statements, charts, tabulations, and similar data offered in evidence at the hearings shall, upon a showing satisfactory to the Presiding Officer of their authenticity, relevancy, and materiality, be received in evidence and shall constitute a part of the record.

(6) Oral argument may be permitted at the discretion of the Presiding Officer and shall be reported as part of the record unless otherwise ordered by the Presiding Officer.

(f)(1) The Presiding Officer shall make an initial decision which shall include written findings and conclusions and the reasons or basis regarding all the material issues of fact, law, or discretion presented on the record. The findings, conclusions, and written decision shall be provided to the parties and made a part of the record. The initial decision shall become the decision of the Administrator without further proceedings, unless there is an appeal to the Administrator or motion for review by the Administrator within 20 days of the date the initial decision was filed. If the Administrator has determined under paragraph (a) of this section that the decision of the Presiding Officer is final, there is no right of appeal to the Administrator.

(2) On appeal from or review of the initial decision, the Administrator shall have all the powers which he or she would have in making the initial decision, including the discretion to require or allow briefs, oral argument, the taking of additional evidence, or the remanding to the Presiding Officer for additional proceedings. The decision by the Administrator may adopt the original decision or shall include written findings and conclusions and the reasons or basis therefor on all the material issues of fact, law, or discretion presented on the appeal or considered in the review.

§ 89.129–96 Right of entry.

(a) Any manufacturer who has applied for certification of a new engine or engine family subject to certification testing under this subpart shall admit or cause to be admitted to any of the following facilities during operating hours any EPA enforcement officer or EPA authorized representative on presentation of credentials.

(1) Any facility where any such certification testing or any procedures or activities connected with such certification testing are or were performed;

(2) Any facility where any new engine which is being, was, or is to be tested is present;

(3) Any facility where any construction process or assembly process used in the modification or buildup of such an engine into a certification engine is taking place or has taken place; and

(4) Any facility where any record or other document relating to any of the above is located.

(b) Upon admission to any facility referred to in paragraph (a)(1) of this section, any EPA enforcement officer or EPA authorized representative shall be allowed:

(1) To inspect and monitor any part or aspect of such procedures, activities, and testing facilities, including, but not limited to, monitoring engine preconditioning, emission tests and service accumulation, maintenance, and engine storage procedures, and to verify correlation or calibration of test equipment;

(2) To inspect and make copies of any such records, designs, or other documents; and

(3) To inspect and photograph any part or aspect of any such certification engine and any components to be used in the construction thereof.

(c) To allow the Administrator to determine whether production engines conform in all material respects to the design specifications applicable to those engines, as described in the application for certification for which a certificate of conformity has been issued, any manufacturer shall admit any EPA enforcement officer or EPA authorized representative on presentation of credentials to:

(1) Any facility where any document, design, or procedure relating to the translation of the design and construction of engines and emission-related components described in the application for certification or used for certification testing into production engines is located or carried on; and

(2) Any facility where any engines to be introduced into commerce are manufactured or assembled.

(d) On admission to any such facility referred to in paragraph (c) of this section, any EPA enforcement officer or EPA authorized representative shall be allowed:

(1) To inspect and monitor any aspects of such manufacture or assembly and other procedures;

(2) To inspect and make copies of any such records, documents or designs; and

(3) To inspect and photograph any part or aspect of any such new engines and any component used in the assembly thereof that are reasonably related to the purpose of his or her entry.

(e) Any EPA enforcement officer or EPA authorized representative shall be furnished by those in charge of a facility being inspected with such reasonable assistance as he or she may request to help the enforcement officer or authorized representative discharge any function listed in this paragraph. Each applicant for or recipient of certification is required to cause those in charge of a facility operated for its benefit to furnish such reasonable assistance without charge to EPA whether or not the applicant controls the facility.

(1) Reasonable assistance includes, but is not limited to, clerical, copying, interpretation and translation services; the making available on request of personnel of the facility being inspected during their working hours to inform the EPA enforcement officer or EPA authorized representative of how the facility operates and to answer the officer's questions; and the performance on request of emission tests on any engine which is being, has been, or will be used for certification testing. Such tests shall be nondestructive, but may require appropriate service accumulation.

(2) A manufacturer may be compelled to cause any employee at a facility being inspected to appear before an EPA enforcement officer or EPA authorized representative. The request for the employee's appearance shall be in writing, signed by the Assistant Administrator for Air and Radiation, and served on the manufacturer. Any employee who has been instructed by the manufacturer to appear will be entitled to be accompanied, represented, and advised by counsel.

(f) The duty to admit or cause to be admitted any EPA enforcement officer or EPA authorized representative applies whether or not the applicant owns or controls the facility in question and applies both to domestic and to foreign manufacturers and facilities. EPA will not attempt to make any inspections which it has been informed that local law forbids. However, if local law makes it impossible to do what is necessary to ensure the accuracy of data generated at a facility, no informed judgment that an engine is certifiable or is covered by a certificate can properly be based on those data. It is the responsibility of the manufacturer to locate its testing and manufacturing facilities in jurisdictions where this situation will not arise.

(g) Any entry without 24 hours prior written or oral notification to the affected manufacturer shall be authorized in writing by the Assistant Administrator for Enforcement.

Subpart C—Averaging, Banking, and Trading Provisions

§ 89.201–96 Applicability.

Nonroad compression-ignition engines subject to the provisions of subpart A of this part are eligible to participate in the averaging, banking, and trading program described in this subpart.

§ 89.202–96 Definitions.

The definitions in subpart A of this part apply to this subpart. The following definitions also apply to this subpart:

Averaging for nonroad engines means the exchange of emission credits among engine families within a given manufacturer's product line.

Banking means the retention of nonroad engine emission credits by the manufacturer generating the emission credits for use in future model year averaging or trading as permitted by these regulations.

Emission credits represent the amount of emission reduction or exceedance, by a nonroad engine family, below or above the emission standard, respectively. Emission reductions below the standard are considered as "positive credits," while emission exceedances above the standard are considered as "negative credits." In addition, "projected credits" refer to emission credits based on the projected applicable production/sales volume of the engine family. "Reserved credits" are emission credits generated within a model year waiting to be reported to EPA at the end of the model year. "Actual credits" refer to emission credits based on actual applicable production/sales volume as contained in the end-of-year reports submitted to EPA. Some or all of these credits may be revoked if EPA review of the end-of-year reports or any subsequent audit action(s) uncovers problems or errors.

Trading means the exchange of nonroad engine emission credits between manufacturers.

§ 89.203–96 General provisions.

(a) The averaging, banking, and trading program for NO_X emissions from eligible nonroad engines is described in this subpart. Participation in this program is voluntary.

(b) A nonroad engine family is eligible to participate in the averaging, banking, and trading program for NO_X emissions if it is subject to regulation under subpart B of this part with certain exceptions specified in subsection (c) of this section. No averaging, banking, and trading program is available for meeting the HC, CO, PM, or smoke emission standards specified in subpart B of this part.

(c) Nonroad engines may not participate in the averaging, banking, and trading program if they are subject to state engine emission standards, are exported, or use an alternate or special test procedure under § 89.114–96.

(d) A manufacturer may certify one or more nonroad engine families at family emission limits (FELs) above or below the applicable emission standard, provided the summation of the manufacturer's projected balance of all credit transactions in a given model year is greater than or equal to zero, as determined under § 89.207–96.

(1) FELs for NO_x may not exceed 14.6 grams per kilowatt hour.

(2) An engine family certified to an FEL is subject to all provisions specified in subparts B, D, E, G, H, I, J, and K of this part, except that the applicable FEL replaces the NO_x emission standard for the family participating in the averaging, banking, and trading program.

(3) A manufacturer of an engine family with an FEL exceeding the applicable emission standard must obtain emission credits sufficient to address the associated credit shortfall via averaging, banking, or trading.

(4) An engine family with an FEL below the applicable standard may generate emission credits for averaging, banking, trading, or a combination thereof. Emission credits may not be used to offset an engine family's emissions that exceed its applicable FEL. Credits may not be used to remedy nonconformity determined by a Selective Enforcement Audit (SEA) or by recall (in-use) testing. However, in the case of an SEA failure, credits may be used to allow subsequent production of engines for the family in question if the manufacturer elects to recertify to a higher FEL.

(e) Credits generated in a given model year may be used in the following three model years. Credits not used by the end of the third model year after being generated are forfeited. Credits generated in one model year may not be used for prior model years.

(f) Manufacturers must demonstrate compliance under the averaging, banking, and trading program for a particular model year by 270 days after the model year. Engine families without an adequate amount of emission credits will violate the conditions of the certificates of conformity. The certificates of conformity may be voided ab initio under § 89.126–96(c) for those engine families.

§ 89.204–96 Averaging.

(a) A manufacturer may use averaging to offset an emission exceedance of a nonroad engine family caused by an FEL above the applicable emission standard. Credits used in averaging may be obtained from credits generated by another engine family in the same model year, credits banked in the three previous model years, or credits obtained through trading.

(b) Credits scheduled to expire in the earliest model year must be used first, before using other available credits.

§ 89.205–96 Banking.

(a) A manufacturer of a nonroad engine family with an FEL below the applicable standard for a given model year may bank credits in that model year for use in averaging and trading in the following three model years. Credits not withdrawn within the three model years after they are banked are forfeited.

(b) A manufacturer of a nonroad engine family may bank credits up to one calendar year prior to the effective date of mandatory certification. Such engines must meet the requirements of subparts A, B, D, E, F, G, H, I, J, and K of this part.

(c) A manufacturer may bank actual credits only after the end of the model year and after EPA has reviewed the manufacturer's end-of-year reports. During the model year and before submittal of the end-of-year report, credits originally designated in the certification process for banking will be considered reserved and may be redesignated for trading or averaging in the end-of-year report and final report.

(d) Credits declared for banking from the previous model year that have not been reviewed by EPA may be used in averaging or trading transactions. However, such credits may be revoked at a later time following EPA review of the end-of-year report or any subsequent audit actions.

§ 89.206–96 Trading.

(a) A nonroad engine manufacturer may exchange emission credits with other nonroad engine manufacturers in trading.

(b) Credits for trading can be obtained from credits banked in the three previous model years or credits generated during the model year of the trading transaction. Traded credits expire if they are not used in averaging within three model years following the model year in which they were generated.

(c) Traded credits can be used for averaging, banking, or further trading transactions.

(d) In the event of a negative credit balance resulting from a transaction, both the buyer and the seller are liable, except in cases involving fraud. Certificates of all engine families participating in a negative trade may be voided ab initio under § 89.126–96(c).

§ 89.207–96 Credit calculation.

For each participating engine family, emission credits (positive or negative) are to be calculated according to one of the following equations and rounded, in accordance with ASTM E29–90, to the nearest one-tenth of a megagram per hour (Mg/hr). ASTM E29–90 has been incorporated by reference. See § 89.6. Consistent units are to be used throughout the equation.

(a) For determining credit availability from all engine families generating credits:

$$\text{Emission credits} = (\text{Std} - \text{FEL}) \times (\text{Volume}) \times (\text{MinPR}) \times (10^{-6})$$

(b) For determining credit usage for all engine families requiring credits to offset emissions in excess of the standard:

$$\text{Emission credits} = (\text{Std} - \text{FEL}) \times (\text{Volume}) \times (\text{MaxPR}) \times (10^{-6})$$

Where:

Std=the current and applicable nonroad engine emission standard in grams per brake horsepower hour.

FEL=the family emission limit for the engine family in grams per brake horsepower hour.

Volume=the number of nonroad engines eligible to participate in the averaging, banking, and trading program within the given engine family during the model year. Quarterly production projections are used for initial certification. Actual applicable production/sales volumes is used for end-of-year compliance determination.

MinPR=the power rating of the configuration within an engine family with the lowest power rating.

MaxPR=the power rating of the configuration within an engine family with the highest power rating.

§ 89.208–96 Labeling.

For all nonroad engines included in the averaging, banking, and trading program, the family emission limit to which the engine is certified must be included on the label required in § 89.110–96.

§ 89.209–96 Certification.

(a) In the application for certification a manufacturer must:

(1) Declare its intent to include specific engine families in the averaging, banking, and trading program.

(2) Submit a statement that the engines for which certification is requested will not, to the best of the manufacturer's belief, cause the manufacturer to have a negative credit balance when all credits are calculated for all the manufacturer's engine families participating in the averaging, banking, and trading program.

(3) Declare an FEL for each engine family participating in averaging, banking, and trading.

(i) The FEL must be to the same number of significant digits as the emission standard.

(ii) In no case may the FEL exceed the upper limit prescribed in § 89.203–96(d).

(4) Indicate the projected number of credits generated/needed for this family; the projected applicable production/sales volume, by quarter; and the values required to calculate credits as given in § 89.207–96.

(5) Submit calculations in accordance with § 89.207–96 of projected emission credits (positive or negative) based on quarterly production projections for each participating family.

(6) (i) If the engine family is projected to have negative emission credits, state specifically the source (manufacturer/engine family or reserved) of the credits necessary to offset the credit deficit according to quarterly projected production.

(ii) If the engine family is projected to generate credits, state specifically (manufacturer/engine family or reserved) where the quarterly projected credits will be applied.

(b) All certificates issued are conditional upon manufacturer compliance with the provisions of this subpart both during and after the model year of production.

(c) Failure to comply with all provisions of this subpart will be considered to be a failure to satisfy the conditions upon which the certificate was issued, and the certificate may be deemed void ab initio.

(d) The manufacturer bears the burden of establishing to the satisfaction of the Administrator that the conditions upon which the certificate was issued were satisfied or waived.

(e) Projected credits based on information supplied in the certification application may be used to obtain a certificate of conformity. However, any such credits may be revoked based on review of end-of-year reports, follow-up audits, and any other verification steps deemed appropriate by the Administrator.

§ 89.210–96 Maintenance of records.

(a) The manufacturer of any nonroad engine that is certified under the averaging, banking, and trading program must establish, maintain, and retain the following adequately organized and indexed records for each such engine produced:

(1) EPA engine family;

(2) Engine identification number;

(3) Engine model year and build date,

(4) Power rating;

(5) Purchaser and destination; and

(6) Assembly plant.

(b) The manufacturer of any nonroad engine family that is certified under the averaging, banking, and trading program must establish, maintain, and retain the following adequately organized and indexed records for each such family:

(1) EPA engine family;

(2) Family emission limit (FEL);

(3) Power rating for each configuration tested;

(4) Projected applicable production/sales volume for the model year; and

(5) Actual applicable production/sales volume for the model year.

(c) Any manufacturer producing an engine family participating in trading reserved credits must maintain the following records on a quarterly basis for each engine family in the trading program:

(1) The engine family;

(2) The actual quarterly and cumulative applicable production/sales volume;

(3) The value required to calculate credits as given in § 89.207–96;

(4) The resulting type and number of credits generated/required;

(5) How and where credit surpluses are dispersed; and

(6) How and through what means credit deficits are met.

(d) The manufacturer must retain all records required to be maintained under this section for a period of eight years from the due date for the end-of-model-year report. Records may be retained as hard copy or reduced to microfilm, ADP diskettes, and so forth, depending on the manufacturer's record retention procedure; provided, that in every case all information contained in the hard copy is retained.

(e) Nothing in this section limits the Administrator's discretion in requiring the manufacturer to retain additional records or submit information not specifically required by this section.

(f) Pursuant to a request made by the Administrator, the manufacturer must submit to the Administrator the information that the manufacturer is required to retain.

(g) EPA may void ab initio under § 89.126–96(c) a certificate of conformity for an engine family for which the manufacturer fails to retain the records required in this section or to provide such information to the Administrator upon request.

§ 89.211–96 End-of-year and final reports.

(a) End-of-year and final reports must indicate the engine family, the actual applicable production/sales volume, the values required to calculate credits as given in § 89.207–96, and the number of credits generated/required. Manufacturers must also submit how and where credit surpluses were dispersed (or are to be banked) and/or how and through what means credit deficits were met. Copies of contracts related to credit trading must be included or supplied by the broker, if applicable. The report shall include a calculation of credit balances to show that the summation of the manufacturer's use of credits results in a credit balance equal to or greater than zero.

(b) The applicable production/sales volume for end-of-year and final reports must be based on the location of the point of first retail sale (for example, retail customer, dealer, secondary manufacturer) also called the final product purchase location.

(c)(1) End-of-year reports must be submitted within 90 days of the end of the model year to: Director, Manufacturers Operations Division (6405–J), U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460.

(2) Final reports must be submitted within 270 days of the end of the model year to: Director, Manufacturers Operations Division (6405–J), U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460.

(d) Failure by a manufacturer participating in the averaging, banking, or trading program to submit any end-of-year or final reports in the specified time for all engines is a violation of sections 203(a)(1) and 213 of the Clean Air Act for each engine.

(e) A manufacturer generating credits for deposit only who fails to submit end-of-year reports in the applicable specified time period (90 days after the end of the model year) may not use the credits until such reports are received and reviewed by EPA. Use of projected credits pending EPA review is not permitted in these circumstances.

(f) Errors discovered by EPA or the manufacturer in the end-of-year report, including errors in credit calculation, may be corrected in the final report up to 270 days from the end of the model year.

(g) If EPA or the manufacturer determines that a reporting error occurred on an end-of-year or final report previously submitted to EPA under this section, the manufacturer's credits and credit calculations will be recalculated. Erroneous positive credits will be void except as provided in paragraph (h) of this section. Erroneous negative credit balances may be adjusted by EPA.

(h) If within 270 days of the end of the model year, EPA review determines a reporting error in the manufacturer's favor (that is, resulting in an increased

credit balance) or if the manufacturer discovers such an error within 270 days of the end of the model year, the credits shall be restored for use by the manufacturer.

§ 89.212–96 Notice of opportunity for hearing.

Any voiding of the certificate under §§ 89.203–96(f), 89.206–96(d), 89.209–96(c) and 89.210–96(g) will be made only after the manufacturer concerned has been offered an opportunity for a hearing conducted in accordance with §§ 89.512 and 89.513 and, if a manufacturer requests such a hearing, will be made only after an initial decision by the Presiding Officer.

Subpart D—Emission Test Equipment Provisions

§ 89.301–96 Scope; applicability.

(a) This subpart describes the equipment required in order to perform exhaust emission tests on new nonroad compression-ignition engines subject to the provisions of subpart B of part 89.

(b) Exhaust gases, either raw or dilute, are sampled while the test engine is operated using an 8-mode test cycle on an engine dynamometer. The exhaust gases receive specific component analysis determining concentration of pollutant, exhaust volume, the fuel flow, and the power output during each mode. Emission is reported as grams per kilowatt hour (g/kw-hr). See subpart E of this part for a complete description of the test procedure.

(c) General equipment and calibration requirements are given in § 89.304–96 through 89.324–96. Sections 89.325–96 through 89.331–96 set forth general test specifications.

(d) Additional information about system design, calibration methodologies, and so forth, for raw gas sampling can be found in part 86, subpart D of this chapter. Examples for system design, calibration methodologies, and so forth, for dilute exhaust gas sampling can be found in part 86, subpart N of this chapter.

§ 89.302–96 Definitions.

The definitions in subpart A of part 89 apply to this subpart. For terms not defined in part 89, the definitions in part 86, subparts A, D, I, and N apply to this subpart. The following definition also applies to this subpart.

Specific emissions, g/kW-hr, is expressed on the basis of observed gross brake power. When it is not possible to test the engine in the gross conditions, for example, if the engine and transmission form a single integral unit, the engine may be tested in the net condition. Power corrections from net to gross conditions will be allowed with prior approval of the Administrator.

§ 89.303–96 Symbols/abbreviations.

(a) The abbreviations in § 86.094–3 or part 89.3 of this chapter apply to this subpart.

(b) The abbreviations in Table 1 in appendix A of this subpart apply to this subpart. Some abbreviations from § 89.3 have been included for the convenience of the reader.

(c) The symbols in Table 2 in appendix A of this subpart apply to this subpart.

§ 89.304–96 Equipment required for gaseous emissions; overview.

(a) All engines subject to this subpart are tested for exhaust emissions. Engines are operated on dynamometers meeting the specification given in § 89.306–96.

(b) The exhaust is tested for gaseous emissions using a raw gas sampling system as described in § 89.412–96 or a constant volume sampling (CVS) system as described in § 89.419–96. Both systems require analyzers (see paragraph (c) of this section) specific to the pollutant being measured.

(c) Analyzers used are a non-dispersive infrared (NDIR) absorption type for carbon monoxide and carbon dioxide analysis; paramagnetic (PMD), zirconia (ZRDO), or electrochemical type (ECS) for oxygen analysis; a heated flame ionization (HFID) type for hydrocarbon analysis; and a chemiluminescent detector (CLD) or heated chemiluminescent detector (HCLD) for oxides of nitrogen analysis. Sections 89.309–96 through 89.324–96 set forth a full description of analyzer requirements and specifications.

§ 89.305–96 Equipment measurement accuracy/calibration frequency.

The accuracy of measurements must be such that the maximum tolerances shown in Table 3 in appendix A of this subpart are not exceeded. Calibrate all equipment and analyzers according to the frequencies shown in Table 3 in Appendix A of this subpart.

§ 89.306–96 Dynamometer specifications and calibration weights.

(a) *Dynamometer specifications.* The dynamometer test stand and other instruments for measurement of power output must meet the accuracy and calibration frequency requirements shown in Table 3 in appendix A of this subpart. The dynamometer must be capable of performing the test cycle described in § 89.410–96.

(b) *Dynamometer calibration weights.* A minimum of six calibration weights for each range used are required. The weights must be spaced to reflect good engineering judgement such that they cover the range of weights required and must be traceable to within 0.5 percent of NIST weights. Laboratories located in foreign countries may certify calibration weights to local government bureau standards.

§ 89.307–96 Dynamometer calibration.

(a) If necessary, follow the dynamometer manufacturer's instructions for initial start-up and basic operating adjustments.

(b) Check the dynamometer torque measurement for each range used by the following method:

(1) Warm up the dynamometer following the dynamometer manufacturer's specifications.

(2) Determine the dynamometer calibration moment arm (a distance/weight measurement). Dynamometer manufacturer's data, actual measurement, or the value recorded from the previous calibration used for this subpart may be used.

(3) When calibrating the engine flywheel torque transducer, any lever arm used to convert a weight or a force through a distance into a torque must be in a horizontal position (±5 degrees).

(4) Calculate the indicated torque (IT) for each calibration weight to be used by:

IT = calibration weight (N) × calibration moment arm (m)

(5) Attach each calibration weight specified in § 89.306–96 to the moment arm at the calibration distance determined in paragraph (b)(2) of this section. Record the power measurement equipment response (N – m) to each weight.

(6) For each calibration weight, compare the torque value measured in paragraph (b)(5) of this section to the calculated torque determined in paragraph (b)(4) of this section.

(7) The measured torque must be within 2 percent of the calculated torque.

(8) If the measured torque is not within 2 percent of the calculated torque, adjust or repair the system. Repeat steps in paragraphs (b)(1) through (b)(6) of this section with the adjusted or repaired system.

(c) Optional. A master load-cell or transfer standard may be used to verify the torque measurement system.

(1) The master load-cell and read out system must be calibrated with weights at each test weight specified in § 89.306–96. The calibration weights must be traceable to within 0.1 percent of applicable national standards.

(2) Warm up the dynamometer following the equipment manufacturer's specifications.

(3) Attach the master load-cell and loading system.

(4) Load the dynamometer to a minimum of 6 equally spaced torque values as indicated by the master load-cell for each in-use range used.

(5) The in-use torque measurement must be within 2 percent of the torque measured by the master system for each load used.

(6) If the in-use torque is not within 2 percent of the master torque, adjust or repair the system. Repeat steps in paragraphs (c)(2) through (c)(5) of this section with the adjusted or repaired system.

(d) Calibrated resistors may not be used for engine flywheel torque transducer calibration, but may be used to span the transducer prior to engine testing.

(e) Perform other engine dynamometer system calibrations as dictated by good engineering practice.

§ 89.308–96 Sampling system requirements for gaseous emissions.

(a) For each component (pump, sample line section, filters, and so forth) in the heated portion of the sampling system that has a separate source of power or heating element, use engineering judgment to locate the coolest portion of that component and monitor the temperature at that location. If several components are within an oven, then only the surface temperature of the component with the largest thermal mass and the oven temperature need be measured.

(b) If water is removed by condensation, the sample gas temperature or sample dewpoint must be monitored either within the water trap or downstream. It may not exceed 7 °C.

§ 89.309–96 Analyzers required for gaseous emissions.

(a) *Analyzers.* The following instruments are required for analyzing the measured gases:

(1) *Carbon Monoxide (CO) analysis.* (i) The carbon monoxide analyzer must be of the non-dispersive infrared (NDIR) absorption type.

(ii) The use of linearizing circuits is permitted.

(2) *Carbon Dioxide (CO_2) analysis.* (i) The carbon dioxide analyzer must be of the non-dispersive infrared (NDIR) absorption type.

(ii) The use of linearizing circuits is permitted.

(3) *Oxygen (O_2) analysis.* Oxygen (O_2) analyzers may be of the paramagnetic (PMD), zirconia (ZRDO) or electrochemical type (ECS).

(4) *Hydrocarbon (HC) analysis.* (i) The hydrocarbon analyzer must be of the heated flame ionization (HFID) type.

(ii) If the temperature of the exhaust gas at the sample probe is below 190 °C, the temperature of the valves, pipework, and so forth, must be controlled so as to maintain a wall temperature of 190 °C ± 11 °C. If the temperature of the exhaust gas at the sample probe is above 190 °C, the temperature of the valves, pipework, and so forth, must be controlled so as to maintain a wall temperature greater than 180 °C.

(iii) The oven must be capable of maintaining temperature within 2 °C of the set point.

(iv) Fuel and burner air must conform to the specifications in § 89.312–96.

(v) The percent of oxygen interference must be less than 3 percent, as specified in § 89.319–96(d).

(5) *Oxides of nitrogen (NO_X) analysis.* (i) This analysis device must consist of the subsequent items, following the sample probe, in the given order:

(A) Pipework, valves, and so forth, controlled so as to maintain a wall temperature above 60 °C.

(B) A NO_2 to NO converter. The NO_2 to NO converter efficiency must be at least 90 percent.

(C) An ice bath or other cooling device located after the NO_X converter.

(D) A chemiluminescent detector (CLD).

(ii) The quench interference must be less than 3.0 percent as measured in § 89.318–96.

(b) Other gas analyzers yielding equivalent results may be used with advance approval of the Administrator.

(c) The following requirements must be incorporated in each system used for testing under this subpart.

(1) Carbon monoxide and carbon dioxide measurements must be made on a dry basis (for raw exhaust measurement only). Specific requirements for the means of drying the sample can be found in § 89.309–96(e).

(2) Calibration or span gases for the NO_X measurement system must pass through the NO_2 to NO converter.

(d) The electromagnetic compatibility (EMC) of the equipment must be on a level as to minimize additional errors.

(e) *Gas drying.* Chemical dryers are not an acceptable method of removing water from the sample. Water removal by condensation is acceptable. A water trap performing this function and meeting the specifications in § 89.308–96(b) is an acceptable method. Means other than condensation may be used only with prior approval from the Administrator.

§ 89.310–96 Analyzer accuracy and specifications.

(a) *Measurement accuracy—general.* The analyzers must have a measuring range which allows them to measure the concentrations of the exhaust gas sample pollutants with the accuracies shown in Table 3 in Appendix A of this subpart.

(1) *Response time.* The analyzer response time must be measured and accounted for before recording of data begins.

(2) *Precision.* The precision of the analyzer must be, at worst, ±1 percent of full-scale concentration for each range used at or above 100 ppm (or ppmC) or ±2 percent for each range used below 100 ppm (or ppmC). The precision is defined as 2.5 times the standard deviation(s) of 10 repetitive responses to a given calibration or span gas.

(3) *Noise.* The analyzer peak-to-peak response to zero and calibration or span gases over any 10-second period must not exceed 2 percent of full-scale chart deflection on all ranges used.

(4) *Zero drift.* The analyzer zero-response drift during a 1-hour period must be less than 2 percent of full-scale chart deflection on the lowest range used. The zero-response is defined as the mean response including noise to a zero-gas during a 30-second time interval.

(5) *Span drift.* The analyzer span drift during a 1-hour period must be less than 2 percent of full-scale chart deflection on the lowest range used. The analyzer span is defined as the difference between the span-response and the zero-response. The span-response is defined as the mean response including noise to a span gas during a 30-second time interval.

(b) *Operating procedure for analyzers and sampling system.* Follow the start-up and operating instructions of the instrument manufacturer. Adhere to the minimum requirements given in § 89.314–96 to § 89.323–96.

(c) *Emission measurement accuracy—Bagged sampling.* (1) Good engineering practice dictates that exhaust emission sample analyzer readings below 15 percent of full-scale chart deflection should generally not be used.

(2) Some high resolution read-out systems, such as computers, data loggers, and so forth, can provide sufficient accuracy and resolution below 15 percent of full scale. Such systems may be used provided that additional calibrations are made to ensure the accuracy of the calibration curves. If a gas divider is used, the gas divider must conform to the accuracy requirements specified in § 89.312–96(c). The

following procedure for calibration below 15 percent of full scale may be used:

(i) Span the full analyzer range using a top range calibration gas meeting the accuracy requirements of § 89.312–96(c).

(ii) Generate a calibration curve according to, and meeting the requirements of, §§ 89.319–96 through 89.323–96.

(iii) Select a calibration gas (a span gas may be used for calibrating the CO_2 analyzer) with a concentration midway between the two lowest calibration gases or non-zero gas divider increments. This gas must be "named" to an accuracy of ±2.0 percent of NIST gas standards, or other standards approved by the Administrator.

(iv) Using the calibration curve fitted to the points generated in paragraphs (c)(2)(i) and (ii) of this section, check the concentration of the gas selected in paragraph (c)(2)(iii) of this section. The concentration derived from the curve must be within ±2.3 percent (±2.8 percent for CO_2 span gas) of the original named gas concentration.

(v) Provided the requirements of paragraph (c)(2)(iv) of this section are met, use the gas divider with the gas selected in paragraph (c)(2)(iii) of this section and determine the remainder of the calibration points. Fit a calibration curve per §§ 89.319–96 through 89.322–96 of this chapter for the entire analyzer range.

(d) *Emission measurement accuracy—continuous sampling.* Analyzers used for continuous analysis must be operated such that the measured concentration falls between 15 and 100 percent of full-scale chart deflection. Exceptions to these limits are:

(1) The analyzer's response may be less than 15 percent or more than 100 percent of full scale if automatic range change circuitry is used and the limits for range changes are between 15 and 100 percent of full-scale chart deflection;

(2) The analyzer's response may be less than 15 percent of full scale if:

(i) Alternative (c)(2) of this section is used to ensure that the accuracy of the calibration curve is maintained below 15 percent; or

(ii) The full-scale value of the range is 155 ppm (or ppmC) or less.

§ 89.311–96 Analyzer calibration frequency.

(a) Prior to initial use and after major repairs, bench check each analyzer (see § 89.315–96).

(b) Calibrations are performed as specified in §§ 89.319–96 through 89.324–96.

(c) At least monthly, or after any maintenance which could alter calibration, the following calibrations and checks are performed.

(1) Leak check the vacuum side of the system (see § 89.316–96).

(2) Check that the analysis system response time has been measured and accounted for.

(3) Verify that the automatic data collection system (if used) meets the requirements found in Table 3 in Appendix A of this subpart.

(4) Check the fuel flow measurement instrument to insure that the specifications in Table 3 in appendix A of this subpart are met.

(d) Verify that all NDIR analyzers meet the water rejection ratio and the CO_2 rejection ratio as specified in § 89.318–96.

(e) Verify that the dynamometer test stand and power output instrumentation meet the specifications in Table 3 in Appendix A of this subpart.

§ 89.312–96 Analytical gases.

(a) The shelf life of all calibration gases must not be exceeded. The expiration date of the calibration gases stated by the gas manufacturer shall be recorded.

(b) *Pure gases.* The required purity of the gases is defined by the contamination limits given below. The following gases must be available for operation:

(1) Purified nitrogen (Contamination ≤ 1 ppm C, ≤ 1 ppm CO, ≤ 400 ppm CO_2, ≤ 0.1 ppm NO)

(2) Purified oxygen (Purity 99.5 percent vol O_2)

(3) Hydrogen-helium mixture (40 ± 2 percent hydrogen, balance helium) (Contamination ≤ 31 ppm C, ≤ 400 ppm CO)

(4) Purified synthetic air (Contamination ≤ 1 ppm C, ≤ 1 ppm CO, ≤ 400 ppm CO_2, ≤ 0.1 ppm NO) (Oxygen content between 18–21 percent vol.)

(c) *Calibration and span gases.* (1) Calibration gas values are to be derived from NIST Standard Reference Materials (SRM's) or other standardized gas samples and are to be single blends as listed in the following paragraph.

(2) Mixtures of gases having the following chemical compositions shall be available:

C_3H_8 and purified synthetic air (dilute measurements);

C_3H_8 and purified nitrogen (raw measurements);

CO and purified nitrogen;

NO_X and purified nitrogen (the amount of NO_2 contained in this calibration gas must not exceed 5 percent of the NO content);

CO_2 and purified nitrogen

(3) The true concentration of a span gas must be within ±2 percent of the NIST gas standard. The true concentration of a calibration gas must be within ±1 percent of the NIST gas standard. The use of precision blending devices (gas dividers) to obtain the required calibration gas concentrations is acceptable, provided that the blended gases are accurate to within ±1.5 percent of NIST gas standards, or other gas standards which have been approved by the Administrator. This accuracy implies that primary gases used (or blending) must be "named" to an accuracy of at least ±1 percent, traceable to NIST or other approved gas standards. All concentrations of calibration gas shall be given on a volume basis (volume percent or volume ppm).

(4) The gas concentrations used for calibration and span may also be obtained by means of a gas divider, either diluting with purified N_2 or diluting with purified synthetic air. The accuracy of the mixing device must be such that the concentration of the diluted gases may be determined to within ±2 percent.

(d) Oxygen interference check gases shall contain propane with 350 ppmC ±75 ppmC hydrocarbon. The concentration value shall be determined to calibration gas tolerances by chromatographic analysis of total hydrocarbons plus impurities or by dynamic blending. Nitrogen shall be the predominant diluent with the balance oxygen.

(e) Fuel for the FID shall be a blend of 40 percent ±2 percent hydrogen with the balance being helium. The mixture shall contain less than 1 ppm equivalent carbon response; 98 to 100 percent hydrogen fuel may be used with advance approval of the Administrator.

(f) *Hydrocarbon analyzer burner air.* The concentration of oxygen must be within 1 mole percent of the oxygen concentration of the burner air used in the latest oxygen interference check (%O_2I). If the difference in oxygen concentration is greater than 1 mole percent, then the oxygen interference must be checked and, if necessary, the analyzer adjusted to meet the %O_2I requirements. The burner air must contain less than 2 ppmC hydrocarbon.

§ 89.313–96 Initial calibration of analyzers.

(a) *Warming-up time.* The warming-up time should be according to the recommendations of the manufacturer. If not specified, a minimum of two hours shall be allowed for warming up the analyzers.

(b) *NDIR and HFID analyzer.* The NDIR analyzer shall be tuned and maintained according to the instrument manufacturer's instructions. The combustion flame of the HFID analyzer shall be optimized in order to meet the specifications in § 89.319–96(b)(2).

(c) *Zero setting and calibration.* (1) Using purified synthetic air (or nitrogen), the CO, CO_2, NO_X, and HC analyzers shall be set at zero.

(2) Introduce the appropriate calibration gases to the analyzers and the values recorded. The same gas flow rates shall be used as when sampling exhaust.

(d) *Rechecking of zero setting.* The zero setting shall be rechecked and the procedure described in paragraph (c) of this section repeated, if necessary.

§ 89.314–96 Pre- and post-test calibration of analyzers.

Each operating range used during the test shall be checked prior to and after each test in accordance with the following procedure. (A chronic need for parameter adjustment can indicate a need for instrument maintenance.):

(a) The calibration is checked by using a zero gas and a span gas whose nominal value is between 80 percent and 100 percent of full-scale, inclusive, of the measuring range.

(b) After the emission test a zero gas and the same span gas will be used for rechecking. The analysis will be considered acceptable if the difference between the two measuring results is less than 2 percent of full scale.

§ 89.315–96 Analyzer bench checks.

(a) Prior to initial use and after major repairs verify that each analyzer complies with the specifications given in Table 3 in appendix A of this subpart.

(b) If a stainless steel NO_2 to NO converter is used, condition all new or replacement converters. The conditioning consists of either purging the converter with air for a minimum of 4 hours or until the converter efficiency is greater than 90 percent. The converter must be at operational temperature while purging. Do not use this procedure prior to checking converter efficiency on in-use converters.

§ 89.316–96 Analyzer leakage and response time.

(a) *Vacuum side leak check.* (1) Any location within the analysis system where a vacuum leak could affect the test results must be checked.

(2) The maximum allowable leakage rate on the vacuum side is 0.5 percent of the in-use flow rate for the portion of the system being checked. The analyzer flows and bypass flows may be used to estimate the in-use flow rates.

(3) The sample probe and the connection between the sample probe and valve V2 (see Figure 1 in appendix B of this subpart) may be excluded from the leak check.

(b) *Pressure side leak check.* The maximum allowable leakage rate on the pressure side is 5 percent of the in-use flow rate.

(c) The response time shall be accounted for in all emission measurement and calculations.

§ 89.317–96 NO_X converter check.

(a) Prior to its introduction into service, and monthly thereafter, the chemiluminescent oxides of nitrogen analyzer shall be checked for NO_2 to NO converter efficiency. Figure 2 in appendix B of this subpart is a reference for the following paragraphs.

(b) Follow good engineering practices for instrument start-up and operation. Adjust the analyzer to optimize performance.

(c) Zero the oxides of nitrogen analyzer with zero-grade air or zero-grade nitrogen.

(d) Connect the outlet of the NO_X generator to the sample inlet of the oxides of nitrogen analyzer which has been set to the most common operating range.

(e) Introduce into the NO_X generator analyzer-system an NO-in-nitrogen (N_2) mixture with an NO concentration equal to approximately 80 percent of the most common operating range. The NO_2 content of the gas mixture shall be less than 5 percent of the NO concentration.

(f) With the oxides of nitrogen analyzer in the NO mode, record the concentration of NO indicated by the analyzer.

(g) Turn on the NO_X generator O_2 (or air) supply and adjust the O_2 (or air) flow rate so that the NO indicated by the analyzer is about 10 percent less than indicated in paragraph (b)(5) of this section. Record the concentration of NO in this $NO+O_2$ mixture.

(h) Switch the NO_X generator to the generation mode and adjust the generation rate so that the NO measured on the analyzer is 20 percent of that measured in paragraph (b)(5) of this section. There must be at least 10 percent unreacted NO at this point. Record the concentration of residual NO.

(i) Switch the oxides of nitrogen analyzer to the NO_X mode and measure total NO_X. Record this value.

(j) Switch off the NO_X generator but maintain gas flow through the system. The oxides of nitrogen analyzer will indicate the NO_X in the $NO+O_2$ mixture. Record this value.

(k) Turn off the NO_X generator O_2 (or air) supply. The analyzer will now indicate the NO_X in the original NO-in-N_2 mixture. This value should be no more than 5 percent above the value indicated in paragraph (b)(4) of this section.

(l) Calculate the efficiency of the NO_X converter by substituting the concentrations obtained into the following equation:

$$\text{percent efficiency} = \left(1 + \frac{a-b}{c-d}\right) \times 100$$

Where:

a=concentration obtained in paragraph (i),

b=concentration obtained in paragraph (j),

c=concentration obtained in paragraph (g),

d=concentration obtained in paragraph (h).

If converter efficiency is not greater than 90 percent, corrective action will be required.

§ 89.318–96 Analyzer interference checks.

(a) Gases present in the exhaust other than the one being analyzed can interfere with the reading in several ways. Positive interference occurs in NDIR and PMD instruments when the interfering gas gives the same effect as the gas being measured, but to a lesser degree. Negative interference occurs in NDIR instruments by the interfering gas broadening the absorption band of the measured gas and in CLD instruments by the interfering gas quenching the radiation. The interference checks described in this section are to be made initially and after any major repairs that could affect analyzer performance.

(b) *CO analyzer water and CO_2 interference checks.* Prior to its introduction into service and annually thereafter, the NDIR carbon monoxide analyzer shall be checked for response to water vapor and CO_2:

(1) Follow good engineering practices for instrument start-up and operation. Adjust the analyzer to optimize performance on the most sensitive range to be used.

(2) Zero the carbon monoxide analyzer with either zero-grade air or zero-grade nitrogen.

(3) Bubble a mixture of 3 percent CO_2 in N_2 through water at room temperature and record analyzer response.

(4) An analyzer response of more than 1 percent of full scale for ranges above 300 ppm full scale or more than 3 ppm on ranges below 300 ppm full scale requires corrective action. (Use of conditioning columns is one form of corrective action which may be taken.)

(c) *NO_X analyzer quench check.* The two gases of concern for CLD (and HCLD) analyzers are CO_2 and water vapor. Quench responses to these two gases are proportional to their concentrations and, therefore, require test techniques to determine quench at the highest expected concentrations experienced during testing.

(1) *NO_X analyzer CO_2 quench check.* A CO_2 span gas having a concentration of 80 percent to 100 percent of full scale of the maximum operating range used during testing shall be passed through the CO_2 NDIR analyzer and the value recorded as *a*. It is diluted approximately 50 percent with NO span gas and then passed through the CO_2 NDIR and CLD (or HCLD), with the CO_2 and NO values recorded as *b* and *c* respectively. The CO_2 shall then be shut off and only the NO span gas passed through the CLD (or HCLD) and the NO value recorded as *d*. Percent CO_2 quench shall be calculated as follows and shall not exceed 3 percent:

$$\%\,CO_2\ \text{quench} = 100 \times \left(1 - \frac{(c \times a)}{(d \times a) - (d \times b)}\right) \times (a / b)$$

Where:
a=Undiluted CO_2 concentration (percent)
b=Diluted CO2 concentration (percent)
c=Diluted NO concentration (ppm)
d=Undiluted NO concentration (ppm)

(2) *NO_X analyzer water quench check.* (i) This check applies to wet measurements only. An NO span gas having a concentration of 80 percent to 100 percent of full scale of a normal operating range shall be passed through the CLD (or HCLD) and the response recorded as *D*. The NO span gas shall then be bubbled through water at room temperature and passed through the CLD (or HCLD) and the analyzer response recorded as *AR*. Determine and record the analyzer absolute operating pressure and the bubbler water temperature. (It is important that the NO span gas contains minimal NO_2 concentration for this check. No allowance for absorption of NO_2 in water has been made in the following quench calculations.)

(ii) Calculations for water quench must consider dilution of the NO span gas with water vapor and scaling of the water vapor concentration of the mixture to that expected during testing. Determine the mixture's saturated vapor pressure (designated as *Pwb*) that corresponds to the bubbler water temperature. Calculate the water concentration (Z1, percent) in the mixture by the following equation:

$$Z1 = 100 \times \frac{Pwb}{GP}$$

where GP = analyzer operating pressure (Pa)

(iii) Calculate the expected dilute NO span gas and water vapor mixture concentration (designated as *D1*) by the following equation:

$$D1 = D \times \left(1 - \frac{Z1}{100}\right)$$

(iv) For diesel (compression-ignition) exhaust, the maximum raw or dilute exhaust water vapor concentration expected during testing (designated as *Wm*) can be estimated from the CO_2 span gas (designated as *A*) criteria in paragraph (c)(1) of this section and the assumption of a fuel atom H/C ratio of 1.8:1 as:

$$Wm(\%) = 0.9 \times A(\%)$$

Where:
A = undiluted CO_2 concentration.

Percent water quench shall not exceed 3 percent and shall be calculated by:

$$\%\,\text{Water Quench} = 100 \times \frac{D1 - AR}{D1} \times \frac{Wm}{Z1}$$

§ 89.319–96 Hydrocarbon analyzer calibration.

(a) The FID hydrocarbon analyzer shall receive the initial and periodic calibration as described in this section. The HFID used with petroleum-fueled diesel (compression-ignition) engines shall be operated to a set point ±5.5 °C between 185 and 197 °C.

(b) *Initial and periodic optimization of detector response.* Prior to introduction into service and at least annually thereafter, adjust the FID hydrocarbon analyzer for optimum hydrocarbon response as specified in this paragraph. Alternate methods yielding equivalent results may be used, if approved in advance by the Administrator.

(1) Follow good engineering practices for initial instrument start-up and basic operating adjustment using the appropriate fuel (see § 89.312–96(e)) and zero-grade air.

(2) One of the following procedures is required for FID or HFID optimization:

(i) The procedure outlined in Society of Automotive Engineers (SAE) paper No. 770141, "Optimization of a Flame Ionization Detector for Determination of Hydrocarbon in Diluted Automotive Exhausts"; author, Glenn D. Reschke. This procedure has been incorporated by reference. See § 89.6.

(ii) The HFID optimization procedures outlined in § 86.331–79 of this chapter.

(iii) Alternative procedures may be used if approved in advance by the Administrator.

(3) After the optimum flow rates have been determined, record them for future reference.

(c) *Initial and periodic calibration.* Prior to introduction into service and monthly thereafter, the FID or HFID hydrocarbon analyzer shall be calibrated on all normally used instrument ranges using the steps in this paragraph. Use the same flow rate and pressures as when analyzing samples. Calibration gases shall be introduced directly at the

analyzer, unless the "overflow" calibration option of § 86.1310–90(b)(3)(i) of this chapter for the HFID is taken.

(1) Adjust analyzer to optimize performance.

(2) Zero the hydrocarbon analyzer with zero-grade air.

(3) Calibrate on each used operating range with propane-in-air (dilute) or propane-in-nitrogen (raw) calibration gases having nominal concentrations starting between 10–15 percent and increasing in at least six incremental steps to 90 percent of that range. The incremental steps are to be spaced to represent good engineering practice. For each range calibrated, if the deviation from a least-squares best-fit straight line is 2 percent or less of the value at each data point, concentration values may be calculated by use of a single calibration factor for that range. If the deviation exceeds 2 percent at any point, the best-fit non-linear equation which represents the data to within 2 percent of each test point shall be used to determine concentration.

(d) *Oxygen interference optimization.* Choose a range where the oxygen interference check gases will fall in the upper 50 percent. Conduct the test, as outlined in this paragraph, with the oven temperature set as required by the instrument manufacturer. Oxygen interference check gas specifications are found in § 89.312–96(d).

(1) Zero the analyzer.

(2) Span the analyzer with the purified synthetic air specified in § 89.312–96(b)(4).

(3) Recheck zero response. If it has changed more than 0.5 percent of full scale repeat paragraphs (d)(1) and (d)(2) of this section to correct problem.

(4) Introduce the 5 percent and 10 percent oxygen interference check gases.

(5) Recheck the zero response. If it has changed more ±1 percent of full scale, repeat the test.

(6) Calculate the percent of oxygen interference (designated as *percent O_2I*) for each mixture in paragraph (d)(4) of this section.

$$\text{percent } O_2I = \frac{(B-C)}{B}(100)$$

A=hydrocarbon concentration (ppmC) of the span gas used in paragraph (d)(2) of this section.

B=hydrocarbon concentration (ppmC) of the oxygen interference check gases used in paragraph (d)(4) of this section.

$$C = \text{analyzer response (ppmC)} = \frac{A}{D}$$

D=percent of full-scale analyzer response due to *A*.

(7) The percent of oxygen interference (designated as *$\%O_2I$*) must be less than ± 3.0 percent for all required oxygen interference check gases prior to testing.

(8) If the oxygen interference is greater than the specifications, incrementally adjust the air flow above and below the manufacturer's specifications, repeating paragraphs (d)(1) through (d)(7) of this section for each flow.

(9) If the oxygen interference is greater than the specification after adjusting the air flow, vary the fuel flow and thereafter the sample flow, repeating paragraphs (d)(1) through (d)(7) of this section for each new setting.

(10) If the oxygen interference is still greater than the specifications, repair or replace the analyzer, FID fuel, or burner air prior to testing. Repeat this section with the repaired or replaced equipment or gases.

§ 89.320–96 Carbon monoxide analyzer calibration.

(a) Calibrate the NDIR carbon monoxide as described in this section.

(b) *Initial and periodic interference check.* Prior to its introduction into service and annually thereafter, the NDIR carbon monoxide analyzer shall be checked for response to water vapor and CO_2 in accordance with § 318.96(b).

(c) *Initial and periodic calibration.* Prior to its introduction into service and monthly thereafter, the NDIR carbon monoxide analyzer shall be calibrated.

(1) Adjust the analyzer to optimize performance.

(2) Zero the carbon monoxide analyzer with either zero-grade air or zero-grade nitrogen.

(3) Calibrate on each used operating range with carbon monoxide-in-N_2 calibration gases having nominal concentrations starting between 10 and 15 percent and increasing in at least six incremental steps to 90 percent of that range. The incremental steps are to be spaced to represent good engineering practice. For each range calibrated, if the deviation from a least-squares best-fit straight line is 2 percent or less of the value at each data point, concentration values may be calculated by use of a single calibration factor for that range. If the deviation exceeds 2 percent at any point, the best-fit non-linear equation which represents the data to within 2 percent of each test point shall be used to determine concentration.

(d) The initial and periodic interference, system check, and calibration test procedures specified in part 86, subpart D of this chapter may be used in lieu of the procedures specified in this section.

§ 89.321–96 Oxides of nitrogen analyzer calibration.

(a) The chemiluminescent oxides of nitrogen analyzer shall receive the initial and periodic calibration described in this section.

(b) Prior to its introduction into service, and monthly thereafter, the chemiluminescent oxides of nitrogen analyzer is checked for NO_2 to NO converter efficiency according to § 89.317–96.

(c) *Initial and periodic calibration.* Prior to its introduction into service, and monthly thereafter, the chemiluminescent oxides of nitrogen analyzer shall be calibrated on all normally used instrument ranges. Use the same flow rate as when analyzing samples. Proceed as follows:

(1) Adjust analyzer to optimize performance.

(2) Zero the oxides of nitrogen analyzer with zero-grade air or zero-grade nitrogen.

(3) Calibrate on each normally used operating range with NO-in-N_2 calibration gases with nominal concentrations starting at between 10 and 15 percent and increasing in at least six incremental steps to 90 percent of that range. The incremental steps are to be spaced to represent good engineering practice. For each range calibrated, if the deviation from a least-squares best-fit straight line is 2 percent or less of the value at each data point, concentration values may be calculated by use of a single calibration factor for that range. If the deviation exceeds 2 percent at any point, the best-fit non-linear equation which represents the data to within 2 percent of each test point shall be used to determine concentration.

(d) The initial and periodic interference, system check, and calibration test procedures specified in part 86, subpart D of this chapter may be used in lieu of the procedures specified in this section.

§ 89.322–96 Carbon dioxide analyzer calibration.

(a) Prior to its introduction into service, and monthly thereafter, the NDIR carbon dioxide analyzer shall be calibrated as follows:

(1) Follow good engineering practices for instrument start-up and operation. Adjust the analyzer to optimize performance.

(2) Zero the carbon dioxide analyzer with either zero-grade air or zero-grade nitrogen.

(3) Calibrate on each normally used operating range with carbon dioxide-in-N_2 calibration or span gases having nominal concentrations starting between 10 and 15 percent and

increasing in at least six incremental steps to 90 percent of that range. The incremental steps are to be spaced to represent good engineering practice. For each range calibrated, if the deviation from a least-squares best-fit straight line is 2 percent or less of the value at each data point, concentration values may be calculated by use of a single calibration factor for that range. If the deviation exceeds 2 percent at any point, the best-fit non-linear equation which represents the data to within 2 percent of each test point shall be used to determine concentration.

(b) The initial and periodic interference, system check, and calibration test procedures specified in part 86, subpart D of this chapter may be used in lieu of the procedures in this section.

§ 89.323–96 NDIR analyzer calibration.

(a) *Detector optimization.* If necessary, follow the instrument manufacturer's instructions for initial start-up and basic operating adjustments.

(b) *Calibration curve.* Develop a calibration curve for each range used as follows:

(1) Zero the analyzer.

(2) Span the analyzer to give a response of approximately 90 percent of full-scale chart deflection.

(3) Recheck the zero response. If it has changed more than 0.5 percent of full scale, repeat the steps given in paragraphs (b)(1) and (b)(2) of this section.

(4) Record the response of calibration gases having nominal concentrations starting between 10 and 15 percent and increasing in at least six incremental steps to 90 percent of that range. The incremental steps are to be spaced to represent good engineering practice.

(5) Generate a calibration curve. The calibration curve shall be of fourth order or less, have five or fewer coefficients. If any range is within 2 percent of being linear a linear calibration may be used. Include zero as a data point. Compensation for known impurities in the zero gas can be made to the zero-data point. The calibration curve must fit the data points within 2 percent of point.

(6) Optional. A new calibration curve need not be generated if:

(i) A calibration curve conforming to paragraph (b)(5) of this section exists; or

(ii) The responses generated in paragraph (b)(4) of this section are within 1 percent of full scale or 2 percent of point, whichever is less, of the responses predicted by the calibration curve for the gases used in paragraph (b)(4) of this section.

(7) If multiple range analyzers are used, the lowest range used must meet the curve fit requirements below 15 percent of full scale.

§ 89.324–96 Calibration of other equipment.

Other test equipment used for testing shall be calibrated as often as required by the instrument manufacturer or as necessary according to good practice.

§ 89.325–96 Engine intake air temperature measurement.

(a) Engine intake air temperature measurement must be made within 122 cm of the engine. The measurement location must be made either in the supply system or in the air stream entering the supply system.

(b) The temperature measurements shall be accurate to within ±2 °C.

§ 89.326–96 Engine intake air humidity measurement.

(a) *Humidity conditioned air supply.* Air that has had its absolute humidity altered is considered humidity-conditioned air. For this type of intake air supply, the humidity measurements must be made within the intake air supply system and after the humidity conditioning has taken place.

(b) *Nonconditioned air supply procedure.* Humidity measurements in nonconditioned intake air supply systems must be made in the intake air stream entering the supply system. Alternatively, the humidity measurements can be measured within the intake air supply stream.

§ 89.327–96 Charge cooling.

For engines with an air-to-air intercooler (or any other low temperature charge air cooling device) between the turbocharger compressor and the intake manifold, follow SAE J1937. This procedure has been incorporated by reference. See § 89.6. The temperature of the cooling medium and the temperature of the charge air shall be monitored and recorded.

§ 89.328–96 Inlet and exhaust restrictions.

(a) The manufacturer is liable for emission compliance over the full range of restrictions that are specified by the manufacturer for that particular engine.

(b) Perform testing at the following inlet and exhaust restriction settings.

(1) Equip the test engine with an air inlet system presenting an air inlet restriction at the upper limit at maximum air flow, as specified by the engine manufacturer for a clean air cleaner. A system representative of the installed engine may be used. In other cases a test shop system may be used.

(2) The exhaust backpressure must be at the upper limit at maximum declared power, as specified by the engine manufacturer. A system representative of the installed engine may be used. In other cases a test shop system may be used.

§ 89.329–96 Engine cooling system.

An engine cooling system is required with sufficient capacity to maintain the engine at normal operating temperatures as prescribed by the engine manufacturer.

§ 89.330–96 Lubricating oil and test fuels.

(a) *Lubricating oil.* Use the engine lubricating oil for testing that meets the requirements as specified by the manufacturer for a particular engine and intended usage. Record the specifications of the lubricating oil used for the test.

(b) *Test fuels.* (1) Use diesel fuels for testing which are clean and bright, with pour and cloud points adequate for operability. The diesel fuel may contain nonmetallic additives as follows: Cetane improver, metal deactivator, antioxidant, dehazer, antirust, pour depressant, dye, dispersant, and biocide.

(2) Use only petroleum fuel meeting the specifications in Table 4 in appendix A of this subpart, or substantially equivalent specifications approved by the Administrator, for exhaust emission testing. Alternatively, petroleum fuel meeting the specifications in Table 5 in appendix A of this subpart may be used in exhaust emission testing. The grade of diesel fuel used must be commercially designated as "Type 2–D" grade diesel fuel and recommended by the engine manufacturer. If the fuel specified in Table 4 in Appendix A of this subpart is used, the adjustment factor specified in § 89.425–96 may be applied to particulate emission values to account for the impact of sulfur in fuel on particulate emissions.

(c) Other fuels may be used for testing provided they meet the following qualifications:

(1) They are commercially available;

(2) Information acceptable to the Administrator is provided to show that only the designated fuel would be used in customer service;

(3) Use of a fuel listed under paragraph (b) of this section would have a detrimental effect on emissions or durability; and

(4) Fuel specifications are approved in writing by the Administrator prior to the start of testing.

(d) Report the specification range of the fuel to be used under paragraphs

(b)(2) and (c)(1) through (c)(4) of this section in the application for certification in accordance with § 89.115–96 (a)(8).

§ 89.331–96 Test conditions.

(a) *General requirements.* Calculate all volumes and volumetric flow rates at standard conditions for temperature and pressure (0 °C and 101.3 kPa), and these conditions must be used consistently throughout all calculations.

(b) *Engine test conditions.* Measure the absolute temperature (designated as *T* and expressed in Kelvin) of the engine air at the inlet to the engine, and the dry atmospheric pressure (designated as *p* and expressed in kPa), and determine the parameter *f* according to the following provisions:

(1) Naturally aspirated and mechanically supercharged engines:

$$f = \frac{99}{p_s} \times \left(\frac{T}{298}\right)^{0.7}$$

(2) Turbocharged engine with or without cooling of inlet air:

$$f = \left(\frac{99}{p_s}\right)^{0.7} \times \left(\frac{T}{298}\right)^{1.5}$$

(c) For a test to be recognized as valid, the parameter *f* shall be between the limits as shown below:

$$0.98 < f < 1.02$$

Appendix A to Subpart D—Tables

TABLE 1.—ABBREVIATIONS USED IN SUBPART D

CLD	Chemiluminescent detector.
CO	Carbon monoxide.
CO_2	Carbon dioxide.
HC	Hydrocarbons.
HCLD	Heated chemiluminescent detector.
HFID	Heated flame ionization detector.
NDIR	Non-dispersive infra-red analyzer.
NIST	National Institute for Standards and Testing.
NO	Nitric Oxide.
NO_2	Nitrogen Dioxide.
NOx	Oxides of nitrogen.
O_2	Oxygen.
PMD	Paramagnetic detector.
ZROD	Zirconiumdioxyde sensor.

TABLE 2.—SYMBOLS USED IN SUBPART D

Symbol	Term	Unit
Conc	Concentration (ppm by volume)	ppm
f	Engine specific parameter considering atmospheric conditions	
F_{FCB}	Fuel specific factor for the carbon balance calculation	
F_{FD}	Fuel specific factor for exhaust flow calculation on dry basis	
F_{FH}	Fuel specific factor representing the hydrogen to carbon ratio	
F_{FW}	Fuel specific factor for exhaust flow calculation on wet basis	
G_{AIRW}	Intake air mass flow rate on wet basis	kg/h
G_{AIRD}	Intake air mass flow rate on dry basis	kg/h
G_{EXHW}	Exhaust gas mass flow rate on wet basis	kg/h
G_{Fuel}	Fuel mass flow rate	kg/h
H	Absolute humidity (water content related to dry air)	g/kg
i	Subscript denoting an individual mode	
K_H	Humidity correction factor	
L	Percent torque related to maximum torque for the test mode	%
Mass	Pollutant mass flow	g/h
$n_{d,i}$	Engine speed (average at the i'th mode during the cycle)	1/min
P_s	Dry atmospheric pressure	kPa
P_d	Test ambient saturation vapor pressure at ambient temperature	kPa
P	Gross power output uncorrected	kW
P_{AUX}	Declared total power absorbed by auxiliaries fitted for the test	kW
P_M	Maximum power measured at the test speed under test conditions	kW
P_i	$P_i = P_{M,i} + P_{AUX,i}$	
P_B	Total barometric pressure (average of the pre-test and post-test values)	kPa
R_a	Relative humidity of the ambient air	%
S	Dynamometer setting	kW
T	Absolute temperature at air inlet	K
T_{bc}	Air temperature after the charge air cooler (if applicable) (average)	K
T_{clout}	Coolant temperature outlet (average)	K
T_{DU}	Absolute dewpoint temperature	K
$T_{d,i}$	Torque (average at the i'th mode during the cycle)	N-m
T_{SC}	Temperature of the intercooled air	K
$T_{ref.}$	Reference temperature	K
V_{EXHD}	Exhaust gas volume flow rate on dry basis	m^3/h
V_{AIRW}	Intake air volume flow rate on wet basis	m^3/h
P_B	Total barometric pressure	kPa
V_{EXHW}	Exhaust gas volume flow rate on wet basis	m^3/h
WF	Weighing factor.	
WF_E	Effective weighing factor.	

TABLE 3.—MEASUREMENT ACCURACY CALIBRATION FREQUENCY (MY96 AND LATER)

No.	Item	Permissible deviation from reading [1]		Calibration frequency
		Nonidle	Idle	
1	Engine speed	±2%	±2%	30 days.

TABLE 3.—MEASUREMENT ACCURACY CALIBRATION FREQUENCY (MY96 AND LATER)—Continued

No.	Item	Permissible deviation from reading [1]		Calibration frequency
		Nonidle	Idle	
2	Torque	±2%	±5%	30 days.
3	Fuel consumption	±1%	±5%	30 days.
4	Air consumption	±2%	±5%	As required.
5	Coolant temperature	±2 °K	Same	As required.
6	Lubricant temperature	±2 °K	Same	As required.
7	Exhaust backpressure	±5%	Same	As required.
8	Inlet depression	±5%	Same	As required.
9	Exhaust gas temperature	±15 °K	Same	As required.
10	Air inlet temperature (combustion air)	±2 °K	Same	As required.
11	Atmospheric pressure	±0.5%	Same	As required.
12	Humidity (combustion air) (relative)	±3.0%	Same	As required.
13	Fuel temperature	±2 °K	Same	As required.
14	Temperature with regard to dilution tunnel	±2 °K	Same	As required.
15	Dilution air humidity	±3% absolute.	Same	As required.
16	HC analyzer	±2% [2]	Same	30 days.
17	CO analyzer	±2% [2]	Same	30 days.
18	NO_X analyzer	±2% [2]	Same	30 days.
19	NO_X converter efficiency check	90%	Same	30 days.
20	CO_2 analyzer	±2% [2]	Same	30 days.

[1] All accuracy requirements pertain to the final recorded value which is inclusive of the data acquisition system.
[2] If reading is under 100 ppm then the accuracy shall be ±2 ppm.

TABLE 4. TEST FUEL SPECIFICATIONS FOR MY96 AND LATER:FEDERAL SPECIFICATIONS

Item	Procedure (ASTM) [1]	Value (type 2–D)
Cetane	D613–86	42–50
Distillation range:		
IBP, °C	D86–90	171–204
10% point, °C	D86–90	204–235
50% point, °C	D86–90	243–283
90% point, °C	D86–90	293–332
EP, °C	D86–90	321–366
Gravity, API	D287–92	33–37
Total sulfur, %mass	D129–91 or D2622–92	>0.05—0.5
Hydrocarbon composition:		
Aromatics, %vol.	D1319–89	[2]10
Parafins,	D1319–89	[3]
Napthenes,		
Olefins,		
Flashpoint, °C (minimum)	D93–90	54
Viscosity @ 38 °C, Centistokes	D445–88	2.0–3.2

[1] All ASTM procedures in this table have been incorporated by reference. See §89.6.
[2] Minimum.
[3] Remainder.

TABLE 5.—TEST FUEL SPECIFICATIONS FOR MY96 AND LATER: CALIFORNIA SPECIFICATIONS

Item	Procedure (ASTM) [1]	Value (type 2–D)
Cetane	D613–86	40–48
Distillation range:		
IBP, °C	D86–90	171–204
10% point, °C	D86–90	204–235
50% point, °C	D86–90	243–283
90% point, °C	D86–90	293–332
EP, °C	D86–90	321–366
Gravity, API	D287–92	33–37
Total sulfur, %mass	D129–91 or D2622–92	.03–.05
Hydrocarbon composition:		
Aromatics %vol.	D1319–89	10[2]
Parafins	D1319–89	([3])
Napthenes		
Olefins		
Flashpoint, °C (minimum)	D93–90	54

TABLE 5.—TEST FUEL SPECIFICATIONS FOR MY96 AND LATER: CALIFORNIA SPECIFICATIONS—Continued

Item	Procedure (ASTM) [1]	Value (type 2–D)
Viscosity @ 38 °C, centistokes	D445–88	2.0–3.2

[1] All ASTM procedures in this table have been incorporated by reference. See § 89.6.
[2] Minimum.
[3] Remainder.

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Appendix B to Subpart D—Figures

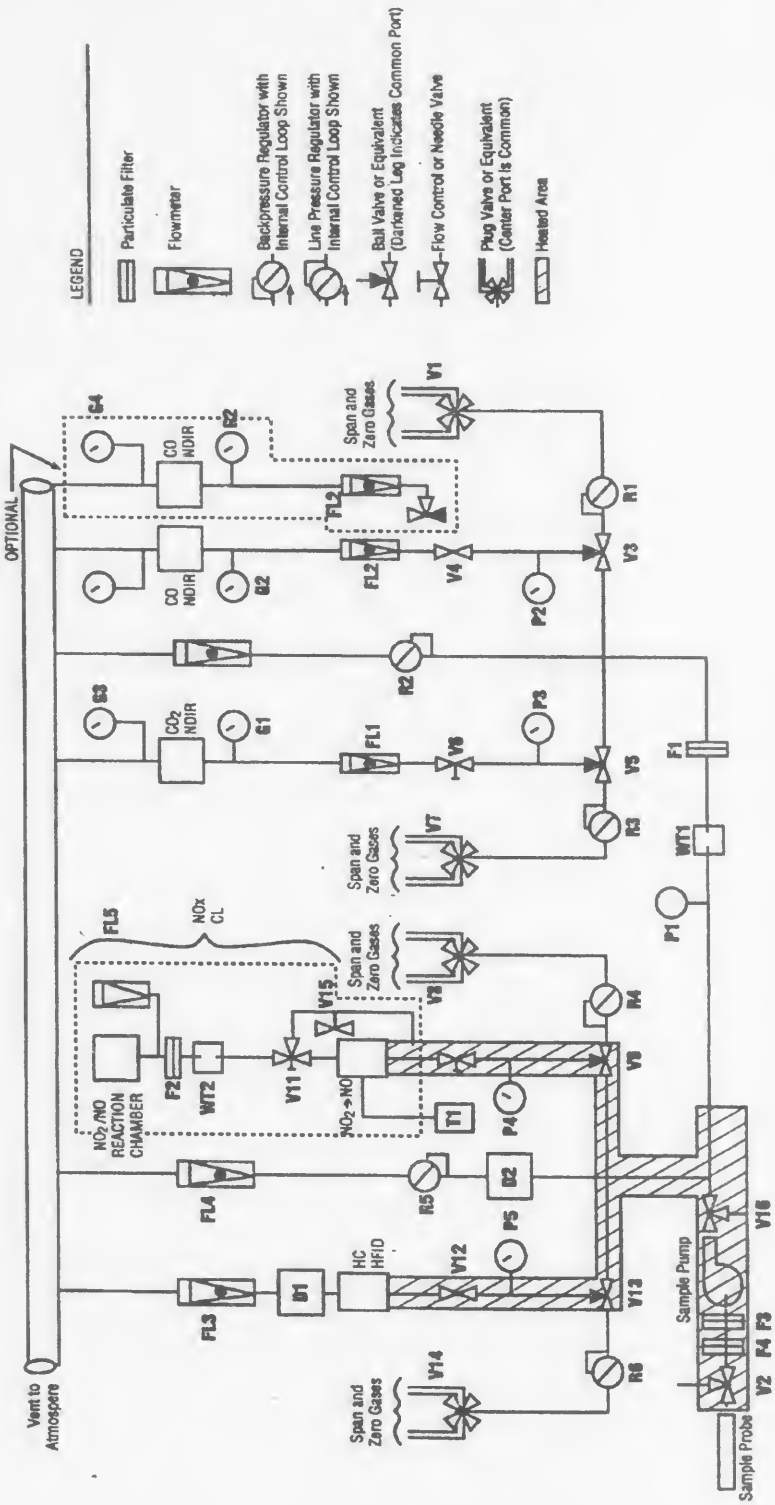

Figure 1. — Exhaust Gas Sampling and Analytical Train

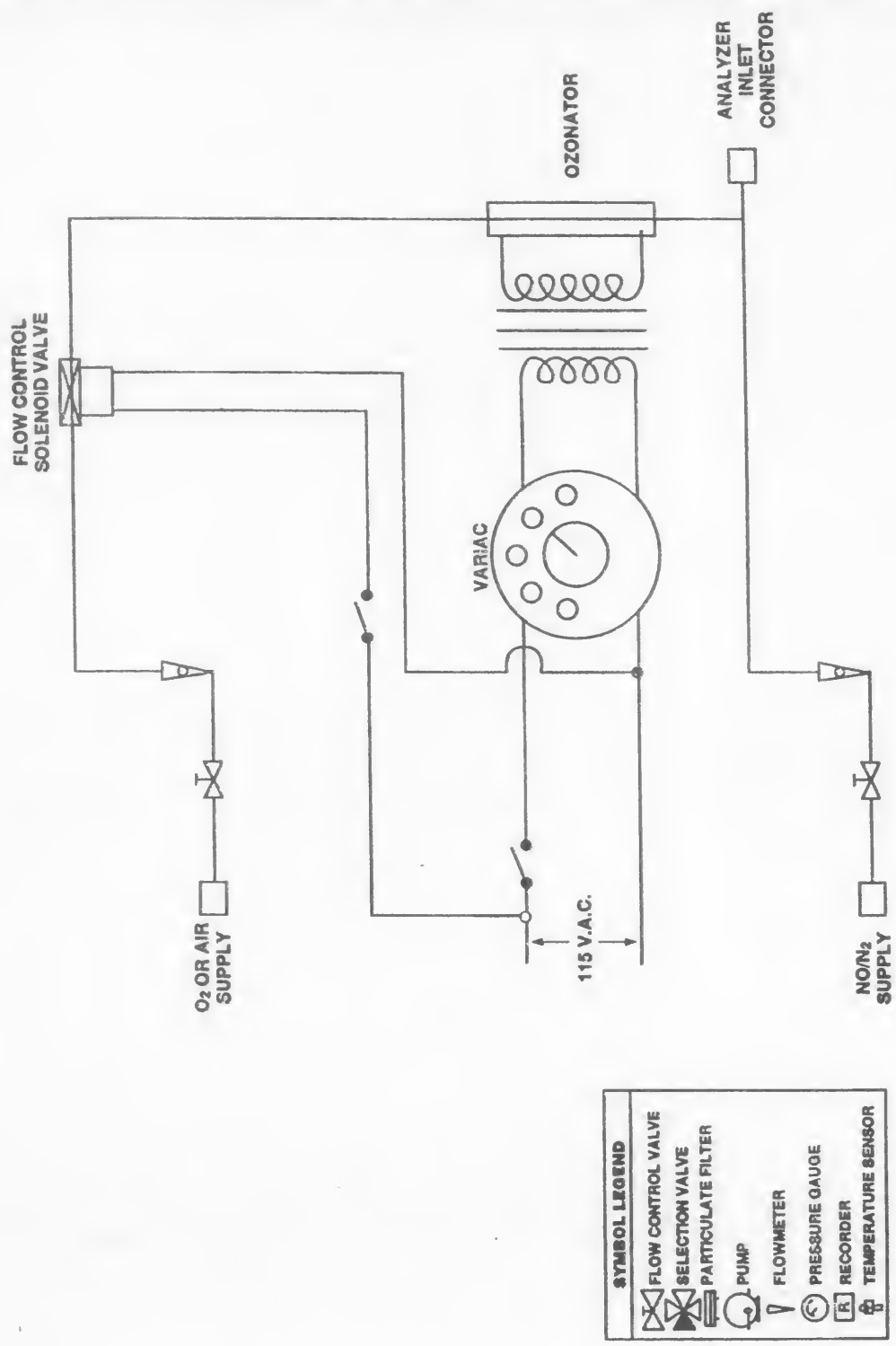

Figure 2. — NOx Converter Efficiency Detector

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Subpart E—Exhaust Emission Test Procedures

§ 89.401–96 Scope; applicability.

(a) This subpart describes the procedures to follow in order to perform exhaust emission tests on new nonroad compression-ignition engines subject to the provisions of subpart B of this part.

(b) Exhaust gases, either raw or dilute, are sampled while the test engine is operated using an 8-mode test cycle on an engine dynamometer. The exhaust gases receive specific component analysis determining concentration of pollutant, exhaust volume, the fuel flow, and the power output during each mode. Emission is reported as grams per kilowatt hour (g/kW-hr).

(c) Requirements for emission test equipment and calibrating this equipment are found in subpart D of this part.

§ 89.402–96 Definitions.

The definitions in subpart A of this part apply to this subpart. For terms not defined in this part, the definitions in part 86, subparts A, D, I, and N of this chapter apply to this subpart. The following definition also applies to this subpart.

Specific emissions, (g/kW-hr), shall be expressed on the basis of observed gross power.

When it is not possible to test the engine in the gross conditions, for example, if the engine and transmission form a single integral unit, the engine may be tested in the net condition. Power corrections from net to gross conditions will be allowed with prior approval of the Administrator.

§ 89.403–96 Symbols/abbreviations.

(a) The abbreviations in § 86.094–3 or § 89.3 of this chapter apply to this subpart.

(b) The abbreviations in Table 1 in appendix A to subpart D also apply to this subpart. Some abbreviations from § 89.3 have been included for the convenience of the reader.

(c) The symbols in Table 2 in appendix A to subpart D apply to this subpart.

§ 89.404–96 Test procedure overview.

(a) The test consists of prescribed sequences of engine operating conditions to be conducted on an engine dynamometer. The exhaust gases, generated raw or dilute during engine operation, are sampled for specific component analysis through the analytical train. The test is applicable to engines equipped with catalytic or direct-flame afterburners, induction system modifications, or other systems, or to uncontrolled engines.

(b) The test is designed to determine the brake-specific emissions of hydrocarbons, carbon monoxide, and oxides of nitrogen. The test consists of one idle mode, four power modes at one speed and three power modes at another speed. These procedures require the determination of the concentration of each pollutant, exhaust volume, the fuel flow, and the power output during each mode. The measured values are weighted and used to calculate the grams of each pollutant emitted per kilowatt hour (g/kW-hr).

(c) (1) When an engine is tested for exhaust emissions, the complete engine shall be tested with all emission control devices installed and functioning.

(2) On air-cooled engines, the fan shall be installed.

(3) Additional accessories (for example, oil cooler, alternators, or air compressors) may be installed but such accessory loading will be considered parasitic in nature and observed power shall be used in the emission calculation.

(d) All emission control systems installed on or incorporated in the application must be functioning during all procedures in this subpart. In cases of component malfunction or failure, maintenance to correct component failure or malfunction must be authorized in accordance with § 86.094–25 of this chapter.

(e) The engine must be equipped with an electrical generation device typical of one used in customer service (such as an alternator). The power drain from it must be no greater than what is sufficient to operate the engine on the test stand.

§ 89.405–96 Recorded information.

(a) The information described in this section must be recorded, where applicable, for each test.

(b) *Engine description and specification.* A copy of the information specified in this paragraph must accompany each engine sent to the Administrator for compliance testing. The manufacturer need not record the information specified in this paragraph for each test if the information, with the exception of paragraphs (b)(3) and (b)(9) of this section, is included in the manufacturer's application for certification.

(1) Engine-system combination.

(2) Engine identification numbers.

(3) Number of hours of operation accumulated on engine.

(4) Rated maximum horsepower and torque.

(5) Maximum horsepower and torque speeds.

(6) Engine displacement.

(7) Governed speed.

(8) Idle rpm.

(9) Fuel consumption at maximum power and torque.

(10) Maximum air flow.

(11) Air inlet restriction.

(12) Exhaust pipe diameter(s).

(13) Maximum exhaust system backpressure.

(c) *Test data; general.*

(1) Engine-system combination.

(2) Engine identification number.

(3) Instrument operator.

(4) Engine operator.

(5) Number of hours of operation accumulated on the engine prior to beginning the warm-up portion of the test.

(6) Fuel identification.

(7) Date of most recent analytical assembly calibration.

(8) All pertinent instrument information such as tuning, gain, serial numbers, detector number, and calibration curve numbers. As long as this information is available for inspection by the Administrator, it may be summarized by system number or analyzer identification numbers.

(d) *Test data; pre-test.*

(1) Date and time of day.

(2) Test number.

(3) Barometric pressure, pre-test segment.

(4) Engine intake humidity, pre-test segment for compression-ignition engines with non-conditioned air supply systems.

(5) Maximum observed torque for intermediate and rated speeds.

(6) Recorder chart or equivalent. Identify for each test segment zero traces for each range used, and span traces for each range used.

(7) Air temperature after and pressure drop across the charge air cooler (if applicable) at maximum observed torque and rated speed.

(e) *Test data; modal.*

(1) Recorder chart or equivalent. Identify for each test mode the emission concentration traces and the associated analyzer range(s). The start and finish of each test.

(2) Observed engine torque.

(3) Observed engine rpm.

(4) Record engine torque and engine rpm continuously with a chart recorder or equivalent recording device.

(5) Intake air flow and depression for each mode.

(6) Engine intake air temperature for each mode.

(7) Mass fuel flow for each mode.

(8) Engine intake humidity.

(9) Coolant temperature outlet.

(10) Engine fuel inlet temperature, location to be representative of in-use as specified by each manufacturer.

(f) *Test data; post-test.*

(1) Recorder chart or equivalent. Identify the zero traces for each range used and the span traces for each range used. Identify hangup check, if performed.

(2) Total number of hours of operation accumulated on the engine.

(3) Barometric pressure, post-test segment.

(4) Engine intake humidity, post-test segment for compression-ignition engines with non-conditioned air supply systems.

§ 89.406–96 Pre-test procedures.

(a) Allow a minimum of 30 minutes warmup in the standby or operating mode prior to spanning the analyzers.

(b) Replace or clean the filter elements and then vacuum leak check the system per § 89.316–96(a). A pressure leak check is also permitted per § 89.316–96(b). Allow the heated sample line, filters, and pumps to reach operating temperature.

(c) Perform the following system checks:

(1) Check the sample-line temperature (see § 86.310–79 of this chapter for raw test procedures or § 86.1310–90 of this chapter for dilute test procedures).

(2) Check that the system response time has been accounted for prior to sample collection data recording.

(3) A hang-up check is permitted, but is optional.

(d) Check analyzer zero and span at a minimum before and after each test. Further, check analyzer zero and span any time a range change is made or at the maximum demonstrated time span for stability for each analyzer used.

(e) Check system flow rates and pressures.

§ 89.407–96 Engine dynamometer test run.

(a) Measure and record the temperature of the air supplied to the engine, the fuel temperature at the pump inlet, and the observed barometric pressure.

(b) The governor and fuel system shall have been adjusted to provide engine performance at the levels reported in the application for certification required under § 89.115–96.

(c) The following steps are taken for each test:

(1) Install instrumentation and sample probes as required.

(2) Perform the pre-test procedure as specified in § 89.406–96.

(3) Read and record the general test data as specified in § 89.405–96(c).

(4) Start cooling system.

(5) Precondition (warm up) the engine in the following manner:

(i) Operate the engine at idle for 2 to 3 minutes;

(ii) Operate the engine at approximately 50 percent power at the peak torque speed for 5 to 7 minutes;

(iii) Operate the engine at rated speed and maximum horsepower for 25 to 30 minutes;

(iv) Optional. It is permitted to precondition the engine at rated speed and maximum horsepower until the oil and water temperatures are stabilized. The temperatures are defined as stabilized if they are maintained within ±2 °C for 2 minutes. The engine must be operated a minimum of 10 minutes for this option. This optional procedure may be substituted for the procedure in paragraph (c)(5)(iii) of this section;

(v) Optional. If the engine has been operating on service accumulation for a minimum of 40 minutes, the service accumulation may be substituted for the procedure in paragraphs (c)(5)(i) through (iii) of this section.

(6) Read and record all pre-test data specified in § 89.405–96(d).

(7) Start the test cycle (see § 89.410–96) within 20 minutes of the end of the warmup. (See paragraph (c)(13) of this section.)

(8) During the first mode calculate the torque corresponding to 75, 50, and 10 percent of the maximum observed torque for the rated speed.

(9) During the fifth mode calculate the torque corresponding to 75 and 50 percent of the maximum observed torque for the intermediate speed.

(10) Record all modal data specified in § 89.405–96(e) during a minimum of the last 60 seconds of each mode.

(11) Record the analyzer(s) response to the exhaust gas during the a minimum of the last 60 seconds of each mode.

(12) Test modes may be repeated, as long as the engine is preconditioned by running the previous mode.

(13) If a delay of more than 20 minutes occurs between the end of one mode and the beginning of another mode, the test is void. If the delay is under four hours, the test may be restarted without preconditioning (begin at the point in the procedure described at paragraph (c)(6) of this section). If the delay exceeds 4 hours, the test shall include preconditioning (begin at paragraph (c)(2) of this section).

(14) The engine speed and torque must be measured within the accuracy requirements of Table 3 (in appendix A to subpart D), and maintained within the requirements of Table 1 (in appendix B to this subpart) during a minimum of the last 60 seconds of each mode.

(15) If at any time during a test mode, the test equipment malfunctions or the specifications in paragraph (c)(14) of this section are not met, the test mode is void and may be aborted. The test mode may be restarted without preconditioning (begin with paragraph (c)(6) of this section).

(16) Fuel flow and air flow during the idle load condition may be determined just prior to or immediately following the dynamometer sequence, if longer times are required for accurate measurements.

(d) *Exhaust gas measurements.* (1) Measure HC, CO, CO_2, and NO_x concentration in the exhaust sample.

(2) Each analyzer range that may be used during a test mode must have the zero and span responses recorded prior to the execution of that test mode. Only the zero and span for the range(s) used to measure the emissions during a test mode are required to be recorded after the completion of the test mode.

(3) It is permissible to change filter elements between test modes.

(4) A leak check is permitted between test segments.

(5) A hangup check is permitted between test segments.

(6) If, during the emission measurement portion of a test segment, the value of the gauges downstream of the NDIR analyzer(s) *G3* or *G4* (see Figure 1 in appendix B to subpart D) differs by more than ±0.5 kPa from the pretest value, the test segment is void.

§ 89.408–96 Post-test procedures.

(a) A hangup check is recommended at the completion of the last test mode using the following procedure:

(1) Within 30 seconds introduce a zero-grade gas or room air into the sample probe or valve *V2* (see Figure 1 in appendix B to subpart D) to check the "hangup zero" response. Simultaneously start a time measurement.

(2) Select the lowest HC range used during the test.

(3) Within four minutes of beginning the time measurement in paragraph (a)(1) of this section, the difference between the span-zero response and the hangup zero response shall not be greater than 5.0 percent of full scale or 10 ppmC whichever is greater.

(b) Begin the analyzer span checks within 6 minutes after the completion of the last mode in the test. Record for each analyzer the zero and span response for each range used during the preceding test or test segment.

(c) If during the test, the filter element(s) were replaced or cleaned, a vacuum check must be performed per § 89.316–96(a) immediately after the span checks. If the vacuum side leak check does not meet the requirements of § 89.316–96(a), the test is void.

(d) Record the post-test data specified in § 89.405–96(f).

(e) For a valid test, the analyzer drift between the before-mode and after-mode span checks for each analyzer must meet the following requirements:

(1) The span drift (defined as the change in the difference between the zero response and the span response) must not exceed 2 percent of full-scale chart deflection for each range used.

(2) The zero response drift must not exceed 2 percent of full-scale chart deflection for each range used above 155 ppm (or ppmC) or 3 percent of full-scale chart deflection for each range below 155 ppm (or ppmC).

§ 89.409–96 Data logging.

(a) A computer or any other automatic data processing device(s) may be used as long as the system meets the requirements of this subpart.

(b) Determine from the data collection records the analyzer responses corresponding to the end of each mode.

(c) Record data at a minimum of once every 5 seconds.

(d) Determine the final value for CO_2, CO, HC, and NO_X concentrations by averaging the concentration of each point taken during the sample period for each mode.

(e) For purposes of this section, calibration data includes calibration curves, linearity curves, span-gas responses, and zero-gas responses.

§ 89.410–96 Engine test cycle.

(a) The 8-mode cycle (see Table 1 in Appendix B to this subpart) shall be followed in dynamometer operation tests of compression-ignition nonroad engines.

(b) During each non-idle mode, hold the specified speed and load to within ±2 percent of point. During each idle mode, speed must be held within the manufacturer's specifications for the engine, and the throttle must be in the fully closed position and torque must not exceed 5 percent of the peak torque value of mode 5.

(c) If the operating conditions specified in paragraph (b) of this section for modes 2, 3, 4, 6, and 7 cannot be maintained, the Administrator may authorize deviations from the specified load conditions. Such deviations shall not exceed 10 percent of the maximum torque at the test speed. The minimum deviations, above and below the specified load, necessary for stable operation shall be determined by the manufacturer and approved by the Administrator prior to the test run.

(d) Power generated during the idle mode may not be included in the calculation of emission results.

§ 89.411–96 Exhaust sample procedure—gaseous components.

(a) *Automatic data collection equipment requirements.* The analyzer response may be read by automatic data collection (ADC) equipment such as computers, data loggers, and so forth. If ADC equipment is used, the following is required:

(1) For bag sample analysis, the analyzer response must be stable at greater than 99 percent of the final reading for the dilute exhaust sample bag. A single value representing the average chart deflection over a 10-second stabilized period shall be stored.

(2) For continuous analysis systems, a single value representing the average integrated concentration over a cycle shall be stored.

(3) The chart deflections or average integrated concentrations required in paragraphs (a)(1) and (a)(2) of this section may be stored on long-term computer storage devices such as computer tapes, storage discs, punch cards, and so forth, or they may be printed in a listing for storage. In either case a chart recorder is not required and records from a chart recorder, if they exist, need not be stored.

(4) If ADC equipment is used to interpret analyzer values, the ADC equipment is subject to the calibration specifications of the analyzer as if the ADC equipment is part of analyzer system.

(b) Data records from any one or a combination of analyzers may be stored as chart recorder records.

(c) *Bag sample analysis.* For bag sample analysis perform the following sequence:

(1) Warm up and stabilize the analyzers; clean and/or replace filter elements, conditioning columns (if used), and so forth, as necessary.

(2) Obtain a stable zero reading.

(3) Zero and span the analyzers with zero and span gases. The span gases must have concentrations between 75 and 100 percent of full-scale chart deflection. The flow rates and system pressures during spanning shall be approximately the same as those encountered during sampling. A sample bag may be used to identify the required analyzer range.

(4) Recheck zero response. If this zero response differs from the zero response recorded in paragraph (c)(3) of this section by more than 1 percent of full scale, then paragraphs (c)(2), (c)(3), and (c)(4) of this section must be repeated.

(5) If a chart recorder is used, identify and record the most recent zero and span response as the pre-analysis values.

(6) If ADC equipment is used, electronically record the most recent zero and span response as the pre-analysis values.

(7) Measure HC, CO, CO_2, and NO_X background concentrations in the sample bag(s) with approximately the same flow rates and pressures used in paragraph (c)(3) of this section. (Constituents measured continuously do not require bag analysis.)

(8) A post-analysis zero and span check of each range must be performed and the values recorded. The number of events that may occur between the pre- and post-analysis checks is not specified. However, the difference between pre-analysis zero and span values (recorded in paragraph (c)(5) or (c)(6) of this section) versus those recorded for the post-analysis check may not exceed the zero drift limit or the span drift limit of 2 percent of full-scale chart deflection for any range used. Otherwise the test is void.

(d) *Continuous sample analysis.* For continuous sample analysis perform the following sequence:

(1) Warm up and stabilize the analyzers; clean and/or replace filter elements, conditioning columns (if used), and so forth, as necessary.

(2) Leak check portions of the sampling system that operate at negative gauge pressures when sampling, and allow heated sample lines, filters, pumps, and so forth to stabilize at operating temperature.

(3) Optional: Perform a hangup check for the HFID sampling system:

(i) Zero the analyzer using zero air introduced at the analyzer port.

(ii) Flow zero air through the overflow sampling system. Check the analyzer response.

(iii) If the overflow zero response exceeds the analyzer zero response by 2 percent or more of the HFID full-scale deflection, hangup is indicated and corrective action must be taken.

(iv) The complete system hangup check specified in paragraph (e) of this section is recommended as a periodic check.

(4) Obtain a stable zero reading.

(5) Zero and span each range to be used on each analyzer operated prior to the beginning of the test cycle. The span gases shall have a concentration between 75 and 100 percent of full-scale chart deflection. The flow rates and system pressures shall be approximately the same as those encountered during sampling. The HFID analyzer shall be zeroed and spanned through the overflow sampling system.

(6) Re-check zero response. If this zero response differs from the zero response recorded in paragraph (d)(5) of this

section by more than 1 percent of full scale, then paragraphs (d)(4), (d)(5), and (d)(6) of this section must be repeated.

(7) If a chart recorder is used, identify and record the most recent zero and span response as the pre-analysis values.

(8) If ADC equipment is used, electronically record the most recent zero and span response as the pre-analysis values.

(9) Collect background HC, CO, CO_2, and NO_x in a sample bag (for dilute exhaust sampling only, see § 89.420–96).

(10) Perform a post-analysis zero and span check for each range used at the conditions specified in paragraph (d)(5) of this section. Record these responses as the post-analysis values.

(11) Neither the zero drift nor the span drift between the pre-analysis and post-analysis checks on any range used may exceed 3 percent for HC, or 2 percent for NO_x, CO, and CO_2, of full scale chart deflection, or the test is void. (If the HC drift is greater than 3 percent of full-scale chart deflection, hydrocarbon hangup is likely.)

(12) Determine background levels of NO_x, CO, or CO_2 (for dilute exhaust sampling only) by the bag sample technique outlined in paragraph (c) of this section.

(e) *Hydrocarbon hangup.* If HC hangup is indicated, the following sequence may be performed:

(1) Fill a clean sample bag with background air.

(2) Zero and span the HFID at the analyzer ports.

(3) Analyze the background air sample bag through the analyzer ports.

(4) Analyze the background air through the entire sample probe system.

(5) If the difference between the readings obtained is 2 ppm or more, clean the sample probe and the sample line.

(6) Reassemble the sample system, heat to specified temperature, and repeat the procedure in paragraphs (e)(1) through (e)(6) of this section.

§ 89.412–96 Raw gaseous exhaust sampling and analytical system description.

(a) *Schematic drawing.* An example of a sampling and analytical system which may be used for testing under this subpart is shown in Figure 1 in appendix B to subpart D. All components or parts of components that are wetted by the sample or corrosive calibration gases shall be either chemically cleaned stainless steel or inert material, for example, polytetrafluoroethylene resin. The use of "gauge savers" or "protectors" with nonreactive diaphragms to reduce dead volumes is permitted.

(b) *Sample probe.* (1) The sample probe shall be a straight, closed-end, stainless steel, multi-hole probe. The inside diameter shall not be greater than the inside diameter of the sample line plus 0.03 cm. The wall thickness of the probe shall not be greater than 0.10 cm. The fitting that attaches the probe to the exhaust pipe shall be as small as practical in order to minimize heat loss from the probe.

(2) The probe shall have a minimum of three holes. The spacing of the radial planes for each hole in the probe must be such that they cover approximately equal cross-sectional areas of the exhaust duct. See Figure 1 in appendix A to this subpart. The angular spacing of the holes must be approximately equal. The angular spacing of any two holes in one plane may not be 180° ±20° (that is, section view C-C of Figure 1 in appendix A to this subpart). The holes should be sized such that each has approximately the same flow. If only three holes are used, they may not all be in the same radial plane.

(3) The probe shall extend radially across the exhaust duct. The probe must pass through the approximate center and must extend across at least 80 percent of the diameter of the duct.

(c) *Sample transfer line.* (1) The maximum inside diameter of the sample line shall not exceed 1.32 cm.

(2) If valve *V2* is used, the sample probe must connect directly to valve *V2*. The location of optional valve *V2* may not be greater than 1.22 m from the exhaust duct.

(3) The location of optional valve *V16* may not be greater than 61 cm from the sample pump. The leakage rate for this section on the pressure side of the sample pump may not exceed the leakage rate specification for the vacuum side of the pump.

(d) *Venting.* All vents, including analyzer vents, bypass flow, and pressure relief vents of regulators, should be vented in such a manner to avoid endangering personnel in the immediate area.

(e) Any variation from the specifications in this subpart including performance specifications and emission detection methods may be used only with prior approval by the Administrator.

(f) Additional components, such as instruments, valves, solenoids, pumps, switches, and so forth, may be employed to provide additional information and coordinate the functions of the component systems.

(g) The following requirements must be incorporated in each system used for raw testing under this subpart.

(1) The sample for all components shall be taken with one sample probe, except as allowed under § 89.413–96, and internally split to the different analyzers.

(2) The sample transport system from the engine exhaust pipe to the HC analyzer and the NO_x analyzer must be heated as indicated in Figure 1 in appendix B of subpart D.

§ 89.413–96 Raw sampling procedures.

Follow these procedures when sampling for gaseous emissions.

(a) The gaseous emission sampling probe must be installed at least 0.5 m or 3 times the diameter of the exhaust pipe—whichever is the larger—upstream of the exit of the exhaust gas system.

(b) In the case of a multi-cylinder engine with a branched exhaust manifold, the inlet of the probe shall be located sufficiently far downstream so as to ensure that the sample is representative of the average exhaust emissions from all cylinders.

(c) In multi-cylinder engines having distinct groups of manifolds, such as in a "Vee" engine configuration, it is permissible to:

(1) Sample after all exhaust pipes have been connected together into a single exhaust pipe.

(2) For each mode, sample from each exhaust pipe and average the gaseous concentrations to determine a value for each mode.

(3) Sample from all exhaust pipes simultaneously with the sample lines connected to a common manifold prior to the analyzer. It must be demonstrated that the flow rate through each individual sample line is ±4 percent of the average flow rate through all the sample lines.

(4) Use another method, if it has been approved in advance by the Administrator.

(d) All heated sampling lines shall be fitted with a heated filter to extract solid particles from the flow of gas required for analysis. The sample line for CO, CO_2, and O_2 analysis may be heated or unheated.

(e) If the composition of the exhaust gas is influenced by any treatment such as heat exchanger or air injection (except catalysts and soot filters) then the exhaust probe must be taken upstream of this device.

§ 89.414–96 Air flow measurement specifications.

(a) The air flow measurement method used must have a range large enough to accurately measure the air flow over the engine operating range during the test. Overall measurement accuracy must be

±2 percent of the reading for all modes except the idle mode. For the idle mode, the measurement accuracy shall be ±5 percent or less of the reading. The Administrator must be advised of the method used prior to testing.

(b) When an engine system incorporates devices that affect the air flow measurement (such as air bleeds) that result in understated exhaust emission results, corrections to the exhaust emission results shall be made to account for such effects.

§ 89.415–96 Fuel flow measurement specifications.

The fuel flow rate measurement instrument must have a minimum accuracy of ±1 percent of full-scale flow rate for each measurement range used. An exception is allowed at the idle point. For this mode (idle), the minimum accuracy is ±2 percent of full-scale flow rate for the measurement range used. The controlling parameters are the elapsed time measurement of the event and the weight or volume measurement.

§ 89.416–96 Raw exhaust gas flow.

The exhaust gas flow shall be determined by one of the methods described in this section and conform to the tolerances of Table 3 in appendix A to subpart D:

(a) Measurement of the air flow and the fuel flow by suitable metering systems (for details see SAE J244. This procedure has been incorporated by reference. See § 89.6.) and calculation of the exhaust gas flow as follows:

$G_{EXHW}=G_{AIRW}+G_{FUEL}$ (for wet exhaust mass)

or

$V_{EXHD}=V_{AIRD}+(-.767)\times G_{FUEL}$ (for dry exhaust volume)

or

$V_{EXHW}=V_{AIRW}+.749\times G_{FUEL}$ (for wet exhaust volume)

(b) Exhaust mass calculation from fuel consumption (see § 89.415–96) and exhaust gas concentrations using the method found in § 89.418–96.

§ 89.417–96 Data evaluation for gaseous emissions.

For the evaluation of the gaseous emission recording, the last 60 seconds of each mode are recorded, and the average values for HC, CO, CO_2, and NO_X during each mode are determined from the average concentration readings determined from the corresponding calibration data.

§ 89.418–96 Raw emission sampling calculations.

(a) The final test results shall be derived through the steps described in this section.

(b) The exhaust gas flow rate G_{EXHW} and V_{EXHW} shall be determined (see § 89.416–96) for each mode.

(c) When applying G_{EXHW} the measured concentration shall be converted to a wet basis according to the following formula, if not already measured on a wet basis.

$$K_W=\left[1-F_{FH}\times\frac{G_{fuel}}{G_{air}}\right]-K_{W1}\text{ only applicable for raw exhaust}$$

F_{FH}=1.783 if air/fuel ratio is 1.00
1.865 if air/fuel ratio is 1.35
1.920 if air/fuel ratio is 3.50

(d) As the NO_X emission depends on ambient air conditions, the NO_X concentration shall be corrected for ambient air temperature and humidity with the factor K_H given in the following formulas. Equation (1) of this paragraph is to be used when testing in uncontrolled dynamometer rooms or at other sites with uncontrolled temperatures and humidities. Equation (2) of this paragraph is to be used for all testing when performed in controlled condition rooms. For engines operating on alternative combustion cycles, other correction formulas may be used if they can be justified or validated.

(1) For compression-ignition engines operating in uncontrolled conditions:

$$K_H=\frac{1}{1+A(H-10.71)+B(T-298)}$$

Where:
A=0.309 (f/a) − 0.0266
B=-0.209 (f/a)+0.00954
T=temperature of the air in K
H=humidity of the inlet air in grams of water per kilogram of dry air in which:

$$H=\frac{6.220\times R_a\times p_d}{(p_B-p_d)\times R_a\times 10^{-2}}$$

(2) For compression-ignition engines operating in controlled conditions:

$$K_H=\frac{1}{(1-0.0182(H-10.71))}$$

If required the dry fuel/air ratio may be calculated from the following equation:
Where:

$$(f/a)\ \text{Stoich}=\frac{M_c+aM_H}{138.18(1+a/4)}$$

$$X=\frac{DCO_2}{10^2}+\frac{DCO}{10^6}+\frac{DHC}{10^6}$$

$K=3.5$

(e) The pollutant mass flow for each mode shall be calculated as follows:

Gas mass = u×Gas conc.×G_{EXHW}
Gas mass = v×Gas conc.×V_{EXHD}
Gas mass = w×Gas conc.×V_{EXHW}

The coefficients u (wet), v (dry), and w (wet) are to be used according to the following table:

Gas	u	v	w	Conc.
NO_X	0.001587	0.00205	0.00205	ppm.
CO	0.000966	0.00125	0.00125	ppm.
HC	0.000478		0.000618	ppm.
CO_2	15.19	19.64	19.64	percent.
O_2	11.05	14.29	14.29	percent.

Note: The given coefficients u, v, and w are calculated for 273.15 °K (0 °C) and 101.3 kPa. In cases where the reference conditions vary from those stated, an error may occur in the calculations.

(f) The following equations may be used to calculate the coefficients u, v, and w in paragraph (e) of this section for other conditions of temperature and pressure.

(1) For ideal gases at 273.15 °K (0 °C) and 101.3 kPa:

For the calculation of u, v, and w for NO_X (as NO_2), CO, HC (in paragraph (e) of this section as $H_{1.85}$; CO_2; O_2

w=4.4615.10^{-5} * M if conc. in ppm

w=4.4615.10^{-1} * M if conc. in percent

v=w

u=w/P_{Air}

M=Molecular weight

p_{Air}=Density of dry air at 273.15 °K (0 °C), 101.3 kPa=1.293 kg/m³

(2) For real gases at 273.15 °K (0 °C) and 101.3 kPa: For the calculation of u, v, and w

w=gas×10^{-6} if conc. in ppm

v=w

u = w/p_{Air}

p_{Gas} = Density of measured gas at 0 °C, 101.3 kPas in g/m³

(3) General formulas for the calculation of concentrations at temperature (designated as T) and pressure (designated as p):

—for ideal gases

$$\text{conc}\frac{g}{m_3} = \frac{M}{M_v} \times \frac{T_o}{T_o + T} \times \frac{P}{P_o} \frac{\text{Conc(ppm)}}{10^6}$$

—for real gases

$$\text{conc}\frac{g}{m_3} = \rho_{Gas} \times \frac{T_o}{T_o + T} \times \frac{P}{P_o} \frac{\text{Conc(ppm)}}{10^6}$$

with:

1% = 10^4 ppm

M = Molecular weight in g/Mol

M_v = Molecular Volume = 22.414 × 10^{-3} m³/Mol for ideal gases

T_o = reference temperature 273.15 K

p_o = reference pressure 101.3 kPa

T = Temperature in °C

p = pressure in kPa

p_{Gas} = Density of the measured gas at 0 °C, 101.3 kPa

Conc. = Gas concentration

(g) The emission shall be calculated for all individual components in the following way:

$$\text{individual gas} = \frac{\sum_{i=1}^{i=n} \text{Gas Mass}_i \times WF_i}{\sum_{i=1}^{i=n-1} P_i \times WF_i}$$

The weighting factors and the number of modes (n) used in the above calculation are according to § 89.410–96.

§ 89.419–96 Dilute gaseous exhaust sampling and analytical system description.

(a) *General.* The exhaust gas sampling system described in this section is designed to measure the true mass of gaseous emissions in the exhaust of petroleum-fueled nonroad compression-ignition engines. This system utilizes the CVS concept (described in § 86.1310–90 of this chapter) of measuring mass emissions of HC, CO, and CO_2. A continuously integrated system is required for HC and NO_X measurement and is allowed for all CO and CO_2 measurements. The mass of gaseous emissions is determined from the sample concentration and total flow over the test period. As an option, the measurement of total fuel mass consumed over a cycle may be substituted for the exhaust measurement of CO_2. General requirements are as follows:

(1) This sampling system requires the use of a PDP–CVS and a heat exchanger or a CFV–CVS with either a heat exchanger or electronic flow compensation. Figure 2 in appendix A to this subpart is a schematic drawing of the PDP–CVS system. Figure 3 in appendix A to this subpart is a schematic drawing of the CFV–CVS system.

(2) The HC analytical system for petroleum-fueled compression-ignition engines requires a heated flame ionization detector (HFID) and heated sample system (191 ±11 °C).

(i) The HFID sample must be taken directly from the diluted exhaust stream through a heated probe and integrated continuously over the test cycle. Unless compensation for varying flow is made, the HFID must be used with a constant flow system to ensure a representative sample.

(ii) The heated probe shall be located in the primary dilution tunnel and far enough downstream of the mixing chamber to ensure a uniform sample distribution across the CVS duct at the point of sampling.

(3) The CO and CO_2 analytical system requires:

(i) Bag sampling (see § 86.1309–90 of this chapter) and analytical capabilities (see § 86.1311–90 of this chapter), as shown in Figure 2 and Figure 3 in appendix A to this subpart; or

(ii) Continuously integrated measurement of diluted CO and CO_2 meeting the minimum requirements and technical specifications contained in paragraph (b)(4) of this section. Unless compensation for varying flow is made, a constant flow system must be used to ensure a representative sample.

(4) The NO_X analytical system requires a continuously integrated measurement of diluted NO_X meeting the minimum requirements and technical specifications contained in paragraph (b)(4) of this section. Unless compensation for varying flow is made, a constant flow system must be used to ensure a representative sample.

(5) Since various configurations can produce equivalent results, exact conformance with these drawings is not required. Additional components such as instruments, valves, solenoids, pumps, and switches may be used to provide additional information and coordinate the functions of the component systems. Other components, such as snubbers, which are not needed to maintain accuracy on some systems, may be excluded if their exclusion is based upon good engineering judgment.

(6) Other sampling and/or analytical systems may be used if shown to yield equivalent results and if approved in advance by the Administrator.

(b) *Component description.* The components necessary for exhaust sampling shall meet the following requirements:

(1) *Exhaust dilution system.* The PDP–CVS shall conform to all of the requirements listed for the exhaust gas PDP–CVS in § 86.1309–90(b) of this chapter. The CFV–CVS shall conform to all of the requirements listed for the exhaust gas CFV–CVS in § 86.1309–90(c) of this chapter. In addition, the CVS must conform to the following requirements:

(i) The flow capacity of the CVS must be sufficient to maintain the diluted exhaust stream at or below the temperature required for the measurement of hydrocarbon emissions noted in the following paragraph and to

prevent condensation of water at any point in the dilution tunnel.

(ii) The flow capacity of the CVS must be sufficient to maintain the diluted exhaust stream in the primary dilution tunnel at a temperature of 191 °C or less at the sampling zone for hydrocarbon measurement and as required to prevent condensation at any point in the dilution tunnel. Gaseous emission samples may be taken directly from this sampling point.

(iii) For the CFV–CVS, either a heat exchanger or electronic flow compensation is required (see Figure 3 in appendix A to this subpart).

(iv) For the CFV–CVS when a heat exchanger is used, the gas mixture temperature, measured at a point immediately ahead of the critical flow venturi, shall be within ±11 °C) of the average operating temperature observed during the test with the simultaneous requirement that condensation does not occur. The temperature measuring system (sensors and readout) shall have an accuracy and precision of ±2 °C. For systems utilizing a flow compensator to maintain proportional flow, the requirement for maintaining constant temperature is not necessary.

(v) The primary dilution air shall have a temperature of 25 °C ±5 °C.

(2) *Continuous HC measurement system.* (i) The continuous HC sample system (as shown in Figure 2 or 3 in appendix A to this subpart) uses an "overflow" zero and span system. In this type of system, excess zero or span gas spills out of the probe when zero and span checks of the analyzer are made. The "overflow" system may also be used to calibrate the HC analyzer per § 86.1321–90(b) of this chapter, although this is not required.

(ii) No other analyzers may draw a sample from the continuous HC sample probe, line or system, unless a common sample pump is used for all analyzers and the sample line system design reflects good engineering practice.

(iii) The overflow gas flow rates into the sample line shall be at least 105 percent of the sample system flow rate.

(iv) The overflow gases shall enter the heated sample line as close as practical to the outside surface of the CVS duct or dilution tunnel.

(v) The continuous HC sampling system shall consist of a probe (which must raise the sample to the specified temperature) and, where used, a sample transfer system (which must maintain the specified temperature). The continuous hydrocarbon sampling system (exclusive of the probe) shall:

(A) Maintain a wall temperature of 191 °C ±11 °C as measured at every separately controlled heated component (that is, filters, heated line sections), using permanent thermocouples located at each of the separate components.

(B) Have a wall temperature of 191 °C ±11 °C over its entire length. The temperature of the system shall be demonstrated by profiling the thermal characteristics of the system where possible at initial installation and after any major maintenance performed on the system. The profiling shall be accomplished using the insertion thermocouple probing technique. The system temperature will be monitored continuously during testing at the locations and temperature described in § 86.1310–90(b)(3)(v).

(C) Maintain a gas temperature of 191 °C ±11 °C immediately before the heated filter and HFID. These gas temperatures will be determined by a temperature sensor located immediately upstream of each component.

(vi) The continuous hydrocarbon sampling probe shall:

(A) Be defined as the first 25 cm to 76 cm of the continuous hydrocarbon sampling system.

(B) Have a 0.48 cm minimum inside diameter.

(C) Be installed in the primary dilution tunnel at a point where the dilution air and exhaust are well mixed (that is, approximately 10 tunnel diameters downstream of the point where the exhaust enters the dilution tunnel).

(D) Be sufficiently distant (radially) from other probes and the tunnel wall so as to be free from the influence of any wakes or eddies.

(E) Increase the gas stream temperature to 191 °C ±11 °C at the exit of the probe. The ability of the probe to accomplish this shall be demonstrated using the insertion thermocouple technique at initial installation and after any major maintenance. Compliance with the temperature specification shall be demonstrated by continuously recording during each test the temperature of either the gas stream or the wall of the sample probe at its terminus.

(vii) The response time of the continuous measurement system shall be no greater than:

(A) 1.5 seconds from an instantaneous step change at the port entrance to the analyzer to within 90 percent of the step change.

(B) 20 seconds from an instantaneous step change at the entrance to the sample probe or overflow span gas port to within 90 percent of the step change. Analysis system response time shall be coordinated with CVS flow fluctuations and sampling time/test cycle offsets if necessary.

(C) For the purpose of verification of response times, the step change shall be at least 60 percent of full-scale chart deflection.

(3) *Primary dilution tunnel.* (i) The primary dilution tunnel shall be:

(A) Small enough in diameter to cause turbulent flow (Reynolds Number greater than 4000) and of sufficient length to cause complete mixing of the exhaust and dilution air;

(B) At least 46 cm in diameter; (engines below 110 kW may use a dilution tunnel that is 20 cm in diameter or larger)

(C) Constructed of electrically conductive material which does not react with the exhaust components; and

(D) Electrically grounded.

(ii) The temperature of the diluted exhaust stream inside of the primary dilution tunnel shall be sufficient to prevent water condensation.

(iii) The engine exhaust shall be directed downstream at the point where it is introduced into the primary dilution tunnel.

(4) *Continuously integrated NO_X, CO, and CO_2 measurement systems.* (i) The sample probe shall:

(A) Be in the same plane as the continuous HC probe, but shall be sufficiently distant (radially) from other probes and the tunnel wall so as to be free from the influences of any wakes or eddies.

(B) Heated and insulated over the entire length, to prevent water condensation, to a minimum temperature of 55 °C. Sample gas temperature immediately before the first filter in the system shall be at least 55 °C.

(ii) The continuous NO_X, CO, or CO_2 sampling and analysis system shall conform to the specifications of part 86, subpart D of this chapter with the following exceptions and revisions:

(A) The system components required to be heated by part 86, subpart D of this chapter need only be heated to prevent water condensation, the minimum component temperature shall be 55 °C.

(B) The system response shall be no greater than 20 seconds. Analysis system response time shall be coordinated with CVS flow fluctuations and sampling time/test cycle offsets, if necessary.

(C) Alternative NO_X measurement techniques outlined in § 86.346–79 of this chapter are not permitted for NO_X measurement in this subpart.

(D) All analytical gases must conform to the specifications of § 89.312–96.

(E) Any range on a linear analyzer below 155 ppm must have and use a calibration curve conforming to § 89.310–96.

(iii) The chart deflections or voltage output of analyzers with non-linear calibration curves shall be converted to concentration values by the calibration curve(s) specified in § 89.323–96 before flow correction (if used) and subsequent integration takes place.

§ 89.420–96 Background sample.

(a) Background samples are produced by drawing a sample of the dilution air during the 60 second exhaust collection phase of each test cycle mode.

(1) Individual background samples may be produced and analyzed for each mode. Hence, a unique background value will be used for the emission calculations for each mode.

(2) Alternatively, a single background sample may be produced by drawing a sample during the collection phase of each of the test cycle modes. Hence, a single cumulative background value will be used for the emission calculations for each mode.

(b) For analysis of the individual sample described in paragraph (a)(1) of this section, a single value representing the average chart deflection over a 10-second stabilized period is stored. All readings taken during the 10-second interval must be stable at the final value to within ±1 percent of full scale.

(c) Measure HC, CO, CO_2, and NO_x exhaust and background concentrations in the sample bag(s) with approximately the same flow rates and pressures used during calibration.

§ 89.421–96 Exhaust gas analytical system; CVS bag sample.

(a) *Schematic drawings.* Figure 4 in appendix A to this subpart is a schematic drawing of the exhaust gas analytical system used for analyzing CVS bag samples from compression-ignition engines. Since various configurations can produce accurate results, exact conformance with the drawing is not required. Additional components such as instruments, valves, solenoids, pumps and switches may be used to provide additional information and coordinate the functions of the component systems. Other components such as snubbers, which are not needed to maintain accuracy in some systems, may be excluded if their exclusion is based upon good engineering judgment.

(b) *Major component description.* The analytical system, Figure 4 in appendix A to this subpart, consists of a flame ionization detector (FID) (heated for petroleum-fueled compression-ignition engines to 191 °C ±6 °C) for the measurement of hydrocarbons, nondispersive infrared analyzers (NDIR) for the measurement of carbon monoxide and carbon dioxide, and a chemiluminescence detector (CLD) (or HCLD) for the measurement of oxides of nitrogen. The exhaust gas analytical system shall conform to the following requirements:

(1) The CLD (or HCLD) requires that the nitrogen dioxide present in the sample be converted to nitric oxide before analysis. Other types of analyzers may be used if shown to yield equivalent results and if approved in advance by the Administrator.

(2) If CO instruments are used which are essentially free of CO_2 and water vapor interference, the use of the conditioning column may be deleted. (See §§ 86.1322–84 and 86.1342–90 of this chapter.)

(3) A CO instrument will be considered to be essentially free of CO_2 and water vapor interference if its response to a mixture of 3 percent CO_2 in N2, which has been bubbled through water at room temperature, produces an equivalent CO response, as measured on the most sensitive CO range, which is less than 1 percent of full scale CO concentration on ranges above 300 ppm full scale or less than 3 ppm on ranges below 300 ppm full scale. (See § 86.1322–84 of this chapter.)

(c) *Alternate analytical systems.* Analysis systems meeting the specifications of part 86, subpart D of this chapter (with the exception of §§ 86.346–79 and 86.347–79) may be used for the testing required under this subpart. Heated analyzers may be used in their heated configuration.

(d) Other analyzers and equipment. Other types of analyzers and equipment may be used if shown to yield equivalent results and if approved in advance by the Administrator.

§ 89.422–96 Dilute sampling procedures—CVS calibration.

(a) The CVS is calibrated using an accurate flowmeter and restrictor valve.

(1) The flowmeter calibration must be traceable to NIST measurements, and will serve as the reference value (NIST "true" value) for the CVS calibration. (Note: In no case should an upstream screen or other restriction which can affect the flow be used ahead of the flowmeter unless calibrated throughout the flow range with such a device.)

(2) The CVS calibration procedures are designed for use of a "metering venturi" type flowmeter. Large radius or ASME flow nozzles are considered equivalent if traceable to NIST measurements. Other measurement systems may be used if shown to be equivalent under the test conditions in this section and traceable to NIST measurements.

(3) Measurements of the various flowmeter parameters are recorded and related to flow through the CVS.

(4) Procedures used by EPA for both PDP–CVS and CFV–CVS are outlined below. Other procedures yielding equivalent results may be used if approved in advance by the Administrator.

(b) After the calibration curve has been obtained, verification of the entire system may be performed by injecting a known mass of gas into the system and comparing the mass indicated by the system to the true mass injected. An indicated error does not necessarily mean that the calibration is wrong, since other factors can influence the accuracy of the system (for example, analyzer calibration, leaks, or HC hangup). A verification procedure is found in paragraph (e) of this section.

(c) *PDP–CVS calibration.* (1) The following calibration procedure outlines the equipment, the test configuration, and the various parameters which must be measured to establish the flow rate of the PDP–CVS pump.

(i) All the parameters related to the pump are simultaneously measured with the parameters related to a flowmeter which is connected in series with the pump.

(ii) The calculated flow rate, in (cm^3/s), (at pump inlet absolute pressure and temperature) can then be plotted versus a correlation function which is the value of a specific combination of pump parameters.

(iii) The linear equation which relates the pump flow and the correlation function is then determined.

(iv) In the event that a CVS has a multiple speed drive, a calibration for each range used must be performed.

(2) This calibration procedure is based on the measurement of the absolute values of the pump and flowmeter parameters that relate the flow rate at each point. Two conditions must be maintained to assure the accuracy and integrity of the calibration curve:

(i) The temperature stability must be maintained during calibration. (Flowmeters are sensitive to inlet temperature oscillations; this can cause the data points to be scattered. Gradual changes in temperature are acceptable as long as they occur over a period of several minutes.)

(ii) All connections and ducting between the flowmeter and the CVS pump must be absolutely void of leakage.

(3) During an exhaust emission test the measurement of these same pump parameters enables the user to calculate the flow rate from the calibration equation.

(4) Connect a system as shown in Figure 5 in appendix A to this subpart. Although particular types of equipment are shown, other configurations that yield equivalent results may be used if approved in advance by the Administrator. For the system indicated, the following measurements and accuracies are required:

CALIBRATION DATA MEASUREMENTS

Parameter	Symbol	Units	Sensor-readout tolerances
Barometric pressure (corrected)	P_B	kPa	±.34 kPa
Ambient temperature	T_A	°C	±.3 °C
Air temperature into metering venturi	*ETI*	°C	±1.1 °C
Pressure drop between the inlet and throat of metering venturi	*EDP*	kPa	±.01 kPa
Air flow	Q_S	m³/min	±.5% of NIST value.
Air temperature at CVS pump inlet	*PTI*	°C	±1.1 °C
Pressure depression at CVS pump inlet	*PPI*	kPa	±.055 kPa
Pressure head at CVS pump outlet	*PPO*	kPa	±.055 kPa
Air temperature at CVS pump outlet (optional)	*PTO*	°C	±1.1 °C
Pump revolutions during test period	*N*	Revs	±1 Rev.
Elapsed time for test period	*t*	s	±.5 s.

(5) After the system has been connected as shown in Figure 5 in appendix A to this subpart, set the variable restrictor in the wide open position and run the CVS pump for 20 minutes. Record the calibration data.

(6) Reset the restrictor valve to a more restricted condition in an increment of pump inlet depression that will yield a minimum of six data points for the total calibration. Allow the system to stabilize for 3 minutes and repeat the data acquisition.

(7) Data analysis:

(i) The air flow rate, Q_s, at each test point is calculated in standard cubic meters per minute (0 °C, 101.3 kPa) from the flowmeter data using the manufacturer's prescribed method.

(ii) The air flow rate is then converted to pump flow, V_o, in cubic meter per revolution at absolute pump inlet temperature and pressure:

$$V_o = \frac{Q_s}{n} \times \frac{T_p}{273} \times \frac{101.3}{P_p}$$

Where:

V_o=Pump flow, (m³/rev) at T_p, P_p.

Q_s=Meter air flow rate in standard cubic meters per minute, standard conditions are 0 °C, 101.3 kPa.

n=Pump speed in revolutions per minute.

T_p=Pump inlet temperature °K=P_{ti}+273 °K, P_{ti}=Pump inlet temp °C

P_p=Absolute pump inlet pressure, (kPa) $=P_B - P_{PI}$

Where:

P_B=barometric pressure, (kPa).

P_{PI}=Pump inlet depression, (kPa).

(iii) The correlation function at each test point is then calculated from the calibration data:

$$X_o = \frac{1}{n}\sqrt{\left(\frac{\Delta p}{P_e}\right)}$$

X_o=correlation function.

Δp=The pressure differential from pump inlet to pump outlet, (kPa). $=P_e - P_p$.

P_e=Absolute pump outlet pressure, (kPa) $=P_B+P_{PO}$

Where:

P_{PO}=Pressure head at pump outlet, (kPa).

(iv) A linear least squares fit is performed to generate the calibration equation which has the form:

$V_o = D_o - M(X_o)$

D_o and M are the intercept and slope constants, respectively, describing the regression line.

(8) A CVS system that has multiple speeds must be calibrated on each speed used. The calibration curves generated for the ranges will be approximately parallel and the intercept values, D_o, will increase as the pump flow range decreases.

(9) If the calibration has been performed carefully, the calculated values from the equation will be within ±0.50 percent of the measured value of V_o. Values of M will vary from one pump to another, but values of D_o for pumps of the same make, model, and range should agree within ±3 percent of each other. Calibrations should be performed at pump start-up and after major maintenance to assure the stability of the pump slip rate. Analysis of mass injection data will also reflect pump slip stability.

(d) *CFV–CVS calibration.* (1) Calibration of the CFV is based upon the flow equation for a critical venturi. Gas flow is a function of inlet pressure and temperature:

$$Q_s = \frac{K_v P}{\sqrt{T}}$$

Where:

Q_S=flow.

K_V=calibration coefficient.

P=absolute pressure.

T=absolute temperature.

The calibration procedure described in paragraph (d)(3) of this section establishes the value of the calibration coefficient at measured values of pressure, temperature, and air flow.

(2) The manufacturer's recommended procedure shall be followed for calibrating electronic portions of the CFV.

(3) Measurements necessary for flow calibration are as follows:

CALIBRATION DATA MEASUREMENTS

Parameter	Symbol	Units	Tolerances
Barometric Pressure (corrected)	P_B	kPa	±.34 kPa
Air temperature, into flowmeter	*ETI*	°C	(±.3 °C
Pressure drop between the inlet and throat of metering venturi	*EDP*	kPa	±.01 kPa
Air flow	Q_S	m³/min.	±.5% of NIST value.
CFV inlet depression	*PPI*	kPa	±.055 kPa
Temperature at venturi inlet	T_V	°C	±2.2 °C

(4) Set up equipment as shown in Figure 6 in Appendix A to subpart and eliminate leaks. (Leaks between the flow measuring devices and the critical flow venturi will seriously affect the accuracy of the calibration.)

(5) Set the variable flow restrictor to the open position, start the blower, and allow the system to stabilize. Record data from all instruments.

(6) Vary the flow restrictor and make at least eight readings across the critical flow range of the venturi.

(7) *Data analysis.* The data recorded during the calibration are to be used in the following calculations:

(i) The air flow rate (designated as Q_s) at each test point is calculated in standard cubic feet per minute from the flow meter data using the manufacturer's prescribed method.

(ii) Calculate values of the calibration coefficient for each test point:

$$K_v = \frac{Q_s\sqrt{T_v}}{P_v}$$

Where:

Q_s = Flow rate in standard cubic meter per minute, at the standard conditions of 0 °C, 101.3 kPa.

T_v = Temperature at venturi inlet, °K.

P_v = PB - PPI (= Pressure at venturi inlet, kPA)

Where:

P_{PI} = Venturi inlet pressure depression, (kPa).

(iii) Plot K_v as a function of venturi inlet pressure. For choked flow, K_v will have a relatively constant value. As pressure decreases (vacuum increases), the venturi becomes unchoked and K_v decreases. (See Figure 7 in appendix A to this subpart.)

(iv) For a minimum of eight points in the critical region calculate an average K_v and the standard deviation.

(v) If the standard deviation exceeds 0.3 percent of the average K_v, take corrective action.

(e) *CVS system verification.* The following "gravimetric" technique can be used to verify that the CVS and analytical instruments can accurately measure a mass of gas that has been injected into the system. (Verification can also be accomplished by constant flow metering using critical flow orifice devices.)

(1) Obtain a small cylinder that has been charged with 99.5 percent or greater propane or carbon monoxide gas (Caution—carbon monoxide is poisonous).

(2) Determine a reference cylinder weight to the nearest 0.01 grams.

(3) Operate the CVS in the normal manner and release a quantity of pure propane into the system during the sampling period (approximately 5 minutes).

(4) The calculations are performed in the normal way except in the case of propane. The density of propane (0.6109 kg/m³/carbon atom)) is used in place of the density of exhaust hydrocarbons.

(5) The gravimetric mass is subtracted from the CVS measured mass and then divided by the gravimetric mass to determine the percent accuracy of the system.

(6) Good engineering practice requires that the cause for any discrepancy greater than ±2 percent must be found and corrected.

§ 89.423–96 CVS calibration frequency.

The CVS positive displacement pump or critical flow venturi shall be calibrated following initial installation, major maintenance or as necessary when indicated by the CVS system verification (described in § 89.352–96(e)).

§ 89.424–96 Dilute emission sampling calculations.

(a) The final reported emission test results are computed by use of the following formula:

$$A_{WM} = \frac{\sum_{i=1}^{i=n}\left(g_i \times WF_i\right)}{\sum_{i=n-1}^{i=1}\left(kW - hr_i \times WF_i\right)}$$

Where:

A_{wm} = Weighted mass emission level (HC, CO, CO_2, or NO_X) in grams per kilowatt-hour.

g_i = Mass emission level in grams, measured during the mode.

WF_i = Effective weighing factor.

$kW\text{-}hr_i$ = Total kilowatt-hours (kilowatts integrated over time) for the mode.

(b) The mass of each pollutant for each mode for bag measurements and diesel heat exchanger system measurements is determined from the following equations:

(1) Hydrocarbon mass:

$HC_{mass} = V_{mix} \times Density_{HC} \times (HC_{conc}/10^6)$

(2) Oxides of nitrogen mass:

$NO_{Xmass} = V_{mix} \times Density_{NO2} \times KH \times (NO_{Xconc}/10^6)$

(3) Carbon monoxide mass:

$CO_{mass} = V_{mix} \times Density_{CO} \times (CO_{conc}/10^6)$

(4) Carbon dioxide mass:

$CO_{2mass} = V_{mix} \times Density_{CO2} \times (CO_{2conc}/10_2)$

(c) The mass of each pollutant for the mode for flow compensated sample systems is determined from the following equations:

$$HC_{mass} = V_{mix} \times Density_{HC} \frac{HC_e - HC_d\left(1 - \frac{1}{DF}\right)}{10^6}$$

$$NOX_{mass} = K_H \frac{NOX_e - NOX_d\left(1 - \frac{1}{DF}\right)}{10^6} V_{mix} \times Density_{NO_2}$$

$$CO_{mass} = V_{mix} \times Density_{CO} \frac{CO_e - CO_d\left(1 - \frac{1}{DF}\right)}{10^6}$$

$$CO_{2_{mass}} = V_{mix} \times Density_{CO_2} \frac{CO_{2_e} - CO_{2_d}\left(1 - \frac{1}{DF}\right)}{10^6}$$

(d) Meaning of symbols:

(1) For hydrocarbon equations:

HC_{mass} = Hydrocarbon emissions, in grams per test mode.

$Density_{HC}$ = Density of hydrocarbons is (.5800 kg/m³) for #1 diesel, and (0.5746 kg/m³) for #2 diesel, assuming an average carbon to hydrogen ratio of 1:1.93 for #1 diesel, and 1:1.80 for #2 diesel at 20 °C and 101.3 kPa pressure.

HC_{conc} = Hydrocarbon concentration of the dilute exhaust sample corrected for background, in ppm carbon equivalent (that is, equivalent propane times 3).

$$HC_{conc} = HC_e - HC_d\left(1 - \frac{1}{DF}\right)$$

Where:

HC_e = Hydrocarbon concentration of the dilute exhaust bag sample or, for diesel heat exchanger systems, average hydrocarbon concentration of the dilute exhaust sample as calculated from the integrated HC traces, in ppm carbon equivalent. For flow compensated sample systems $(HC_e)_i$ is the instantaneous concentration.

HC_d = Hydrocarbon concentration of the dilution air as measured, in ppm carbon equivalent.

(2) For oxides of nitrogen equations:

NO_{Xmass} = Oxides of nitrogen emissions, in grams per test mode.

Density NO_2 = Density of oxides of nitrogen is 1.913 kg/m³, assuming they are in the form of nitrogen dioxide, at 20 °C and 101.3 kPa pressure.

NO_{Xconc} = Oxides of nitrogen concentration of the dilute exhaust sample corrected for background, in ppm:

$$NOx_{conc} = NOx_e - NOx_d\left(1 - \frac{1}{DF}\right)$$

Where:

NO_{Xe} = Oxides of nitrogen concentration of the dilute exhaust bag sample as measured, in ppm. For flow compensated sample systems $(NO_{Xe})_i$ is the instantaneous concentration.

NO_{Xd} = Oxides of nitrogen concentration of the dilute air as measured, in ppm.

(3) For carbon monoxide equations:

CO_{mass}=Carbon monoxide emissions, grams per test mode.

$Density_{CO}$=Density of carbon monoxide (1.164 kg/m³ at 20 °C and 101.3 kPa pressure).

CO_{conc}=Carbon monoxide concentration of the dilute exhaust sample corrected for background, water vapor, and CO_2 extraction, ppm.

$$CO_{conc} = CO_e - CO_d\left(1 - \frac{1}{DF}\right)$$

Where:

CO_e=Carbon monoxide concentration of the dilute exhaust bag sample volume corrected for water vapor and carbon dioxide extraction, ppm. For flow compensated sample systems, $(CO_e)_i$ is the instantaneous concentration.

The following calculation assumes the carbon to hydrogen ratio of the fuel is 1:1.85. As an option the measured actual carbon to hydrogen ratio may be used:

$CO_e = [1 - 0.01925CO_{2e} - 0.000323R]CO_{em}$

Where:

CO_{em}=Carbon monoxide concentration of the dilute exhaust sample as measured, ppm.

CO_{2e}=Carbon dioxide concentration of the dilute exhaust bag sample, in percent, if measured. For flow compensated sample systems, $(CO_{2e})_i$ is the instantaneous concentration. For cases where exhaust sampling of CO_2 is not performed, the following approximation is permitted:

$$CO_{2_e} = \frac{44.010}{12.011 + 1.008\alpha} \frac{M^1\ 453.6}{Density_{CO_2}} \frac{100}{V_{mix}}$$

^{a}=Average carbon to hydrogen ratio.

M^1=Fuel mass consumed during the test cycle.

R=Relative humidity of the dilution air, percent.

CO_d=Carbon monoxide concentration of the dilution air corrected for water vapor extraction, ppm.

$CO_d = (1 - 0.000323R)CO_{dm}$

Where:

CO_{dm}=Carbon monoxide concentration of the dilution air sample as measured, ppm.

Note: If a CO instrument which meets the criteria specified in § 86.1311–90 of this chapter is used and the conditioning column has been deleted, CO_{em} must be substituted directly for CO_e and CO_{dm} must be substituted directly for CO_d.

(4) For carbon dioxide equation:

CO_{2mass}=Carbon dioxide emissions, in grams per test mode.

Density CO_2=Density of carbon dioxide is 1.830 kg/m³, at 20 °C and 760 mm Hg pressure.

CO_{2conc}=Carbon dioxide concentration of the dilute exhaust sample corrected for background, in percent.

$$CO_{2_{mass}} = CO_{2_e} - CO_{2_d}\left(1 - \frac{1}{DF}\right)$$

Where:

CO_{2d}=Carbon dioxide concentration of the dilution air as measured, in percent.

$$(5)\ DF = \frac{13.4}{CO_{2_e} + \left(HC_e + CO_e \times 10^{-4}\right)},\ \text{or}\ DF = \frac{13.4}{CO_{2_e}}.$$

(6) KH=Humidity correction factor.
For compression-ignition engines:
$KH = 1/[1 - 0.0182\ (H - 10.71)]$.
Where:
H=Absolute humidity of the engine intake air in grams of water per kilogram of dry air and
$H = (6.211)R_i \times P_d)/(P_b - (P_d \times R_i/100))$
Where:
R_i=Relative humidity of the engine intake air, in percent.
P_d=Saturated vapor pressure (kPa) at the engine intake air dry bulb temperature.
P_B=Barometric pressure (kPa).

(e) The final reported brake-specific fuel consumption (*BSFC*) shall be computed by use of the following formula:

$$BSFC = \frac{M}{kW - hr}$$

Where:
BSFC=brake-specific fuel consumption in grams of fuel per kilowatt-hr (kW-hr)
M=mass of fuel in grams, used by the engine during a mode
kW-hr=total kilowatts integrated with respect to time for a mode

(f) The mass of fuel for the mode is determined from mass fuel flow measurements made during the mode, or from the following equation:

$$M = \left(\frac{G_S}{R_2}\right)\left(\frac{1}{273.15}\right)$$

Where:
M=Mass of fuel, in grams, used by the engine during the mode.
G_s=Grams of carbon measured during the mode:

$$G_S = \left[\frac{12.011}{12.011 + \alpha\ (1.008)}\right] HC_{mass} + 0.429CO_{mass} + 0.273CO_{2_{mass}}$$

R_2=Grams C in fuel per gram of fuel
Where:
HC_{mass}=hydrocarbon emissions, in grams for the mode
CO_{2mass}=carbon monoxide emissions, in grams for the mode
CO_{2mass}=carbon dioxide emissions, in grams for the mode
α=The atomic hydrogen to carbon ratio of the fuel.

§ 89.425–96 Particulate adjustment factor.

The following equation may be used to adjust the particulate measurement when the test fuel specified in Table 4 of Subpart D of this Part is used:
$PM_{adj} = PM - [BSFC * 0.0917 * (FSF - USLF_{CA})]$
Where:
PM_{adj}=adjusted measured PM level [g/Kw-hr]
PM=measured weighted PM level [g/Kw-hr]
BSFC=measured brake specific fuel consumption [G/Kw-hr]
FSF=fuel sulfur weight fraction
$USLF_{CA}$=upper sulfur level weight fraction of California specification.

This adjustment only applies to engines with no exhaust gas after treatment. No adjustment is provided for engines with exhaust gas after treatment.

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Appendix A to Subpart E—Figures

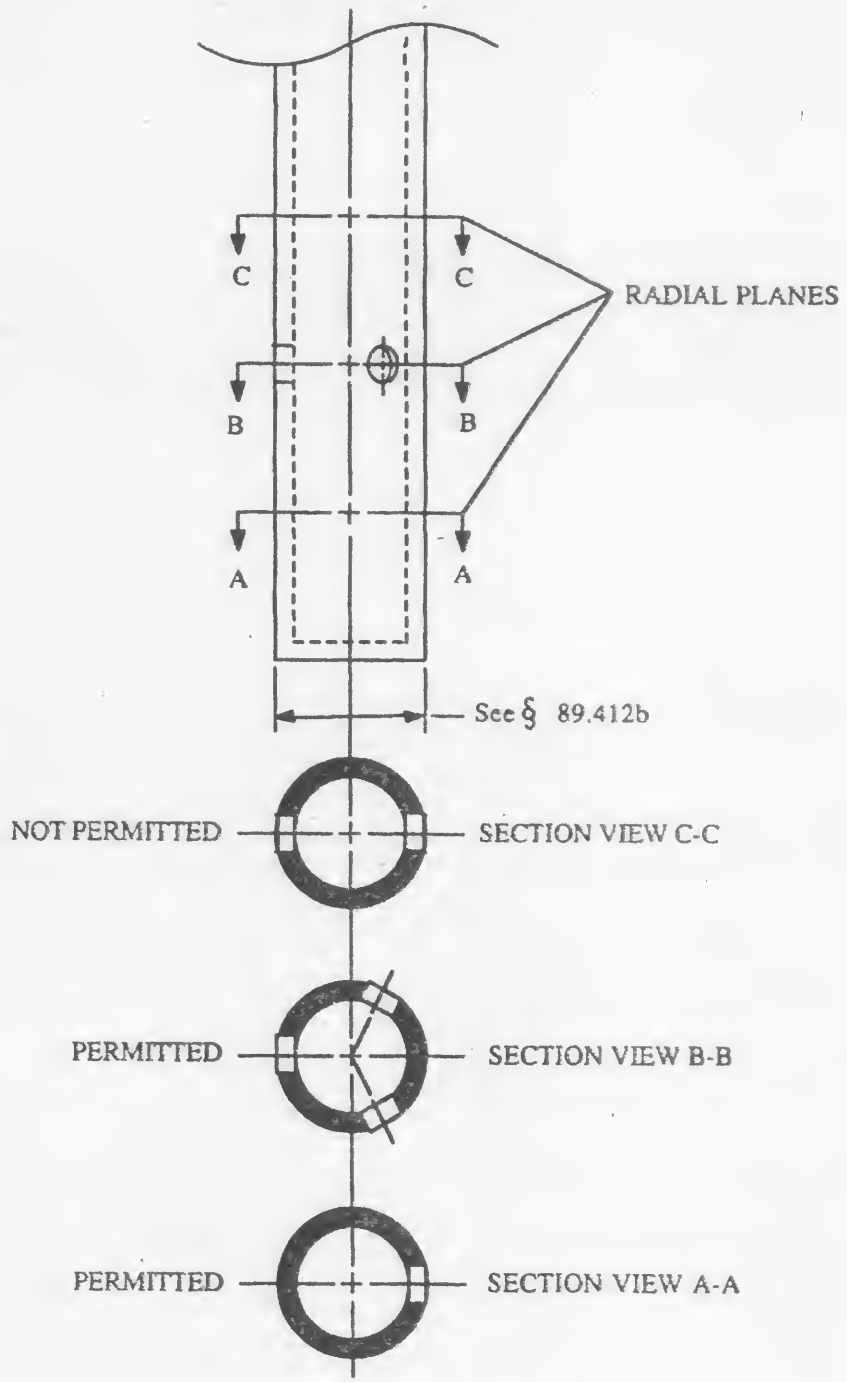

Figure 1.--SAMPLE PROBE AND TYPICAL HOLE SPACING

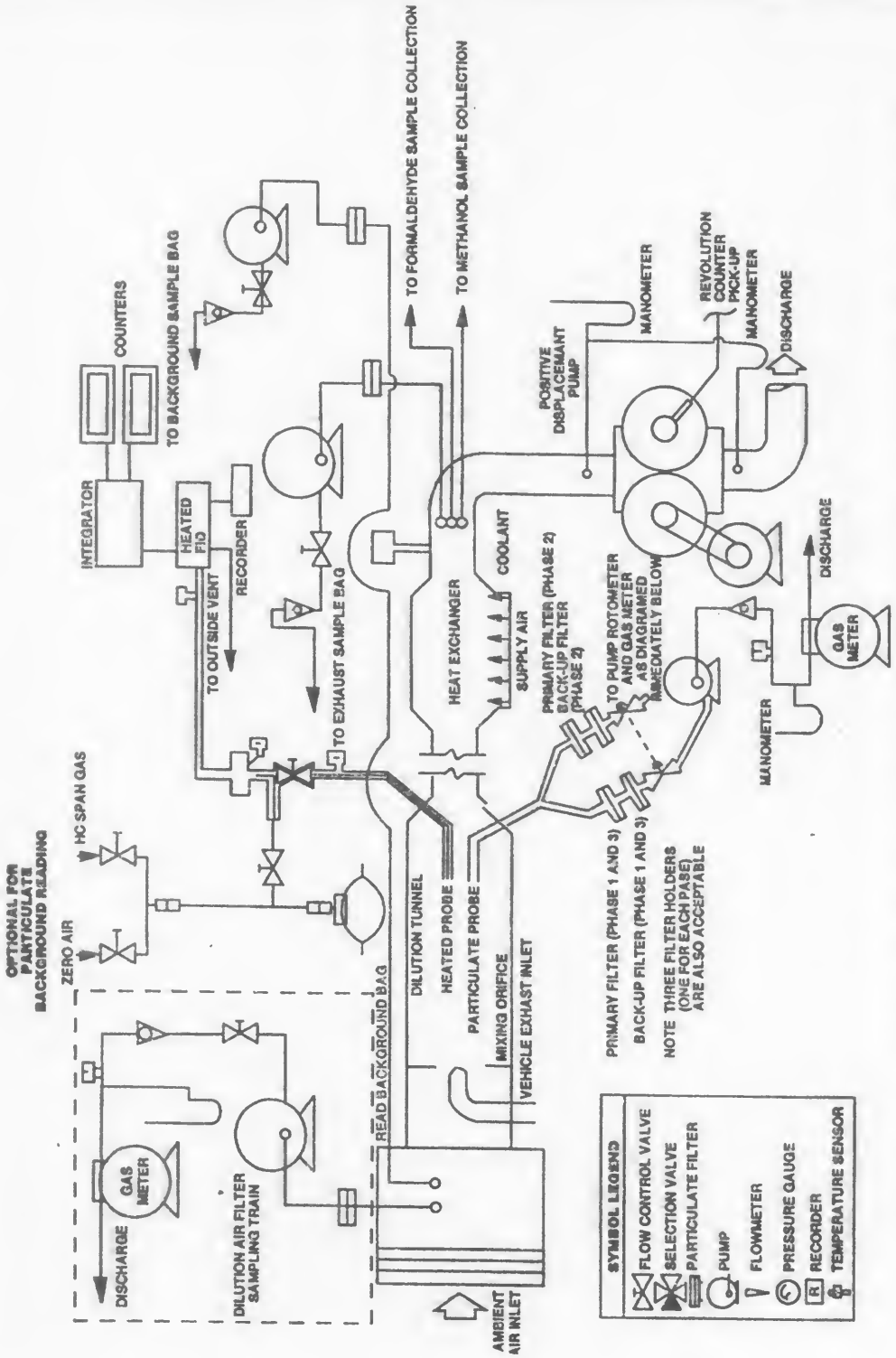

Figure 2 — Gaseous & Particulate Emissions Sampling System (PDP-CVS)

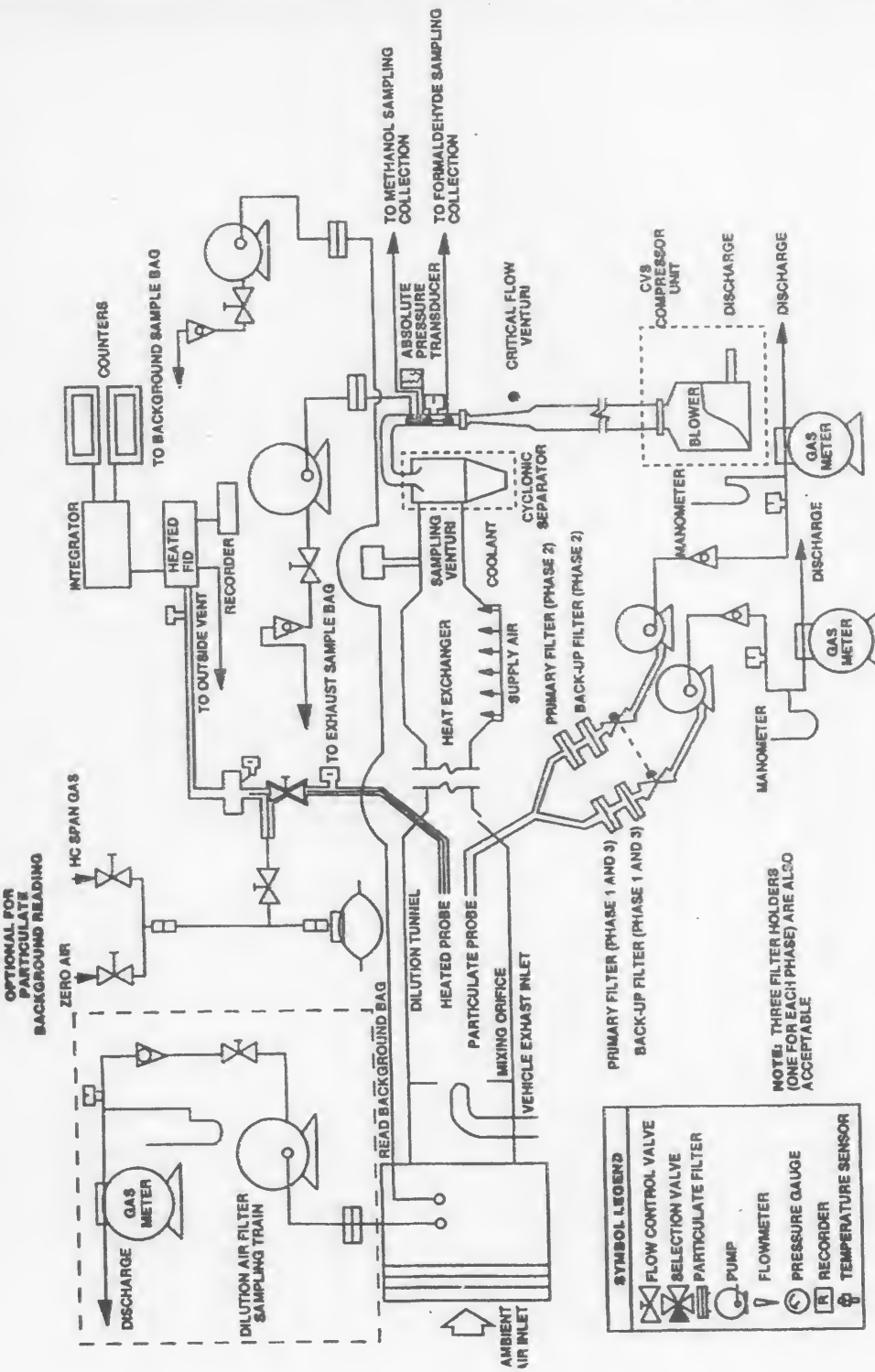

Figure 3. — Gaseous and Particulate Emissions Sampling System (CVF-CVS)

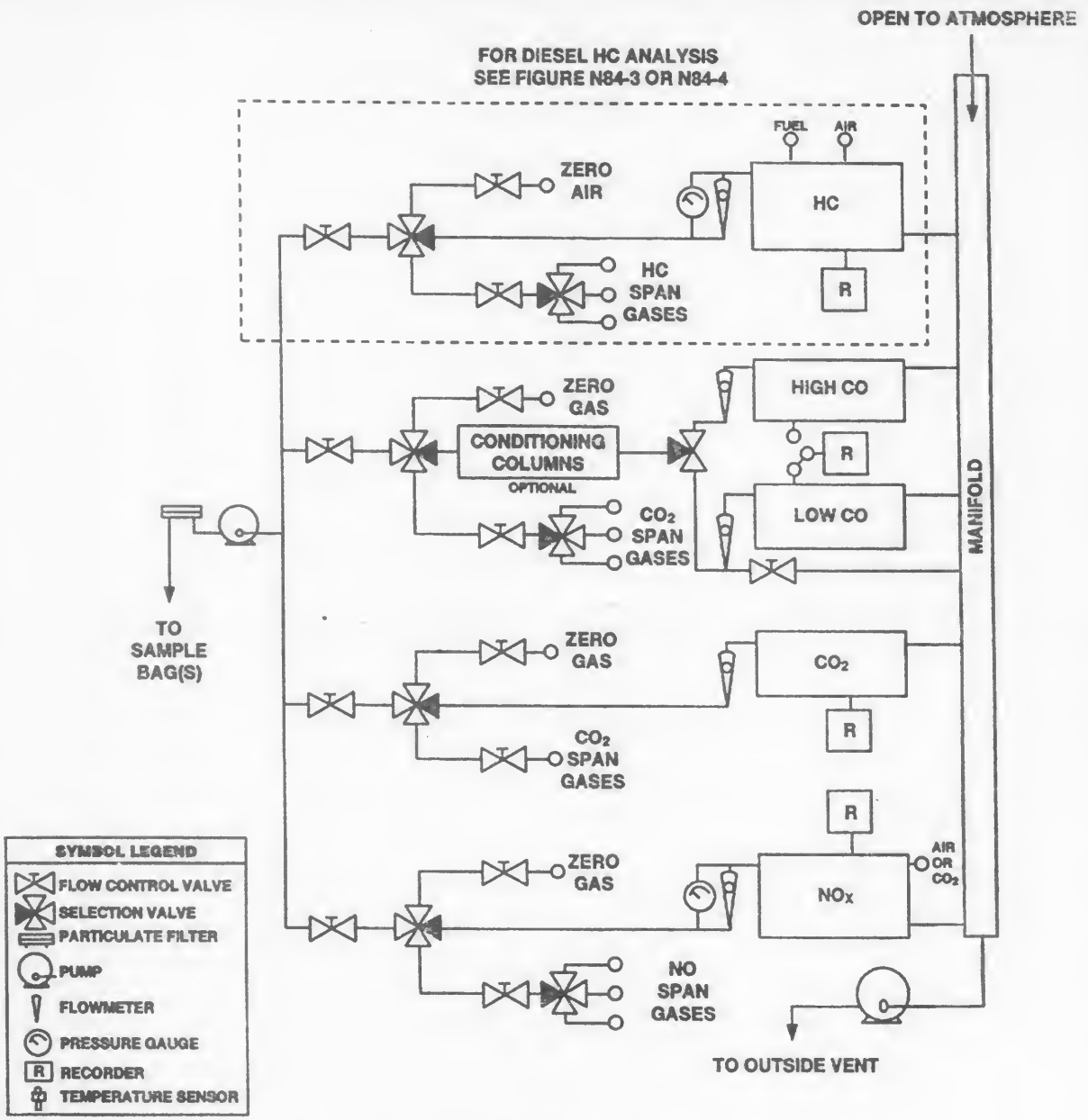

Figure 4. — Exhaust Gas Analytical System

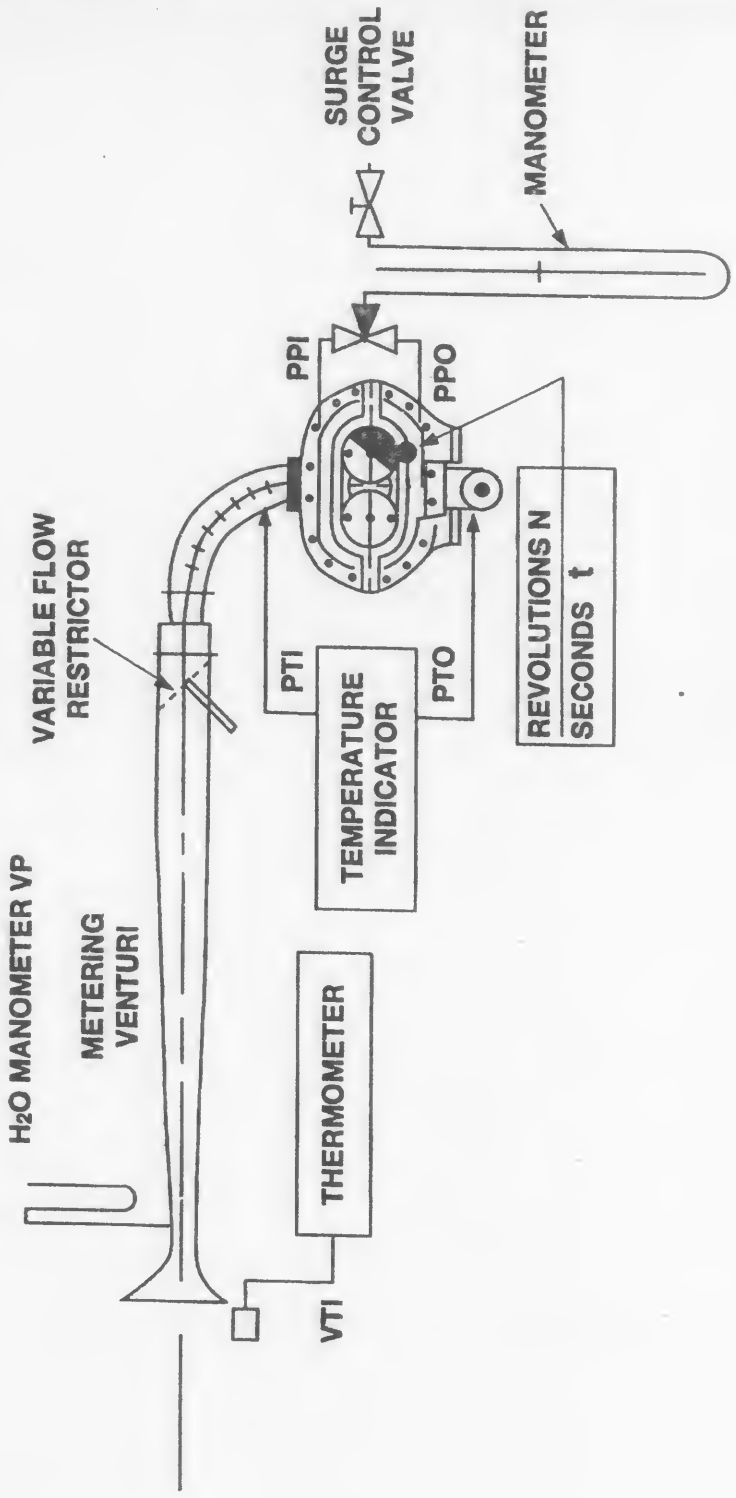

Figure 5. — PDP-CVS Calibration Configuration

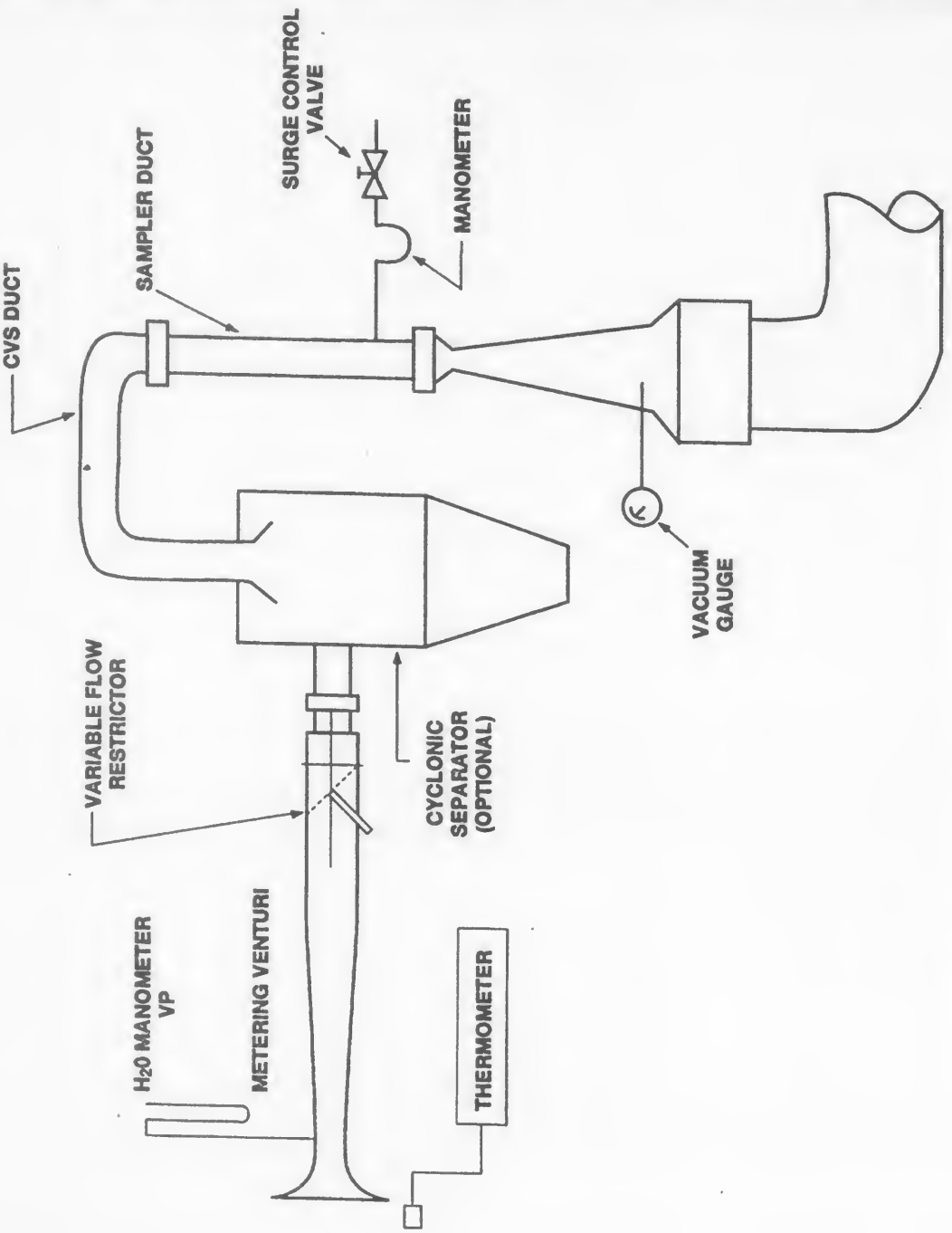

Figure 6. — CFV-CVS Calibration Configuration

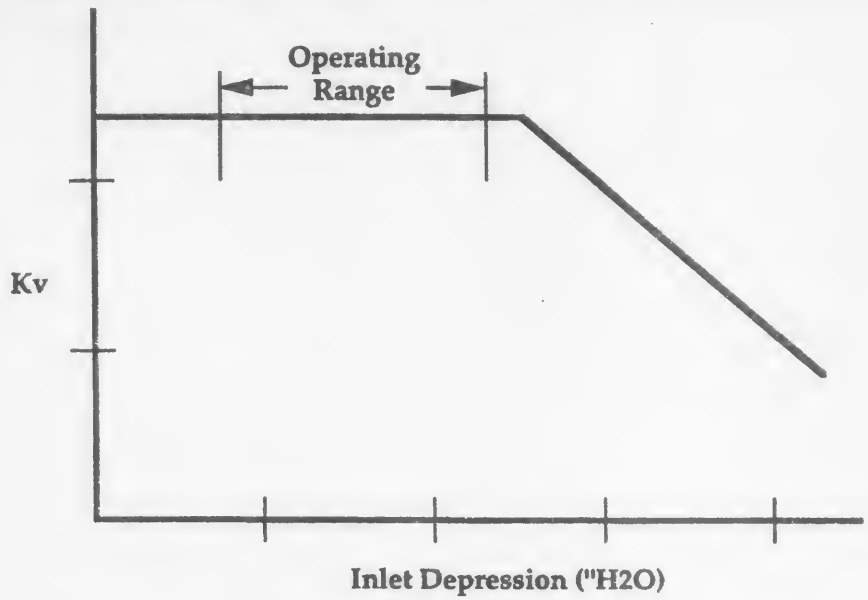

Figure 7.—Sonic Flow Choking

BILLING CODE 6560-50-C

Appendix B to Subpart E—Table 1

TABLE 1.—8. MODE TEST CYCLE (MY96 AND LATER)

Test segment	Mode No.	Engine speed (1)	Observed torque (2) (percent of maximum observed)	Time in mode (minutes)		Weighting factors
				Min	Max	
1	1	Rated	100	5.0	20.0	0.15
1	2	Rated	75	5.0	20.0	0.15
1	3	Rated	50	5.0	20.0	0.15
1	4	Rated	10	5.0	20.0	0.10
2	5	Int	100	5.0	20.0	0.10
2	6	Int	75	5.0	20.0	0.10
2	7	Int	50	5.0	20.0	0.10
2	8	Idle	0	5.0	20.0	0.15

(1) Engine speed (non-idle): ±1 percent of rated or ±3 rpm, which ever is greater. Engine speed (idle): Within manufacturer's specifications. Rated speed, intermediate speed, and idle speed are specified by the manufacturer. If no intermediate speed is stated, 60 percent of rated speed shall be used.

(2) Torque (non-idle): Throttle fully open for 100 percent points. Other non-idle points: ±2 percent of set point. Torque (idle): Throttle fully closed. Load less than 5 percent of peak torque.

Subpart F—Selective Enforcement Auditing

§ 89.501–96 Applicability.

The requirements of subpart F are applicable to all nonroad engines subject to the provisions of subpart A of part 89.

§ 89.502–96 Definitions.

The definitions in subpart A of this part apply to this subpart. The following definitions also apply to this subpart.

Acceptable quality level (AQL) means the maximum percentage of failing engines that can be considered a satisfactory process average for sampling inspections.

Configuration means any subclassification of an engine family which can be described on the basis of gross power, emission control system, governed speed, injector size, engine calibration, and other parameters as designated by the Administrator.

Inspection criteria means the pass and fail numbers associated with a particular sampling plan.

Test engine means an engine in a test sample.

Test sample means the collection of engines selected from the population of an engine family for emission testing.

§ 89.503–96 Test orders.

(a) A test order addressed to the manufacturer is required for any testing under this subpart.

(b) The test order is signed by the Assistant Administrator for Air and Radiation or his or her designee. The test order must be delivered in person by an EPA enforcement officer or EPA authorized representative to a company representative or sent by registered mail, return receipt requested, to the manufacturer's representative who signed the application for certification submitted by the manufacturer, pursuant to the requirements of the applicable section of subpart B of this part. Upon receipt of a test order, the manufacturer must comply with all of the provisions of this subpart and instructions in the test order.

(c) *Information included in test order.* (1) The test order will specify the engine family to be selected for testing, the manufacturer's engine assembly plant or associated storage facility or port facility (for imported engines) from which the engines must be selected, the time and location at which engines must be selected, and the procedure by which engines of the specified family must be selected. The test order may specify the configuration to be audited and/or the number of engines to be selected per day. Engine manufacturers are required to select a minimum of four engines per day unless an alternate selection procedure is approved pursuant to § 89.507–96(a), or unless total production of the specified configuration is less than four engines per day. If total production of the specified configuration is less than four engines per day, the manufacturer selects the actual number of engines produced per day.

(2) The test order may include alternate families to be selected for testing at the Administrator's discretion in the event that engines of the specified family are not available for testing because those engines are not being manufactured during the specified time or are not being stored at the specified assembly plant, associated storage facilities, or port of entry.

(3) If the specified family is not being manufactured at a rate of at least two engines per day in the case of manufacturers specified in § 89.508–96(g)(1), or one engine per day in the case of manufacturers specified in § 89.508–96(g)(2), over the expected duration of the audit, the Assistant Administrator or her or his designated representative may select engines of the alternate family for testing.

(4) In addition, the test order may include other directions or information essential to the administration of the required testing.

(d) A manufacturer may submit a list of engine families and the corresponding assembly plants, associated storage facilities, or (in the case of imported engines) port facilities from which the manufacturer prefers to have engines selected for testing in response to a test order. In order that a manufacturer's preferred location be considered for inclusion in a test order for a particular engine family, the list must be submitted prior to issuance of the test order. Notwithstanding the fact that a manufacturer has submitted the list, the Administrator may order selection at other than a preferred location.

(e) Upon receipt of a test order, a manufacturer must proceed in accordance with the provisions of this subpart.

(f)(1) During a given model year, the Administrator may not issue to a manufacturer more Selective Enforcement Auditing (SEA) test orders than an annual limit determined to be the larger of the following factors:

(i) Production factor, determined by dividing the projected nonroad engine sales in the United States for that model year, as declared by the manufacturer under § 89.505- 96(c)(1), by 16,000 and rounding to the nearest whole number. If the projected sales are less than 8,000, this factor is one.

(ii) Family factor, determined by dividing the manufacturer's total number of certified engine families by five and rounding to the nearest whole number.

(2) If a manufacturer submits to EPA in writing prior to or during the model year a reliable sales projection update or adds engine families or deletes engine families from its production, that information is used for recalculating the manufacturer's annual limit of SEA test orders.

(3) Any SEA test order for which the family fails under § 89.510–96 or for which testing is not completed is not counted against the annual limit.

(4) When the annual limit has been met, the Administrator may issue additional test orders to test those families for which evidence exists indicating noncompliance. An SEA test order issued on this basis will include a statement as to the reason for its issuance.

§ 89.504–96 Testing by the Administrator.

(a) The Administrator may require by test order under § 89.503–96 that engines of a specified family be selected in a manner consistent with the requirements of § 89.507–96 and submitted to the Administrator at the place designated for the purpose of conducting emission tests. These tests will be conducted in accordance with § 89.508–96 to determine whether engines manufactured by the manufacturer conform with the regulations with respect to which the certificate of conformity was issued.

(b) *Designating official data.* (1) Whenever the Administrator conducts a test on a test engine or the Administrator and manufacturer each conduct a test on the same test engine, the results of the Administrator's test comprise the official data for that engine.

(2) Whenever the manufacturer conducts all tests on a test engine, the manufacturer's test data is accepted as the official data, provided that if the Administrator makes a determination based on testing conducted under paragraph (a) of this section that there is a substantial lack of agreement between the manufacturer's test results and the Administrator's test results, no manufacturer's test data from the manufacturer's test facility will be accepted for purposes of this subpart.

(c) If testing conducted under § 89.503–96 is unacceptable under paragraph (b)(2) of this section, the Administrator must:

(1) Notify the manufacturer in writing of the Administrator's determination that the test facility is inappropriate for conducting the tests required by this subpart and the reasons therefor; and

(2) Reinstate any manufacturer's data upon a showing by the manufacturer that the data acquired under § 89.503–96 was erroneous and the manufacturer's data was correct.

(d) The manufacturer may request in writing that the Administrator reconsider the determination in paragraph (b)(2) of this section based on data or information which indicates that changes have been made to the test facility and these changes have resolved the reasons for disqualification.

§ 89.505–96 Maintenance of records; submittal of information.

(a) The manufacturer of any new nonroad engine subject to any of the provisions of this subpart must establish, maintain, and retain the following adequately organized and indexed records:

(1) *General records.* A description of all equipment used to test engines in

accordance with § 89.508–96 pursuant to a test order issued under this subpart, specifically, the equipment requirements specified in §§ 86.884–8 and 86.884–9 of this chapter and the equipment requirements specified in §§ 89.306–96, 89.308–96, 89.309–96, and 89.312–96.

(2) *Individual records.* These records pertain to each audit conducted pursuant to this subpart and include:

(i) The date, time, and location of each test;

(ii) The number of hours of service accumulated on the engine when the test began and ended;

(iii) The names of all supervisory personnel involved in the conduct of the audit;

(iv) A record and description of any repairs performed prior to and/or subsequent to approval by the Administrator, giving the date, associated time, justification, name(s) of the authorizing personnel, and names of all supervisory personnel responsible for the conduct of the repair;

(v) The date the engine was shipped from the assembly plant, associated storage facility or port facility, and date the engine was received at the testing facility;

(vi) A complete record of all emission tests performed pursuant to this subpart (except tests performed directly by EPA), including all individual worksheets and/or other documentation relating to each test, or exact copies thereof, to be in accordance with the record requirements specified in § 89.404–96 or § 86.884–10 of this chapter.

(vii) A brief description of any significant audit events not described under paragraph (a)(2) of this section, commencing with the test engine selection process and including such extraordinary events as engine damage during shipment.

(3) The manufacturer must record test equipment description, pursuant to paragraph (a)(1) of this section, for each test cell that can be used to perform emission testing under this subpart.

(b) The manufacturer must retain all records required to be maintained under this subpart for a period of one year after completion of all testing in response to a test order. Records may be retained as hard copy or reduced to microfilm, floppy disc, and so forth, depending upon the manufacturer's record retention procedure; provided, that in every case, all the information contained in the hard copy is retained.

(c) The manufacturer must, upon request by the Administrator, submit the following information with regard to engine production:

(1) Projected production for each engine configuration within each engine family for which certification is requested;

(2) Number of engines, by configuration and assembly plant, scheduled for production for the time period designated in the request;

(3) Number of engines, by configuration and by assembly plant, storage facility or port facility, scheduled to be stored at facilities for the time period designated in the request; and

(4) Number of engines, by configuration and assembly plant, produced during the time period designated in the request that are complete for introduction into commerce.

(d) Nothing in this section limits the Administrator's discretion in requiring the manufacturer to retain additional records or submit information not specifically required by this section.

(e) All reports, submissions, notifications, and requests for approvals made under this subpart are addressed to: Director, Manufacturers Operations Division, U.S. Environmental Protection Agency, 6405–J, 401 M Street SW, Washington, DC 20460.

§ 89.506–96 Right of entry and access.

(a) To allow the Administrator to determine whether a manufacturer is complying with the provisions of this subpart and a test order issued thereunder, EPA enforcement officers or EPA authorized representatives may enter during operating hours and upon presentation of credentials any of the following places:

(1) Any facility where any engine to be introduced into commerce, including ports of entry, or any emission-related component is manufactured, assembled, or stored;

(2) Any facility where any tests conducted pursuant to a test order or any procedures or activities connected with these tests are or were performed;

(3) Any facility where any engine which is being tested, was tested, or will be tested is present; and

(4) Any facility where any record or other document relating to any of the above is located.

(b) Upon admission to any facility referred to in paragraph (a) of this section, EPA enforcement officers or EPA authorized representatives are authorized to perform the following inspection-related activities:

(1) To inspect and monitor any aspects of engine manufacture, assembly, storage, testing and other procedures, and the facilities in which these procedures are conducted;

(2) To inspect and monitor any aspect of engine test procedures or activities, including, but not limited to, engine selection, preparation, service accumulation, emission test cycles, and maintenance and verification of test equipment calibration;

(3) To inspect and make copies of any records or documents related to the assembly, storage, selection, and testing of an engine in compliance with a test order; and

(4) To inspect and photograph any part or aspect of any engine and any component used in the assembly thereof that is reasonably related to the purpose of the entry.

(c) EPA enforcement officers or EPA authorized representatives are authorized to obtain reasonable assistance without cost from those in charge of a facility to help the officers perform any function listed in this subpart and they are authorized to request the recipient of a test order to make arrangements with those in charge of a facility operated for the manufacturer's benefit to furnish reasonable assistance without cost to EPA whether or not the recipient controls the facility.

(1) Reasonable assistance includes, but is not limited to, clerical, copying, interpretation and translation services; the making available on an EPA enforcement officer's or EPA authorized representative's request of personnel of the facility being inspected during their working hours to inform the EPA enforcement officer or EPA authorized representative of how the facility operates and to answer the officer's or representative's questions; and the performance on request of emission tests on any engine which is being, has been, or will be used for SEA testing.

(2) A manufacturer may be compelled to cause the personal appearance of any employee at such a facility before an EPA enforcement officer or EPA authorized representative by written request for his appearance, signed by the Assistant Administrator for Air and Radiation, served on the manufacturer. Any such employee who has been instructed by the manufacturer to appear will be entitled to be accompanied, represented, and advised by counsel.

(d) EPA enforcement officers or EPA authorized representatives are authorized to seek a warrant or court order authorizing the EPA enforcement officers or EPA authorized representatives to conduct activities related to entry and access as authorized in this section, as appropriate, to execute the functions specified in this section. EPA enforcement officers or

authorized representatives may proceed ex parte to obtain a warrant whether or not the EPA enforcement officers or EPA authorized representatives first attempted to seek permission of the recipient of the test order or the party in charge of the facilities in question to conduct activities related to entry and access as authorized in this section.

(e) A recipient of a test order must permit an EPA enforcement officer(s) or EPA authorized representative(s) who presents a warrant or court order to conduct activities related to entry and access as authorized in this section and as described in the warrant or court order. The recipient must also cause those in charge of its facility or a facility operated for its benefit to permit entry and access as authorized in this section pursuant to a warrant or court order whether or not the recipient controls the facility. In the absence of a warrant or court order, an EPA enforcement officer(s) or EPA authorized representative(s) may conduct activities related to entry and access as authorized in this section only upon the consent of the recipient of the test order or the party in charge of the facilities in question.

(f) It is not a violation of this part or the Clean Air Act for any person to refuse to permit an EPA enforcement officer(s) or EPA authorized representative(s) to conduct activities related to entry and access as authorized in this section if the officer(s) or representative(s) appears without a warrant or court order.

(g) A manufacturer is responsible for locating its foreign testing and manufacturing facilities in jurisdictions where local law prohibits an EPA enforcement officer(s) or EPA authorized representative(s) from conducting the entry and access activities specified in this section. EPA will not attempt to make any inspections which it has been informed that local foreign law prohibits.

§ 89.507–96 Sample selection.

(a) Engines comprising a test sample will be selected at the location and in the manner specified in the test order. If a manufacturer determines that the test engines cannot be selected in the manner specified in the test order, an alternative selection procedure may be employed, provided the manufacturer requests approval of the alternative procedure prior to the start of test sample selection, and the Administrator approves the procedure.

(b) The manufacturer must assemble the test engines of the family selected for testing using its normal mass production process for engines to be distributed into commerce. If, between the time the manufacturer is notified of a test order and the time the manufacturer finishes selecting test engines, the manufacturer implements any change(s) in its production processes, including quality control, which may reasonably be expected to affect the emissions of the engines selected, then the manufacturer must, during the audit, inform the Administrator of such changes. If the test engines are selected at a location where they do not have their operational and emission control systems installed, the test order will specify the manner and location for selection of components to complete assembly of the engines. The manufacturer must assemble these components onto the test engines using normal assembly and quality control procedures as documented by the manufacturer.

(c) No quality control, testing, or assembly procedures will be used on the test engine or any portion thereof, including parts and subassemblies, that have not been or will not be used during the production and assembly of all other engines of that family, unless the Administrator approves the modification in assembly procedures pursuant to paragraph (b) of this section.

(d) The test order may specify that an EPA enforcement officer(s) or authorized representative(s), rather than the manufacturer, select the test engines according to the method specified in the test order.

(e) The order in which test engines are selected determines the order in which test results are to be used in applying the sampling plan in accordance with § 89.510–96.

(f) The manufacturer must keep on hand all untested engines, if any, comprising the test sample until a pass or fail decision is reached in accordance with § 89.510–96(e). The manufacturer may ship any tested engine which has not failed the requirements as set forth in § 89.510–96(b). However, once the manufacturer ships any test engine, it relinquishes the prerogative to conduct retests as provided in § 89.508–96(i).

§ 89.508–96 Test procedures.

(a)(1) For nonroad engines subject to the provisions of this subpart, the prescribed test procedures are the nonroad engine 8-mode test procedure as described in subpart E of this part, the federal smoke test as described in part 86, subpart I of this chapter, and the particulate test procedure as adopted in the California Regulations for New 1996 and Later Heavy-Duty Off-Road Diesel Cycle Engines. This procedure is incorporated by reference. See § 89.6.

(2) The Administrator may, on the basis of a written application by a manufacturer, prescribe test procedures other than those specified in paragraph (a)(1) of this section for any nonroad engine he or she determines is not susceptible to satisfactory testing using the procedures specified in paragraph (a)(1) of this section.

(b)(1) The manufacturer may not adjust, repair, prepare, or modify the engines selected for testing and may not perform any emission tests on engines selected for testing pursuant to the test order unless this adjustment, repair, preparation, modification, and/or tests are documented in the manufacturer's engine assembly and inspection procedures and are actually performed or unless these adjustments and/or tests are required or permitted under this subpart or are approved in advance by the Administrator.

(2) The Administrator may adjust or cause to be adjusted any engine parameter which the Administrator has determined to be subject to adjustment for certification and Selective Enforcement Audit testing in accordance with § 89.108–96, to any setting within the physically adjustable range of that parameter, as determined by the Administrator in accordance with § 89.108–96, prior to the performance of any tests. However, if the idle speed parameter is one which the Administrator has determined to be subject to adjustment, the Administrator may not adjust it to any setting which causes a lower engine idle speed than would have been possible within the physically adjustable range of the idle speed parameter if the manufacturer had accumulated 125 hours of service on the engine under paragraph (c) of this section, all other parameters being identically adjusted for the purpose of the comparison. The manufacturer may be requested to supply information needed to establish an alternate minimum idle speed. The Administrator, in making or specifying these adjustments, may consider the effect of the deviation from the manufacturer's recommended setting on emission performance characteristics as well as the likelihood that similar settings will occur on in-use engines. In determining likelihood, the Administrator may consider factors such as, but not limited to, the effect of the adjustment on engine performance characteristics and surveillance information from similar in-use engines.

(c) *Service Accumulation.* Prior to performing exhaust emission testing on an SEA test engine, the manufacturer

may accumulate on each engine a number of hours of service equal to the greater of 125 hours or the number of hours the manufacturer accumulated during certification on the emission data engine corresponding to the family specified in the test order.

(1) Service accumulation must be performed in a manner using good engineering judgment to obtain emission results representative of normal production engines. This service accumulation must be consistent with the new engine break-in instructions contained in the applicable owner's manual.

(2) The manufacturer must accumulate service at a minimum rate of 16 hours per engine during each 24-hour period, unless otherwise approved by the Administrator.

(i) The first 24-hour period for service begins as soon as authorized checks, inspections, and preparations are completed on each engine.

(ii) The minimum service or mileage accumulation rate does not apply on weekends or holidays.

(iii) If the manufacturer's service or target is less than the minimum rate specified (16 hours per day), then the minimum daily accumulation rate is equal to the manufacturer's service target.

(3) Service accumulation must be completed on a sufficient number of test engines during consecutive 24-hour periods to assure that the number of engines tested per day fulfills the requirements of paragraphs (g)(1) and (g)(2) of this section.

(d) The manufacturer may not perform any maintenance on test engines after selection for testing, nor may the Administrator allow deletion of any engine from the test sequence, unless requested by the manufacturer and approved by the Administrator before any engine maintenance or deletion.

(e) The manufacturer must expeditiously ship test engines from the point of selection to the test facility. If the test facility is not located at or in close proximity to the point of selection, the manufacturer must assure that test engines arrive at the test facility within 24 hours of selection. The Administrator may approve more time for shipment based upon a request by the manufacturer accompanied by a satisfactory justification.

(f) If an engine cannot complete the service accumulation or an emission test because of a malfunction, the manufacturer may request that the Administrator authorize either the repair of that engine or its deletion from the test sequence.

(g) Whenever a manufacturer conducts testing pursuant to a test order issued under this subpart, the manufacturer must notify the Administrator within one working day of receipt of the test order as to which test facility will be used to comply with the test order. If no test cells are available at a desired facility, the manufacturer must provide alternate testing capability satisfactory to the Administrator.

(1) A manufacturer with projected nonroad engine sales for the United States market for the applicable year of 7,500 or greater must complete emission testing at a minimum rate of two engines per 24-hour period, including each voided test and each smoke test.

(2) A manufacturer with projected nonroad engine sales for the United States market for the applicable year of less than 7,500 must complete emission testing at a minimum rate of one engine per 24-hour period, including each voided test and each smoke test.

(3) The Administrator may approve a lower daily rate of emission testing based upon a request by a manufacturer accompanied by a satisfactory justification.

(h) The manufacturer must perform test engine selection, shipping, preparation, service accumulation, and testing in such a manner as to assure that the audit is performed in an expeditious manner.

(i) *Retesting.* (1) The manufacturer may retest any engines tested during a Selective Enforcement Audit once a fail decision for the audit has been reached in accordance with § 89.510–96(e).

(2) The Administrator may approve retesting at other times based upon a request by the manufacturer accompanied by a satisfactory justification.

(3) The manufacturer may retest each engine a total of three times. The manufacturer must test each engine or vehicle the same number of times. The manufacturer may accumulate additional service before conducting a retest, subject to the provisions of paragraph (c) of this section.

(j) A manufacturer must test engines with the test procedure specified in subpart E of this part to demonstrate compliance with the exhaust emission standard (or applicable FEL) for oxides of nitrogen. If alternate procedures were used in certification pursuant to § 89.114–96, then those alternate procedures must be used.

§ 89.509–96 Calculation and reporting of test results.

(a) Initial test results are calculated following the applicable test procedure specified in paragraph (a) of § 89.508–96. The manufacturer rounds these results, in accordance with ASTM E29–90, to the number of decimal places contained in the applicable emission standard expressed to one additional significant figure. This procedure has been incorporated by reference. See § 89.6.

(b) Final test results are calculated by summing the initial test results derived in paragraph (a) of this section for each test engine, dividing by the number of tests conducted on the engine, and rounding in accordance with ASTM E29–90 to the same number of decimal places contained in the applicable standard expressed to one additional significant figure.

(c) Within five working days after completion of testing of all engines pursuant to a test order, the manufacturer must submit to the Administrator a report which includes the following information:

(1) The location and description of the manufacturer's exhaust emission test facilities which were utilized to conduct testing reported pursuant to this section;

(2) The applicable standards and/or FEL against which the engines were tested;

(3) A description of the engine and its associated emission-related component selection method used;

(4) For each test conducted;

(i) Test engine description, including:

(A) Configuration and engine family identification;

(B) Year, make, and build date;

(C) Engine identification number; and

(D) Number of hours of service accumulated on engine prior to testing;

(ii) Location where service accumulation was conducted and description of accumulation procedure and schedule;

(iii) Test number, date, test procedure used, initial test results before and after rounding, and final test results for all exhaust emission tests, whether valid or invalid, and the reason for invalidation, if applicable;

(iv) A complete description of any modification, repair, preparation, maintenance, and/or testing which was performed on the test engine and has not been reported pursuant to any other paragraph of this subpart and will not be performed on all other production engines;

(v) Where an engine was deleted from the test sequence by authorization of the Administrator, the reason for the deletion;

(vi) Any other information the Administrator may request relevant to the determination as to whether the new engines being manufactured by the

manufacturer do in fact conform with the regulations with respect to which the certificate of conformity was issued; and

(5) The following statement and endorsement:

This report is submitted pursuant to sections 213 and 208 of the Clean Air Act. This Selective Enforcement Audit was conducted in complete conformance with all applicable regulations under 40 CFR part 89 *et seq.* and the conditions of the test order. No emission-related changes to production processes or quality control procedures for the engine family tested have been made between receipt of the test order and conclusion of the audit. All data and information reported herein is, to the best of (Company Name) knowledge, true and accurate. I am aware of the penalties associated with violations of the Clean Air Act and the regulations thereunder. (Authorized Company Representative.)

§ 89.510–96 Compliance with acceptable quality level and passing and failing criteria for selective enforcement audits.

(a) The prescribed acceptable quality level is 40 percent.

(b) A failed engine is one whose final test results pursuant to § 89.509–96(b), for one or more of the applicable pollutants, exceed the applicable emission standard or family emission level.

(c) The manufacturer must test engines comprising the test sample until a pass decision is reached for all pollutants or a fail decision is reached for one pollutant. A pass decision is reached when the cumulative number of failed engines, as defined in paragraph (b) of this section, for each pollutant is less than or equal to the pass decision number, as defined in paragraph (d) of this section, appropriate to the cumulative number of engines tested. A fail decision is reached when the cumulative number of failed engines for one or more pollutants is greater than or equal to the fail decision number, as defined in paragraph (d) of this section, appropriate to the cumulative number of engines tested.

(d) The pass and fail decision numbers associated with the cumulative number of engines tested are determined by using the tables in appendix A to this subpart, "Sampling Plans for Selective Enforcement Auditing of Nonroad Engines," appropriate to the projected sales as made by the manufacturer in its report to EPA under § 89.505–96(c)(1). In the tables in appendix A to this subpart, sampling plan "stage" refers to the cumulative number of engines tested. Once a pass or fail decision has been made for a particular pollutant, the number of engines with final test results exceeding the emission standard for that pollutant shall not be considered any further for the purposes of the audit.

(e) Passing or failing of an SEA occurs when the decision is made on the last engine required to make a decision under paragraph (c) of this section.

(f) The Administrator may terminate testing earlier than required in paragraph (c) of this section.

§ 89.511–96 Suspension and revocation of certificates of conformity.

(a) The certificate of conformity is suspended with respect to any engine failing pursuant to paragraph (b) of § 89.510–96 effective from the time that testing of that engine is completed.

(b) The Administrator may suspend the certificate of conformity for a family which does not pass an SEA, pursuant to paragraph § 89.510–96(c), based on the first test or all tests conducted on each engine. This suspension will not occur before ten days after failure of the audit, unless the manufacturer requests an earlier suspension.

(c) If the results of testing pursuant to these regulations indicate that engines of a particular family produced at one plant of a manufacturer do not conform to the regulations with respect to which the certificate of conformity was issued, the Administrator may suspend the certificate of conformity with respect to that family for engines manufactured by the manufacturer at all other plants.

(d) Notwithstanding the fact that engines described in the application may be covered by a certificate of conformity, the Administrator may suspend such certificate immediately in whole or in part if the Administrator finds any one of the following infractions to be substantial:

(1) The manufacturer refuses to comply with the provisions of a test order issued by the Administrator under § 89.503–96.

(2) The manufacturer refuses to comply with any of the requirements of this subpart.

(3) The manufacturer submits false or incomplete information in any report or information provided to the Administrator under this subpart.

(4) The manufacturer renders inaccurate any test data submitted under this subpart.

(5) An EPA enforcement officer(s) or EPA authorized representative(s) is denied the opportunity to conduct activities related to entry and access as authorized in this subpart and a warrant or court order is presented to the manufacturer or the party in charge of a facility in question.

(6) An EPA enforcement officer(s) or EPA authorized representative(s) is unable to conduct activities related to entry and access as authorized in § 89.506–96 because a manufacturer has located a facility in a foreign jurisdiction where local law prohibits those activities.

(e) The Administrator must notify the manufacturer in writing of any suspension or revocation of a certificate of conformity in whole or in part; a suspension or revocation is effective upon receipt of the notification or ten days, except that the certificate is immediately suspended with respect to any failed engines as provided for in paragraph (a) of this section.

(f) The Administrator may revoke a certificate of conformity for a family when the certificate has been suspended pursuant to paragraph (b) or (c) of this section if the proposed remedy for the nonconformity, as reported by the manufacturer to the Administrator, is one requiring a design change or changes to the engine and/or emission control system as described in the application for certification of the affected family.

(g) Once a certificate has been suspended for a failed engine, as provided for in paragraph (a) of this section, the manufacturer must take the following actions before the certificate is reinstated for that failed engine:

(1) Remedy the nonconformity.

(2) Demonstrate that the engine conforms to applicable standards or family emission levels by retesting the engine in accordance with these regulations.

(3) Submit a written report to the Administrator, after successful completion of testing on the failed engine, which contains a description of the remedy and test results for each engine in addition to other information that may be required by this part.

(h) Once a certificate for a failed family has been suspended pursuant to paragraph (b) or (c) of this section, the manufacturer must take the following actions before the Administrator will consider reinstating the certificate:

(1) Submit a written report to the Administrator which identifies the reason for the noncompliance of the engines, describes the proposed remedy, including a description of any proposed quality control and/or quality assurance measures to be taken by the manufacturer to prevent future occurrences of the problem, and states the date on which the remedies will be implemented.

(2) Demonstrate that the engine family for which the certificate of conformity has been suspended does in fact comply with these regulations by testing engines selected from normal production runs of

that engine family, at the plant(s), port facility(ies) or associated storage facility(ies) specified by the Administrator, in accordance with the conditions specified in the initial test order. If the manufacturer elects to continue testing individual engines after suspension of a certificate, the certificate is reinstated for an engine actually determined to be in conformance with the applicable standards or family emission levels through testing in accordance with the applicable test procedures, provided that the Administrator has not revoked the certificate pursuant to paragraph (f) of this section.

(i) Once the certificate for a family has been revoked under paragraph (f) of this section and the manufacturer desires to continue introduction into commerce of a modified version of that family, the following actions must be taken before the Administrator may consider issuing a certificate for that modified family:

(1) If the Administrator determines that the proposed change(s) in engine design may have an effect on emission performance deterioration, the Administrator will notify the manufacturer, within five working days after receipt of the report in paragraph (g) of this section, whether subsequent testing under this subpart is sufficient to evaluate the proposed change or changes or whether additional testing is required; and

(2) After implementing the change or changes intended to remedy the nonconformity, the manufacturer must demonstrate that the modified engine family does in fact conform with these regulations by testing engines selected from normal production runs of that modified engine family in accordance with the conditions specified in the initial test order. If the subsequent audit results in passing of the audit, the Administrator will reissue the certificate or issue a new certificate, as the case may be, to include that family, provided that the manufacturer has satisfied the testing requirements of paragraph (i)(1) of this section. If the subsequent audit is failed, the revocation remains in effect. Any design change approvals under this subpart are limited to the family affected by the test order.

(j) At any time subsequent to an initial suspension of a certificate of conformity for a test engine pursuant to paragraph (a) of this section, but not later than 15 days (or such other period as may be allowed by the Administrator) after notification of the Administrator's decision to suspend or revoke a certificate of conformity in whole or in part pursuant to paragraph (b), (c), or (f) of this section, a manufacturer may request a hearing as to whether the tests have been properly conducted or any sampling methods have been properly applied.

(k) Any suspension of a certificate of conformity under paragraph (d) of this section:

(1) will be in writing and will include the offer of an opportunity for a hearing conducted in accordance with §§ 89.512–96, 89.513–96, and 89.514–96 and

(2) need not apply to engines no longer in the hands of the manufacturer.

(l) After the Administrator suspends or revokes a certificate of conformity pursuant to this section and prior to the commencement of a hearing under § 89.512–96, if the manufacturer demonstrates to the Administrator's satisfaction that the decision to suspend, revoke, or void the certificate was based on erroneous information, the Administrator will reinstate the certificate.

(m) To permit a manufacturer to avoid storing non-test engines when conducting an audit of a family subsequent to a failure of an SEA and while reauditing of the failed family, it may request that the Administrator conditionally reinstate the certificate for that family. The Administrator may reinstate the certificate subject to the condition that the manufacturer consents to recall all engines of that family produced from the time the certificate is conditionally reinstated if the family fails the subsequent audit at the level of the standard and to remedy any nonconformity at no expense to the owner.

§ 89.512–96 Request for public hearing.

(a) If the manufacturer disagrees with the Administrator's decision under § 89.511–96 (b), (c), (d), or (f) to suspend or revoke a certificate or disputes the basis for an automatic suspension pursuant to § 89.511–96 (a), the manufacturer may request a public hearing.

(b) The manufacturer's request must be filed with the Administrator not later than 15 days after the Administrator's notification of the decision to suspend or revoke, unless otherwise specified by the Administrator. The manufacturer must simultaneously serve two copies of this request upon the Director of the Manufacturers Operations Division and file two copies with the Hearing Clerk of the Agency. Failure of the manufacturer to request a hearing within the time provided constitutes a waiver of the right to a hearing. Subsequent to the expiration of the period for requesting a hearing as of right, the Administrator may, at her or his discretion and for good cause shown, grant the manufacturer a hearing to contest the suspension or revocation.

(c) The manufacturer's request for a public hearing must include:

(1) A statement as to which engine configuration(s) within a family is to be the subject of the hearing;

(2) A concise statement of the issues to be raised by the manufacturer at the hearing, except that in the case of the hearing requested under § 89.511–96(j), the hearing is restricted to the following issues:

(i) Whether tests have been properly conducted, specifically, whether the tests were conducted in accordance with applicable regulations under this part and whether test equipment was properly calibrated and functioning;

(ii) Whether sampling plans have been properly applied, specifically, whether sampling procedures specified in Appendix A of this subpart were followed and whether there exists a basis for distinguishing engines produced at plants other than the one from which engines were selected for testing which would invalidate the Administrator's decision under § 89.511–96(c);

(3) A statement specifying reasons why the manufacturer believes it will prevail on the merits of each of the issues raised; and

(4) A summary of the evidence which supports the manufacturer's position on each of the issues raised.

(d) A copy of all requests for public hearings will be kept on file in the Office of the Hearing Clerk and will be made available to the public during Agency business hours.

§ 89.513–96 Administrative procedures for public hearing.

(a) The Presiding Officer is an Administrative Law Judge appointed pursuant to 5 U.S.C. 3105 (see also 5 CFR part 930 as amended).

(b) The Judicial Officer is an officer or employee of the Agency appointed as a Judicial Officer by the Administrator, pursuant to this section, who meets the qualifications and performs functions as follows:

(1) *Qualifications.* A Judicial Officer may be a permanent or temporary employee of the Agency who performs other duties for the Agency. The Judicial Officer may not be employed by the Office of Enforcement or have any connection with the preparation or presentation of evidence for a hearing held pursuant to this subpart. The Judicial Officer must be a graduate of an accredited law school and a member in good standing of a recognized Bar

Association of any state or the District of Columbia.

(2) *Functions.* The Administrator may consult with the Judicial Officer or delegate all or part of the Administrator's authority to act in a given case under this section to a Judicial Officer, provided that this delegation does not preclude the Judicial Officer from referring any motion or case to the Administrator when the Judicial Officer determines such referral to be appropriate.

(c) For the purposes of this section, one or more Judicial Officers may be designated. As work requires, a Judicial Officer may be designated to act for the purposes of a particular case.

(d) *Summary decision.* (1) In the case of a hearing requested under § 89.511–96(j), when it clearly appears from the data and other information contained in the request for a hearing that no genuine and substantial question of fact or law exists with respect to the issues specified in § 89.512–96(c)(2), the Administrator may enter an order denying the request for a hearing and reaffirming the original decision to suspend or revoke a certificate of conformity.

(2) In the case of a hearing requested under § 89.512–96 to challenge a suspension of a certificate of conformity for the reasons specified in § 89.511–96(d), when it clearly appears from the data and other information contained in the request for the hearing that no genuine and substantial question of fact or law exists with respect to the issue of whether the refusal to comply with the provisions of a test order or any other requirement of § 89.503–96 was caused by conditions and circumstances outside the control of the manufacturer, the Administrator may enter an order denying the request for a hearing and suspending the certificate of conformity.

(3) Any order issued under paragraph (d)(1) or (d)(2) of this section has the force and effect of a final decision of the Administrator, as issued pursuant to § 89.515–96.

(4) If the Administrator determines that a genuine and substantial question of fact or law does exist with respect to any of the issues referred to in paragraphs (d)(1) and (d)(2) of this section, the Administrator will grant the request for a hearing and publish a notice of public hearing in the **Federal Register** or by such other means as the Administrator finds appropriate to provide notice to the public.

(e) *Filing and service.* (1) An original and two copies of all documents or papers required or permitted to be filed pursuant to this section and § 89.512–96(c) must be filed with the Hearing Clerk of the Agency. Filing is considered timely if mailed, as determined by the postmark, to the Hearing Clerk within the time allowed by this section and § 89.512–96(b). If filing is to be accomplished by mailing, the documents must be sent to the address set forth in the notice of public hearing referred to in paragraph (d)(4) of this section.

(2) To the maximum extent possible, testimony will be presented in written form. Copies of written testimony will be served upon all parties as soon as practicable prior to the start of the hearing. A certificate of service will be provided on or accompany each document or paper filed with the Hearing Clerk. Documents to be served upon the Director of the Manufacturers Operations Division must be sent by registered mail to: Director, Manufacturers Operations Division, U.S. Environmental Protection Agency, 6405–J, 401 M Street SW, Washington, DC 20460. Service by registered mail is complete upon mailing.

(f) *Computation of Time.* (1) In computing any period of time prescribed or allowed by this section, except as otherwise provided, the day of the act or event from which the designated period of time begins to run is not included. Saturdays, Sundays, and federal legal holidays are included in computing the period allowed for the filing of any document or paper, except that when the period expires on a Saturday, Sunday, or federal legal holiday, the period is extended to include the next following business day.

(2) A prescribed period of time within which a party is required or permitted to do an act is computed from the time of service, except that when service is accomplished by mail, three days will be added to the prescribed period.

(g) *Consolidation.* The Administrator or the Presiding Officer in his discretion may consolidate two or more proceedings to be held under this section for the purpose of resolving one or more issues whenever it appears that consolidation will expedite or simplify consideration of these issues. Consolidation does not affect the right of any party to raise issues that could have been raised if consolidation had not occurred.

(h) *Hearing Date.* To the extent possible hearings under § 89.512–96 will be scheduled to commence within 14 days of receipt of the application in § 89.512–96.

§ 89.514–96 Hearing procedures.

The procedures provided in § 86.1014–84 (i) to (s) apply for hearings requested pursuant to § 89.512–96, suspension, revocation, or voiding of a certificate of conformity.

§ 89.515–96 Appeal of hearing decision.

The procedures provided in § 86.1014–84 (t) to (aa) apply for appeals filed with respect to hearings held pursuant to § 89.514–96.

§ 89.516–96 Treatment of confidential information.

The provisions for treatment of confidential information as described in § 89.7 apply.

Appendix A to Subpart F of Part 89—Sampling Plans for Selective Enforcement Auditing of Nonroad Engines

TABLE 1.—SAMPLING PLAN CODE LETTER

Annual engine family sales	Code letter
20–50	AA[1]
20–99	A
100–299	B
300–299	C
500 or greater	D

[1] A manufacturer may optionally use either the sampling plan for code letter "AA" or sampling plan for code letter "A" for Selective Enforcement Audits of engine families with annual sales between 20 and 50 engines. Additionally, the manufacturer may switch between these plans during the audit.

TABLE 2.—SAMPLING PLAN FOR CODE LETTER "AA"

[Sample inspection criteria]

Stage	Pass No.	Fail No.
1	([1])	([2])
2	([1])	([2])
3	0	([2])
4	0	([2])
5	1	5
6	1	6
7	2	6
8	2	7
9	3	7
10	3	8
11	4	8
12	4	9
13	5	9
14	5	10
15	6	10
16	6	10
17	7	10
18	8	10
19	8	10
20	9	10

[1] Test sample passing not permitted at this stage.

[2] Test sample failure not permitted at this stage.

TABLE 3.—SAMPLING PLAN FOR CODE LETTER "A"

[Sample inspection criteria]

Stage	Pass No.	Fail No.
1	(1)	(2)
2	(1)	(2)
3	(1)	(2)
4	0	(2)
5	0	(2)
6	1	6
7	1	7
8	2	7
9	2	8
10	3	8
11	3	8
12	4	9
13	5	10
14	5	10
15	6	11
16	6	11
17	7	12
18	7	12
19	8	13
20	8	13
21	9	14
22	10	14
23	10	15
24	11	15
25	11	16
26	12	16
27	12	17
28	13	17
29	14	17
30	16	17

[1] Test sample passing not permitted at this stage.
[2] Test sample failure not permitted at this stage.

TABLE 4.—SAMPLING PLAN FOR CODE LETTER "B"

[Sample Inspection Criteria]

Stage	Pass No.	Fail No.
1	(1)	(2)
2	(1)	(2)
3	(1)	(2)
4	(1)	(2)
5	0	(2)
6	1	6
7	1	7
8	2	7
9	2	8
10	3	8
11	3	9
12	4	9
13	4	10
14	5	10
15	5	11
16	6	12
17	6	12
18	7	13
19	8	13
20	8	14
21	9	14
22	9	15
23	10	15
24	10	16
25	11	16
26	11	17
27	12	17
28	12	18
29	13	18
30	13	19
31	14	19
32	14	20
33	15	20
34	16	21
35	16	21
36	17	22
37	17	22
38	18	22
39	18	22
40	21	22

[1] Test sample passing not permitted at this stage.
[2] Test sample failure not permitted at this stage.

TABLE 5.—SAMPLING PLAN FOR CODE LETTER "C"

[Sample Inspection Criteria]

Stage	Pass No.	Fail No.
1	(1)	(2)
2	(1)	(2)
3	(1)	(2)
4	(1)	(2)
5	0	(2)
6	0	6
7	1	7
8	2	7
9	2	8
10	3	9
11	3	9
12	4	10
13	4	10
14	5	11
15	5	11
16	6	12
17	6	12
18	7	13
19	7	13
20	8	14
21	8	14
22	9	15
23	10	15
24	10	16
25	11	16
26	11	17
27	12	17
28	12	18
29	13	18
30	13	19
31	14	19
32	14	20
33	15	20
34	15	21
35	16	21
36	16	22
37	17	22
38	18	23
39	18	23
40	19	24
41	19	24
42	20	25
43	20	25
44	21	26
45	21	27
46	22	27
47	22	27
48	23	27
49	23	27
50	26	27

[1] Test sample passing not permitted at this stage.
[2] Test sample failure not permitted at this stage.

TABLE 6.—SAMPLING PLAN FOR CODE LETTER "D"

[Sample Inspection Criteria]

Stage	Pass No.	Fail No.
1	(1)	(2)
2	(1)	(2)
3	(1)	(2)
4	(1)	(2)
5	0	(2)
6	0	6
7	1	7
8	2	8
9	2	8
10	3	9
11	3	9
12	4	10
13	4	10
14	5	11
15	5	11
16	6	12
17	6	12
18	7	13
19	7	13
20	8	14
21	8	14
22	9	15
23	9	15
24	10	16
25	11	16
26	11	17
27	12	17
28	12	18
29	13	19
30	13	19
31	14	20
32	14	20
33	15	21
34	15	21
35	16	22
36	16	22
37	17	23
38	17	23
39	18	24
40	18	24
41	19	25
42	19	26
43	20	26
44	21	27
45	21	27
46	22	28
47	22	28
48	23	29
49	23	29
50	24	30
51	24	30

TABLE 6.—SAMPLING PLAN FOR CODE LETTER "D"—Continued

[Sample Inspection Criteria]

Stage	Pass No.	Fail No.
52	25	31
53	25	31
54	26	32
55	26	32
56	27	33
57	27	33
58	28	33
59	28	33
60	32	33

[1] Test sample passing not permitted at this stage.

[2] Test sample failure not permitted at this stage.

Subpart G—Importation of Nonconforming Nonroad Engines

§ 89.601–96 Applicability.

(a) Except where otherwise indicated, this subpart is applicable to nonroad engines for which the Administrator has promulgated regulations under this part prescribing emission standards and nonroad vehicles and equipment containing such nonroad engines that are offered for importation or imported into the United States, but which engines, at the time of conditional importation, are not covered by certificates of conformity issued under section 213 and section 206(a) of the Clean Air Act as amended (that is, which are nonconforming nonroad engines as defined in § 89.602–96), and this part. Compliance with regulations under this subpart does not relieve any person or entity from compliance with other applicable provisions of the Clean Air Act.

(b) Regulations prescribing further procedures for the importation of nonroad engines and nonroad vehicles and equipment into the customs territory of the United States, as defined in 19 U.S.C. 1202, are set forth in U.S. Bureau of Customs regulations.

(c) For the purposes of this subpart, the term "nonroad engine" includes all nonroad engines incorporated into nonroad equipment or nonroad vehicles at the time they are imported or offered for import into the United States.

§ 89.602–96 Definitions.

The definitions in subpart A of this part apply to this subpart. The following definitions also apply to this subpart.

Certificate of conformity. The document issued by the Administrator under section 213 and section 206(a) of the Act.

Currently valid certificate of conformity. A certificate of conformity for which the current date is within the effective period as specified on the certificate of conformity, and which has not been withdrawn, superseded, voided, suspended, revoked, or otherwise rendered invalid.

Fifteen working day hold period. The period of time between a request for final admission and the automatic granting of final admission (unless EPA intervenes) for a nonconforming nonroad engine conditionally imported pursuant to § 89.605–96 or § 89.609–96. Day one of the hold period is the first working day (see definition below) after the Manufacturers Operations Division of EPA receives a complete and valid application for final admission.

Independent commercial importer (ICI). An importer who is not an original engine manufacturer (OEM) (see definition below), but is the entity in whose name a certificate of conformity for a class of nonroad engines has been issued.

Model year for imported engines. The manufacturer's annual production period (as determined by the Administrator) which includes January 1 of the calendar year; provided, that if the manufacturer has no annual production period, the term "model year" means the calendar year in which a nonroad engine is modified. An independent commercial importer (ICI) is deemed to have produced a nonroad engine when the ICI has modified (including labeling) the nonconforming nonroad engine to meet applicable emission requirements.

Nonconforming nonroad engine. A nonroad engine which is not covered by a certificate of conformity prior to final or conditional admission (or for which such coverage has not been adequately demonstrated to EPA) and which has not been finally admitted into the United States under the provisions of § 89.605–96 or § 89.609–96.

Original engine manufacturer (OEM). The entity which originally manufactured the nonroad engine.

Original production (OP) year. The calendar year in which the nonroad engine was originally produced by the OEM.

Original production (OP) years old. The age of a nonroad engine as determined by subtracting the original production year of the nonroad engine from the calendar year of importation.

Production changes. Those changes in nonroad engine configuration, equipment, or calibration which are made by an OEM or ICI in the course of nonroad engine production and required to be reported under § 89.123–96.

United States. United States includes the customs territory of the United States as defined in 19 U.S.C. 1202, and the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

Useful life. A period of time as specified in subpart B of this part which for a nonconforming nonroad engine begins at the time of resale (for a nonroad engine owned by the ICI at the time of importation) or release to the owner (for a nonroad engine not owned by the ICI at the time of importation) of the nonroad engine by the ICI after modification and/or testing pursuant to § 89.605–96 or § 89.609–96.

Working day. Any day on which federal government offices are open for normal business. Saturdays, Sundays, and official federal holidays are not working days.

§ 89.603–96 General requirements for importation of nonconforming nonroad engines.

(a) A nonconforming nonroad engine offered for importation into the United States is to be imported only by an Independent Commercial Importer (ICI) who is a holder of a currently valid certificate of conformity unless an exemption or exclusion is granted by the Administrator under § 89.611–96 of this subpart. For a nonroad engine imported pursuant to § 89.605–96, the ICI must hold a currently valid certificate of conformity for that specific nonroad engine model.

(b) Any nonroad engine imported into the United States must have a legible unique engine identification number permanently affixed to or engraved on the engine.

(c) Final admission may not be granted unless:

(1) The nonroad engine is covered by a certificate of conformity issued under subpart B of this part in the name of the ICI and the ICI has complied with all requirements of § 89.605–96; or

(2) The nonroad engine is modified and emission tested in accordance with the provisions of § 89.609–96 and the ICI has complied with all other requirements of § 89.609–96; or

(3) The nonroad engine is exempted or excluded under § 89.611–96.

(d) The ICI must submit to the Manufacturers Operations Division of EPA a copy of all approved applications for certification used to obtain certificates of conformity for the purpose of importing nonconforming nonroad engines pursuant to § 89.605–96 or § 89.609–96. In addition, the ICI must submit to the Manufacturers Operations Division a copy of all approved production changes implemented pursuant to § 89.605–96 or subpart B of this part. Documentation

submitted pursuant to this paragraph must be provided to the Manufacturers Operations Division within 10 working days of approval of the certification application (or production change) by the Certification Division of EPA.

§ 89.604–96 Conditional admission.

(a) A nonroad engine offered for importation under § 89.605–96 or § 89.609–96 may be conditionally admitted into the United States. These engines are refused final admission, unless at the time of conditional admission the importer has submitted to the Administrator a written report that the subject nonroad engine has been permitted conditional admission pending EPA approval of its application for final admission under § 89.605–96 or § 89.609–96. This written report is to contain the following:

(1) Identification of the importer of the nonroad engine and the importer's address, telephone number, and taxpayer identification number;

(2) Identification of the nonroad engine owner, the owner's address, telephone number, and taxpayer identification number;

(3) Identification of the nonroad engine including make, model, identification number, and original production year;

(4) Information indicating under what provision of these regulations the nonroad engine is to be imported;

(5) Identification of the place where the subject nonroad engine is to be stored until EPA approval of the importer's application to the Administrator for final admission;

(6) Authorization for EPA enforcement officers to conduct inspections or testing otherwise permitted by the Act or regulations thereunder;

(7) Identification of the Independent Commercial Importer's (ICI) certificate of conformity that permits the ICI to import that nonroad engine (for importation under § 89.605–96 or § 89.609–96); and

(8) Such other information as is deemed necessary by the Administrator.

(b) EPA will not require a U.S. Customs Service bond for a nonconforming nonroad engine which is imported under § 89.605–96 or § 89.609–96. The period of conditional admission may not exceed 120 days. Nonroad engines imported under § 89.605–96 or § 89.609–96 may not be operated during the period of conditional admission except for that operation necessary to comply with the requirements of this subpart. During the period of conditional admission applicable to § 89.605–96 or § 89.609–96, the importer must store the nonroad engine at a location where the Administrator has reasonable access to the nonroad engine for inspection.

(c) During the period of conditional admission under § 89.605–96 or § 89.609–96, an ICI may transfer responsibility of a nonroad engine to another qualified ICI for the purposes of complying with this subpart.

(1) The transferee ICI must be a holder of a currently valid certificate of conformity for the specific nonroad engine being transferred or be authorized to import the nonroad engine pursuant to § 89.609–96 as of the transfer date. The transferee ICI must comply with all the requirements of § 89.603–96, § 89.604–96, and either § 89.605–96 or § 89.609–96, as applicable.

(2) For the purpose of this subpart, the transferee ICI has "imported" the nonroad engine as of the transfer date as designated in a written record that is signed by both ICIs.

(3) The ICI that originally imported the nonroad engine is responsible for all requirements of this subpart from the actual date of importation until the date of transfer as designated in the written record. The transferee ICI is responsible for all requirements of this subpart beginning on the date of transfer.

(4) A copy of the written record is to be submitted to the Manufacturers Operations Division of EPA within five working days of the transfer date.

(d) Notwithstanding any other requirement of this subpart or U.S. Customs Service regulations, an ICI may also assume responsibility for the modification and testing of a nonconforming nonroad engine which was previously imported by another party. The ICI must be a holder of a currently valid certificate of conformity for that specific nonroad engine or authorized to import it pursuant to § 89.609–96 at the time of assuming such responsibility. The ICI must comply with all the requirements of § 89.603–96, § 89.604–96, and either § 89.605–96 or § 89.609–96, as applicable. For the purposes of this subpart, the ICI has "imported" the nonroad engine as of the date the ICI assumes responsibility for the modification and testing of the nonroad engine. The ICI must submit written notification to the Manufacturers Operations Division of EPA within 10 working days of the assumption of that responsibility.

§ 89.605–96 Final admission of certified nonroad engines.

(a) A nonroad engine may be finally admitted into the United States upon approval of the ICI's application to the Administrator. The application is made by completing EPA forms in accordance with EPA instructions. The application contains:

(1) The information required in § 89.604–96(a);

(2) Information demonstrating that the nonroad engine has been modified in accordance with a valid certificate of conformity. Demonstration is made in one of the following ways:

(i) The ICI attests that the nonroad engine has been modified in accordance with the provisions of the ICI's certificate of conformity; presents to EPA a statement written by the applicable Original Engine Manufacturer (OEM) that the OEM must provide to the ICI, and to EPA, information concerning production changes to the class of nonroad engines described in the ICI's application for certification; delivers to the Manufacturers Operations Division of EPA notification by the ICI of any production changes already implemented by the OEM at the time of application and their effect on emissions; and obtains from EPA written approval to use this demonstration option; or

(ii) The ICI attests that the nonroad engine has been modified in accordance with the provisions of the ICI's certificate of conformity. The ICI also attests that it has conducted, within 120 days of entry, an applicable and valid emission test on every third nonroad engine imported under that certificate of conformity to demonstrate compliance with federal emission requirements. The test is to be conducted at a laboratory located within the United States. Sequencing of the tests is determined by the date of importation of each nonroad engine beginning with the prototype nonroad engine used to obtain the applicable certificate of conformity. Should the ICI exceed a threshold of 300 nonroad engines imported under the certificate of conformity without adjustments or other changes in accordance with paragraph (a)(3) of this section, the amount of required testing is reduced to every fifth nonroad engine.

(3) The results of every emission test which the ICI conducted on the nonroad engine pursuant to paragraph (a)(2)(ii) of this section. Should a subject nonroad engine fail an emission test at any time, the following procedures are applicable:

(i) The ICI may either:

(A) Conduct one retest that involves no adjustment of the nonroad engine from the previous test (for example, adjusting the RPM, timing, air-to-fuel ratio, and so forth) other than adjustments to adjustable parameters

that, upon inspection, were found to be out of tolerance. When such an allowable adjustment is made, the parameter may be reset only to the specified (that is, nominal) value (and not any other value within the tolerance band); or

(B) Initiate a change in production (production change) under the provisions of subpart B of this part that causes the nonroad engine to meet federal emission requirements.

(ii) If the ICI chooses to retest in accordance with paragraph (a)(3)(i)(A) of this section:

(A) The retests are to be completed no later than five working days subsequent to the first emission test;

(B) Should the subject nonroad engine fail the second emission test, then the ICI must initiate a change in production (a production change) under the provisions of subpart B of this part that causes the nonroad engine to meet federal emission requirements.

(iii) If the ICI chooses to initiate a change in production (a production change) under the provisions of subpart B of this part that causes the nonroad engine to meet federal requirements, a change involving adjustments of adjustable nonroad engine parameters (for example, adjusting the RPM, timing, air/fuel ratio) represents a change in the specified (that is, nominal) value to be deemed acceptable by EPA.

(iv) A production change made in accordance with this section is to be implemented on all subsequent nonroad engines imported under the certificate of conformity after the date of importation of the nonroad engine which gave rise to the production change.

(v) Commencing with the first nonroad engine receiving the production change, every third nonroad engine imported under the certificate of conformity is to be emission tested to demonstrate compliance with federal emission requirements until, as in paragraph (a)(2)(ii) of this section, a threshold of 300 nonroad engines imported under the certificate of conformity is exceeded without adjustments or other changes in accordance with paragraph (a)(3)(i)(A) of this section, at which time the amount of required emission testing is reduced to every fifth nonroad engine.

(vi) A report concerning these production changes is to be made to both the Manufacturers Operations and Certification Divisions of EPA within ten working days of initiation of the production change. The cause of any failure of an emission test is to be identified, if known;

(4) The applicable deterioration factor, if any;

(5) The emission test results adjusted by the deterioration factor;

(6) Other information that may be specified by applicable regulations or on the certificate of conformity under which the nonroad engine has been modified in order to assure compliance with requirements of the Act;

(7) All information required under § 89.610–96 related to maintenance, warranties, and labeling;

(8) An attestation by the ICI that the ICI is responsible for the nonroad engine's compliance with federal emission requirements, regardless of whether the ICI owns the nonroad engine imported under this section;

(9) The name, address, and telephone number of the person who the ICI prefers to receive EPA notification under § 89.605–96(c);

(10) An attestation by the ICI that all requirements of § 89.607–96 and § 89.610–96 have been met; and

(11) Other information as is deemed necessary by the Administrator.

(b) EPA approval for final admission of a nonroad engine under this section is to be presumed not to have been granted if a requirement of this subpart has not been met. This includes, but is not limited to, properly modifying the nonroad engine to be in conformity in all material respects with the description in the application for certification or not complying with the provisions of § 89.605–96(a)(2) or if the final emission test results, adjusted by the deterioration factor, if applicable, do not comply with applicable emission standards.

(c) Except as provided in paragraph (b) of this section, EPA approval for final admission of a nonroad engine under this section is presumed to have been granted if the ICI does not receive oral or written notice from EPA to the contrary within 15 working days of the date that the Manufacturers Operations Division of EPA receives the ICI's application under paragraph (a) of this section. EPA notice of nonapproval may be made to any employee of the ICI. It is the responsibility of the ICI to ensure that the Manufacturers Operations Division of EPA receives the application and to confirm the date of receipt. During this 15 working day hold period, the nonroad engine is to be stored at a location where the Administrator has reasonable access to the nonroad engine for the Administrator's inspection. The storage is to be within 50 miles of the ICI's testing facility to allow the Administrator reasonable access for inspection and/or testing. A storage facility not meeting this criterion must be approved in writing by the Administrator prior to the submittal of the ICI's application under paragraph (a) of this section.

§ 89.606–96 Inspection and testing of imported nonroad engines.

(a) In order to allow the Administrator to determine whether an ICI's production nonroad engines comply with applicable emission requirements or requirements of this subpart, an EPA enforcement officer or authorized representative is authorized to conduct inspections and/or tests of nonroad engines imported by the ICI. The ICI must admit an EPA enforcement officer or authorized representative during operating hours to any of the following places upon demand and upon presentation of credentials:

(1) Any facility where any nonroad engine imported by the ICI under this subpart was or is being modified, tested, or stored and

(2) Any facility where any record or other document relating to modification, testing, or storage of the nonroad engine, or required to be kept by § 89.607–96, is located. EPA may require inspection or testing of nonroad engines at the test facility used by the ICI or at an EPA-designated testing facility, with transportation and/or testing costs to be borne by the ICI.

(b) Upon admission to any facility referred to in paragraph (a) of this section, an EPA enforcement officer or authorized representative is allowed during operating hours:

(1) To inspect and monitor any part or aspect of activities relating to the ICI's modification, testing, and/or storage of nonroad engines imported under this subpart;

(2) To inspect and make copies of record(s) or document(s) related to modification, testing, and storage of a nonroad engine, or required by § 89.607–96; and

(3) To inspect and photograph any part or aspect of the nonroad engine and any component used in the assembly thereof.

(c) An EPA enforcement officer or authorized representative is to be furnished, by those in charge of a facility being inspected, with such reasonable assistance as the officer or representative may request to help discharge any function listed in this subpart. An ICI must make arrangements with those in charge of a facility operated for its benefit to furnish such reasonable assistance without charge to EPA. Reasonable assistance includes, but is not limited to, clerical, copying, interpretation and translation services, and the making available on

request of personnel of the facility being inspected during their working hours to inform the EPA enforcement officer or authorized representative of how the facility operates and to answer any questions.

(d) The requirements of paragraphs (a), (b), and (c) of this section apply whether or not the ICI owns or controls the facility in question. It is the ICI's responsibility to make such arrangements as may be necessary to assure compliance with paragraphs (a), (b), and (c) of this section. Failure to do so, or other failure to comply with paragraphs (a), (b), or (c), may result in sanctions as provided for in the Act or § 89.612–96(e).

(e) Duly designated enforcement officers are authorized to proceed ex parte to seek warrants authorizing the inspection or testing of the nonroad engines described in paragraph (a) of this section whether or not the enforcement officers first attempted to seek permission from the ICI or facility owner to inspect such nonroad engines.

(f) The results of the Administrator's test under this section comprise the official test data for the nonroad engine for purposes of determining whether the nonroad engine should be permitted final entry under § 89.605–96 or § 89.609–96.

§ 89.607–96 Maintenance of independent commercial importer's records.

(a) The Independent Commercial Importer (ICI) subject to any of the provisions of this subpart must establish and maintain adequately organized and indexed records, correspondence and other applicable documents relating to the certification, modification, test, purchase, sale, storage, registration, and importation of that nonroad engine. The ICI must retain such records for 8 years from the date of final admission or exportation of a nonconforming nonroad engine imported by the ICI. These records include, but are not limited to:

(1) The declaration required by U.S. Bureau of Customs regulations.

(2) Any documents or other written information required by a federal government agency to be submitted or retained in conjunction with the certification, importation or emission testing (if applicable) of nonroad engines;

(3) All bills of sale, invoices, purchase agreements, purchase orders, principal or agent agreements, and correspondence between the ICI and the ultimate purchaser of each nonroad engine and between any agents of the above parties;

(4) For nonroad engines imported by an ICI pursuant to § 89.605–96 or § 89.609–96, documents providing parts identification data (including calibration changes and part numbers and location of such parts on each nonroad engine) associated with the emission control system installed on each nonroad engine demonstrating that such emission control system was properly installed on such nonroad engine;

(5) For nonroad engines imported by an ICI pursuant to § 89.605–96 or § 89.609–96, documents demonstrating that, where applicable, each nonroad engine was emission tested in accordance with subpart E of this part and part 86, subpart I of this chapter;

(6) Documents providing evidence that the requirements of § 89.610–96 have been met;

(7) Documents providing evidence of compliance with all relevant requirements of the Clean Air Act;

(8) Documents providing evidence of the initiation of the 15 working day hold period (that is, evidence that the application submitted pursuant to § 89.605–96(a) or § 89.609–96(b) was received by EPA) for each nonroad engine imported pursuant to § 89.605–96 or § 89.609–96;

(9) For nonroad engines owned by the ICI at the time of importation, documents providing evidence of the date of sale and date of delivery to the ultimate purchaser, together with the name, address, and telephone number of the ultimate purchaser for each nonroad engine imported pursuant to § 89.605–96 or § 89.609–96;

(10) For nonroad engines not owned by the ICI at the time of importation, documents providing evidence and date of release to the owner (including owner's name, address, and telephone number) for each nonroad engine imported pursuant to § 89.605–96 or § 89.609–96;

(11) Documents providing evidence of the date of original manufacture of the nonroad engine. The importer may substitute an alternate date in lieu of the date of original manufacture, provided that the substitution of such alternate date is approved in advance by the Administrator.

(b) The ICI is responsible for ensuring the maintenance of records required by this section, regardless of whether or not facilities used by the ICI to comply with requirements of this subpart are under the control of the ICI.

§ 89.608–96 "In Use" inspections and recall requirements.

(a) Nonroad engines which have been imported by an Independent Commercial Importer (ICI) pursuant to § 89.605–96 or § 89.609–96 and finally admitted by EPA may be inspected and emission tested by EPA for the recall period specified in § 89.104–96(b).

(b) ICIs must maintain for eight years, and provide to EPA upon request, a list of owners or ultimate purchasers of all nonroad engines imported by the ICI under this subpart.

(c) The Administrator must notify the ICI whenever the Administrator has determined that a substantial number of a class or category of the ICI's nonroad engines, although properly maintained and used, do not conform to the regulations prescribed under section 213 of the Act when in actual use throughout their useful lives. After such notification, the recall regulations at subpart H of this part govern the ICI's responsibilities. References to a manufacturer in the recall regulations apply to the ICI.

§ 89.609–96 Final admission of modification nonroad engines and test nonroad engines.

(a) A nonroad engine may be imported under this section by an Independent Commercial Importer (ICI) possessing a currently valid certificate of conformity only if:

(1) The nonroad engine is six original production years old or older; and

(2) The ICI's name has not been placed on a currently effective EPA list of ICIs ineligible to import such modification/test nonroad engines, as described in paragraph (e) of this section; and

(3) The ICI has a currently valid certificate of conformity for the same nonroad engine class and fuel type as the nonroad engine being imported.

(b) A nonroad engine conditionally imported under this section may be finally admitted into the United States upon approval of the ICI's application by the Administrator. The application is to be made by completing EPA forms, in accordance with EPA instructions. The ICI includes in the application:

(1) The identification information required in § 89.604–96;

(2) An attestation by the ICI that the nonroad engine has been modified and tested in accordance with the applicable emission tests as specified in Subpart B § 89.119–96(a) of this part at a laboratory within the United States;

(3) The results of all emission tests;

(4) The applicable deterioration factor assigned by EPA, if any;

(5) The emission test results adjusted by the applicable deterioration factor;

(6) All information required under § 89.610–96 related to maintenance, warranties, and labeling;

(7) An attestation by the ICI that the ICI is responsible for the nonroad

engine's compliance with federal emission requirements, regardless of whether the ICI owns the nonroad engine imported under this section;

(8) The applicable address and telephone number of the ICI, or the name, address, and telephone number of the person who the ICI prefers to receive EPA notification under § 89.609–96(d);

(9) An attestation by the ICI that all requirements of § 89.607–95 and § 89.610–96 have been met; and

(10) Such other information as is deemed necessary by the Administrator.

(c) EPA approval for final admission of a nonroad engine under this section is presumed not to have been granted if any requirement of this subpart has not been met.

(d) Except as provided in paragraph (c) of this section, EPA approval for final admission of a nonroad engine under this section is presumed to have been granted if the ICI does not receive oral or written notice from EPA to the contrary within 15 working days of the date that the Manufacturers Operations Division of EPA receives the ICI's application under paragraph (b) of this section. Such EPA notice of nonapproval may be made to any employee of the ICI. It is the responsibility of the ICI to ensure that the Manufacturers Operations Division of EPA receives the application and to confirm the date of receipt. During this 15 working day hold period, the nonroad engine is stored at a location where the Administrator has reasonable access to the nonroad engine for the Administrator's inspection. The storage is to be within 50 miles of the ICI's testing facility to allow the Administrator reasonable access for inspection and/or testing. A storage facility not meeting this criterion must be approved in writing by the Administrator prior to the submittal of the ICI's application under paragraph (b) of this section.

(e) *EPA list of ICIs ineligible to import nonroad engines for modification/test.* EPA maintains a current list of ICIs who have been determined to be ineligible to import nonroad engines under this section. The determination of ineligibility is made in accordance with the criteria and procedures in § 89.612–96(e) of this subpart.

(f) *Inspections.* Prior to final admission, a nonroad engine imported under this section is subject to special inspections as described in § 89.606–96 with these additional provisions:

(1) If, in the judgment of the Administrator, a significant number of nonroad engines imported by an ICI fail to comply with emission requirements upon inspection or retest or if the ICI fails to comply with a provision of these regulations that pertain to nonroad engines imported pursuant to § 89.609–96, the ICI may be placed on the EPA list of ICIs ineligible to import nonroad engines under this section as specified in paragraph (e) of this section and § 89.612–96(e).

(2) An individual nonroad engine which fails a retest or inspection is to be repaired and retested, as applicable, to demonstrate compliance with emission requirements before final admission is granted by EPA.

(3) Unless otherwise specified by EPA, the ICI bears the costs of all retesting under this subsection, including transportation.

(g) *In-use inspection and testing.* A nonroad engine imported under this section may be tested or inspected by EPA at any time during the recall period specified in § 89.104–96(b), in accordance with § 89.608–96(a). If, in the judgment of the Administrator, a significant number of properly maintained and used nonroad engines imported by the ICI pursuant to this section fail to meet emission requirements, the name of the ICI may be placed on the EPA list of ICIs ineligible to import nonroad engines under the modification/test provision as specified in paragraph (e) of this section and § 89.612–96(e).

§ 89.610–96 Maintenance instructions, warranties, emission labeling.

The provisions of this section are applicable to all nonroad engines imported under the provisions of § 89.605–96 or § 89.609–96.

(a) *Maintenance Instructions.* (1) The Independent Commercial Importer (ICI) must furnish to the purchaser, or to the owner of each nonroad engine imported under § 89.605–96 or § 89.609–96 of this subpart, written instructions for the maintenance and use of the nonroad engine by the purchaser or owner. Each application for final admission of a nonroad engine is to provide an attestation that such instructions have been or will be (if the ultimate purchaser is unknown) furnished to the purchaser or owner of such nonroad engine at the time of sale or delivery. The ICI must maintain a record of having furnished such instructions.

(2) For each nonroad engine imported under § 89.609–96, a copy of the maintenance and use instructions is to be maintained in a file containing the records for that nonroad engine.

(3) The maintenance and use instructions are not to contain requirements more restrictive than those set forth in § 89.109–96 (Maintenance Instructions) and are to be in sufficient detail and clarity that a mechanic of average training and ability can maintain or repair the nonroad engine.

(4) For each nonroad engine imported pursuant to § 89.605–96 or § 89.609–96, ICIs must furnish with each nonroad engine a list of the emission control parts, emission-related parts added by the ICI, and the emission control and emission-related parts furnished by the Original Engine Manufacturer (OEM).

(5) The information required in this section to be furnished to the ultimate purchaser or owner is to be copied and maintained in a file containing the records for that nonroad engine prior to submitting each application for final admission pursuant to § 89.605–96(a) or § 89.609–96(b).

(b) *Warranties.* (1) ICIs must submit to the Manufacturers Operations Division of EPA sample copies (including revisions) of any warranty documents required by this section prior to importing nonroad engines under this subpart.

(2) ICIs must provide to nonroad engine owners emission warranties identical to those required by sections 207(a) of the Act. The warranty period for each nonroad engine is to commence on the date the nonroad engine is delivered by the ICI to the ultimate purchaser or owner.

(3) ICIs must provide warranty insurance coverage by a prepaid mandatory service insurance policy underwritten by an independent insurance company. The policy is to:

(i) Be subject to the approval of the Administrator if the insurance coverage is less than the required warranty;

(ii) At a minimum, provide coverage for emission-related components installed or modified by the ICI and, to the maximum extent possible, the emission-related components installed by the OEM;

(iii) Be transferable to each successive owner for the periods specified in § 89.104–96(c); and

(iv) Provide that in the absence of an ICI's facility being reasonably available (that is, within 50 miles) for performance of warranty repairs, the warranty repairs may be performed anywhere.

(4) ICIs must attest in each application for final admission that the warranty requirements have been met, that the mandatory insurance has been paid and is in effect, and that certificates and statements of the warranties have been or will be provided to the owner or ultimate purchaser. A copy of the warranties and evidence that the warranties are paid and in effect is to be maintained in a file containing the records for each nonroad engine prior to

submitting each application for final admission pursuant to § 89.605–96(a) or § 89.609–96(b).

(c) *Emission labeling.* (1) For each nonroad engine imported pursuant to § 89.605–96 or § 89.609–96, the ICI must affix a permanent legible label which identifies each nonroad engine and also satisfies the following:

(i) The label meets all the requirements of § 89.110–96 and contains the following statement "This nonroad engine was originally produced in (month and year of original production). It has been imported and modified by (ICI's name, address, and telephone number) to conform to United States emission regulations applicable to the (year) model year."

(ii) If the nonroad engine is owned by the ICI at the time of importation, the label also states "This nonroad engine is warranted for five years or 3000 hours of operation from the date of purchase, whichever first occurs."

(iii) If the nonroad engine is not owned by the ICI at the time of importation, the label states "This nonroad engine is warranted for five years or 3000 hours of operation from the date of release to the owner, whichever first occurs."

(iv) For nonroad engines imported under § 89.609–96, the label clearly states in bold letters that "This nonroad engine has not been manufactured under a certificate of conformity but conforms to United States emission regulations under a modification/test program." For all nonroad engines imported pursuant to § 89.605–96 or § 89.609–96, the label contains the vacuum hose routing diagram applicable to the nonroad engines.

(2) As part of the application to the Administrator for final admission of each individual nonroad engine under § 89.609–96, the ICI must maintain a copy of the labels for each nonroad engine in a file containing the records for that nonroad engine prior to submitting each application for final admission. ICIs importing under § 89.605–96 or § 89.609–96 must attest to compliance with the preceding labeling requirements of this section in each application for final admission.

§ 89.611–96 Exemptions and exclusions.

(a) Individuals, as well as ICIs, are eligible for importing nonroad engines into the United States under the provisions of this section, unless otherwise specified.

(b) Notwithstanding other requirements of this subpart, a nonroad engine entitled to one of the temporary exemptions of this paragraph may be conditionally admitted into the United States if prior written approval for the conditional admission is obtained from the Administrator. Conditional admission is to be under bond. The Administrator may request that the U.S. Customs Service require a specific bond amount to ensure compliance with the requirements of the Act and this subpart. A written request for approval from the Administrator is to contain the identification required in § 89.604–96(a) (except for § 89.604–96(a)(5)) and information that demonstrates that the importer is entitled to the exemption. Noncompliance with provisions of this section may result in the forfeiture of the total amount of the bond or exportation of the nonroad engine. The following temporary exemptions are permitted by this paragraph:

(1) *Exemption for repairs or alterations.* Upon written approval by EPA, an owner of nonroad engines may conditionally import under bond such nonroad engines solely for purpose of repair(s) or alteration(s). The nonroad engines may not be operated in the United States other than for the sole purpose of repair or alteration. They may not be sold or leased in the United States and are to be exported upon completion of the repair(s) or alteration(s).

(2) *Testing exemption.* A test nonroad engine may be conditionally imported by a person subject to the requirements of § 89.905. A test nonroad engine may be operated in the United States provided that the operation is an integral part of the test. This exemption is limited to a period not exceeding one year from the date of importation unless a request is made by the appropriate importer concerning the nonroad engine in accordance with § 89.905(f) for a subsequent one-year period.

(3) *Precertification exemption.* A prototype nonroad engine for use in applying to EPA for certification pursuant to this subpart may be conditionally imported subject to applicable provisions of § 89.906 and the following requirements:

(i) No more than one prototype nonroad engine for each engine family for which an importer is seeking certification is to be imported.

(ii) The granting of precertification exemptions by the Administrator is discretionary. Normally, no more than three outstanding precertification exemptions are allowed for each importer. No precertification exemption is allowed if the importer requesting the exemption is in noncompliance with any requirement of this subpart until the noncompliance is corrected.

(iii) Unless a certificate of conformity is issued for the prototype nonroad engine and the nonroad engine is finally admitted pursuant to the requirements of § 89.605 within 180 days from the date of entry, the total amount of the bond is to be forfeited or the nonroad engine exported unless an extension is granted by the Administrator. A request for an extension is to be in writing and received by the Administrator prior to the date that the precertification exemption expires.

(iv) Such precertification nonroad engine may not be operated in the United States other than for the sole purpose of the precertification exemption.

(4) *Display exemptions.* (i) A nonroad engine intended solely for display may be conditionally imported subject to the requirements of § 89.907.

(ii) A display nonroad engine may be imported by any person for purposes related to a business or the public interest. Such purposes do not include collections normally inaccessible or unavailable to the public on a daily basis, display of a nonroad engine at a dealership, private use, or other purpose that the Administrator determines is not appropriate for display exemptions. A display nonroad engine may not be sold in the United States and may not be operated in the United States except for the operation incident and necessary to the display purpose.

(iii) A temporary display exemption is granted for 12 months or for the duration of the display purpose, whichever is shorter. Two extensions of up to 12 months each are available upon approval by the Administrator. In no circumstances, however, may the total period of exemption exceed 36 months. The U.S. Customs Service bonds a temporary display exemption.

(c) Notwithstanding any other requirement of this subpart, a nonroad engine may be finally admitted into the United States under this paragraph if prior written approval for such final admission is obtained from the Administrator. Conditional admission of these nonroad engines under this subpart is not permitted for the purpose of obtaining such written approval from the Administrator. A request for approval is to contain the identification information required in § 89.604–96(a) (except for § 89.604–96(a)(5)) and information that demonstrates that the importer is entitled to the exemption or exclusion. The following exemptions or exclusions are permitted by this paragraph:

(1) *National security exemption.* A nonroad engine may be imported under the national security exemption found at § 89.908.

(2) *Hardship exemption.* The Administrator may exempt on a case-by-case basis a nonroad engine from federal emission requirements to accommodate unforeseen cases of extreme hardship or extraordinary circumstances.

(3) *Exemption for nonroad engines identical to United States certified versions.*

(i) A person (including businesses) is eligible for importing a nonroad engine into the United States under the provisions of this paragraph. An exemption will be granted if the nonroad engine:

(A) is owned by the importer;

(B) is not offered for importation for the purpose of resale; and

(C) is proven to be identical, in all material respects, to a nonroad engine certified by the Original Engine Manufacturer (OEM) for sale in the United States or is proven to have been modified to be identical, in all material respects, to a nonroad engine certified by the OEM for sale in the United States according to complete written instructions provided by the OEM's United States representative, or his/her designee.

(ii) *Proof of Conformity.* (A) Documentation submitted pursuant to this section for the purpose of proving conformity of individual nonroad engines is to contain sufficiently organized data or evidence demonstrating that the nonroad engine identified pursuant to § 89.604–96(a) is identical, in all material respects, to a nonroad engine identified in an OEM's application for certification.

(B) If the documentation does not contain all the information required by this part, or is not sufficiently organized, EPA notifies the importer of any areas of inadequacy, and that the documentation does not receive further consideration until the required information or organization is provided.

(C) If EPA determines that the documentation does not clearly or sufficiently demonstrate that a nonroad engine is eligible for importation, EPA notifies the importer in writing.

(D) If EPA determines that the documentation clearly and sufficiently demonstrates that a nonroad engine is eligible for importation, EPA grants approval for importation and notifies the importer in writing. Notwithstanding any other requirement of this subpart, the notice constitutes approval for final admission into the United States.

(d) Foreign diplomatic and military personnel may import a nonconforming nonroad engine without bond. At the time of admission, the importer must submit to the Administrator the written report required in § 89.604–96(a) (except for information required by § 89.604–96(a)(5)) and a statement from the U.S. Department of State confirming qualification for this exemption. The nonroad engine may not be sold in the United States and must be exported if the individual's diplomatic status is no longer applicable, as determined by the Department of State, unless subsequently brought into conformity in accordance with §§ 89.605–96, 89.609–96, or 89.611–96(c)(3).

(e) *Competition exclusion.* A nonconforming engine may be imported by any person provided the importer demonstrates to the Administrator that the engine is used to propel a vehicle used solely for competition and obtains prior written approval from the Administrator. A nonconforming engine imported pursuant to this paragraph may not be operated in the United States except for that operation incident and necessary for the competition purpose, unless subsequently brought into conformity with United States emission requirements in accordance with §§ 89.605–96, 89.609–96, or 89.611–96(c)(3).

(f) *Exclusions/exemptions based on date of original manufacture.* (1) Notwithstanding any other requirements of this subpart, the following nonroad engines are excluded, as determined by the engine's gross power output, from the requirements of the Act in accordance with section 213 of the Act and may be imported by any person:

(i) All nonroad engines greater than or equal to 37 kW but less than 75 kW originally manufactured prior to January 1, 1998.

(ii) All nonroad engines greater than or equal to 75 kW but less than 130 kW originally manufactured prior to January 1, 1997.

(iii) All nonroad engines greater than or equal to 130 kW but less than or equal to 560 kW originally manufactured prior to January 1, 1996.

(iv) All nonroad engines greater than 560 kW originally manufactured prior to January 1, 2000.

(2) Notwithstanding other requirements of this subpart, a nonroad engine not subject to an exclusion under § 89.611–96(f)(1) but greater than 20 original production (OP) years old is entitled to an exemption from the requirements of the Act, provided that it has not been modified in those 20 OP years and it is imported into the United States by an ICI. At the time of admission, the ICI must submit to the Administrator the written report required in § 89.604–96(a) (except for information required by § 89.604–96(a)(5)).

(g) An application for exemption and exclusion provided for in paragraphs (b), (c), and (e) of this section is to be mailed to: U.S. Environmental Protection Agency, Office of Mobile Sources, Manufacturers Operations Division (6405–J), 401 M Street, SW, Washington, DC 20460, Attention: Imports.

§ 89.612–96 Prohibited acts; penalties.

(a) The importation of a nonroad engine, including a nonroad engine incorporated into a nonroad vehicle or nonroad equipment, which is not covered by a certificate of conformity other than in accordance with this subpart and the entry regulations of the U.S. Customs Service is prohibited. Failure to comply with this section is a violation of section 213(d) and section 203 of the Act.

(b) Unless otherwise permitted by this subpart, during a period of conditional admission, the importer of a nonroad engine may not:

(1) Register, license, or operate the nonroad engine in the United States;

(2) Sell or offer the nonroad engine for sale;

(3) Store the nonroad engine on the premises of a dealer (unless approved by the Administrator), owner, or purchaser;

(4) Relinquish control of the nonroad engine to the owner or purchaser; or

(5) Cause a nonroad engine to be altered in any manner subsequent to modification and testing, if applicable, for which an application for final admission is based and submitted to the Administrator, unless approved in advance by the Administrator.

(c) A nonroad engine conditionally admitted pursuant to § 89.604–96 and not granted final admission within 120 days of such conditional admission, or within such additional time as the Administrator and the U.S. Customs Service may allow, is deemed to be unlawfully imported into the United States in violation of section 213(d) and section 203 of the Act, unless the nonroad engine has been delivered to the U.S. Customs Service for export or other disposition under applicable Customs laws and regulations. A nonroad engine not so delivered is subject to seizure by the U.S. Customs Service.

(d) An importer who violates section 213(d) and section 203 of the Act is subject to the provisions of section 209 of the Act and is also subject to a civil penalty under section 205 of the Act of not more than $25,000 for each nonroad engine subject to the violation. In addition to the penalty provided in the Act, where applicable, a person or entity

who imports an engine under the exemption provisions of § 89.611–96(b) and, who fails to deliver the nonroad engine to the U.S. Customs Service is liable for liquidated damages in the amount of the bond required by applicable Customs laws and regulations.

(e)(1) An ICI whose nonroad engines imported under § 89.605–96 or § 89.609–96 fail to conform to federal emission requirements after modification and/or testing or who fails to comply with applicable provisions of this subpart, may, in addition to any other applicable sanctions and penalties, be subject to any, or all, of the following sanctions:

(i) The ICI's currently held certificates of conformity may be revoked or suspended;

(ii) The ICI may be deemed ineligible to apply for new certificates of conformity for up to three years; and

(iii) The ICI may be deemed ineligible to import nonroad engines under § 89.609–96 in the future and be placed on a list of ICIs ineligible to import nonroad engines under the provisions of § 89.609–96.

(2) Grounds for the actions described in paragraph (e)(1) of this section include, but are not limited to, the following:

(i) Action or inaction by the ICI or the laboratory performing the emission test on behalf of the ICI, which results in fraudulent, deceitful, or grossly inaccurate representation of any fact or condition which affects a nonroad engine's eligibility for admission to the United States under this subpart;

(ii) Failure of a significant number of imported nonroad engines to comply with federal emission requirements upon EPA inspection or retest; or

(iii) Failure by an ICI to comply with requirements of this subpart.

(3) The following procedures govern any decision to suspend, revoke, or refuse to issue certificates of conformity under this subpart:

(i) When grounds appear to exist for the actions described in paragraph (e)(1) of this section, the Administrator must notify the ICI in writing of any intended suspension or revocation of a certificate of conformity, proposed ineligibility to apply for new certificates of conformity, or intended suspension of eligibility to conduct modification/testing under § 89.609–96, and the grounds for such action.

(ii) Except as provided by paragraph (e)(3)(iv), the ICI must take the following actions before the Administrator will consider withdrawing notice of intent to suspend or revoke the ICI's certificate of conformity or to deem the ICI ineligible to apply for new certification or to deem the ICI ineligible to perform modification/testing under § 89.609–96:

(A) Submit a written report to the Administrator which identifies the reason for the noncompliance of the nonroad engine, describes the proposed remedy, including a description of any proposed quality control and/or quality assurance measures to be taken by the ICI to prevent the future occurrence of the problem, and states the date on which the remedies are to be implemented or

(B) Demonstrate that the nonroad engine does in fact comply with applicable regulations in this chapter by retesting, if applicable, the nonroad engine in accordance with the applicable emission test specified in subpart E of this part.

(iii) An ICI may request, within 15 calendar days of the Administrator's notice of intent to suspend or revoke the ICI's certificate of conformity or to deem the ICI ineligible to apply for new certificates or to deem the ICI ineligible to perform modification/testing under § 89.609- 96, that the Administrator grant such ICI a hearing:

(A) As to whether the tests, if applicable, have been properly conducted,

(B) As to any substantial factual issue raised by the Administrator's proposed action.

(iv) If, after the Administrator notifies an ICI of the intent to suspend or revoke the ICI's certificate of conformity or to deem the ICI ineligible to apply for new certificates or to deem the ICI ineligible to perform modification/testing under § 89.609–96 and prior to any final suspension or revocation, the ICI demonstrates to the Administrator's satisfaction that the decision to initiate suspension or revocation of the certificate of conformity or eligibility to perform modification/testing under § 89.609- 96 was based on erroneous information, the Administrator will withdraw the notice of intent.

(4) Hearings on suspensions and revocations of certificates of conformity or of eligibility to apply for new certificates or of eligibility to perform modification/testing under § 89.609–96 will be held in accordance with the following:

(i) The procedures prescribed by this section will apply whenever an ICI requests a hearing pursuant to paragraph (e)(3)(iii) of this section.

(ii) Hearings under paragraph (e)(3)(iii) will be held in accordance with the procedures outlined in § 86.614 of this chapter, where applicable, provided that where § 86.612 is referred to in § 86.614: § 86.612(a) is replaced by § 89.612–96(e)(2); and § 86.612(i) is replaced by § 89.612–96(e)(3)(iii).

(5) When a hearing is requested under this section and it clearly appears from the data or other information contained in the request for a hearing, or submitted at the hearing, that no genuine and substantial question of fact exists with respect to the issue of whether the ICI failed to comply with this subpart, the Administrator will enter an order denying the request for a hearing, or terminating the hearing, and suspending or revoking the certificate of conformity and/or deeming the ICI ineligible to apply for new certificates or to perform modification/testing under § 89.609–96.

(6) In lieu of requesting a hearing under paragraph (e)(3)(iii) of this section, an ICI may respond in writing to EPA's charges in the notice of intent to suspend or revoke. An ICI's written response must be received by EPA within 30 days of the date of EPA's notice of intent. No final decision to suspend or revoke will be made before that time.

§ 89.613–96 Treatment of confidential information.

The provisions for treatment of confidential information as described in § 89.7 apply.

Subpart H—Recall Regulations

§ 89.701 Applicability.

The requirements of subpart H are applicable to all nonroad engines subject to the provisions of subpart A of part 89.

§ 89.702 Definitions.

The definitions in subpart A of this part apply to this subpart.

§ 89.703 Applicability of part 85, subpart S.

(a) Nonroad engines subject to provisions of subpart B of this part are subject to recall regulations specified in part 85, subpart S of this title, except for the items set forth in this section.

(b) Reference to section 214 of the Clean Air Act in § 85.1801 is replaced by reference to section 216 of the Clean Air Act.

(c) Reference to section 202 of the Act in § 85.1802(a) is replaced by reference to section 213 of the Act.

(d) Reference to "family particulate emission limits as defined in Part 86 promulgated under section 202 of the Act" in § 85.1803(a) and § 85.1805(a)(1) is replaced by reference to family emission limits as defined in part 89 promulgated under section 213 of the Act.

(e) Reference to "vehicles or engines" throughout the subpart is replaced by reference to "engines."

Subpart I—Emission Defect Reporting Requirements

§ 89.801 Applicability.

The requirements of subpart I are applicable to all nonroad engines subject to the provisions of subpart A of part 89. The requirement to report emission-related defects affecting a given class or category of engines remains applicable for five years from the end of the model year in which such engines were manufactured.

§ 89.802 Definitions.

The definitions in subpart A of this part apply to this subpart.

§ 89.803 Applicability of part 85, subpart T.

(a) Nonroad engines subject to provisions of subpart B of this part are subject to emission defect reporting requirements specified in part 85, subpart T of this chapter, except for the items set forth in this section.

(b) Section 85.1901 is replaced by § 89.801.

(c) Reference to the Clean Air Act, 42 U.S.C. 1857 in § 85.1902(a) is replaced by reference to the Clean Air Act, 42 U.S.C. 7401.

(d) Reference to the "approved Application for Certification required by 40 CFR 86.077–22 and like provisions of Part 85 and Part 86 of Title 40 of the Code of Federal Regulations" in § 85.1902(b) is replaced by reference to the approved application for certification required by § 89.115–96 and like provisions of part 89 of this chapter.

(e) Reference to section 202(d) of the Act in § 85.1902(c) is replaced by reference to section 202(d) and section 213 of the Act.

(f) Reference to section 214 of the Act in § 85.1902 (e) and (f) is replaced by reference to section 216 of the Act.

(g) Reference to "vehicles or engines" throughout the subpart is replaced by reference to "engines."

Subpart J—Exemption Provisions

§ 89.901 Applicability.

The requirements of subpart J are applicable to all nonroad engines subject to the provisions of subpart A of part 89.

§ 89.902 Definitions.

The definitions in subpart A of this part apply to this subpart. The following definitions also apply to this subpart.

Exemption means exemption from the prohibitions of § 89.1006.

Export exemption means an exemption granted under § 89.1004(b) for the purpose of exporting new nonroad engines.

National security exemption means an exemption which may be granted under § 89.1004(b) for the purpose of national security.

Manufacturer-owned nonroad engine means an uncertified nonroad engine owned and controlled by a nonroad engine manufacturer and used in a manner not involving lease or sale by itself or in a vehicle or piece of equipment employed from year to year in the ordinary course of business for product development, production method assessment, and market promotion purposes.

Testing exemption means an exemption which may be granted under § 89.1004(b) for the purpose of research investigations, studies, demonstrations or training, but not including national security.

§ 89.903 Application of section 216(10) of the Act.

(a) For the purpose of determining the applicability of section 216(10) of the Act, an internal combustion engine (including the fuel system) that is not used in a motor vehicle is deemed a nonroad engine if it meets the definition in subpart A of this part.

(b) EPA will maintain a list of nonroad engines that have been determined to be excluded because they are used solely for competition. This list will be available to the public and may be obtained by writing to the following address: Chief, Selective Enforcement Auditing Section, Manufacturers Operations Division (6405–J), Environmental Protection Agency, 401 M Street SW, Washington, DC 20460.

(c) Upon written request, EPA will make written determinations as to whether certain engines are or are not nonroad engines. Engines that are determined not to be nonroad engines are excluded from regulations under this part.

§ 89.904 Who may request an exemption.

(a) Any person may request a testing exemption under § 89.905.

(b) Any nonroad engine manufacturer may request a national security exemption under § 89.908.

(c) For nonroad engine manufacturers, nonroad engines manufactured for export purposes are exempt without application, subject to the provisions of § 89.909.

(d) For eligible manufacturers, as determined by § 89.906, manufacturer-owned nonroad engines are exempt without application, subject to the provisions of § 89.906.

(e) For any person, display nonroad engines are exempt without application, subject to the provisions of § 89.907.

§ 89.905 Testing exemption.

(a) Any person requesting a testing exemption must demonstrate the following:

(1) That the proposed test program has a purpose which constitutes an appropriate basis for an exemption in accordance with this section;

(2) That the proposed test program necessitates the granting of an exemption;

(3) That the proposed test program exhibits reasonableness in scope; and

(4) That the proposed test program exhibits a degree of control consonant with the purpose of the test program and EPA's monitoring requirements.

(5) Paragraphs (b), (c), (d), and (e) of this section describe what constitutes a sufficient demonstration for each of the four identified elements.

(b) With respect to the purpose of the proposed test program, an appropriate purpose would be research, investigations, studies, demonstrations, or training, but not national security. A concise statement of purpose is a required item of information.

(c) With respect to the necessity that an exemption be granted, necessity arises from an inability to achieve the stated purpose in a practicable manner without performing or causing to be performed one or more of the prohibited acts under § 89.1003. In appropriate circumstances, time constraints may be a sufficient basis for necessity, but the cost of certification alone, in the absence of extraordinary circumstances, is not a basis for necessity.

(d) With respect to reasonableness, a test program must exhibit a duration of reasonable length and affect a reasonable number of engines. In this regard, required items of information include:

(1) An estimate of the program's duration, and

(2) The maximum number of nonroad engines involved.

(e) With respect to control, the test program must incorporate procedures consistent with the purpose of the test and be capable of affording EPA monitoring capability. As a minimum, required items of information include:

(1) The technical nature of the test;

(2) The site of the test;

(3) The time or mileage duration of the test;

(4) The ownership arrangement with regard to the engines involved in the test;

(5) The intended final disposition of the engines;

(6) The manner in which the engine identification numbers will be identified, recorded, and made available; and

(7) The means or procedure whereby test results will be recorded.

(f) A manufacturer of new nonroad engines may request a testing exemption to cover nonroad engines intended for use in test programs planned or anticipated over the course of a subsequent one-year period. Unless otherwise required by the Director, Manufacturers Operations Division, a manufacturer requesting such an exemption need only furnish the information required by paragraphs (a)(1) and (d)(2) of this section along with a description of the record-keeping and control procedures that will be employed to assure that the engines are used for purposes consistent with paragraph (a) of this section.

§ 89.906 Manufacturer-owned exemption and precertification exemption.

(a) Except as provided in paragraph (b) of this section, any manufacturer-owned nonroad engine, as defined by § 89.902, is exempt from § 89.1003, without application, if the manufacturer complies with the following terms and conditions:

(1) The manufacturer must establish, maintain, and retain the following adequately organized and indexed information on each exempted engine:

(i) Engine identification number,

(ii) Use of the engine on exempt status and

(iii) Final disposition of any engine removed from exempt status; and

(2) The manufacturer must provide right of entry and access to these records to EPA authorized representatives as outlined in § 89.506–96.

(3) Unless the requirement is waived or an alternate procedure is approved by the Director, Manufacturers Operations Division, the manufacturer must permanently affix a label to each nonroad engine on exempt status. This label should

(i) Be affixed in a readily visible portion of the engine,

(ii) Be attached in such a manner that cannot be removed without destruction or defacement,

(iii) State in the English language and in block letters and numerals of a color that contrasts with the background of the label, the following information:

(A) The label heading "Emission Control Information;"

(B) Full corporate name and trademark of manufacturer;

(C) Engine displacement, engine family identification, and model year of engine; or person of office to be contacted for further information about the engine;

(D) The statement "This nonroad engine is exempt from the prohibitions of 40 CFR section 90.1003."

(4) No provision of paragraph (a)(3) of this section prevents a manufacturer from including any other information it desires on the label.

(b) Any independent commercial importer that desires a precertification exemption pursuant to § 89.611(b)(3) and is in the business of importing, modifying, or testing uncertified nonroad engines for resale under the provisions of § 89.611 et seq., must apply to the Director, Manufacturers Operations Division. The Director may require such independent commercial importer to submit information regarding the general nature of the fleet activities, the number of nonroad engines involved, and a demonstration that adequate record-keeping procedures for control purposes will be employed.

§ 89.907 Display exemption.

Where an uncertified nonroad engine is a display engine to be used solely for display purposes, will only be operated incident and necessary to the display purpose, and will not be sold unless an applicable certificate of conformity has been received or the engine has been finally admitted pursuant to subpart G of this part, no request for exemption of the engine is necessary.

§ 89.908 National security exemption.

A manufacturer requesting a national security exemption must state the purpose for which the exemption is required and the request must be endorsed by an agency of the federal government charged with responsibility for national defense.

§ 89.909 Export exemptions.

(a) A new nonroad engine intended solely for export, and so labeled or tagged on the outside of the container and on the engine itself, is subject to the provisions of § 89.1003, unless the importing country has new nonroad engine emission standards which differ from EPA standards.

(b) For the purpose of paragraph (a) of this section, a country having no standards, whatsoever, is deemed to be a country having emission standards which differ from EPA standards.

(c) EPA will maintain a list of foreign countries that have in force nonroad emission standards identical to EPA standards and have so notified EPA. This list may be obtained by writing to the following address: Chief, Selective Enforcement Auditing Section, Manufacturers Operations Division (6405–J), Environmental Protection Agency, 401 M Street, S.W., Washington, D.C. 20460. New nonroad engines exported to such countries must comply with EPA certification regulations.

(d) It is a condition of any exemption for the purpose of export under paragraph (a) of this section, that such exemption is void ab initio with respect to a new nonroad engine intended solely for export, where such nonroad engine is sold, or offered for sale, to an ultimate purchaser or otherwise distributed or introduced into commerce in the United States for purposes other than export.

§ 89.910 Granting of exemptions.

(a) If upon completion of the review of an exemption request made pursuant to § 89.905 or § 89.908, EPA determines it is appropriate to grant such an exemption, a memorandum of exemption is to be prepared and submitted to the person requesting the exemption. The memorandum is to set forth the basis for the exemption, its scope, and such terms and conditions as are deemed necessary. Such terms and conditions generally include, but are not limited to, agreements by the applicant to conduct the exempt activity in the manner described to EPA, create and maintain adequate records accessible to EPA at reasonable times, employ labels for the exempt engines setting forth the nature of the exemption, take appropriate measures to assure that the terms of the exemption are met, and advise EPA of the termination of the activity and the ultimate disposition of the engines.

(b) Any exemption granted pursuant to paragraph (a) of this section is deemed to cover any subject engine only to the extent that the specified terms and conditions are complied with. A breach of any term or condition causes the exemption to be void ab initio with respect to any engine. Consequently, the causing or the performing of an act prohibited under § 89.1003(a)(1) or (a)(3), other than in strict conformity with all terms and conditions of this exemption, renders the person to whom the exemption is granted, and any other person to whom the provisions of § 89.1003(a) are applicable, liable to suit under sections 204 and 205 of the Act.

§ 89.911 Submission of exemption requests.

Requests for exemption or further information concerning exemptions and/or the exemption request review procedure should be addressed to: Chief, Selective Enforcement Auditing

Section, Manufacturers Operations Division (6405–J), Environmental Protection Agency, 401 M Street SW, Washington, DC 20460.

§ 89.912 Treatment of confidential information.

The provisions for treatment of confidential information as described in § 89.7 apply.

Subpart K—General Enforcement Provisions and Prohibited Acts

§ 89.1001 Applicability.

The requirements of subpart K are applicable to all nonroad engines subject to the provisions of subpart A of part 89, and to all nonroad vehicles and equipment that contain such nonroad engines.

§ 89.1002 Definitions.

The definitions in subpart A of this part apply to this subpart.

§ 89.1003 Prohibited acts.

(a) The following acts and the causing thereof are prohibited:

(1)(i) In the case of a manufacturer of new nonroad engines, vehicles, or equipment for distribution in commerce, the sale, or the offering for sale, or the introduction, or delivery for introduction, into commerce, of any new nonroad engine manufactured after the applicable effective date under this part, or any nonroad vehicle or equipment containing such engine, unless such engine is covered by a certificate of conformity issued (and in effect) under regulations found in this part.

(ii) In the case of any person, except as provided in subpart G of this part, the importation into the United States of any new nonroad engine manufactured after the applicable effective date under this part, or any nonroad vehicle or equipment containing such engine, unless such engine is covered by a certificate of conformity issued (and in effect) under regulations found in this part.

(2)(i) For a person to fail or refuse to permit access to or copying of records or to fail to make reports or provide information required under § 89.1004.

(ii) For a person to fail or refuse to permit entry, testing, or inspection authorized under §§ 89.129–96, 89.506–96 or 89.1004.

(iii) For a person to fail or refuse to perform tests, or to have tests performed as required under §§ 89.119–96 or 89.1004.

(iv) For a person to fail to establish or maintain records as required under § 89.1004.

(3)(i) For a person to remove or render inoperative a device or element of design installed on or in a nonroad engine, vehicle or equipment in compliance with regulations under this part prior to its sale and delivery to the ultimate purchaser, or for a person knowingly to remove or render inoperative such a device or element of design after the sale and delivery to the ultimate purchaser; or

(ii) For a person to manufacture, sell or offer to sell, or install, a part or component intended for use with, or as part of, a nonroad engine, vehicle or equipment, where a principal effect of the part or component is to bypass, defeat, or render inoperative a device or element of design installed on or in a nonroad engine in compliance with regulations issued under this part, and where the person knows or should know that the part or component is being offered for sale or installed for this use or put to such use.

(4) For a manufacturer of a new nonroad engine subject to standards prescribed under this part:

(i) To sell, offer for sale, or introduce or deliver into commerce, a nonroad engine unless the manufacturer has complied with the requirements of § 89.1007.

(ii) To sell, offer for sale, or introduce or deliver into commerce, a nonroad engine unless a label or tag is affixed to the engine in accordance with § 89.110–96.

(iii) To fail or refuse to comply with the requirements of § 89.1008.

(iv) Except as provided in § 89.109–96, to provide directly or indirectly in any communication to the ultimate purchaser or a subsequent purchaser that the coverage of a warranty under the Act is conditioned upon use of a part, component, or system manufactured by the manufacturer or a person acting for the manufacturer or under its control, or conditioned upon service performed by such persons.

(v) To fail or refuse to comply with the terms and conditions of the warranty under § 89.1007.

(5) For a person to circumvent or attempt to circumvent the residence time requirements of subsection (b)(2)(iii) of the nonroad engine definition in § 89.2.

(6) For a manufacturer of nonroad vehicles or equipment to distribute in commerce, sell, offer for sale, or introduce into commerce nonroad vehicles or equipment which contain an engine not covered by a certificate of conformity.

(b) For the purposes of enforcement of this part, the following apply:

(1) Nothing in paragraph (a)(3) of this section is to be construed to require the use of manufacturer parts in maintaining or repairing a nonroad engine.

(2) Actions for the purpose of repair or replacement of a device or element of design or any other item are not considered prohibited acts under § 89.1003(a) if the action is a necessary and temporary procedure, the device or element is replaced upon completion of the procedure, and the action results in the proper functioning of the device or element of design.

(3) Actions for the purpose of a conversion of a nonroad engine for use of a clean alternative fuel (as defined in Title II of the Act) are not considered prohibited acts under § 89.1003(a) if:

(i) the vehicle complies with the applicable standard when operating on the alternative fuel, and the device or element is replaced upon completion of the conversion procedure, and

(ii) in the case of engines converted to dual fuel or flexible use, the action results in proper functioning of the device or element when the nonroad engine operates on conventional fuel.

(4) Certified nonroad engines shall be used in all vehicles and equipment that are self-propelled, portable, transportable, or are intended to be propelled while performing their function unless the manufacturer of the vehicle or equipment can prove that the vehicle or equipment will be used in a manner consistent with paragraph (2) of the definition of nonroad engine in § 89.2 of this part. Nonroad vehicle and equipment manufacturers may continue to use noncertified nonroad engines built prior to the effective date until noncertified engine inventories are depleted; however, stockpiling of noncertified nonroad engines will be considered a violation of this section.

§ 89.1004 General enforcement provisions.

(a) *Information collection provisions.* (1) Every manufacturer of new nonroad engines and other persons subject to the requirements of this part must establish and maintain records, perform tests where such testing is not otherwise reasonably available under this part, make reports and provide information the Administrator may reasonably require to determine whether the manufacturer or other person has acted or is acting in compliance with this part or to otherwise carry out the provisions of this part, and must, upon request of an officer or employee duly designated by the Administrator, permit the officer or employee at reasonable times to have access to and copy such records. The manufacturer shall comply in all

respects with the requirements of Subpart I of this part.

(2) For purposes of enforcement of this part, an officer or employee duly designated by the Administrator, upon presenting appropriate credentials, is authorized:

(i) to enter, at reasonable times, any establishment of the manufacturer, or of any person whom the manufacturer engaged to perform any activity required under paragraph (a) (1) of this section, for the purposes of inspecting or observing any activity conducted pursuant to paragraph (a)(1) of this section, and

(2) to inspect records, files, papers, processes, controls, and facilities used in performing an activity required by paragraph (a)(1) of this section, by the manufacturer or by a person whom the manufacturer engaged to perform the activity.

(b) *Exemption provision.* The Administrator may exempt a new nonroad engine from § 89.1003 upon such terms and conditions as the Administrator may find necessary for the purpose of export, research, investigations, studies, demonstrations, or training, or for reasons of national security.

(c) *Importation provision.* (1) A new nonroad engine, vehicle, or equipment offered for importation or imported by a person in violation of § 89.1003 is to be refused admission into the United States, but the Secretary of the Treasury and the Administrator may, by joint regulation, provide for deferring a final determination as to admission and authorizing the delivery of such a nonroad engine offered for import to the owner or consignee thereof upon such terms and conditions (including the furnishing of a bond) as may appear to them appropriate to insure that the nonroad engine will be brought into conformity with the standards, requirements, and limitations applicable to it under this part.

(2) If a nonroad engine is finally refused admission under this paragraph, the Secretary of the Treasury shall cause disposition thereof in accordance with the customs laws unless it is exported, under regulations prescribed by the Secretary, within 90 days of the date of notice of the refusal or additional time as may be permitted pursuant to the regulations.

(3) Disposition in accordance with the customs laws may not be made in such manner as may result, directly or indirectly, in the sale, to the ultimate consumer, of a new nonroad engine that fails to comply with applicable standards of the Administrator under this part.

(d) *Export provision.* A new nonroad engine intended solely for export, and so labeled or tagged on the outside of the container and on the engine itself, shall be subject to the provisions of § 89.1003, except that if the country that is to receive the engine has emission standards that differ from the standards prescribed under subpart B of this part, then the engine must comply with the standards of the country that is to receive the engine.

§ 89.1005 Injunction proceedings for prohibited acts.

(a) The district courts of the United States have jurisdiction to restrain violations of § 89.1003(a).

(b) Actions to restrain violations of § 89.1003(a) must be brought by and in the name of the United States. In an action, subpoenas for witnesses who are required to attend a district court in any district may run into any other district.

§ 89.1006 Penalties.

(a) *Violations.* A violation of the requirements of this subpart is a violation of the applicable provisions of the Act, including sections 213(d) and 203, and is subject to the penalty provisions thereunder.

(1) A person who violates § 89.1003(a)(1), (a)(4), or (a)(6), or a manufacturer or dealer who violates § 89.1003(a)(3)(i), is subject to a civil penalty of not more than $25,000 for each violation.

(2) A person other than a manufacturer or dealer who violates § 89.1003(a)(3)(i) or any person who violates § 89.1003(a)(3)(ii) is subject to a civil penalty of not more than $2,500 for each violation.

(3) A violation with respect to § 89.1003 (a)(1), (a)(3)(i), (a)(4), or (a)(6) constitutes a separate offense with respect to each nonroad engine.

(4) A violation with respect to § 89.1003(a)(3)(ii) constitutes a separate offense with respect to each part or component. Each day of a violation with respect to § 89.1003(a)(5) constitutes a separate offense.

(5) A person who violates § 89.1003(a)(2) or (a)(5) is subject to a civil penalty of not more than $25,000 per day of violation.

(b) *Civil actions.* The Administrator may commence a civil action to assess and recover any civil penalty under paragraph (a) of this section.

(1) An action under this paragraph may be brought in the district court of the United States for the district in which the defendant resides or has the Administrator's principal place of business, and the court has jurisdiction to assess a civil penalty.

(2) In determining the amount of a civil penalty to be assessed under this paragraph, the court is to take into account the gravity of the violation, the economic benefit or savings (if any) resulting from the violation, the size of the violator's business, the violator's history of compliance with Title II of the Act, action taken to remedy the violation, the effect of the penalty on the violator's ability to continue in business, and such other matters as justice may require.

(3) In any such action, subpoenas for witnesses who are required to attend a district court in any district may run into any other district.

(c) *Administrative assessment of certain penalties*—(1) *Administrative penalty authority.* In lieu of commencing a civil action under paragraph (b) of this section, the Administrator may assess any civil penalty prescribed in paragraph (a) of this section, except that the maximum amount of penalty sought against each violator in a penalty assessment proceeding shall not exceed $200,000, unless the Administrator and the Attorney General jointly determine that a matter involving a larger penalty amount is appropriate for administrative penalty assessment. Any such determination by the Administrator and the Attorney General is not subject to judicial review. Assessment of a civil penalty shall be by an order made on the record after opportunity for a hearing held in accordance with the procedures found at part 22 of this chapter. The Administrator may compromise, or remit, with or without conditions, any administrative penalty which may be imposed under this section.

(2) *Determining amount.* In determining the amount of any civil penalty assessed under this paragraph, the Administrator shall take into account the gravity of the violation, the economic benefit or savings (if any) resulting from the violation, the size of the violator's business, the violator's history of compliance with Title II of the Act, action taken to remedy the violation, the effect of the penalty on the violator's ability to continue in business, and such other matters as justice may require.

(3) *Effect of administrator's action.*

(i) Action by the Administrator under this paragraph does not affect or limit the Administrator's authority to enforce any provisions of the Act; except that any violation with respect to which the Administrator has commenced and is diligently prosecuting an action under this paragraph, or for which the Administrator has issued a final order

not subject to further judicial review and for which the violator has paid a penalty assessment under this paragraph shall not be the subject of a civil penalty action under paragraph (b) of this section.

(ii) No action by the Administrator under this paragraph shall affect a person's obligation to comply with a section of this part.

(4) *Finality of order.* An order issued under this subsection is to become final 30 days after its issuance unless a petition for judicial review is filed under paragraph (c)(5) of this section.

(5) *Judicial review.* A person against whom a civil penalty is assessed in accordance with this subsection may seek review of the assessment in the United States District Court for the District of Columbia or for the district in which the violation is alleged to have occurred, in which such person resides, or where the person's principal place of business is located, within the 30-day period beginning on the date a civil penalty order is issued. The person shall simultaneously send a copy of the filing by certified mail to the Administrator and the Attorney General. The Administrator shall file in the court within 30 days a certified copy, or certified index, as appropriate, of the record on which the order was issued. The court is not to set aside or remand any order issued in accordance with the requirements of this paragraph unless substantial evidence does not exist in the record, taken as a whole, to support the finding of a violation or unless the Administrator's assessment of the penalty constitutes an abuse of discretion, and the court is not to impose additional civil penalties unless the Administrator's assessment of the penalty constitutes an abuse of discretion. In any proceedings, the United States may seek to recover civil penalties assessed under this section.

(6) *Collection.* (i) If any person fails to pay an assessment of a civil penalty imposed by the Administrator as provided in this part after the order making the assessment has become final or after a court in an action brought under paragraph (c)(5) of this section has entered a final judgment in favor of the Administrator, the Administrator shall request that the Attorney General bring a civil action in an appropriate district court to recover the amount assessed (plus interest at rates established pursuant to section 6621(a)(2) of the Internal Revenue Code of 1986 from the date of the final order or the date of final judgment, as the case may be). In such an action, the validity, amount, and appropriateness of the penalty is not subject to review.

(ii) A person who fails to pay on a timely basis the amount of an assessment of a civil penalty as described in paragraph (c)(6)(i) of this section shall be required to pay, in addition to that amount and interest, the United States' enforcement expenses, including attorney's fees and costs for collection proceedings, and a quarterly nonpayment penalty for each quarter during which the failure to pay persists. The nonpayment penalty is an amount equal to ten percent of the aggregate amount of that person's penalties and nonpayment penalties which are unpaid as of the beginning of such quarter.

§ 89.1007 Warranty provisions.

(a) The manufacturer of each nonroad engine must warrant to the ultimate purchaser and each subsequent purchaser that the engine is designed, built, and equipped so as to conform at the time of sale with applicable regulations under section 213 of the Act, and is free from defects in materials and workmanship which cause such engine to fail to conform with applicable regulations for its warranty period (as determined under § 89.104–96).

(b) In the case of a nonroad engine part, the manufacturer or rebuilder of the part may certify according to § 85.2112 that use of the part will not result in a failure of the engine to comply with emission standards promulgated in this part.

(c) For the purposes of this section, the owner of any nonroad engine warranted under this part is responsible for the proper maintenance of the engine. Proper maintenance includes replacement and service, at the owner's expense at a service establishment or facility of the owner's choosing, such items as spark plugs, points, condensers, and any other part, item, or device related to emission control (but not designed for emission control) under the terms of the last sentence of section 207(a)(3) of the Act, unless such part, item, or device is covered by any warranty not mandated by this Act.

§ 89.1008 In-use compliance provisions.

(a) Effective with respect to nonroad vehicles, equipment, and engines manufactured during model years 1996 and after:

(1) If the Administrator determines that a substantial number of any class or category of engines, although properly maintained and used, do not conform to the regulations prescribed under section 213 of the Act when in actual use throughout their recall period (as defined under § 89.104–96(b)), the Administrator shall immediately notify the manufacturer of such nonconformity and require the manufacturer to submit a plan for remedying the nonconformity of the engines with respect to which such notification is given.

(i) The manufacturer's plan shall provide that the nonconformity of any such engines which are properly used and maintained will be remedied at the expense of the manufacturer.

(ii) If the manufacturer disagrees with such determination of nonconformity and so advises the Administrator, the Administrator shall afford the manufacturer and other interested persons an opportunity to present their views and evidence in support thereof at a public hearing. Unless, as a result of such hearing, the Administrator withdraws such determination of nonconformity, the Administrator shall, within 60 days after the completion of such hearing, order the manufacturer to provide prompt notification of such nonconformity in accordance with paragraph (a)(2) of this section. The manufacturer shall comply in all respects with the requirements of subpart G of this part.

(2) Any notification required to be given by the manufacturer under paragraph (a)(1) of this section with respect to any class or category of engines shall be given to dealers, ultimate purchasers, and subsequent purchasers (if known) in such manner and containing such information as required in subparts H and I of this part.

(3)(i) The manufacturer shall furnish with each new nonroad engine written instructions for the proper maintenance and use of the engine by the ultimate purchaser as required under § 89.109–96. The manufacturer shall provide in boldface type on the first page of the written maintenance instructions notice that maintenance, replacement, or repair of the emission control devices and systems may be performed by any nonroad engine repair establishment or individual using any nonroad engine part which has been certified as provided in § 89.1007(a).

(ii) The instruction under paragraph (3)(i) of this section must not include any condition on the ultimate purchaser's using, in connection with such engine, any component or service (other than a component or service provided without charge under the terms of the purchase agreement) which is identified by brand, trade, or corporate name. Subject instructions also must not directly or indirectly distinguish between service performed by the franchised dealers of such manufacturer, or any other service establishments with which such manufacturer has a commercial relationship, and service performed by

independent nonroad engine repair facilities with which such manufacturer has no commercial relationship.

(iii) The prohibition of paragraph (a)(3)(ii) of this section may be waived by the Administrator if:

(A) The manufacturer satisfies the Administrator that the engine will function properly only if the component or service so identified is used in connection with such engine, and

(B) The Administrator finds that such a waiver is in the public interest.

(iv) In addition, the manufacturer shall indicate by means of a label or tag permanently affixed to the engine that the engine is covered by a certificate of conformity issued for the purpose of assuring achievement of emission standards prescribed under section 213 of the Act. This label or tag shall also contain information relating to control of emissions as prescribed under § 89.110–96.

(b) The manufacturer bears all cost obligation a dealer incurs as a result of a requirement imposed by paragraph (a) of this section. The transfer of any such cost obligation from a manufacturer to a dealer through franchise or other agreement is prohibited.

(c) If a manufacturer includes in an advertisement a statement respecting the cost or value of emission control devices or systems, the manufacturer shall set forth in the statement the cost or value attributed to these devices or systems by the Secretary of Labor (through the Bureau of Labor Statistics). The Secretary of Labor, and his or her representatives, has the same access for this purpose to the books, documents, papers, and records of a manufacturer as the Comptroller General has to those of a recipient of assistance for purposes of section 311 of the Act.

(d) Any inspection of a nonroad engine for purposes of paragraph (a)(1) of this section, after its sale to the ultimate purchaser, is to be made only if the owner of such vehicle or engine voluntarily permits such inspection to be made, except as may be provided by any state or local inspection program.

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Federal Register

Friday
June 17, 1994

Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 333 and 369

Tentative Final Monograph for Health-Care Antiseptic Drug Products; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 333 and 369

[Docket No. 75N–183H]

RIN 0905–AA06

Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Tentative Final Monograph for Health-Care Antiseptic Drug Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing a notice of proposed rulemaking in the form of an amended tentative final monograph that would establish conditions under which over-the-counter (OTC) topical health-care antiseptic drug products are generally recognized as safe and effective and not misbranded. FDA is issuing this notice of proposed rulemaking to amend the previous notice of proposed rulemaking on topical antimicrobial drug products (see the **Federal Register** of January 6, 1978, 43 FR 1210) after considering the public comments on that notice and other information in the administrative record for this rulemaking. FDA is also requesting data and information concerning the safety and effectiveness of topical antimicrobials for use as hand sanitizers or dips. This proposal is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Written comments, objections, or requests for an oral hearing on the proposed regulation before the Commissioner of Food and Drugs by December 14, 1994. Because of the length and complexity of this proposed regulation, the agency is allowing a period of 180 days for comments and objections instead of the normal 60 days. New data by June 19, 1995. Comments on the new data by August 17, 1995. Written comments on the agency's economic impact determination by December 14, 1994.

ADDRESSES: Written comments, objections, new data, or requests for an oral hearing to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD–810), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5000.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 13, 1974 (39 FR 33103), FDA published, under § 330.10(a)(6) (21 CFR 330.10(a)(6)), an advance notice of proposed rulemaking to establish a monograph for OTC topical antimicrobial drug products, together with the recommendations of the Advisory Review Panel on OTC Topical Antimicrobial I Drug Products (Antimicrobial I Panel), which was the advisory review panel responsible for evaluating data on the active ingredients in this drug class. Interested persons were invited to submit comments by November 12, 1974. Reply comments in response to comments filed in the initial comment period could be submitted by December 12, 1974. In response to numerous requests, the agency issued a notice in the **Federal Register** of October 17, 1974 (39 FR 37066) granting an extension of the deadline for comments until December 12, 1974, and for reply comments until January 13, 1975.

In the **Federal Register** of January 6, 1978 (43 FR 1210), FDA published, under § 330.10(a)(7), a notice of proposed rulemaking to establish a monograph for OTC topical antimicrobial drug products, based on the recommendations of the Antimicrobial I Panel and the agency's response to comments submitted following publication of the advance notice of proposed rulemaking. Interested persons were invited to submit objections or requests for oral hearing by February 6, 1978. In response to numerous requests to extend the time period for submitting objections or requests for oral hearing, the agency issued a notice in the **Federal Register** of February 3, 1978 (43 FR 4637) granting an extension of the deadline to March 6, 1978. During this time period, the agency received 6 petitions that requested reopening the administrative record and 11 requests for an oral hearing. In a notice published in the **Federal Register** of March 9, 1979 (44 FR 13041), the agency deferred action on the requests for a hearing, but granted the petitions to reopen the record to allow interested persons to submit comments and any new or additional data by June 7, 1979, and reply comments by July 9, 1979. FDA also stated its intent to publish an updated (amended) tentative final monograph based on the review and evaluation of new submissions and a reevaluation of existing data.

In a notice published in the **Federal Register** of October 26, 1979 (44 FR 61609), the agency again reopened the administrative record for the submission of new data by March 26, 1980, and for comments on the new data by May 27, 1980. This action was taken to permit manufacturers to submit the results of testing to FDA as expeditiously as possible prior to establishment of a final monograph.

Subsequent to the June 7, 1979, closing date for the submission of new data, and prior to the October 26, 1979, reopening of the administrative record, data and information were submitted to FDA. In a notice published in the **Federal Register** of March 21, 1980 (45 FR 18398), the agency advised that it had reopened the administrative record for OTC topical antimicrobial drug products to allow for consideration of data and information that had been filed in the Dockets Management Branch after the date the administrative record on the tentative final monograph had officially closed on March 6, 1978. The agency concluded that any new data and information filed prior to March 21, 1980, should be available to the agency in developing a proposed regulation in the form of a tentative final monograph.

In a notice published in the **Federal Register** on January 5, 1982 (47 FR 436), the agency advised that it had again reopened the administrative record for OTC topical antimicrobial drug products to allow for consideration of the recommendations of the Advisory Review Panel on OTC Miscellaneous External Drug Products (Miscellaneous External Panel) on mercury-containing drug products. Interested persons were invited to submit comments by April 5, 1982, and reply comments by May 5, 1982. FDA stated that the proceeding to develop a monograph for mercury-containing drug products would be merged with the general proceeding to establish a monograph for OTC topical antimicrobial drug products.

In a notice published in the **Federal Register** on May 21, 1982 (47 FR 22324), the agency advised that it had again reopened the administrative record for OTC topical antimicrobial drug products to allow for consideration of the recommendations of the Miscellaneous External Panel on alcohol drug products. Interested persons were invited to submit comments by August 19, 1982, and reply comments by September 20, 1982. The notice stated that the proceeding to develop a monograph for alcohol drug products would be merged with the general proceeding to establish a monograph for OTC topical antimicrobial drug products.

In the **Federal Register** of September 7, 1982 (47 FR 39406), FDA issued a notice to reopen the administrative record for OTC topical antimicrobial drug products to allow for consideration

of the Miscellaneous External Panel's recommendations on topical antimicrobial drug products used for the treatment of diaper rash. The agency discussed topical antimicrobial active ingredients for this use in the Federal Register of June 20, 1990 (55 FR 25246).

In accordance with § 330.10(a)(10), the data and information considered by the Panels were put on public display in the Dockets Management Branch (address above), after deletion of a small amount of trade secret information. In response to the previous tentative final monograph and the advance notice of proposed rulemaking for mercury-containing drug products and the advance notice of proposed rulemaking for alcohol drug products, 4 drug manufacturers' associations, 44 drug manufacturers, 1 medical device manufacturer, 1 drug distributor, 2 medical schools, 2 research laboratories, 1 law firm, and 1 consulting firm submitted comments. Copies of the comments received are also on public display in the Dockets Management Branch.

The advance notice of proposed rulemaking, which was published in the Federal Register of September 13, 1974 (39 FR 33103), was designated as a "proposed monograph" in order to conform to terminology used in the OTC drug review regulations (§ 330.10). Similarly, the notice of proposed rulemaking, which was published in the Federal Register of January 6, 1978 (43 FR 1210), was designated as a "tentative final monograph." The present document is also designated as a "tentative final monograph." The legal status of each tentative final monograph, however, is that of a proposed rule. The present document is a reproposal regarding health-care antiseptic drug products.

This antimicrobial rulemaking is broad in scope, encompassing products that may contain the same active ingredients, but are labeled and marketed for different intended uses. For example, one group of products is primarily used by consumers for "first aid" and includes skin antiseptics, skin wound cleansers, and skin wound protectants. Another group of products, antiseptic handwashes, are used by consumers on a more frequent, even daily, basis and includes products for personal use in the home, such as when caring for invalids and during family illness. A third group of products is generally intended for use by health professionals and includes health-care personnel handwashes, patient preoperative skin preparations, and surgical hand scrubs.

In order to expedite the completion of the first aid section of the antimicrobial monograph, the agency published a separate tentative final monograph for these products in the Federal Register of July 22, 1991 (56 FR 33644). The non-first aid uses of topical antimicrobials, now identified as "health-care antiseptics," are addressed in this document. Although the amended tentative final monographs for first-aid antiseptics and health-care antiseptics are being published separately, both categories will eventually be included under part 333 (21 CFR part 333).

The agency also has decided that OTC topical antimicrobial and topical antibiotic drug products should be included within the same monograph. Although an advance notice of proposed rulemaking to establish a monograph for OTC topical antibiotic drug products was published under part 342 (21 CFR part 342) on April 1, 1977 (42 FR 17642), the final monograph for those products was issued on December 11, 1987 (52 FR 47312) as a new subpart of the OTC topical antimicrobial monograph, part 333, subpart B—Topical First Aid Antibiotic Drug Products. Subpart A will cover first aid antiseptic drug products; subpart C will cover antifungal drug products; subpart D covers acne drug products; and new subpart E will cover health-care antiseptic drug products.

In this tentative final monograph (proposed rule) to establish subpart E of part 333, FDA states its position on the establishment of a monograph for OTC health-care antiseptic drug products. This document addresses only those comments and data concerning the previous antimicrobial tentative final monograph that are related to "non-first aid uses," including products for personal use in the home and products used by health-care professionals.

This proposal constitutes FDA's reevaluation of the January 6, 1978 tentative final monograph based on the comments received and the agency's independent evaluation of the Miscellaneous External Panel's reports on OTC alcohol and mercury-containing drug products and the comments received. The following sections of the January 6, 1978 tentative final monograph for topical antimicrobial drug products are being addressed in this document: §§ 333.1, 333.3, 333.30, 333.50, 333.85, 333.87, 333.97, and 333.99. The following sections of the advance notice of proposed rulemaking for alcohol drug products are being addressed in this document: §§ 333.55 and 333.98. Modifications have been made for clarity and regulatory accuracy and to reflect new information. Such new information has been placed on file in the Dockets Management Branch (address above). These modifications are reflected in the following summary of the comments and FDA's responses to them. (See section I.)

The OTC drug procedural regulations (21 CFR 330.10) provide that any testing necessary to resolve the safety or effectiveness issues that formerly resulted in a Category III classification, and submission to FDA of the results of that testing or any other data, must be done during the OTC drug rulemaking process before the establishment of a final monograph. Accordingly, FDA does not use the terms "Category I" (generally recognized as safe and effective and not misbranded), "Category II" (not generally recognized as safe and effective or misbranded), and "Category III" (available data are insufficient to classify as safe and effective, and further testing is required) at the final monograph stage. In place of Category I, the term "monograph conditions" is used; in place of Categories II and III, the term "nonmonograph conditions" is used. This document retains the concepts of Categories I, II, and III at the tentative final monograph stage.

The agency advises that the conditions under which the drug products that are subject to this monograph would be generally recognized as safe and effective and not misbranded (monograph conditions) will be effective 12 months after the date of publication of the final monograph in the Federal Register. On or after that date, no OTC drug product that is subject to the monograph and that contains a nonmonograph condition, i.e., a condition that would cause the drug to be not generally recognized as safe and effective or to be misbranded, may be initially introduced or initially delivered for introduction into interstate commerce unless it is the subject of an approved application or abbreviated application (hereinafter called application). Further, any OTC drug product subject to this monograph that is repackaged or relabeled after the effective date of the monograph must be in compliance with the monograph regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce. Manufacturers are encouraged to comply voluntarily with the monograph at the earliest possible date.

In the advance notice of proposed rulemaking for OTC topical antimicrobial drug products (39 FR 33103), the agency suggested that the conditions included in the monograph

(Category I) be effective 30 days after the date of publication of the final monograph in the **Federal Register** and that the conditions excluded from the monograph (Category II) be eliminated from OTC drug products effective 6 months after the date of publication of the final monograph, regardless of whether further testing was undertaken to justify their future use. Experience has shown that relabeling of products covered by the monograph is necessary in order for manufacturers to comply with the monograph. New labels containing the monograph labeling have to be written, ordered, received, and incorporated into the manufacturing process. The agency has determined that it is impractical to expect new labeling to be in effect 30 days after the date of publication of the final monograph. Experience has shown also that if the deadline for relabeling is too short, the agency is burdened with extension requests and related paperwork.

In addition, some products will have to be reformulated to comply with the monograph. Reformulation often involves the need to do stability testing on the new product. An accelerated aging process may be used to test a new formulation; however, if the stability testing is not successful, and if further reformulation is required, there could be a further delay in having a new product available for manufacture. The agency wishes to establish a reasonable period of time for relabeling and reformulation in order to avoid an unnecessary disruption of the marketplace that could not only result in economic loss, but also interfere with consumers' access to safe and effective drug products. Therefore, the agency is proposing that the final monograph be effective 12 months after the date of its publication in the **Federal Register**. The agency believes that within 12 months after the date of publication most manufacturers can order new labeling and reformulate their products and have them in compliance in the marketplace. If the agency determines that any labeling for a condition included in the final monograph should be implemented sooner than the 12-month effective date, a shorter deadline may be established. Similarly, if a safety problem is identified for a particular nonmonograph condition, a shorter deadline may be set for removal of that condition from OTC drug products.

All "OTC Volumes" cited throughout this document refer to the submissions made by interested persons pursuant to the call-for-data notice published in the **Federal Register** of January 7, 1972 (37 FR 235) or to additional information that has come to the agency's attention since publication of the advance notice of proposed rulemaking. The volumes are on public display in the Dockets Management Branch (address above).

I. The Agency's Tentative Conclusions on the Comments and Reply Comments

A. General Comments

1. Two comments contended that OTC drug monographs are interpretive, as opposed to substantive, regulations. One comment referred to statements on this issue submitted earlier to other OTC drug rulemaking proceedings.

The agency addressed this issue in paragraphs 85 through 91 of the preamble to the procedures for classification of OTC drug products, published in the **Federal Register** of May 11, 1972 (37 FR 9464 at 9471 to 9472), and in paragraph 3 of the preamble to the tentative final monograph for OTC antacid drug products, published in the **Federal Register** of November 12, 1973 (38 FR 31260). FDA reaffirms the conclusions stated in those documents. Court decisions have confirmed the agency's authority to issue substantive regulations by rulemaking. (See, e.g., *National Nutritional Foods Association* v. *Weinberger*, 512 F.2d 688, 696 to 698 (2d Cir. 1975) and *National Association of Pharmaceutical Manufacturers* v. *FDA*, 487 F. Supp. 412 (S.D.N.Y. 1980), aff'd, 637 F.2d 887 (2d Cir. 1981).)

2. One comment pointed out that under "Subpart B—Active Ingredients" of the tentative final monograph, no CFR part number was assigned to the category "skin antiseptic." However, part numbers were assigned to other categories without any Category I ingredients, with the term "reserved" in parentheses. The comment requested that this omission be corrected in the amended tentative final monograph.

The omission pointed out by the comment was an oversight. However, it is no longer necessary to assign a CFR part number to the category "skin antiseptic," because skin antiseptics have been included in broader categories identified as first aid antiseptics in the amended tentative final monograph for first aid antiseptics (56 FR 33644) and as health-care antiseptics in this tentative final monograph. (See section I.B., comment 3.) All Category I first aid antiseptic and health-care antiseptic active ingredients have been listed in the amended tentative final monograph under subpart A and subpart E, respectively.

B. General Comments on Antimicrobials

3. A number of comments objected to the Panel's recommendation for separate statements of identity in the labeling of products containing the same antimicrobial active ingredient. As an example, several comments noted that povidone-iodine has several professional uses (health-care personnel handwash, skin antiseptic, and surgical hand scrub) and marketing a product in conformance with two or more product categories becomes difficult because there are different labeling requirements for each drug product category. Some comments requested FDA to combine the drug product category designations or to add a new multipurpose product category that allows the combining of labeling indications now included in several product categories. One comment specifically recommended that the agency consider changing product class designations and/or adding a new product class "Multi Purpose Skin Prep" or "Skin Prep," with the indications for use including those listed under § 333.85 (health-care personnel hand wash), § 333.87 (patient preoperative skin preparation), § 333.90 (skin antiseptic), and § 333.97 (surgical hand scrub).

Another comment stated that the word "skin" was superfluous because all OTC antiseptics are intended only for use on the skin; still another comment contended that the statement of identity "antiseptic" is preferable to "skin antiseptic" because these products are used on cuts, scratches, and mucous membranes as well as skin.

In response to the advance notice of proposed rulemaking and reopening of the administrative record for alcohol drug products for topical antimicrobial OTC use published in the **Federal Register** of May 21, 1982 (47 FR 22324), one comment objected to the statement of identity in proposed § 333.98(a) which read, "alcohol for topical antimicrobial use," (47 FR 22324 at 22332). The comment stated that this term would be confusing to the consumer and suggested the term "antiseptic for the skin."

The agency agrees that OTC topical antimicrobial drug products need not have multiple statements of identity. In reviewing the statements of identity recommended by the Antimicrobial I Panel (39 FR 33103), i.e., health-care personnel handwash, patient preoperative skin preparation, skin antiseptic, surgical hand scrub, and the statement of identity recommended by the Miscellaneous External Panel (47 FR 22324), i.e., alcohol for topical antimicrobial use, the agency has determined that the general term "antiseptic" broadly describes all proposed product categories and reflects the basic intended uses of these

products. The agency believes that the statement of identity of "multiple purpose skin prep" or "skin prep" recommended by one comment would not as clearly and succinctly describe the use of these products as the statement of identity "antiseptic." As discussed in section I.B., comment 5, the agency is also proposing an additional term "antiseptic handwash" as a statement of identity to describe products for home use.

As discussed in the first aid antiseptic segment of this rulemaking (56 FR 33644 at 33647), the term "skin" has been deleted from the previously proposed statement of identity "skin antiseptic." Although several comments felt that the word "skin" was superfluous, the agency has no objection to the statement "antiseptic for the skin" or "skin antiseptic" appearing elsewhere in the labeling of these products as additional information to the consumer or health-care professional, provided it does not appear in any portion of the labeling required by the monograph and does not detract from such required information. (See section I.I., comment 19.)

As stated in the first aid antiseptic segment of this rulemaking (56 FR 33644 at 33647), the agency believes that the term "antiseptic" is readily understood by consumers. The agency also finds this to be true for health professionals. The agency is therefore proposing the term "antiseptic" as the general statement of identity for all OTC topical antimicrobial ingredients included in this tentative final monograph. Further, FDA is also proposing that manufacturers may have an option to provide an alternate statement of identity describing only the specific intended use(s) of the product. Specifically, the agency is proposing that the statement of identity for antiseptic drug products in § 333.450(a) read as follows: "The labeling of a single-use product contains the established name of the drug, if any, and identifies the product as an 'antiseptic' and/or with the appropriate statement of identity described in §§ 333.455(a), 333.460(a), or 333.465(a). The labeling of a multiple-use product contains the established name of the drug, if any, and may use the single statement of identity 'antiseptic' and/or the appropriate statements of identity described in §§ 333.455(a), 333.460(a), and 333.465(a). When 'antiseptic' is used as the only statement of identity on a single-use or a multiple-use product, the intended use(s), such as patient preoperative skin preparation, is to be included under the indications. For multiple-use products, a statement of the intended use should also precede the specific directions for each use."

The agency believes that the proposed labeling for these multiple-use products is flexible and provides manufacturers with a number of options. However, the agency recognizes that some manufacturers may wish to label their antiseptic drug products with all of the allowable indications for a particular active ingredient and that this may give rise to difficulties in incorporating all of the information on a product's various uses in the limited space on an OTC label. The agency wishes to point out that some portions of the proposed indications are optional, i.e., the examples included in both the antiseptic and health-care personnel handwash indications, and need not be incorporated in the labeling at all. In addition, manufacturers are free to design ways of incorporating all the information on the various uses of their drug product through the use of flap labels, redesigned packages, or package inserts.

The agency is providing several examples of labeling for an antiseptic product containing povidone-iodine when labeled as a single-use or as a multiple-use product, as follows:

1. When labeled as a single-use product, i.e., patient preoperative skin preparation.

a. Established name: povidone-iodine.

b. Statement of identity (any of these is acceptable):

(1) "antiseptic";

(2) "patient preoperative skin preparation";

(3) "antiseptic/patient preoperative skin preparation."

c. Indications:

(1) When only "antiseptic" is used in the statement of identity:

"Patient preoperative skin preparation:

Helps to reduce bacteria that potentially can cause skin infection."

(2) When patient preoperative skin preparation is used as or included as part of the statement of identity: "Helps to reduce bacteria that potentially can cause skin infection."

d. Directions: (Insert directions in § 333.460(d).)

2. When labeled as a multiple-use product, i.e., patient preoperative skin preparation, antiseptic handwash or health-care personnel handwash, and surgical hand scrub.

a. Established name: povidone-iodine.

b. Statement of identity (any of these is acceptable):

(1) "antiseptic";

(2) "patient preoperative skin preparation, antiseptic handwash or health-care personnel handwash, and surgical hand scrub";

(3) "antiseptic/patient preoperative skin preparation, antiseptic handwash or health-care personnel handwash, and surgical hand scrub."

c. Indications: Irrespective of which statement of identity is used, the following is required: "Patient preoperative skin preparation: Helps to reduce bacteria that potentially can cause skin infection. Antiseptic handwash: For handwashing to reduce bacteria on the skin (which may be followed by one or more of the following: after changing diapers, after assisting ill persons, or before contact with a person under medical care or treatment). Health-care personnel handwash: Handwash to help reduce bacteria that potentially can cause disease or For handwashing to reduce bacteria on the skin (which may be followed by one or more of the following: after changing diapers, after assisting ill persons, or before contact with a person under medical care or treatment). Surgical hand scrub: Significantly reduces the number of micro-organisms on the hands and forearms prior to surgery or patient care."

d. Directions: The following is required: Patient preoperative skin preparation: (Insert directions in § 333.460(d).) Antiseptic handwash or health-care personnel handwash: (Insert directions in § 333.455(c).) Surgical handscrub: (Insert directions in § 333.465(c).)

4. One comment requested that scrubbing devices such as brushes or sponges that are impregnated with approved antimicrobial ingredients be included in the monograph. Another comment requested clarification of the agency's views on trays or kits that contain povidone-iodine and disposable instruments (scissors, forceps, and hemostats) packed in a sterile package, which are designed to reduce the incidence of cross-infection in hospitals.

This tentative final monograph does not provide for the use of devices such as brushes or sponges impregnated with antimicrobials, or of trays or kits that contain povidone-iodine and disposable instruments, because the monograph is intended to regulate only OTC drug active ingredients. Since these comments were submitted, the agency has established procedures (see 21 CFR part 3) describing how it determines which agency component has primary jurisdiction for the premarket review and regulation of products comprised of any combination of a drug and a device. In addition, interested parties are encouraged to read the following document (Ref. 1) for guidance: "Intercenter Agreement Between the

Center for Drug Evaluation and Research and the Center for Devices and Radiological Health." (See § 3.5 (21 CFR 3.5).) This agreement is on file in the Dockets Management Branch (address above).

(1) Intercenter Agreement Between the Center for Drug Evaluation and Research and the Center for Devices and Radiological Health in OTC Vol. 230001, Docket No. 75N–183H, Dockets Management Branch.

5. One comment expressed concern that the tentative final monograph failed to provide consumers with an antibacterial skin cleanser for home use. The comment noted that, in addition to professional health care personnel, many consumers have a need for cleansing products containing antibacterial agents for the purpose of promoting good individual and family hygiene. Uses for such products include the following: (1) To reduce bacteria on the hands and face to a greater extent than can be accomplished with ordinary soap, and to prevent accumulation of bacteria from potential sources of contamination. The following examples were cited: Cleansing oneself after changing a baby's diaper, or after assisting aged or ill members of the household with their toilet needs, and before preparing a family meal. (2) The added benefit of an antibacterial cleanser for the minute cuts and abrasions from shaving and other minor traumas. (3) The need for an antibacterial cleanser other than bar soap on local parts of the body such as the face because soap (alkali salts of fatty acids) can be irritating or too drying for some individuals' needs. The comment recommended a new product class under proposed § 333.90(a) (skin antiseptic) to be identified as "Antimicrobial (or Antibacterial) Personal Cleanser" with claims such as "decreases bacteria on the skin" and "contains an antibacterial agent." The comment also suggested that the 10-day maximum use limitation would not be appropriate for this product class, but use could be restricted to 5 or 10 times daily.

Another comment recommended that antimicrobial soaps be allowed to make claims relating to general health care and personal hygiene similar to the claims allowed for health-care personnel handwashes. The comment stated that an antimicrobial soap will reduce bacteria or the transfer of potentially pathogenic micro-organisms in the home and, therefore, serves as a preventive health care aid in controlling diseases.

A third comment requested the addition of a fourth indication for alcohol active ingredients in proposed § 333.98(b) to allow use as an antibacterial handwash to avoid cross-contamination from one individual to another. The comment argued that products containing alcohols are often used as handwashes by athletic trainers to help prevent the spread of skin infections from one individual to another in situations in which soap and water are not available, e.g., on the playing field.

A fourth comment asserted that numerous other meaningful and truthful indications can be used which enhance the safe and effective use of a health-care personnel handwash. For example, the terms "microbicidal cleanser" or "antiseptic germicidal skin cleanser" are appropriate and meaningful terminology describing this use indication.

The agency agrees that antibacterial or antiseptic personal cleanser products are practical for home use, to help prevent cross contamination from one person to another, especially after diaper changing and caring for invalids or ill family members. The agency also agrees with one comment that claims relating to general health-care and personal hygiene similar to the claims allowed for health-care personnel handwashes may be suitable because such claims explain the uses of these products in lay terms.

In the **Federal Register** of July 22, 1991 (56 FR 33644), the agency separated the first aid antiseptic uses of OTC topical antimicrobial drug products from the "non-first aid uses." In that document, the agency proposed that the following terms and categories be deleted: skin antiseptics, skin wound protectants, and skin wound cleansers; and the agency proposed that the appropriate labeling, instead, be included in a new category called "first aid antiseptics" (56 FR 33644 at 33649). Several uses proposed by one comment, i.e., "minute cuts and abrasions from shaving and other minor traumas," are considered as describing "first aid uses" and are adequately covered by the labeling provided for "first aid antiseptics" in proposed § 333.50(b) (56 FR 33677), which contains the following: "First aid to help" (select one of the following: "prevent," ("decrease" ("the risk of" or "the chance of")), ("reduce" ("the risk of" or "the chance of")), "guard against," or "protect against") (select one of the following: "infection," "bacterial contamination," or "skin infection") "in minor cuts, scrapes, and burns." The agency believes that the first aid indication is sufficiently broad to cover minute cuts and abrasions from shaving and that it is not necessary to include the words "other minor traumas" in the indications statement.

Beyond the first aid uses described in the first comment, the agency recognizes a need for an OTC "antiseptic handwash" product for repeated or daily use over an extended period of time for some of the other uses described by the comment. The agency agrees with the comments that health-care personnel handwashes are appropriate for such use because submitted data from effectiveness studies, for uses subject to this rulemaking, were derived from handwashing tests similar to or the same as tests described in the agency's previously proposed testing guidelines (see 43 FR 1210 at 1240), i.e., "Modified Cade Procedure," "Glove Juice Test," and "Test for Health-Care Personnel Handwash Effectiveness." The agency is proposing in this tentative final monograph in § 333.455(a) that a health-care personnel handwash can also bear a statement of identity of "antiseptic handwash." (See section I.B., comment 3.) For products labeled for multiple uses including both antiseptic handwash and first aid labeling claims, the general statement of identity would be "antiseptic" as described in section I.B., comment 3. The product would then need to incorporate the monograph labeling for both antiseptic handwash as well as first aid antiseptic.

The term "cleanser" included in claims requested by the comments is not appropriate in this rulemaking because it is considered to be a cosmetic claim in view of the fact that the Federal Food, Drug, and Cosmetic Act (the act) defines a cosmetic as "articles intended to be * * * applied to the human body * * * for cleansing * * *" (21 U.S.C. 321(i)(1)) and thus may be misleading to consumers. As discussed in section I.I., comment 19, the terms "microbicidal" and "germicidal" may appear in the labeling of OTC antiseptic drug products under certain conditions.

Accordingly, the agency is proposing as the indication for products bearing the statement of identity "antiseptic handwash" a general claim similar to one recommended by one of the comments, i.e., "for handwashing to decrease bacteria on the skin." The agency has determined that this claim may, at the manufacturer's option, be followed by one or more of the following examples: "after changing diapers," "after assisting ill persons," or "before contact with a person under medical care or treatment."

Descriptive statements such as "contains antibacterial ingredients" and "for the purpose of promoting good

individual and family hygiene" are considered to be examples of statements not significantly related to the safe and effective use of the product and thus are outside the scope of the rulemaking. Such statements may be included in the labeling of these OTC drug products subject to the statutory provisions against false or misleading labeling.

The agency has determined that the indication proposed for antiseptic handwash drug products is also appropriate for health-care personnel handwashes and is also proposing the following indication for health-care personnel handwashes. "For handwashing to decrease bacteria on the skin" (which may be followed by one or more of the following: "after changing diapers," "after assisting ill persons," or "before contact with a person under medical care or treatment.") In addition to the indication proposed above, the agency is proposing that health-care personnel handwashes may also bear the following indication: "Handwash to help reduce bacteria that potentially can cause disease." The agency is proposing the statement "recommended for repeated use" as an "other allowable indication" for antiseptic or health-care personnel handwash drug products (see below).

The agency sees no reason to continue to include "antimicrobial soap" as a separate product category. Soap is considered to be a dosage form, and specific dosage forms are not being included in the monograph unless there is a particular safety or efficacy reason for doing so. Antimicrobial ingredients may be formulated as soaps for some of the uses discussed in this document, e.g., handwash; however, the designation "antimicrobial soap" is no longer being proposed for inclusion in the monograph. In addition, the agency considers the other product categories that are being proposed to be more informative to the users of these products.

Based upon the comments, the agency is proposing labeling appropriate for professional or consumer uses as follows:

Section 333.455 Labeling of Antiseptic Handwash or Health-Care Personnel Handwash Drug Products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as an "antiseptic," as stated above under § 333.450(a), and/or "antiseptic handwash," or "health-care personnel handwash."

(b) *Indications.* * * *

(1) *For products labeled as a health-care personnel handwash.* "Handwash to help reduce bacteria that potentially can cause disease" or "For handwashing to decrease bacteria on the skin" (which may be followed by one or more of the following: "after changing diapers," "after assisting ill persons," or "before contact with a person under medical care or treatment.")

(2) *For products labeled as an antiseptic handwash.* "For handwashing to decrease bacteria on the skin" (which may be followed by one or more of the following: "after changing diapers," "after assisting ill persons," or "before contact with a person under medical care or treatment.")

(3) *Other allowable indications for products labeled as either antiseptic or health-care personnel handwash.* The labeling of the product may also contain the following phrase: "Recommended for repeated use."

Other labeling claims requested by the comments for first aid antiseptics are not being included in the tentative final monograph. The agency believes that the general claim "for handwashing to decrease bacteria on the skin" encompasses the variety of uses for promoting good individual and family hygiene. The agency tentatively concludes that the labeling statements proposed above express the same concepts as the labeling suggested by the comments in language that can be more readily understood by the consumer.

C. Comments on Definitions

6. One comment objected to a portion of the definition for health-care personnel handwash in § 333.3(d) of the tentative final monograph that states that the antimicrobial agent is "broad-spectrum" and "if possible, persistent." The comment argued that, because these handwashes are used 50 to 100 times daily, persistence of effect is unnecessary. The comment also questioned the need for a broad-spectrum antimicrobial, stating that *Staphylococcus epidermidis* (*S. epidermidis*) generally is the only natural resident bacteria on the skin, and other transient micro-organisms are more likely to be removed mechanically by washing than by antimicrobial action. The comment suggested that the choice to use or not to use a broad-spectrum antimicrobial ingredient should be left to the manufacturer.

Another comment pointed out that the requirement for "broad spectrum" activity is inconsistently applied in the definitions for health-care personnel handwash, patient preoperative skin preparation, and surgical hand scrub (§ 333.3(d), (e), and (i), respectively) because "broad spectrum" activity is mandatory for the first two classes and only "desirable" for surgical hand scrubs. The comment cited comment 93 (43 FR 1210 at 1224) and the testing guidelines for safety and effectiveness of OTC topical antimicrobials (43 FR 1239) to show the agency's awareness of possible shifts in microbial flora due to a lack of broad spectrum activity. The comment urged that all three product classes include the requirement for each product to at least demonstrate in vitro "cidal" activity against gram-negative bacteria, fungi, and lipophilic and hydrophilic viruses in addition to the gram-positive activity.

In § 333.3(d) of the previous tentative final monograph, a health-care personnel handwash was defined as an "* * * antimicrobial-containing preparation designed for frequent use; it reduces the number of transient micro-organisms on intact skin to an initial baseline level after adequate washing, rinsing, and drying, and it is broad-spectrum, fast acting, and, if possible, persistent." In the tentative final monograph, the agency agreed with the Panel that persistence, defined as prolonged activity, is a valuable attribute that assures antimicrobial activity during the interval between washings and is important to a safe and effective health-care personnel handwash (43 FR 1215). The Panel explained that a property such as persistence, which acts to prevent the growth or establishment of transient micro-organisms as part of the normal baseline or resident flora, would be an added benefit (39 FR 33103 at 33115). Although the Panel did not propose persistence as a mandatory requirement for a health-care personnel handwash, the agency is retaining the words "if possible, persistent" in the definition in this amended tentative final monograph because this is a desirable trait for these products.

Regarding the comment's objection to the broad-spectrum requirement, the Panel in its discussion of the normal skin flora stated that the predominant members of the normal flora are gram positive cocci and diptheroids and not *S. epidermidis*, as the comment indicates. The Panel stated further that a small number of gram negative species, such as coliforms and related micro-organisms, as well as higher forms such as yeast may also be residents of the skin of healthy individuals (39 FR 33103 at 33107). In its discussion of health-care personnel handwash drug products, the Panel acknowledged that, in all likelihood, the specified effect of these products (i.e., removal of transient micro-organisms) can be achieved with a well formulated

nonantimicrobial soap or detergent product. However, the Panel concluded that transient micro-organisms may become part of the established "resident" flora with time, and stated that in a health-care situation, the fast, effective removal of transient micro-organisms is a requirement because they may be pathogenic (39 FR 33103 at 33115). The Panel recommended that health-care personnel handwash drug products containing an antimicrobial ingredient should be broad spectrum. The Panel defined "broad spectrum" in reference to microbiological activity as meaning the antimicrobial has activity against more than one type of micro-organism, that is, activity against gram positive and gram negative bacteria, fungi, and viruses (39 FR 33115). Because transient micro-organisms present on the skin may include widely diverse species, resulting from contact with contaminated persons and materials, the agency concludes that a greater reduction of transient micro-organisms on the skin can be achieved if the antimicrobial containing drug product used as a health-care personnel handwash provides broad spectrum activity.

In addition, because the principal intended use of these professional use products is the prevention of nosocomial (hospital acquired) infections, the agency believes that these drug products should have demonstrable antimicrobial activity against a microbial spectrum that includes the micro-organisms associated with these infections. As discussed in section I.N., comment 28, the agency is proposing, in § 333.470(a)(1)(ii) of the testing requirements, a list of micro-organisms that reflects a spectrum of antimicrobial activity pertinent to the intended use of these drug products and against which the products must be tested. The agency is proposing the following definition of broad spectrum activity in § 333.403(b) of this amended tentative final monograph: "*Broad spectrum activity.* A properly formulated drug product, containing an ingredient included in the monograph, that possesses in vitro activity against the micro-organisms listed in § 333.470(a)(1)(ii), as demonstrated by in vitro minimum inhibitory concentration determinations conducted according to methodology in § 333.470(a)(1)(ii)." This methodology has been developed by the National Committee for Clinical Standards (NCCLS) (Ref. 1). Although micro-organisms in addition to those listed may also be used for testing, the agency will use the test micro-organisms identified in § 333.470(a)(1)(ii) for any necessary compliance testing.

The agency wants to emphasize that in this amended tentative final monograph the broad-spectrum criterion applies to final-formulated drug products used as an antiseptic handwash or health-care personnel handwash, patient preoperative skin preparation, and surgical hand scrub. Although the Category I active ingredients currently included in this amended tentative final monograph are broad spectrum independent of formulation, some Category III antiseptic ingredients have limited spectra (activity against only gram positive bacteria; for example, chloroxylenol (see section I.G., comment 12) and triclosan (see section I.L., comment 23)), but when properly formulated in a final product the spectrum can be broadened to include additional activity against the test micro-organisms, thereby possibly enabling these ingredients to become Category I. Although the agency agrees with the first comment that the manufacturer may use or not use a broad-spectrum ingredient in a particular health-care antiseptic drug product, the finished product must demonstrate in vitro activity against the specific micro-organisms listed in proposed § 333.470(a)(1)(ii).

In response to the second comment, that broad spectrum was inconsistently applied in the definitions of the three product classes, the agency has reevaluated the issue and believes that all product classes should be broad spectrum. As stated in the tentative final monograph (43 FR 1210 at 1212), maintaining the balance among species of micro-organisms constituting the normal skin flora is more likely to be threatened by use of antimicrobial products with a limited spectrum. Also much of the data concerning the spread of infections in hospitals indicates that the use of an antimicrobial with broad spectrum activity would help prevent this (see section I.D., comment 9). Based on the reasons mentioned above, the agency is proposing to include "broad spectrum" in the definitions of the three product classes included in this tentative final monograph.

Reference

(1) National Committee for Clinical Laboratory Standards, "Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria that Grow Aerobically—2d ed.; Approved Standard," NCCLS Document M7–A2, 10:8, 1990.

D. Comments on Labeling

7. Several comments contended that FDA does not have the authority to restrict OTC labeling claims to exact wording, to the exclusion of what the comments described as other "equally truthful claims for the products." One comment pointed out that numerous other meaningful and truthful statements will provide useful information and will enhance the safe and effective use of these products. Several comments maintained that manufacturers have a constitutional right to use any truthful, nonmisleading labeling under the first amendment. To support their position, the comments cited *Bigelow* v. *Virginia*, 421 U.S. 809 (1975); *Virginia State Board of Pharmacy* v. *Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976); *Linmark Associates, Inc.* v. *Willingboro*, 431 U.S. 85 (1977); *Bates* v. *State Bar of Arizona*, 433 U.S. 350 (1977); *Federal Trade Commission* v. *Beneficial Corp.*, 542 F.2d 611, 97 S. Ct. 1679 (1977); and *Warner-Lambert Co.* v. *Federal Trade Commission*, 562 F.2d 749 at 768 (D.C. Cir. 1977).

In the Federal Register of May 1, 1986 (51 FR 16258), the agency published a final rule changing its labeling policy for stating the indications for use of OTC drug products. Under 21 CFR 330.1(c)(2), the label and labeling of OTC drug products are required to contain in a prominent and conspicuous location, either (1) the specific wording on indications for use established under an OTC drug monograph, which may appear within a boxed area designated "APPROVED USES"; (2) other wording describing such indications for use that meets the statutory prohibitions against false or misleading labeling, which shall neither appear within a boxed area nor be designated "APPROVED USES"; or (3) the approved monograph language on indications, which may appear within a boxed area designated "APPROVED USES," plus alternative language describing indications for use that is not false or misleading, which shall appear elsewhere in the labeling. All other OTC drug labeling required by a monograph or other regulation (e.g., statement of identity, warnings, and directions) must appear in the specific wording established under the OTC drug monograph or other regulation where exact language has been established and identified by quotation marks, e.g., 21 CFR 201.63 or 330.1(g).

In the previous tentative final monograph, supplemental language relating to indications had been proposed and captioned as *Other Allowable Statements* in §§ 333.85, 333.87 and 333.97. Under FDA's revised labeling policy (51 FR 16258), such statements are included at the tentative final stage as examples of other truthful

and nonmisleading language that would be allowed elsewhere in the labeling. In accordance with the revised labeling policy, such statements would not be included in a final monograph.

In preparing this amended tentative final monograph, the agency has reevaluated these "other allowable statements" to determine whether they should be incorporated, wherever possible, as part of the indications developed under the monograph.

The agency has reviewed the "*Other Allowable Statements*" proposed in the previous tentative final monograph in § 333.85 for health-care personnel handwash, in § 333.87 for patient preoperative skin preparation, and in § 333.97 for surgical hand scrub. The statement "recommended for repeated use" proposed for a health-care personnel handwash has been included in this amended tentative final monograph as an "other allowable indication" in proposed § 333.455 for antiseptic handwash or health-care personnel handwash drug products. (See section I.B., comment 5.)

The terms "broad spectrum" and "fast-acting" (if applicable) were proposed as "*Other Allowable Statements*" for all three of these product classes in the previous tentative final monograph. As discussed in section I.C., comment 6, the agency is proposing to include "broad spectrum" in the definition of the three product classes included in this amended tentative final monograph. Although the term "broad spectrum" is included in the definitions of these product classes, the agency does not see a need to include this information in the "indications" for these products. Likewise, the term "fast-acting" is included in the definitions of these product classes, but the agency does not see a need to include this information in the indications for these products. This type of information may appear elsewhere in the labeling of these products as additional information to the health-care professional, provided it does not appear in any portion of the labeling required by the monograph and does not detract from such required information. Other previously proposed "*Other Allowable Statements*," i.e., "contains antibacterial ingredient(s)," "contains antimicrobial ingredient(s)," and "nonirritating," are not related in a significant way to the safe and effective use of these products. The agency does not believe that statements such as "contains antibacterial ingredient(s)" or "contains antimicrobial ingredient(s)" are necessary on products intended primarily for health professionals, but has no objection to such statements appearing in the labeling as other information not intertwined with any portion of the labeling required by the monograph. Likewise, the term "nonirritating" may appear as additional information to the health-care professional, provided it does not appear in any portion of the labeling required by the monograph and does not detract from such required information. However, such statements are subject to the provisions of section 502 of the act (21 U.S.C. 352) relating to labeling that is false or misleading. Such statements will be evaluated on a product-by-product basis, under the provisions of section 502 of the act relating to labeling that is false or misleading.

8. Several comments requested that certain warnings required in the labeling of OTC drug products marketed for the general public should not be required on such products distributed only to health professionals and labeled primarily for use in health-care facilities as in proposed § 333.99 "Professional labeling" (43 FR 1210 at 1248 and 1249). Examples cited were the cautionary statements for "skin antiseptic" and "skin wound protectant" in proposed §§ 333.90(c)(3) and 333.93(c)(3) "Do not use this product for more than 10 days. If the infection (condition) worsens or persists, see your physician," and for "skin wound protectant" in proposed § 333.93(c)(7) "Do not use on chronic skin conditions such as leg ulcers, diaper rash, or hand eczema." The comments stated that the professional use of these products sometimes differs from consumer use and that products which are marketed only to health-care institutions and are dispensed and administered by professionals should only contain warnings that apply to professional use. One comment concluded that requiring professional labeling to contain a caution such as in proposed § 333.93(c)(7) could possibly subject the health-care facility and the physician to unwarranted product liability claims, although the particular use of the product under medical supervision is entirely justified and necessary for proper treatment of the patient. One of the comments stated that flexibility should be provided so that manufacturers can utilize only those warnings that are appropriate for professional personnel when packages are restricted to health-care facilities or where a topical antimicrobial product is used as part of a course of treatment selected by the clinician.

In the **Federal Register** of November 12, 1973 (38 FR 31260), the agency published the tentative final monograph for OTC antacid drug products, in which the concept of ethical labeling for OTC drug products was first discussed in comment 56 at 38 FR 31264. There, the agency stated that the warning statements appearing on OTC drug products should be included in ethical (professional) labeling.

Subsequently, in the previous tentative final monograph for OTC topical antimicrobial drug products, published in the **Federal Register** of January 6, 1978 (43 FR 1210), the agency proposed § 333.99 ("Professional labeling") which stated that the labeling of products (covered by the monograph) that is provided only to health professionals and the labeling for those products primarily used in health-care facilities shall include all of the warnings required in each subsection of the monograph, e.g., those in § 333.90 for "skin antiseptic" or § 333.93 for "skin wound protectant."

As described in the first aid antiseptic segment of the tentative final monograph for OTC antimicrobial drug products, published in the **Federal Register** of July 22, 1991 (56 FR 33644), the agency has proposed deletion of the categories cited by the comments, i.e., "skin antiseptic" and "skin wound protectant," as separate drug categories and included them in a single drug product category identified as "first aid antiseptic." The cautionary statements referred to by the comments are addressed in that document.

In this document, the agency is addressing the uses other than first-aid, i.e., health-care antiseptic uses, of topical antimicrobial drug products. These products may contain the same antiseptic active ingredient(s) as the first aid antiseptic drug products, but they are labeled and marketed for different uses. The cautionary statements previously proposed in §§ 333.90(c)(3) and 333.93(c)(3) addressed short-term first aid uses of products primarily proposed as "consumer products." These products were not principally intended to be marketed for hospital or professional use. Therefore, the agency agrees with the comments that such cautionary statements do not apply to professional use of antiseptic drug products and need not appear in the labeling of antiseptic products marketed as antiseptic handwashes or health-care personnel handwashes, patient preoperative skin preparations, and surgical hand scrubs. Likewise the agency believes that health-care antiseptic drug products, marketed principally to health-care professionals, do not need to bear a cautionary statement not to use the product on chronic skin conditions such as leg ulcers, diaper rash, or hand eczema. As

the comment pointed out, professional use of these products is different than consumer use and, in some instances, use of the product on the above-mentioned skin conditions under medical supervision may be justified and necessary for proper treatment of the patient. Therefore, this cautionary statement is not being included in this tentative final monograph.

This tentative final monograph addresses specifically the use of these topical antiseptic drug products by health-care professionals and in health-care facilities. The labeling proposed for those products in this document represents that labeling which the agency believes health-care professionals need to properly use these products. Therefore, the agency believes that the warnings proposed in § 333.450(c) of this tentative final monograph should appear in the labeling of these products that are directed to health-care professionals and health-care facilities, even if the product is marketed principally to these sources only. However, the agency believes that one of these warnings can be modified if the product is labeled "For Hospital and Professional Use Only." In such cases, the second sentence of the warning proposed in § 333.450(c)(3), regarding consulting a doctor, can be deleted. This concept is being included in this tentative final monograph. (See § 333.450(d).)

In responding to the comments regarding the warnings in the "Professional labeling" section (§ 333.99) of the previous tentative final monograph, the agency has determined that these warnings are no longer necessary. Accordingly, § 333.99 is not being included in this amended tentative final monograph. (See section I.D., comment 9 for discussion of § 333.99(a), and section I.J., comment 21 for discussion of § 333.99(b). Also, see section II.B., paragraph 14 in the first aid antiseptic segment of this tentative final monograph (56 FR 33644 at 33675) for discussion of § 333.99(c).)

9. Several comments made recommendations regarding the requirement that professional labeling for all classes of OTC topical antimicrobial drug products must contain the caution statement in proposed § 333.99(a), "Caution: Overuse of this and other antimicrobial products may result in an overgrowth of gram-negative micro-organisms, particularly *Pseudomonas*." Some of the comments stated that this caution statement should be required only for antimicrobials where there is valid scientific evidence to show that such caution is appropriate, for example, quaternary ammonium compounds and triclosan, which have been associated with the overgrowth of gram-negative micro-organisms, specifically *Pseudomonas*. Three comments contended that reports of contamination of benzalkonium chloride solutions with *Pseudomonas* and *Enterobacteria* species were basically the result of misuse, improper storage and dilution, poor technique, and contamination with neutralizing chemicals. One comment recommended that the proposed caution statement in § 333.99(a) should be changed to read: "Improper use or overuse * * *." and cited the discussion of the proposed warning for quaternary ammonium compounds by the agency at 43 FR 1237 where the phrase "misuse or overuse" was included. Another comment objected to the caution, arguing that it is based on theoretical considerations only and there is no published clinical evidence implicating quaternary ammonium compounds. Still another comment stated that its quaternary ammonium compound product passed the commonly used test for *Pseudomonas* activity.

In defense of triclosan's implication in *Pseudomonas* overgrowth, one comment argued that overgrowth was just an unproven hypothesis and submitted the "Summary for Basis of Approval" from an approved new drug application (NDA) for chlorhexidine gluconate (Ref. 1) which included data on a skin flora study that indicated an increasing, continuous gram-negative growth only in the axillary area over a 6-month period, even though chlorhexidine is active against gram-negative micro-organisms. The comment referred to FDA's Division of Anti-Infective Drug Products as having recognized that gram-negative overgrowth can be adequately controlled by restricting use to indications provided in the labeling of a product.

Several comments pointed out that data on povidone-iodine have proven broad spectrum effectiveness, referring to the Centers for Disease Control and Prevention's (CDC) recommendation (Ref. 2) for using this ingredient for skin preparation before intravenous catheter insertion and other procedures to reduce infection. The comments also noted that in a study by Houang et al. (Ref. 3), in which 20 transfers of 7 gram-negative micro-organisms (including *Pseudomonas aeruginosa* (*P. aeruginosa*)) were made, the minimum inhibitory concentration did not change, supporting the fact that repeated use of povidone-iodine would not result in resistant micro-organisms. For these reasons, these comments recommended that § 333.99(a) should be revised to exclude povidone-iodine.

After a thorough review and evaluation of the available data, the agency concludes that the professional labeling caution that overuse of an antimicrobial drug product may cause an overgrowth of gram-negative micro-organisms is not necessary. In the previous tentative final monograph (43 FR 1210 at 1212), the agency stated its awareness of the theory that gram-negative bacteria will replace gram-positive bacteria that are reduced in number or eliminated by use of antimicrobials and encouraged research to test the validity of the theory. The agency also recalled the Panel's highlighting the need for research on microbial ecology of the skin and its concern about the effect of overuse of antimicrobial drug products, especially products with a limited spectrum, in hospitals and other closed populations. Therefore, the agency proposed the professional labeling caution in § 333.99(a) "for certain antimicrobial ingredients approved for OTC drug use * * * used in health-care facilities" (43 FR 1213). However, the agency concluded that the limited consumer use of these products in the population at large did not constitute a risk that would warrant such a label warning. Although benzalkonium chloride has been frequently implicated in *Pseudomonas* hospital infections, the agency's review of numerous reports and studies on quaternary ammonium compounds and other antimicrobials (Refs. 4 through 10) indicates that specific causes for contamination, such as lack of aseptic technique when applying intravenous infusions and sterilization failure of the items used (bottles, tubing, distilled water used in diluting benzalkonium chloride), were the problem and not overuse of benzalkonium chloride. The agency discussed this problem in the previous tentative final monograph and stated that it appears that practices in the health-care facility environments where quaternary ammonium compounds are commonly used often fall short of the minimum necessary to prevent outbreaks of infection. (See comment 51 43 FR 1210 at 1218.) Benzalkonium chloride is more prone to become contaminated for several reasons that were brought out in the studies: (1) *Pseudomonas* species are among the bacteria most resistant to surface-active agents like quaternary ammonium compounds. (2) The usual quaternary ammonium compound concentration appears to be ineffective against some species, such as *Pseudomonas cepacia*,

an organism which has been reported to have been associated with hospital infections. One study showed that this organism survived 14 years in a salt solution preserved with 0.05 percent benzalkonium chloride. (3) Organic materials (gauze, cotton, cork in stoppers, soaps), inorganic matter, protein, and anionic substances inactivate quaternary ammonium compounds. (4) Hospital personnel are unfamiliar with these problems and with procedures for using quaternary ammonium compounds safely and effectively. Based on these reports, the agency agrees with the comments that "improper" use, not "overuse," is the cause of benzalkonium chloride being implicated in *Pseudomonas* contamination and that there is a lack of data demonstrating "overuse" to be the cause.

The agency also agrees with the comment which stated that it was an unproven hypothesis that overuse of an antiseptic causes *Pseudomonas* overgrowth. The "Summary for Basis of Approval" from an approved NDA for chlorhexidine gluconate (Ref. 1) cites a skin flora study that indicated that the axilla was an area where gram-negative micro-organisms continued to be isolated even though chlorhexidine gluconate has shown gram-negative effectiveness. The comment cited FDA's Division of Anti-Infective Drug Products' recognition that for health-care uses, such as surgical scrub and health-care personnel handwash, there would be no problem with *Pseudomonas* overgrowth because the hands are an area of the body not likely to support the growth of *Pseudomonas* because of the lack of moisture. In defending triclosan, the comment contended that this ingredient is bacteriostatic and does not eliminate all gram-positive bacteria; therefore, it would not predispose for gram-negative overgrowth. Triclosan has been implicated in *Pseudomonas* contamination because it is primarily effective against gram-positive bacteria, has limited in vitro and in vivo activity against gram-negative bacteria, and no activity against *Pseudomonas* (43 FR 1210 at 1232). One report showed that triclosan was effective against some gram-negative micro-organisms, but not effective against *Serratia* and *Pseudomonas* (Ref. 11). *Pseudomonas* and *Serratia* resistance caused the contamination, not overuse of the antiseptic.

The agency agrees with the comments that quaternary ammonium compounds and triclosan have been implicated in *Pseudomonas* hospital infections more frequently than povidone-iodine, but studies indicate that 'overuse' of these or any antimicrobial has not been the cause. *Pseudomonas* species may become dominant because of inherent resistant factors which enable them to survive the effects of many antibiotics and antiseptics (Refs. 12, 13, and 14). In addition, this genus is ubiquitous, found in both soil and water, and can multiply in almost any moist environment with even a trace of organic material (Ref. 15).

The agency believes that the data and reports have not provided specific evidence that repeated use of health-care antiseptics, including benzalkonium chloride and triclosan, have brought about overgrowth of gram-negative bacteria, particularly *Pseudomonas*. The agency agrees with the comments that improper use, failure of hospital personnel to use according to labeling indications, nonaseptic technique in diluting and handling, and lack of good quality control to ensure sterility of items in contact with antiseptics, such as sterile distilled water, hosing, and receptacles, are responsible.

The study by Houang et al. (Ref. 3) shows that repeated in vitro exposure of seven gram-negative micro-organisms, including *P. aeruginosa*, in povidone-iodine dilutions did not result in the development of resistance. The agency notes that CDC previously recommended povidone-iodine for use in intravenous catheter and other procedures (Ref. 2). However, there has been one report from CDC (Ref. 16) which described *Pseudomonas* hospital infections caused by intrinsically contaminated povidone-iodine (contaminated during manufacture, indicating failure of control of microbiological contamination). Compliance with the agency's regulations governing current good manufacturing practice for finished pharmaceuticals (21 CFR part 211) should prevent intrinsic contamination.

Accordingly, the agency concludes that a cautionary statement against overuse is not needed in the professional labeling of health-care antiseptic drug products. Therefore, the previously proposed caution in § 333.99(a) is not being included in this tentative final monograph. If new information indicates a need for a cautionary statement, the agency will consider appropriate action at that time.

References

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(16) "Contaminated Povidone-Iodine Solution—Northeastern United States," Morbidity and Mortality Weekly Report, Public Health Service, Centers for Disease Control, HHS Publication No. (CDC) 81–8017, 29:553–555, 1980.

E. Comment on Alcohol

10. One comment submitted data on the safety and effectiveness of 62

percent alcohol formulated in an emolliented vehicle and dispensed as a foam (Ref. 1) and requested that alcohol be included in the topical antimicrobial monograph as a surgical hand scrub, health-care personnel handwash, and hand degermer.

Data on the safety and effectiveness of alcohol formulated in an emolliented vehicle for use as a surgical hand scrub, health-care personnel handwash, and hand degermer were submitted to the Miscellaneous External Panel (Refs. 2 and 3). However, the data were not reviewed or categorized for these uses during that rulemaking. In reviewing alcohol for short-term uses, that Panel stated, "ethyl alcohol acts relatively quickly to decrease the number of micro-organisms on the skin surface. Each minute that scrubbed hands and arms were immersed in approximately 77 percent ethyl alcohol by volume was found to be equivalent to 6.5 minutes of scrubbing in water; if the skin was scrubbed with the alcohol, the rate was further increased" (47 FR 22324 at 22328). The Panel found ethyl alcohol safe and effective for use as a topical antimicrobial preparation in concentrations of 60 to 95 percent by volume in an aqueous solution. The following indications were proposed:

(1) "For first aid use to decrease germs in minor cuts and scrapes."

(2) "To decrease germs on the skin prior to removing a splinter or other foreign object."

(3) "For preparation of the skin prior to an injection." (See the advance notice of proposed rulemaking for OTC alcohol drug products for topical antimicrobial use, in the **Federal Register** of May 21, 1982, 47 FR 22324.)

The submissions (Refs. 1 and 2) included effectiveness data and labeling for a currently marketed product containing 62 percent ethyl alcohol formulated in an emolliented vehicle and dispensed as a foam used "* * * to degerm hands * * *." The agency has reviewed these data, derived from effectiveness testing as a surgical hand scrub (glove juice test) and health-care personnel handwash, and finds that they meet the procedures in the testing guidelines in the previous tentative final monograph (43 FR 1210 at 1242). Statistical analyses showed microbial reduction to be highly significant. A glove juice test showed that alcohol foam reduced the baseline number of bacteria present in normal skin flora, after first use, by 1.87 logs, and, after continued use for 5 days, by 2.36 logs. The reduction of the baseline number of bacteria was maintained for up to 6 hours under surgical gloves. A health-care personnel handwash effectiveness test showed microbial reduction on test subjects' hands, artificially contaminated with *Serratia marcescens* (*S. marcescens*). Microbial reduction averaged 3.3 logs after 5 treatments and 3.63 logs after 25 treatments. In vitro data, derived from studies using *S. marcescens* as the test bacteria, showed that alcohol properly formulated in an emolliented vehicle and dispensed as a foam, significantly reduced the number of test bacteria, in 10 percent serum, within 15 seconds.

Based on these data and the conclusions of the Miscellaneous External Panel (47 FR 22324), the agency concludes that alcohol, when properly formulated, is effective for use as a surgical hand scrub and antiseptic handwash or health-care personnel handwash. Because it is well established that alcohol alone does not provide persistence, the agency notes that a preservative agent in the vehicle provided the persistent effect to maintain reduction in the baseline number of bacteria for 6 hours as required to demonstrate efficacy as a surgical hand scrub drug product.

The agency is including alcohol in proposed § 333.410(a) (antiseptic handwash or health-care personnel handwash), § 333.412(a) (patient preoperative skin preparation), and § 333.414(a) (surgical hand scrub), as follows: "Alcohol 60 to 95 percent by volume in an aqueous solution denatured according to Bureau of Alcohol, Tobacco and Firearms regulations in 27 CFR part 20." Further, the agency finds the Miscellaneous External Panel's proposed Category I indication for OTC alcohol drug products, i.e., "for preparation of the skin prior to an injection" to be an appropriate indication for patient preoperative skin preparation drug products. Based on that Panel's recommendations, the agency is including this indication as an additional claim for alcohol drug products in § 333.460(b)(2) of the proposed monograph. In addition, based on that Panel's similar recommendations for isopropyl alcohol (47 FR 22324 at 22329 and 22332), the agency is proposing this indication for OTC isopropyl alcohol drug products in § 333.460(b)(3). As discussed in section I.N., comment 28, the agency is proposing new effectiveness criteria for drug products labeled for this use.

The monograph will also state that an alcohol drug product must be properly formulated, such as the product in an emolliented vehicle dispensed as a foam discussed above, to meet the test requirements in § 333.470. This means that alcohol when intended for certain uses must be able to demonstrate effectiveness by certain tests proposed in this tentative final monograph, as follows: (1) Antiseptic or health-care personnel handwash—§ 333.470(b)(2), (2) patient preoperative skin preparation—§ 333.470(b) (3), and (3) surgical hand scrub—§ 333.470(b)(1). As discussed in section I.B., comment 5, the term "antiseptic handwash" in lieu of "hand degermer" is being proposed in the monograph as the statement of identity for this type of product.

The labeling for the alcohol product (Ref. 1) provides directions for use without water rinsing, where water is not readily available, as follows: "A 'palmful' (5 grams) is dispensed in one hand. It is spread on both hands and rubbed into the skin until dry (approximately 1 to 2 minutes). A smaller amount (2.5 grams) is then dispensed into one hand, spread over both hands to wrist, and rubbed into the skin until dry (approximately 30 seconds)." The agency concurs with these directions and is incorporating them into its proposed directions for use for OTC topical antiseptic drug products, including alcohol, formulated for use without water in this tentative final monograph. See proposed § 333.455(c) and § 333.465(c).

References

(1) Unpublished studies on emolliented alcohol foam (62 percent alcohol), Comments No. C105, C144, and CR7, Docket No. 75N–0183, Dockets Management Branch.

(a) Microbiological evaluation of "Alcare Hand Degermer" on personnel in a newborn intensive care unit, May 12, 1977.

(b) Results of a study of efficacy against experimental contamination of human skin, June 20, 1978.

(c) Efficacy study with Vestal Foam results of a glove fluid study, January 27, 1975.

(d) *Serratia marcescens* efficacy data for Alcare, February 20, 1978.

(e) Amended labeling for Alcare Foamed Alcohol, August 19, 1982.

(2) OTC Vol. 160377.

(3) OTC Vol. 160382.

F. Comments on Chlorhexidine Gluconate

11. Several comments requested that the agency include chlorhexidine gluconate as a Category I ingredient in any amended tentative final monograph. The comments submitted references and data to establish general recognition of safety and effectiveness (Ref. 1), and stated that chlorhexidine gluconate solution is recognized in the "British Pharmacopeia" (Ref. 2) and is formulated in a wide range of products that have been successfully marketed to a material extent and for a material length of time in other countries. The comments asserted that when

formulated in compliance with FDA's current good manufacturing practice regulations (21 CFR part 211), chlorhexidine products are safe and effective for use as skin wound cleansers, skin wound protectants, patient preoperative skin preparations, skin antiseptics, surgical hand scrubs, and health-care personnel handwashes.

A reply comment argued that chlorhexidine gluconate, currently marketed in the United States under approved new drug applications (NDA's), is not eligible for an OTC drug monograph because the ingredient has not been marketed within this country to a material extent and for a material length of time. The comment added that variations in final formulations may alter the safety and effectiveness of the ingredient. The comment submitted data (Ref. 3) to support this viewpoint and requested that chlorhexidine gluconate be classified in Category II.

In the previous tentative final monograph (43 FR 1210), chlorhexidine gluconate (4 percent solution) was neither addressed nor categorized as Category I, II, or III. However, subsequent to the tentative final monograph, the agency granted a petition (Ref. 4) and in the **Federal Register** of March 9, 1979, reopened the administrative record to allow interested persons an opportunity to submit data and information (44 FR 13041). The comments (Ref. 1) and reply comment (Ref. 2) were submitted in response to that notice. However, since that time a majority of the comments on chlorhexidine submitted in response to the notice have been withdrawn (Ref. 5). While the withdrawn comments remain on public display as part of the administrative record, they are no longer being considered in this rulemaking.

The agency has reviewed the marketing history of chlorhexidine gluconate and finds that although it has been marketed for professional or hospital use under NDA's, insufficient data remain in the public administrative record for this rulemaking to support general recognition of safety and effectiveness for OTC use. Accordingly, chlorhexidine gluconate 4 percent aqueous solution as a health-care antiseptic is a new drug and is not included in this tentative final monograph.

References

(1) Comments No. C110, C116, C120, C130, C131, C136, C137, EXT18, RC2, RC5, CP3, LET12, LET14, LET16, SUP30, SUP33, SUP38, and SUP40, Docket No. 75N–0183, Dockets Management Branch.

(2) "British Pharmacopeia," Vol. I, Her Majesty's Stationery Office, London, pp. 100–101, 1980.

(3) Comments No. RC1 and RC4, Docket No. 75N–0183, Dockets Management Branch.

(4) Comment No. CP3, Docket No. 75N–0183, Dockets Management Branch.

(5) Comments No. WDL3, WDL4, and WDL5, Docket No. 75N–0183, Dockets Management Branch.

G. Comments on Chloroxylenol

12. A number of comments disagreed with the agency's Category III classification of chloroxylenol in the tentative final monograph. They argued that a reevaluation of the data previously submitted to the agency along with new data that have been submitted (Refs. 1 through 16) would provide adequate justification for classifying chloroxylenol in Category I for safety and effectiveness for use in antimicrobial soaps, health-care personnel handwashes, patient preoperative skin preparations, skin antiseptics, skin wound cleansers, skin wound protectants, and surgical hand scrubs. Several comments pointed out that the Antimicrobial II Panel unanimously concluded that chloroxylenol is generally recognized as safe for topical use in athlete's foot and jock-itch preparations.

Based upon the submitted data (Refs. 1 through 16) and other information reviewed by the Antimicrobial Panels, the agency concluded in the amended tentative final monograph for OTC first aid antiseptic drug products that chloroxylenol (0.24 percent to 3.75 percent) was safe but not effective for short-term use as an OTC topical first aid antiseptic (54 FR 33644 at 33658). These data (Refs. 1 through 16) and new data submitted under the agency's "feedback" procedures (Refs. 17 through 30) are insufficient to support a Category I classification of the safety and effectiveness of the ingredient for other long-term uses, e.g., antiseptic handwash or health-care personnel handwash and surgical hand scrub. The agency concludes that chloroxylenol remains classified in Category III as an active ingredient for these uses. However, the ingredient would be considered safe for short-term use as a patient preoperative skin preparation but remains in Category III due to a lack of effectiveness data for this use.

In the previous tentative final monograph (43 FR 1210 at 1222 and 1238), the agency stated that the data were insufficient to reclassify chloroxylenol into Category I, and the ingredient remained in Category III for safety and effectiveness. Indicating concern about the absorption of topically applied antimicrobial drug products used repeatedly by consumers over a number of years, the agency stated the following regarding the safety of the ingredient:

> Only the most superficial toxicity data in animals were submitted to and reviewed by the Panel. The Commissioner concurs with the Panel that toxicity in rodent and nonrodent species, substantivity, blood levels, distribution and metabolism, as well as any subsequent systemic absorption studies must be characterized * * *. The degree of absorption of PCMX following topical administration has not been established. The target organ for PCMX toxicity in animals also remains unidentified and should be shown in a long-term animal toxicity study.

While safety data (Refs. 1, 2, 6, and 7) are sufficient to establish safety for short-term use such as for a patient preoperative skin preparation drug product, these data do not resolve concerns about long-term chronic toxicity. Conclusions on these data, which were also reviewed by the Advisory Review Panel on OTC Antimicrobial II Drug Products (Antimicrobial II Panel) in conjunction with its review of OTC topical antifungal drug products, were published in the **Federal Register** of March 23, 1982 (47 FR 12480). That Panel, which evaluated the safety of the ingredient for use in OTC topical antifungal drug products, categorized chloroxylenol (0.5 to 3.75 percent) as safe (Category I) for short-term use (up to 13 weeks) and advised, "* * * relatively low doses of chloroxylenol can be systemically tolerated, at least over a 13-week period. The Panel is concerned about the effect of chronic administration on the liver, but does not consider that topical application of chloroxylenol to small areas of the skin over short periods of time would result in liver damage." (47 FR 12480 at 12534). The agency subsequently agreed with the Panel's conclusions concerning the safety of using the ingredient in OTC topical antifungal drug products for the treatment of athlete's foot, jock itch, and ringworm (maximum treatment duration 4 weeks) in its tentative final monograph for these OTC drug products, published in the **Federal Register** of December 12, 1989 (54 FR 51136 at 51139). The agency subsequently finalized these conclusions in the final rule for OTC topical antifungal drug products published in the **Federal Register** of September 23, 1993 (58 FR 49890).

Regarding long-term chronic toxicity, data and information provided by one manufacturer included final reports of completed studies and interim reports

of incomplete studies (Ref. 2). The information also contained a protocol of a planned preclinical study (projected starting and completion dates for experiments) which identified a 2-year rat feeding study. Because this study might resolve concerns about long-term chronic toxicity, the agency requested the raw data (Ref. 31); however, the manufacturer declined to submit the data, explaining that it is no longer interested in marketing chloroxylenol, that its study had not been completed, and that the study was conducted prior to establishment of the Good Laboratory Practices regulations (Ref. 32).

In response to the agency's determination that data from a 2-year rat feeding study were essential (Ref. 33), another manufacturer submitted additional information along with copies of already available safety data (Ref. 34). The manufacturer explained that it believes that long-term safety data, i.e., 2-year oral feeding study, while not currently available, may not be a necessity. Citing statements made by the Panel, that its recommended guidelines for the safety testing of these drug products were developed primarily for antimicrobial agents applied to the entire body surface and that appropriate tests should be chosen to reflect the intended use of the antimicrobial drug product (39 FR 33103 at 33135), the manufacturer contended that the guidelines were developed to address the most extreme exposure to an antimicrobial ingredient rather than to describe the minimal requirements for safety data that the Panel would find acceptable. Noting the contrast between the use of surgical hand scrub drug products (products used by adults in a limited area of the body for a specified time span) with lifetime application to the entire body in bar soaps, the manufacturer contended that while the use of a surgical hand scrub is considered chronic use, the exposure to the antimicrobial ingredient during such use is limited to the hand and half the distance to the elbow. The manufacturer further suggested that one might simply regard the use of health-care antiseptic ingredients in handwashes and surgical scrubs as repeated daily use in a limited area of the body.

The manufacturer contended that data from a 2-year feeding study would not contribute any information on the long-term safety of chloroxylenol that is not already available from subchronic studies (Ref. 35). In support of its contention, the manufacturer submitted data from subchronic animal toxicity and human bathing studies (Ref. 18) previously submitted in response to the tentative final monograph for OTC topical antimicrobial drug products and to the Antimicrobial II Panel. The data also included computer simulation models (Ref. 36) of plasma levels of chloroxylenol that might occur after dermal applications of varying concentrations of the ingredient. The simulations, based on urinary excretion data from human bathing studies, predict a lack of potential for accumulation of the ingredient in humans. Subsequent submissions from the same manufacturer included a review article on the toxicity of chloroxylenol (Ref. 19), a retrospective analysis of the value of chronic animal toxicology studies of pharmaceutical compounds (Ref. 20), and copies of all available toxicity data for chloroxylenol (Ref. 21). Included in the toxicity data was a kinetic analysis (Ref. 37) of data from human and animal studies of the ingredient previously submitted to the agency that also predicts that accumulation in humans is not likely to occur at reasonable exposure levels. Based on the above data and information, the manufacturer requested that the agency reconsider the necessity of a long-term animal study. In response to the manufacturer's request, a public meeting was held to discuss the available toxicity data for chloroxylenol. At that meeting, the agency noted that many of the subchronic studies of the ingredient are of limited usefulness because they were conducted using a formulated product that contained isopropyl alcohol, turpineols, and castor oil soap in addition to chloroxylenol. The kinetic model used in the studies was considered inappropriate. A one-compartment model, as used in the analysis, is not relevant to chloroxylenol due to its lipophilic nature. The agency's detailed comments are on file in the Dockets Management Branch (Refs. 38 and 39).

After considering the manufacturer's comments and evaluating the data available at the time, the agency concluded that the information was not adequate to characterize the level of absorption, the distribution, the metabolism, and the excretion of chloroxylenol following topical administration. In a 1988 letter to the manufacturer (Ref. 40), the agency stated: (1) That data from the human bathing studies reviewed are highly variable (absorption 0.5 to 15.7 percent), (2) the analytical methodology used in the studies had not been validated and (3) that the small number of subjects included in the studies made it difficult to draw meaningful conclusions from the reported results. The agency commented further that submitted accumulation predictions were not adequate to define the toxicity that might occur with repeated exposure to the ingredient because no data have been submitted to support or validate the model's assumptions in characterizing exposure and stated that additional data are needed to justify, support, and verify the assumptions and data used in the predictions. Pointing out that accumulation is not the sole issue of long-term toxicity, the agency asserted that long-term toxicity may be related to repeated daily exposure to low levels of the ingredient over a lifetime.

In that same letter, the agency stated that it had reexamined the necessity for a long-term animal study based on the manufacturer's assertion that use of the ingredient as an antiseptic handwash and surgical scrub should be regarded as repeated use to a limited area of the body, and had concluded that data from additional short-term studies conducted under actual use conditions (i.e., where abrasion is followed by occlusion, with the level of absorption, distribution, metabolism, and elimination of the ingredient being shown under these conditions) could provide adequate information to determine whether or not a long-term animal study is necessary. Protocols for a pharmacokinetic surgical scrub study to develop such data were submitted to the agency (Refs. 41 and 42); however, to date the agency has not received any data from such a study. The agency's detailed comments are on file in the Dockets Management Branch (Refs. 43 and 44).

More recently, the agency received additional data pertaining to the safety of chloroxylenol from another manufacturer (Ref. 30). The data included an assessment of the ingredient's mutagenic potential by a series of in vitro and in vivo assays (Ames test, unscheduled DNA synthesis in rat primary hepatocytes, chromosomal aberrations in Chinese hamster ovary cells, and an in vivo mouse micronucleus assay). The data also included a dose range-finding study for a teratology study of the ingredient in rats and the subsequent teratology study.

Two of the four mutagenicity assays included in the submission yielded suspect or equivocal results. The in vitro administration of 19, 38, 75, and 150 micrograms per milliliter (µg/mL) doses of chloroxylenol to Chinese hamster ovary cells produced a statistically significant increase relative to the solvent control in the mean number of chromosome aberrations per cell at the 75 and 150 µg/mL dose level both in the presence and absence of

metabolic activation. Statistically significant increases in the percent of aberrant cells were also seen at the 75 µg/mL dose in the absence of metabolic activation and at the 75 and 150 µg/mL doses in the presence of metabolic activation. No dose response was apparent in either the activated or nonactivated systems. The investigator concluded that the results were equivocal in the nonactivated test system and suspect in the activated test system.

The results of the in vivo mouse micronucleus assay demonstrated a statistically significant increase in micronucleated polychromatic erythrocytes in female mice 24 and 72 hours after oral dosing with 250 and 833 milligrams per kilogram (mg/kg) doses of chloroxylenol. However, no dose response was apparent. The investigator considered the results to be a statistical anomaly based on unusually low mean micronucleus values in the negative control group and the lack of a dose response. However, the agency believes that because the observed increases were significantly elevated over those of the negative controls ($p \leq 0.01$) and were reproducible at two dose levels, these results should be considered equivocal. The manufacturer has provided additional information (Ref. 45) in response to the agency's interpretation of the results of the mouse micronucleus assay. However, the agency continues to believe that reliance on data from historical controls is inappropriate and has not changed its position on the data. The agency's detailed comments are on file in the Dockets Management Branch (Refs. 46 and 47).

In light of the new data (Ref. 30) and the issues that they raise, the agency has again reexamined the data requirements necessary to support the safe chronic use of this ingredient. The agency finds it necessary to broaden the additional testing requirements in order to clearly assess potential risks associated with chronic use of chloroxylenol. Therefore, data obtained from the following are necessary: (1) Human studies conducted under maximal use conditions, i.e., repeated use as a surgical scrub use where abrasion is followed by occlusion, characterizing the level of absorption, the distribution, metabolism, and elimination of the ingredient, (2) a lifetime dermal carcinogenicity study (up to 2 years) in mice, and (3) an appropriate human epidemiological study performed to determine the effects on health-care professionals in countries, such as England, where the ingredient has been used extensively for a long period of time are necessary. Further, in order to relate the data derived from the chronic animal study to humans, the lifetime dermal carcinogenicity study should also include concomitant absorption, distribution, metabolism, and excretion studies. A protocol for an 18-month dermal carcinogenicity study has been submitted to the agency (Ref. 48). The agency's detailed comments and evaluation of the data and protocol are on file in the Dockets Management Branch (Ref. 47).

Regarding the effectiveness of chloroxylenol, the agency stated the following in the previous tentative final monograph: "Claims for broad spectrum activity have been made * * *; however, the Commissioner finds that inadequate effectiveness data were submitted. Many studies were old and not performed with modern antiseptic testing procedures. * * * effectiveness testing both in vitro and in vivo should be done in accordance with the Guidelines" (43 FR 1238).

The applicable effectiveness data submitted by the comments were derived from in vivo and in vitro studies (Refs. 1 through 7 and 13 through 16), along with data subsequently submitted under the "feedback" procedures (Refs. 22 through 28 and 50).

Data from in vivo glove juice studies (Refs. 1, 2, 19, and 50) demonstrated the antiseptic activity of chloroxylenol in a range of 3 to 3.75 percent when formulated in an aqueous surfactant vehicle. Chloroxylenol formulations are substantive in their activity, i.e., they do not produce an initial high reduction in the number of bacteria but after repeated use (routine use), they reduce the baseline number of bacteria and suppress bacterial growth for 6 hours. In vivo data for surgical hand scrub products containing chloroxylenol at concentrations lower than 3 percent are insufficient. Aqueous solutions of chloroxylenol in a pine oil vehicle (1:40 dilution of Dettol®) consistently reduced more than 99 percent *Staphylococcus aureus* (*S. aureus*) from the hands of test subjects (Ref. 25).

In vivo cup scrubbing and other appropriate data (Refs. 22, 23, and 24) indicate that chloroxylenol, in 70 percent alcohol, is fast acting as a patient preoperative skin preparation. However, alcohol itself meets the criteria for a preoperative skin preparation and is a significant contributor for fast acting contaminant reduction. The data are not sufficient to demonstrate that chloroxylenol in this formulation contributes to the total antimicrobial effect.

In vitro study data (Refs. 1, 3, 4, 5, 13, 14, 16, and 26) show that chloroxylenol in various vehicles is effective against gram-negative bacteria, i.e., *Escherichia coli* (*E. coli*), *P. aeruginosa*, *Proteus vulgaris*, and *Klebsiella aerogenes* (*K. aerogenes*). This anti-gram-negative activity is formulation dependent. Tested aqueous solutions of pure chloroxylenol with no other additives show that low concentrations (0.3 mg/mL) reduced 95 percent of some *Pseudomonas* in 10 minutes.

Data regarding the antiseptic activity of chloroxylenol itself are not adequate. While the data are considered sufficient to support in vitro effectiveness for the finished products, the available data are inadequate to show the contribution of the chloroxylenol. Because these finished products contain several additional ingredients, e.g., surfactants, isopropanol, pine oil, or ethylenediaminetetraacetic acid (EDTA), which contributed substantial germicidal activity, conclusions regarding chloroxylenol's active contribution to the product's efficacy cannot be supported. The agency's detailed comments and evaluations of the submitted data are on file in the Dockets Management Branch (Refs. 51 and 52). One manufacturer has responded to FDA's concern and provided additional data (Ref. 53). These data are currently being reviewed by the agency and will be discussed in the final rule for these drug products. In summary, the data are sufficient to support the in vitro and in vivo effectiveness of the formulations tested. However, additional data are needed to demonstrate that chloroxylenol contributes to the activity of these formulations. In addition, data from glove juice studies indicate that the antimicrobial activity of chloroxylenol is substantive in nature and does not produce an initial high reduction of bacteria, but that repeated use of the ingredient will produce a reduction in bacteria as well as a suppression of the baseline number of bacteria of the normal skin flora for 6 hours. As discussed in section I.N., comment 28, the agency is proposing that all antimicrobial products indicated for use as a surgical scrub or health-care personnel handwash be able to demonstrate an immediate reduction in bacteria and is inviting comment on the use of substantive antimicrobials in health-care antiseptic drug products.

The agency, therefore, is proposing that chloroxylenol at the concentrations evaluated (0.24 percent to 3.75 percent) be classified as Category I for safety and Category III for effectiveness for short-term use as a patient preoperative skin preparation and in Category III for safety and effectiveness for long-term uses, i.e., antiseptic handwash or health-care

personnel handwash and surgical hand scrub. The existing data are not adequate to extrapolate and assess the chronic toxicity of chloroxylenol for long-term use. Before chloroxylenol may be generally recognized as effective, the agency recommends that appropriate in vitro and in vivo effectiveness data be submitted. The data should include results obtained from both in vitro and in vivo tests as described in the testing procedures below. (See section I.N., comment 28.)

References

(1) Unpublished Clinical Safety and Effectiveness Studies on Aqueous Soap Formulations, Comment No. 0B7, Docket No. 75N–0183, Dockets Management Branch.

(a) Controlled Clinical Study Comparing the Activity of Fresh, Camay Soap, and Phisohex Against the Natural Bacterial Flora of the Hand.

(b) Antimicrobial Activity of PCMX, Triclosan, and TCC.

(c) Repeated Insult Patch Testing of Fresh Soap.

(2) Unpublished Nonclinical and Clinical Studies, and Protocols, Comment No. C96, Docket No. 75N–0183, Dockets Management Branch.

(a) Part I: PCMX Toxicosis, final reports of completed studies, interim reports of incomplete studies, and Preclinical Testing Protocol.

(b) Part II: Complete Reports on Clinical Safety and Efficacy and In Vitro Efficacy Studies.

(3) Unpublished Clinical Effectiveness Studies on Aqueous Soap Formulations, Comment No. C122, Docket No. 75N–0183, Dockets Management Branch.

(a) Protocol and Results of a Glove Juice Hand Washing Test Performed with PHLO Antimicrobial Skin Cleanser.

(b) Results of a Zone of Inhibition and Assay Performed on Aged Samples of PHLO Antimicrobial Skin Cleanser.

(4) Unpublished Clinical Safety and Effectiveness Studies on Aqueous Soap Formulations, Comment No. C123, Docket No. 75N–0183, Dockets Management Branch.

(a) Bactericidal Activity of Envair Antiseptic Hand Soap.

(b) Dermal Irritation Study.

(c) Insult Patch Test.

(d) Bacterial Kill Test.

(e) Hand-wash Effectiveness Test.

(5) Unpublished In Vitro Effectiveness Studies Performed on Aqueous Soap Solutions, Comment No. C125, Docket No. 75N–0183, Dockets Management Branch.

(a) AOAC Available Chlorine Germicidal Equivalent Concentration Test.

(b) The Antimicrobial Activity of a Sample.

(6) Published and Unpublished Nonclinical and Clinical Safety Studies, Comment No. SUP11, Docket No. 75N–0183, Dockets Management Branch.

(7) Comment No. SUP12, Docket No. 75N–0183, Dockets Management Branch.

(8) Unpublished Clinical Safety an Effectiveness Studies, Comment No. SUP10, Docket No. 75N–0183, Dockets Management Branch.

(a) The Effects of Vaseline Petroleum Jelly and Vaseline First Aid Carbolated Petroleum Jelly on Epidermal Wound Healing—A Controlled Clinical Laboratory Study, April 29, 1976.

(b) The Effect of Vaseline Petroleum Jelly and Vaseline First Aid Carbolated Petroleum Jelly on Healing of Experimental Skin Wounds, January 13, 1977.

(9) Bradbury, S. J., and J. Hayden, "Effect of Dettol® Wound Healing in Rats," Report No. RC 76132, unpublished study, Comment No. SUP5, Docket No. 75N–0183, Dockets Management Branch.

(10) Bradbury, S.J., and E.J. Hayden, "Dettol® Wound Healing," unpublished study, Project No. RC 1081, 1978, Comment No. SUP12, Docket No. 75N–0183, Dockets Management Branch.

(11) Maibach, H.I., "The Effects of Vaseline® Petroleum Jelly and Vaseline® First Aid Carbolated Petroleum Jelly on Epidermal Wound Healing—A Controlled Clinical Laboratory Study," unpublished study, Comment No. SUP10, Docket No. 75N–0183, Dockets Management Branch.

(12) Maibach, H.I., "The Effect of Vaseline® Petroleum Jelly and Vaseline® First Aid Carbolated Petroleum Jelly on Healing of Experimental Skin Wounds," unpublished study, Comment No. SUP10, Docket No. 75N–0183, Dockets Management Branch.

(13) Munton, T.J., and J. Prince, "The Bacteriostatic and Bactericidal Activity of Dettol® Against a Range of Recently Isolated Mesophilic Strains Including Members of the Normal Flora and Cutaneous Pathogens of the Skin," unpublished study, No. BL 75/4, 1975, Comment No. SUP3, Docket No. 75N–0183, Dockets Management Branch.

(14) Prince, J., and K.A. Barker, "A Comparison of the In-Vitro Activity of Dettol®, Hexylresorcinol, and Benzalkonium Chloride," unpublished study, No. BL 76/28, 1976, Comment No. SUP3, Docket No. 75N–0183, Dockets Management Branch.

(15) Munton, T.J., and J. Prince, "The Bactericidal Activity of Dettol® on Skin Artificially Contaminated with Micro-organisms Using the Replica Plating Technique," unpublished study, No. BL 75/14, RC 7565, 1975, Comment No. SUP3, Docket No. 75N–0183, Dockets Management Branch.

(16) "Scientific Information on the 'In-vitro' and 'In-vivo' Antimicrobial Activity of Dettol® as Determined in the Bacteriological Laboratories of Reckitt and Colman, Hull," unpublished report, Comment No. C62, Docket No. 75N–0183, Dockets Management Branch.

(17) Comment No. LET65, Docket No. 75N–0183, Dockets Management Branch.

(18) Comment No. SUP47, Docket No. 75N–0183, Dockets Management Branch.

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(20) Lumley, C.E., and S.R. Walker, "The Value of Chronic Animal Toxicology Studies of Pharmaceutical Compounds: A Retrospective Analysis," *Fundamental and Applied Toxicology*, 5:1007–1024, 1985.

(21) Comment No. RPT6, Docket No. 75N–0183, Dockets Management Branch.

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(28) Comment No. RPT3, Docket No. 75N–0183, Dockets Management Branch.

(29) Comment No. RC6, Docket No. 75N–0183, Dockets Management Branch.

(30) Comment No. C171, Docket No. 75N–0183, Dockets Management Branch.

(31) Letter from W.E. Gilbertson, FDA, to C. Rose, Pennwalt Corp., coded LET54, Docket No. 75N–0183, Dockets Management Branch.

(32) Letter from C. Rose, Pennwalt Corporation, to W.E. Gilbertson, FDA, coded LET59, Docket No. 75N–0183, Dockets Management Branch.

(33) Letters from W.E. Gilbertson, FDA, to J. Nalls, Ferro Corp., C. Rose, Pennwalt Corp., M.E. Garabedian, Dexide, Inc., M. Berdick, Chesebrough-Ponds, Inc., W.F. Stephen, Scientific and Regulatory Services, H.S. Chapman, Chemical Specialties, Inc., C.A. Wiseman, Sani-Fresh, Division of Envair, Inc., J. Rowan, Seagull Chemical, Inc., coded LET70, LET71, LET72, LET73, LET74, LET75, LET76, and LET77, respectively, in Docket No. 75N–0183, Dockets Management Branch.

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(35) Memorandum of meeting between representatives of Dexide, Inc., Ferro Corp., and FDA, coded MM8, Docket No. 75N–0183, Dockets Management Branch.

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(38) Letter from W. E. Gilbertson, FDA, to M. K. Bruch, Dexide, Inc., coded LET79, Docket No. 75N–0183, Dockets Management Branch.

(39) Memorandum of meeting between representatives of Dexide, Inc., Ferro Corp., and FDA, coded MM11, Docket No. 75N–0183, Dockets Management Branch.

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(41) Comment No. C165, Docket No. 75N–0183, Dockets Management Branch.

(42) Comment No. SUP51, Docket No. 75N–0183, Dockets Management Branch.

(43) Letter from W. E. Gilbertson, FDA, to M. K. Bruch, Dexide, Inc., coded LET93, Docket No. 75N–0183, Dockets Management Branch.

(44) Memorandum of meeting between representatives of Dexide, Inc., Ferro Corp., and FDA, coded MM15, Docket No. 75N–0183, Dockets Management Branch.

(45) Comment No. C172, Docket No. 75N–0183, Dockets Management Branch.

(46) Letter from W. E. Gilbertson, FDA, to G. R. Kramzar, NIPA Laboratories, Inc., coded LET97, Docket No. 75N–0183, Dockets Management Branch.

(47) Letter from W. E. Gilbertson, FDA to G. R. Kramzar, NIPA Laboratories, Inc., coded C174, Docket No. 75N–0183, Dockets Management Branch.

(48) Comment No. C173, Docket No. 75N-0183, Dockets Management Branch.

(49) Comment No. LET65, vol. 4, 5, and 6, Docket No. 75N–0183, Dockets Management Branch.

(50) McCracken, A., "Effectiveness of Ultradex Scrub Sponge Determined in a Clinical Setting," unpublished study, coded LET65, vol. 6, Docket No. 75N–0183, Dockets Management Branch.

(51) Letter from W. E. Gilbertson, FDA, to M. K. Bruch, Dexide, Inc., coded LET87, Docket No. 75N–0183, Dockets Management Branch.

(52) Letter from W. E. Gilbertson, FDA, to M. K. Bruch, Dexide, Inc., coded LET90, Docket No. 75N–0183, Dockets Management Branch.

(53) Letter from M. K. Bruch, Dexide, Inc., to W. E. Gilbertson, FDA, coded LET91, Docket No. 75N–0183, Dockets Management Branch.

H. Comment on Hexachlorophene

13. One comment urged reconsideration of hexachlorophene as an OTC "handwashing agent and antimicrobial skin cleanser for use in the hospital, doctor's office, and by adult consumers." The comment stated that adequate data to support Category I status were submitted in response to the advance notice of proposed rulemaking, but were only superficially discussed by the agency in comment 61 of the tentative final monograph. (See the **Federal Register** of January 6, 1978, 43 FR 1210 at 1220.) The comment submitted additional data to support the safety of hexachlorophene, including a retrospective study on 3 percent hexachlorophene in baby bathing (Ref. 1) and a study of hexachlorophene blood levels in infants receiving routine antiseptic skin care (Ref. 2). The comment also included a comprehensive review article on the safety and effectiveness of hexachlorophene (Ref. 3).

The agency has reevaluated the data discussed in comment 61 in the tentative final monograph (43 FR 1220) and evaluated the new data, and has determined that the data do not warrant changing the classification of hexachlorophene as a prescription drug. The infant data (Refs. 1 and 2) were discussed in detail in the tentative final monograph for OTC antimicrobial diaper rash drug products (55 FR 25246 at 25261 to 25263).

Summaries of handwash studies were also submitted, but no data were included. In one study, 3 percent hexachlorophene was tested as a surgical scrub under exaggerated use conditions (Ref. 4). Subjects (number not specified) washed their hands and forearms in 20 mL hexachlorophene for 10 minutes, 5 times daily, 6 days a week for a total of 58 days. No signs of toxicity were reported. The blood levels of hexachlorophene reached a plateau within 3 days at mean levels of 0.07 µg/mL.

The agency believes that it would be necessary to test a very large group of subjects (the number of subjects required to obtain a statistically significant result) with a variety of skin conditions to determine the true degree of absorption. A similar study reviewed by the Panel (39 FR 33103 at 33118) reported blood levels of 0.5 µg/mL or higher.

In the other study, subjects washed their hands and face three times daily for 3 weeks with either 2 or 5 mL of 3 percent hexachlorophene (Ref. 4). Blood concentrations reached a plateau within 7 days at mean levels of 0.21 µg/mL for the 2-mL group and 0.22 µg/mL for the 5-mL group.

Other additional data contained only a brief summary of the historical use of hexachlorophene and primarily cited publications in the medical literature (Ref. 5). The references provided no new information. Consequently, the agency has determined that hexachlorophene will continue on prescription status subject to the existing regulation in 21 CFR 250.250.

In order for hexachlorophene to be switched to OTC status, the concerns expressed by the Antimicrobial I Panel that hexachlorophene does not have an adequate margin of safety for OTC use (39 FR 33103 at 33117) should be addressed. After reviewing the submitted data, the agency concludes that the safety of this ingredient for OTC use on infants has not been demonstrated. For OTC status for use by adults, any further submission of data should specifically address the safe OTC use of hexachlorophene in adults.

Based upon the discussion above, the agency is proposing that hexachlorophene remain available by prescription only, except when used as a preservative at concentrations of 0.1 percent or less.

The agency's detailed comments and evaluation of the data are on file in the Dockets Management Branch (Ref. 6).

References

(1) Plueckhahn, V. D., and R. B. Collins, "Hexachlorophene Emulsions and Antiseptic Skin Care of Newborn Infants," *Medical Journal of Australia*, 1:815–819, 1976.

(2) Plueckhahn, V. D., "Blood Hexachlorophene Concentrations in New-Born Infants Undergoing Routine Antiseptic Skin Care with a 3% Hexachlorophene Emulsion," unpublished study contained in SUP13, Docket No. 75N–0183, Dockets Management Branch.

(3) Plueckhahn, V. D., "Infant Antiseptic Skin Care with Hexachlorophene Emulsions and Powders," unpublished study contained in SUP28, Docket No. 75N–0183, Dockets Management Branch.

(4) Comment No. SUP13, Docket No. 75N–0183, Dockets Management Branch.

(5) Comment No. C116, Docket No. 75N–0183, Dockets Management Branch.

(6) Letter from W. E. Gilbertson, FDA, to G. S. Goldstein, Sterling Drug Inc., coded LET63, Docket No. 75N–0183, Dockets Management Branch.

I. Comments on Iodine and Iodophors

14. One comment pointed out that poloxamer-iodine complex appeared to be incorrectly included in the Category II list under "health-care personnel handwash" (43 FR 1210 at 1227), while it is properly listed in Category III for use as a "health-care personnel handwash" (43 FR 1210 at 1229). The comment stated that deletion from the Category II list would correct the error.

The agency concurs with the comment that poloxamer-iodine complex for use as a health-care personnel handwash was incorrectly listed as Category II (43 FR 1227) and that the listing as Category III (43 FR 1229) was correct.

15. One comment submitted data on the safety and effectiveness of a "mixed iodophor" consisting of iodine complexed by ammonium ether sulfate and polyoxyethylene sorbitan monolaurate (Ref. 1). The comment stated that this information had been previously submitted in May 1974, but that the ingredient had not been mentioned in the Panel's report or in the agency's proposed monograph and requested that the agency include it in the monograph. The comment pointed out that the iodophor, formulated as a liquid hand scrub, is intended for use by surgeons, food handlers, and others for whom reduced bacterial skin flora is of public health significance.

Regarding the comment's statement that the data were previously submitted,

the agency has no record of any submission of these data in 1974. Because this hand scrub was not previously reviewed or categorized as an OTC topical antimicrobial drug product, the agency reviewed the product's marketing history and considers it appropriate to include this product in the OTC drug review. The agency has evaluated the data submitted by the comment (Ref. 1) and determined that iodine complexed by ammonium ether sulfate and polyoxyethylene sorbitan monolaurate is safe for use as a surgical hand scrub and health-care personnel handwash, but that there are insufficient data available to determine its effectiveness for these uses. Therefore, the ingredient is being classified in Category III.

The data included several studies on the absorption of the iodine complex, blood levels of iodine, and the systemic toxicity of the iodine complex. Protein-bound iodine (PBI) and iodine blood levels in rabbits were determined following two studies of acute dermal applications. In the first study, either 2 or 5 mL/kilogram (kg) of the test iodine complex was applied to the shaved backs of rabbits in one experiment. The method of occlusion, if any, was not stated, but the test material was washed off after 24 hours. In another experiment, 2 mL/kg of the test iodine complex was compared with a povidone-iodine complex and both were applied as in the first experiment. PBI and total iodine in blood were determined at 0, 24, and 48 hours in both experiments. In all treated animals, the level of PBI was extremely high at certain times, primarily at 24 hours. Animals receiving the higher dose of iodine complex in the first experiment seemed to return to normal sooner than those receiving the lower dose. All animals returned to normal by 14 days. For purposes of comparison, the second experiment showed that serum total iodine increased from 1.4 to 30.7 milligrams/deciliter (mg/dL) in the test iodine complex group compared to from 1.23 to 37.9 mg/dL in the povidone-iodine group in the 24 hours that the application remained on. In the second study, 5 mL/kg of the test iodine complex was applied to the shaved backs of two groups of five rabbits each. In one group the shaved backs were occluded for 24 hours and in the other group, the shaved backs were scrubbed for 10 minutes followed by rinsing and occlusion. An additional group served as an untreated control group. Blood samples for iodine determinations were taken at 0, 24, and 48 hours and at 14 days. All five animals in the group in which the iodine complex remained occluded on intact skin for 24 hours had markedly elevated levels of PBI and iodine at both 24 and 48 hours, but were only slightly above normal at 14 days. For the 10-minute scrub animals, the PBI levels were increased in two of five animals at 24 hours, slightly in all five animals at 48 hours, and were normal at 14 days.

A study to determine the effect on blood PBI levels of a routine scrubbing procedure in which exposure to the iodine complex exceeded normal use showed no alteration in PBI levels in four humans who scrubbed twice daily (each scrub consisting of two 5 minute hand washes with 5 mL) for 26 consecutive days. Also, no irritation was observed. In a similar study in which the subjects wore gloves for 2 hours after each scrub, PBI levels were not increased, but total iodine was slightly increased. In two subjects, this increase was greater in the middle of the study, but the total iodine blood levels were near normal by the end of the study.

A dermal absorption study in which the shaved backs of four monkeys were rubbed with 0.17 mL/kg of radioactive iodine complex for 10 minutes, rinsed, wrapped for 2 hours, and the animals sacrificed after 24 hours, revealed that less than 0.1 percent of the application was recovered in the thyroid, the target organ for iodine.

A 90-day sub-acute dermal toxicity study was conducted in three groups of monkeys divided into one control group and two test groups. One test group was scrubbed once for 10 minutes daily with 0.17 mL/kg of the iodine surgical scrub detergent product and the second group was scrubbed three times with 0.34 mL/kg (once for 10 minutes and twice for 3 minutes each day). To simulate the wearing of surgical gloves, the treated area of each animal, which consisted of a shaved area of the back equivalent to about 10 percent of the body area, was wrapped with a rubber dam for 30 to 90 minutes. The study lasted 13 weeks during which the animals were monitored. Neither test group showed any effects of iodophor treatment except elevated PBI levels in the high dose group, which peaked at one month. Also, there was no significant effect on the thyroid in the treated groups.

The agency believes this iodine complex is safe for humans based on the data from human, rabbit, and monkey studies. Test data showed very little iodine absorption when the product was used as a scrub, negligible uptake (following acute dermal application of radioactive iodine complex) by the thyroid in monkeys, and an unchanged thyroid weight in test groups of monkeys following 90 days of sub-acute applications of the iodine complex.

The comment submitted data from one clinical study for evaluating effectiveness as a surgical hand scrub but did not provide the testing protocol used. Five subjects scrubbed three times daily for 5 days with the iodophor formulation (containing 1.1 percent iodine). Four subjects completed the study. Surgical gloves were worn for 2 hours after the first wash of the day. Subjects' hands were sampled once each day at the end of the 2-hour gloved period using a single-basin Cade method. The initial sampling was used to establish a baseline microbial count for each subject. Study results were reported as the number of organisms per mL of basin water and the percent reduction in the number of organisms recovered. The reduction in the bacterial population ranged from 89 to 98 percent on the first day. By the fifth day, the reduction ranged from 99 to 100 percent. Similar results were obtained in a comparative study on six subjects using povidone-iodine.

Although it is clear that the test used was not the glove juice test which is described in the antimicrobial tentative final monograph (43 FR 1210 at 1242), alternative methods may be acceptable. However, because of the small number of subjects included in the study, the data are not sufficient to support the Category I classification of this ingredient for use as a surgical hand scrub. Additional studies, of the type described in § 333.470(b)(1) of this amended tentative final monograph, are necessary to support the effectiveness of this surfactant iodine complex for this use.

In the previous tentative final monograph (43 FR 1235), the agency recognized that elemental iodine complexed with a surfactant type "carrier" molecule reduces the amount of immediate "free" iodine, because most of the formulated iodine is bound in the complex. Effectiveness of all iodophors is dependent on the release of free iodine as the active agent from the complexing molecule which acts only as a carrier. The agency acknowledges that iodine complexed with a surfactant is an acceptable way of presenting iodine as an antimicrobial agent to the skin. However, because most of the formulated iodine may be tied up in the complex and because the information submitted by the comment to support in vitro efficacy (Ref. 2) dealt only with aqueous and/or tincture solutions of free iodine, testing of the complete formulation is necessary to judge the importance of formulation on the release of the active ingredient and,

thus, its influence on aspects of effectiveness.

Based on the data submitted, the agency concludes that iodine complexed by ammonium ether sulfate and polyoxyethylene sorbitan monolaurate is safe but additional data from appropriate studies are needed to establish general recognition of effectiveness for use as a surgical hand scrub and health-care personnel handwash. The data should include results obtained from both in vitro and in vivo testing procedures. (See section I.N., comment 28.)

References

(1) Unpublished Nonclinical and Clinical Studies on V.I.S., Vestal Iodine Scrub (iodine complexed by ammonium ether sulfate and polyoxyethylene sorbitan monolaurate), Comment No. C106, Docket No. 75N–0183, Dockets Management Branch.

(a) Acute Dermal Toxicity in Rabbits.

(b) Acute Dermal Application—Rabbits.

(c) Determination of the Influence of Scrubbing with Vestal Iodine Surgical Scrub Detergent on the Protein Bound Iodine Level of the Blood.

(d) Determination of the Influence of Scrubbing with Vestal Iodine Surgical Scrub Detergent on the Protein Bound Iodine and Total Serum Iodine Levels in the Blood.

(e) Percutaneous Absorption of Iodine in Monkeys from the Dermal Application of an Iodine Surgical Scrub Detergent.

(f) Three Month Sub-Acute Dermal Toxicity Study in Monkeys with Vestal Iodine Scrub Detergent.

(g) Iodine Surgical Scrub Detergent, Surgical Hand Scrub Study in Five Human Test Subjects.

(2) Gershenfeld, L., "Iodine," in "Disinfection, Sterilization, and Preservation" 1st ed., Lee and Febiger, Philadelphia, pp. 329–347, 1968.

16. Several comments objected to the warning proposed for the professional labeling for povidone-iodine and iodophor-surfactant products: "Caution: Do not use this product in the presence of starch-containing products. Starch can adsorb iodophors and the resulting complex can cause serosal adhesions (abnormal union of the serous membranes) and other undesirable effects in the body" (43 FR 1210 at 1221). The comments pointed out that the study by Goodrich, Prine, and Wilson (Ref. 1) on which the warning is based is not well controlled, is rudimentary, and lacks rigorous testing that produces evidence which can be statistically analyzed. The comments contended that this article is not sufficient basis for the warning. The comments requested that the impact of the article by Goodrich, Prine, and Wilson on the labeling of nonsurfactant iodophors be reevaluated and that povidone-iodine be exempt from the required warning relating to contact of starch and iodophors. One comment stated that there are numerous papers in the literature describing the antiadhesive effect of povidone and povidone-iodine and submitted nine references dealing with humans and animals that support an antiadhesive effect when povidone or povidone-iodine is used in intraperitoneal surgery (Ref. 2). Another comment explained that starch is well known for producing granuloma and that every package of surgeons' gloves carries a warning statement to the effect that the outside of the gloves must be cleansed of starch powder prior to use. The comment concluded that FDA should require a warning label on the gloves, but not on products containing the drug.

FDA has reevaluated the article by Goodrich et al. (Ref. 1), considered the additional cited references (Ref. 2), and examined current policy on the labeling of United States Pharmacopeia (U.S.P.) Absorbable Dusting Powder (cornstarch). Goodrich, Prine, and Wilson (Ref. 1) provide data from observations and arbitrary scoring of adhesions after intraperitoneal injection into 4 groups of 13 adult female mice with: (1) Powdered starch suspended in 1.5 mL of normal saline, (2) powdered starch treated with 5 mL of an iodophor and washed three times in saline before resuspension in 1.5 mL normal saline, (3) powdered starch treated with 5 mL of a 10-percent solution of surfactant washed three times in saline and resuspended in 1.5 mL of normal saline and (4) normal saline (control animals). The data do not indicate any significant difference between suspensions of the surfactant mixed with starch and the surfactant-iodophor mixed with starch. The agency's policy on the labeling of surgical gloves treated with Absorbable Dusting Powder U.S.P., determined upon evidence presented during the Drug Efficacy Study Implementation, was published in the **Federal Register** of May 25, 1971 (36 FR 9475). The agency requires the following statement on surgical gloves treated with Absorbable Dusting Powder U.S.P.: "Caution: after donning, remove powder by wiping gloves thoroughly with a sterile wet sponge, sterile wet towel, or other effective method." Products containing Absorbable Dusting Powder U.S.P. for lubricating surgical gloves were formerly classified as new drugs, but are now regarded as transitional devices, for which premarket approval is required under the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act (42 FR 63472 at 63474). FDA's Center for Devices and Radiological Health is establishing categories for all surgical devices, including surgical gloves lubricated with powdered starch. Any changes in the labeling for this class of products will be dealt with in a separate rulemaking procedure and separate **Federal Register** notice.

The agency believes that the user's removal of dusting powder from surgical medical devices (rubber goods) treated with Absorbable Dusting Powder U.S.P. decreases the incidence of adhesions and is not persuaded that the data in the article by Goodrich, Prine, and Wilson provide a sufficient scientific basis for a warning label. Therefore, the warning about the interaction of iodophors and starch-containing products proposed in comment 66 of the previous tentative final monograph is not included in this amended tentative final monograph.

References

(1) Goodrich, E. O., J. R. Prine, and J. S. Wilson, "Iodized Starch Granules as a Cause of Starch Peritonitis," *Surgical Forum*, 25:372–374, 1974.

(2) Nonclinical and Clinical Safety Studies on Postoperative Observations of Abrasions, Comment No. C111, vol. 4, tabs 6–14, Docket No. 75N–0183, Dockets Management Branch.

17. A number of comments submitted new data (Ref. 1) to establish that povidone-iodine is safe and effective as a topical antimicrobial drug. The comments requested that povidone-iodine be reclassified from Category III to Category I as a topical antimicrobial ingredient for use as an antimicrobial soap, health-care personnel handwash, surgical hand scrub, patient preoperative skin preparation, skin antiseptic, skin wound cleanser, and skin wound protectant.

As discussed earlier in this document, this amended tentative final monograph addresses only topical antiseptics for health-care antiseptic uses as a surgical hand scrub, antiseptic handwash or health-care personnel handwash, and patient preoperative skin preparation. As discussed in section I.B., comment 5, antimicrobial soaps are no longer included in this rulemaking. The agency addressed the other use categories mentioned in the comment in a separate **Federal Register** notice for OTC first aid antiseptic drug products (56 FR 33644). As discussed in comment 38 of that document (56 FR 33660), FDA has tentatively concluded that povidone-iodine should be classified in Category I for use as a first aid antiseptic (formerly designated skin antiseptic, skin wound cleanser, and skin wound protectant).

The agency has considered the new data submitted and other information in

support of the request to reclassify povidone-iodine from Category III to Category I. On the basis of these data and information, the agency tentatively concludes that povidone-iodine should be reclassified from Category III to Category I as a topical antiseptic ingredient for use in surgical hand scrub, patient preoperative skin preparation, and health-care personnel or antiseptic handwash drug products.

The general safety aspects of povidone-iodine that concerned the agency in the previous tentative final monograph (43 FR 1210 at 1234 to 1236) are addressed elsewhere as follows: (1) The effect of povidone-iodine on wound healing. Based upon submitted data, the agency concluded in the first aid antiseptic segment of this rulemaking that non-surfactant iodophor products (povidone-iodine) do not delay wound healing. See comment 42 of that document (56 FR 33644 at 33662). Also, the Advisory Review Panel on OTC Antimicrobial II Drug Products reviewed povidone-iodine's effect on wound healing in its report on topical antifungal drug products and concluded that the drug did not affect wound healing (47 FR 12480 at 12545). (2) The effect of povidone-iodine on thyroid function. In comment 41 of the tentative final monograph for OTC first aid antiseptic drug products (56 FR 33644 at 33661), the agency discusses studies that indicate that topically applied povidone-iodine does not cause thyroid dysfunction. (3) The proposed warning about the interaction of starch-containing products with iodophors resulting in serosal adhesions and other undesirable effects, i.e., "Caution: Do not use this product in the presence of starch-containing products. Starch can adsorb iodophors and the resulting complex can cause serosal adhesions (abnormal union of the serous membranes) and other undesirable effects in the body" (43 FR 1210 at 1221). The agency has reevaluated the proposal and decided that the warning is not supported by the data. (See section I.I., comment 16.) (4) The agency's concern regarding molecular weights of povidone-iodine greater than 35,000 daltons not being excreted by the kidney and causing lymph node changes. In section I.I., comment 18, the agency discusses a previously proposed warning regarding this subject and determines, based on more recent data, that larger povidone-iodine molecules are not a risk when the product is limited to the topical uses included in this tentative final monograph.

The agency's concern about the need for expiration dates (not to exceed 2 years after manufacture) because of the lack of stability data for several iodophor preparations, which relates to the effectiveness of the product, can be satisfied by compliance with the current good manufacturing practices regulations (21 CFR parts 210 and 211). These regulations include, among other things, requirements regarding stability testing and expiration dating (see §§ 211.137 and 211.166). Therefore, as discussed in comment 40 of the tentative final monograph for OTC first aid antiseptic drug products (56 FR 33644 at 33661), data on the stability of povidone-iodine and the proposed 2-year expiration date are no longer considered needed in this rulemaking proceeding.

A second agency concern relating to effectiveness was the rate of release of "free" iodine from the complex and whether there was evidence of germicidal activity over a period of time in clinical application (43 FR 1210 at 1235). As discussed in the tentative final monograph for OTC topical acne drug products (comment 5, 50 FR 2172 at 2173), iodine is released from the povidone-iodine complex within milliseconds, thus resolving this concern.

With regard to the effectiveness of health-care antiseptic uses subject to this rulemaking, the agency has reviewed the data and information on povidone-iodine's germicidal in vitro and antiseptic in vivo effectiveness (Refs. 1 through 19) and concludes that the data are sufficient to reclassify this ingredient from Category III to Category I.

A series of in vitro controlled studies (Ref. 1–C133, Volume 1) included a broad spectrum of test micro-organisms which were associated with between 40 to 60 percent of the nosocomial infections in the urinary tract, surgical wounds, pneumonia, and bloodstream, reported by the National Nosocomial Infections Surveillance System (NNIS) for the period from January 1985 to August 1988 (Ref. 2). In most instances, these test micro-organisms, as proposed in § 333.470(a)(1)(ii) (see section I.C., comment 6), were killed after 0.5 to 5 minutes exposure to povidone-iodine. A minimum inhibitory concentration (MIC) study (Ref. 1–C133) using 30 cultures, both American Type Culture Collection (ATCC) and recent skin isolates, was also included in this series of in vitro studies. The results indicated a range for MIC from 87 parts per million (ppm) to 492 ppm for dilutions of povidone-iodine solution and 83 ppm to 476 ppm for dilutions of povidone-iodine surgical scrub depending on the test micro-organism. Tests with controls, neutralizer, and organic load using a serial dilution method were included in the study.

Gocke, Ponticas, and Pollack (Ref. 3) evaluated the susceptibility of 230 clinical isolates from blood, urine, sputum, and wound cultures to the bacteriocidal activity of povidone-iodine. These clinical isolates contained over half the organisms included in § 333.470(a)(1)(ii). Results indicated that 106 of the 230 organisms tested (46 percent) were killed when 1 mL of a standardized suspension containing 10^8 organisms was exposed to a 10 percent povidone-iodine solution for 15 seconds. Povidone-iodine showed its highest activity against gram-negative isolates, with 72 of the 94 isolates (75 percent) being killed after a 15-second exposure. Only 34 of the 134 (25 percent) gram-positive isolates were killed under the same conditions. However, further testing of organisms not killed after a 15-second exposure indicated that increases in exposure time to 120 seconds killed all of the previously "resistant" isolates. The study design incorporated the use of a neutralizer and controls.

The effectiveness of a povidone-iodine formulation on micro-organisms in a clinical setting was demonstrated by Michael (Ref. 4). The study included 100 subjects with decubitus ulcers following a spinal cord injury. Cultures of the wounds were taken prior to, during, and upon completion of a once-a-day povidone-iodine treatment. Prior to treatment, subjects had positive cultures for the following organisms: *S. aureus* (60 subjects), *Klebsiella/Enterobacter* species (20 subjects), *E. coli* (15 subjects), and *Pseudomonas* species (15 species). Following an 8-to-10 week period of treatment with povidone-iodine, cultures revealed that 90 of the 110 subjects no longer had positive cultures for these organisms.

Pereira, Lee, and Wade (Ref. 5) conducted an in vivo gloved hand test that is supportive of the effectiveness of povidone-iodine as a surgical hand scrub. They examined the effects of surgical scrub duration and type of antiseptic on the reduction of resident microbial flora. Thirty-four subjects scrubbed with a 7.5 percent povidone-iodine formulation or another antiseptic formulation using either a 5 minute initial/3 minute consecutive scrub procedure or a 3 minute initial/30 second scrub procedure. Subjects were assigned to one of four groups, and each group was assigned to one of the four treatments. Sampling was done by the glove juice method using a sampling solution containing a neutralizer. Glove juice samples were taken from both hands immediately before scrubbing

(baseline), from the nondominant hand immediately after the initial scrub, 2 hours after the initial surgical scrub but before the consecutive scrub (dominant hand), and 2 hours after one consecutive surgical scrub (dominant hand). No significant difference was found between the two durations of scrubbing with povidone-iodine. Povidone-iodine produced an immediate 1.2 $\log_{10}$ reduction on the dominant hand after an initial 5 minute scrub and a 1.0 $\log_{10}$ reduction on the dominant hand immediately after the 3 minute initial scrub. Baseline was not exceeded 2 hours after either the 5 or 3 minute scrub.

Aly and Maibach (Ref. 6) evaluated the characteristics of two antimicrobial impregnated surgical hand scrub sponge/brush drug products. The study, which included a widely used povidone-iodine impregnated surgical hand scrub sponge/brush, evaluated both the immediate and persistent effect on the resident bacterial flora of the hands plus the effect of blood on the persistent antimicrobial activity of the surgical hand scrub drug products. In the first phase of the study, 13 subjects with left and right hand baseline counts of $>10^6$ organisms were randomly assigned to perform a total of 11 scrubs with the povidone-iodine impregnated sponge/brush. Glove juice samples were taken from the right hand of each subject immediately following the first scrub of the day and from the left hand at either 3 or 6 hours. The entire procedure was repeated on test days 2 and 5. A similar procedure was used in phase two of the study, except that 2 mL of bacteriologically sterile blood was spread over the hands of 6 subjects following the initial scrub, and sampling occurred only at 3 and 6 hours. Neutralizers were incorporated into the stripping solution, diluent, and culture media. On day 1, povidone-iodine produced an immediate mean $\log_{10}$ reduction of 1.2, and baseline was not exceeded at 3 hours. On days 2 and 5, povidone-iodine produced immediate mean $\log_{10}$ reductions of 2.2 and 2.8, respectively, and bacterial counts did not exceed baseline at 6 hours. While counts for povidone-iodine approached baseline in the presence of blood, counts did not exceed baseline at 6 hours on any day.

Another study (Ref. 1–C104), employing a method similar to the effectiveness testing procedures described in proposed § 333.470(b)(2) of this amended tentative final monograph, demonstrated the effectiveness of povidone-iodine 5 percent as a health-care personnel handwash. Twenty-five consecutive handwashings were done in 10 human subjects with a 5 minute rest between washings. Before each washing the hands were dipped in broth culture containing 2.0×10^9 organisms (*Bacillus subtilis* var. *niger* ATCC 9372) per mL; the contaminant was spread up over the wrists to the forearms. Bacterial counts were done at the completion of every fifth washing by the glove juice sampling method. Both the dilution fluid and growth media incorporated a neutralizer. The transient microbial flora of the hands was reduced by an average of 5.8 logs from baseline.

Dineen (Ref. 7) used a 7.5 percent povidone-iodine formulation as a reference antiseptic in an open crossover evaluation of a health-care personnel handwash drug product. Participation in the study followed a 1-week prewash period in which study subjects used only a bland nonantiseptic soap. On day 1 of the study, samples were taken prior to contamination and again after a second contamination followed by a 15-second wash with a bland nonantiseptic soap, using the glove juice sampling method. Following the post-wash sampling, subjects washed for 5 minutes with povidone-iodine to remove any remaining inoculum. The hands of the first three subjects were contaminated with a 1 mL inoculum containing 1×10^{14} *S. marcescens, E. coli, P. aeruginosa,* and *Providentia stuartii* (*P. stuartii*). The hands of the seven other subjects were contaminated with a 1 mL inoculum containing 8×10^{14} to 2×10^{15} *S. marcescens* and *P. stuartii.* Inocula concentrations were determined each test day in a parallel experiment. On days 3 or 4 and 5, the procedure was repeated except that subjects were randomly assigned to wash with either (1) the reference antiseptic or the test preparation or (2) were crossed over to the preparation not used the previous day. In the interim between test days, subjects followed the wash and sampling procedure using only the nonantiseptic soap. The number of organisms included in the 1 mL inoculum was taken as the baseline, and all reductions were calculated on this basis. Neutralizers were incorporated in both the diluent and the culture medium. When corrected for the average log reduction produced by the nonantiseptic soap (4-$\log_{10}$), the reductions produced by povidone-iodine ranged from 7 to 9 $\log_{10}$.

Studies conducted by Ulrich (Ref. 8) and Newsom and Matthews (Ref. 9) are supportive of the effectiveness of povidone-iodine for this indication. Ulrich (Ref. 8) conducted a study using povidone-iodine 7.5 percent in 25 subjects. Both hands of each subject were contaminated with a stock culture of *Micrococcus roseus* (2.75×10^8 organisms per hand, the baseline count) and allowed to air dry for 60 seconds. This artificial hand contamination was followed by a 15-second wash with 5 mL of the povidone-iodine preparation, and this same procedure was repeated until 25 contaminations/washes had been performed. Glove fluid samples were taken after every fifth contamination/wash. Dilutions of the glove fluid were made in a sterile diluent that included a neutralizer. A neutralizer was also incorporated into the culture medium. Based on the average of both hands, the povidone-iodine preparation produced a 4.9 and a 5.2 log reduction of the transient micro-organisms from baseline by the 5th and 10th wash, respectively. By the end of the 25th wash the povidone-iodine preparation demonstrated a 5.5 $\log_{10}$ reduction from the baseline bacterial count.

Newsom and Matthews (Ref. 9) studied test solutions containing 5 or 10 percent povidone-iodine on hands artificially contaminated with an overnight culture of *E. coli.* The numbers of micro-organisms were measured before and immediately after hand disinfection with the test solution in 15 subjects. Sampling of the hands was accomplished by kneading the fingertips in a "recovery" broth that included a neutralizer. A mean 4.4 log reduction from baseline was reported for the bacterial counts taken immediately after the antiseptic wash.

Ayliffe, Babb, and Quoraishi (Ref. 10) evaluated the effect of various detergent and alcoholic antiseptic formulations (including a 7.5 percent povidone-iodine formulation) on the removal of *S. aureus, Staphylococcus saprophyticus* (*S. saprophyticus*), *P. aeruginosa,* or *E. coli* from contaminated fingertips. In one set of experiments, six subjects performed an initial wash with an unmedicated soap, followed by the inoculation of the tips of the subjects' fingers and thumbs with 0.02 mL of a broth culture containing either *S. aureus* or *P. aeruginosa.* Following contamination, subjects performed either a 30-second wash with 5 mL of a detergent or alcoholic antiseptic preparation, a 30-second wash with an unmedicated soap, or no wash at all. Bacterial sampling was accomplished by rubbing the fingers and thumbs on glass beads immersed in 100 mL of nutrient broth containing neutralizers. All treatments were tested against each organism. Results were reported as the log of the average number of viable organisms recovered from each subject. Against *S. aureus,* povidone-iodine

produced a 3.2 log reduction, which was significantly superior to the reduction achieved by the unmedicated soap. Against *P. aeruginosa*, povidone-iodine produced a 2.7 log reduction. However, this was not significantly different from the 2.2 log reduction demonstrated by the unmedicated soap.

In a second set of experiments (Ref. 10), the same authors assessed the effectiveness of three antiseptic formulations, including povidone-iodine, and an unmedicated soap in the removal of *S. aureus*, *S. saprophyticus*, or *E. coli* from contaminated fingertips. Under conditions similar to those in the previous study, povidone-iodine demonstrated a 3-log reduction in the baseline number of *S. aureus*, which was significantly superior to the log reduction demonstrated by the unmedicated soap. Povidone-iodine produced an average 2.1 log reduction in the number of *S. saprophyticus* and a 2.8 reduction in the number of *E. coli*. However, neither of these reductions was significantly different from the reductions produced by the unmedicated soap.

Rotter (Ref. 11) evaluated the influence of differences in two testing methodologies on the demonstration of the effectiveness of povidone-iodine. One test method used is the standard test method (Vienna) for the evaluation of drug products for hygienic disinfection adopted by the Austrian and German Societies for Hygiene and Microbiology. In this test model, the release of *E. coli* from the finger tips of artificially contaminated hands was determined before and after a 1-minute wash with povidone-iodine. The second model, based on agency recommendations for the testing of health-care personnel handwashes, evaluated the release of the *E. coli* from all surfaces of artificially contaminated hands by the glove juice sampling method before and after a 1 minute wash with the ingredient. These comparisons showed no significant difference in the reduction factor produced by povidone-iodine when tested with the two methods. Povidone-iodine when tested by the Vienna test method produced a 3.3 $\log_{10}$ reduction from the baseline count. When tested by the second method, the ingredient produced a 3.2 $\log_{10}$ reduction.

Rotter (Ref. 11) also used the Vienna test method to assess the effectiveness of rubbing antiseptics onto the hands versus washing with an antiseptic. Two povidone-iodine containing formulations were included in the assessment. A watery solution of povidone-iodine with 1 percent available free iodine rubbed onto the skin produced a 4 $\log_{10}$ reduction. Washing with a detergent formulation of the ingredient produced a 3.2 $\log_{10}$ reduction. However, this reduction was not statistically different from the reduction produced by washing with a nonantiseptic soap.

Rotter, Koller, and Wewalka (Ref. 12) used the Vienna test model to assess the effectiveness of a povidone-iodine liquid soap preparation (containing 0.75 percent available free iodine) for hygienic hand disinfection. The subjects' hands were contaminated by immersing them up to the mid-metacarpals in a broth culture of *E. coli*. The hands were allowed to air dry for 3 minutes prior to a pretreatment sampling. Sampling was accomplished by rubbing the finger tips of each hand for 1 minute on the bottom of a Petri dish containing a phosphate buffer sampling solution with neutralizers. After a 2-minute wash with the povidone-iodine or liquid soap followed by a 20-second rinse, the hands were again sampled. Average log values of the counts from the right and left hands of each subject were calculated, and the difference (log reduction factor) was determined. The povidone-iodine liquid soap formulation produced a 3.2 $\log_{10}$ reduction in the transient organisms.

Wade and Casewell (Ref. 13) evaluated the residual effectiveness of povidone-iodine against two clinical isolates associated with hospital outbreaks of infection. An initial determination of the survival of the test organisms on untreated hands of three subjects was made by contaminating the subjects' finger tips with either of the test organisms and sampling the individual fingers immediately after contamination and at 1, 3, 10, and 30 minutes. The subjects' hands were then pretreated by performing three 30-second washes at 5 minute intervals with various alcoholic and aqueous antiseptic test formulations, including a 7.5 percent povidone-iodine formulation and an unmedicated bar soap. The contamination and sampling procedure was repeated as before. All formulations were tested against both organisms. The median value of the log counts for the three subjects as each sampling was plotted against time. The survival curves for both organisms on hands pretreated by washing with an unmedicated soap and on hands with no pretreatment were similar. Pretreatment with povidone-iodine resulted in counts that were consistently less than for the untreated hands and for the hands pretreated by washing with an unmedicated soap and water for both organisms. After 30 minutes, hands pretreated with the povidone-iodine formulation demonstrated a 2.5 $\log_{10}$ reduction in the number of viable *Enterococcus faecium* and a 3.9 reduction in the number of viable *Enterobacter cloacae*.

The agency concludes that these data demonstrate the effectiveness of povidone-iodine 5 to 10 percent for use as a health-care personnel handwash.

Many *published* studies referenced in the submitted data and in the published literature (Refs. 1 and 14 through 19) have evaluated the effectiveness of povidone-iodine for use as a patient preoperative skin preparation. Although the procedures followed are different from those in the previous FDA testing procedures (43 FR 1210 at 1244) and from those proposed in § 333.470 of this amended tentative final monograph, the essential criteria have been met.

Georgiade et al. (Ref. 15) evaluated the effectiveness of two povidone-iodine formulations for use in the preoperative skin preparation of 150 subjects scheduled for elective surgical procedures. An initial sample for culture was taken from the unbroken skin of the operation site prior to the use of the formulations, and a baseline bacterial count was determined. Sampling was by a cup scrubbing method, using a sterile wash solution that incorporated a neutralizer. The operative site was then gently treated for 5 minutes with a povidone-iodine surgical scrub formulation and allowed to dry. Following the initial disinfection, a povidone-iodine antiseptic solution was evenly applied to the site and allowed to dry. The sample site was rinsed with sterile water and a second sample for culture was done. Upon completion of surgical procedures lasting from 30 to 180 minutes, the sample site was again cultured and sterile dressings were applied. The reported mean post-scrub reduction in the baseline number of bacteria of the sample site was 30,599 (4.5 $\log_{10}$ reduction). This reduction was maintained through the surgery as evidenced by the reported post-operative mean reduction of 30,613 organisms.

Vorherr, Vorherr, and Moss (Ref. 16) compared three antiseptic preparations (including 10 percent povidone-iodine), in 150 female subjects (50 to each preparation) for effectiveness in reducing the numbers of bacteria in the perineum and groin. The mean log reductions in bacteria after skin preparation with povidone-iodine at 10 minutes and 3 hours, respectively, were reported as 3.65/3.09 for the perineum and 3.42/2.85 for the groin. Another study by Dzubow et al. (Ref. 17) evaluated three antiseptic skin

preparations frequently used for dermatologic surgical procedures. A 60-second wipe with 1-percent povidone-iodine was performed in 14 subjects after which aerobic and anaerobic cultures were taken at 5 and 60 minutes. The aerobic flora were reduced by 2.8 and 2.5 log at 5 and 60 minutes, respectively. The reduction in anaerobic flora was reported to be 1.7 log at 5 minutes and 1.2 log at 60 minutes.

Leaper, Lewis, and Speller (Ref. 18) compared the effectiveness of povidone-iodine impregnated drapes, povidone-iodine with a sterile drape, and conventional preoperative skin preparation with povidone-iodine for the reduction of skin bacteria. Forty-five subjects scheduled to undergo elective groin surgery were randomized to one of the three treatments. Impression plates and skin swabs were taken immediately before and after surgery, and swabs were taken before and after skin incision and closure. Conventional preoperative skin prepping with povidone-iodine produced the greatest reduction of the bacterial flora (240 colony counts to 34 colony counts, 2.3 $\log_{10}$ reduction).

Duignan and Lowe (Ref. 19) studied the effectiveness of povidone-iodine for reducing pathogenic bacteria in the vagina. A 1:10 solution of a povidone-iodine formulation containing 0.75 percent available free iodine was instilled into the vagina of 35 subjects and left in situ for 1 to 3 minutes. Aspirate cultures were taken from the vagina before and after preoperative disinfection and subcultured into thioglycollate broth containing neutralizers. Povidone-iodine removed 92 percent of the bacteroides species, anaerobic streptococci, gram negative bacilli, and *Streptococcus pyogenes* present prior to the preoperative disinfection.

A surveillance report (Ref. 1–C132) of hospital infections showed that the use of povidone-iodine in preparing patients for catheterization significantly reduced the rate of urinary tract infections. A 5-year study showed that the rate of urinary tract infections before October 1977 ranged from 5.2 percent to 11.5 percent (mean 7.8 percent), but beginning in October 1977 when povidone-iodine was the antiseptic solution in use, the rate ranged from 1.0 percent to 4.0 percent (mean 2.4 percent). At the 95 percent confidence level this is statistically significant. No method data accompanied the report except that the urethral meatus was cleansed with cotton dipped in the antiseptic solution before catheterization.

The agency believes that these studies and other published and publicly available medical and scientific data demonstrate that povidone-iodine is effective for use as a patient preoperative skin preparation. Although all of the trials were not done the same way, and thus they are not strictly comparable, the weight of the evidence shows that povidone-iodine is effective both as a preoperative skin preparation and surgical hand scrub, reducing the normal microbial flora by more than 90 percent and not showing any significant qualitative selection among the normal species found on the skin. In conclusion, povidone-iodine was effective against a wide spectrum of pathogenic and normal skin micro-organisms and maintained some suppressive effect on skin counts after the initial use.

In addition to the data reviewed supporting the safety and effectiveness of povidone-iodine for these professional uses, the agency classified povidone-iodine 5 to 10 percent as Category I as a first aid antiseptic in the tentative final monograph published in the **Federal Register** on July 22, 1991 (56 FR 33644). Accordingly, the agency is reclassifying povidone-iodine 5 to 10 percent from Category III to Category I for use as a topical antiseptic ingredient for use in surgical hand scrub, patient preoperative skin preparation, and antiseptic handwash or health-care personnel handwash drug products.

References

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13. Several comments objected to the agency's proposal that the professional labeling of povidone-iodine products containing molecules greater than 35,000 daltons should include warnings against parenteral use and against exposure of open surgical wounds or deep wounds to the product. (See comment 71, 43 FR 1210 at 1221.) Some of the comments contended that the Panel recommended such warnings because it felt there was widespread misuse (unapproved use) of povidone-iodine solution by surgeons bathing the peritoneal cavity with povidone-iodine during major surgery and then cleansing the area by rinsing. Another comment stated that because health-care personnel handwashes or surgical hand scrubs require a surfactant, such products so formulated would never be

considered for peritoneal lavage by surgeons. One comment argued that labeling to warn against parenteral use is clearly beyond the scope of the OTC drug review and FDA's regulatory authority. Another comment stated that it is unnecessary to establish an arbitrary molecular weight limit for povidone-iodine because no parenteral use of povidone-iodine is permitted in any of the approved labeling in the new drug applications for those products.

One comment stated that povidone-iodine is generally recognized as safe and effective for use in open wounds and a warning against such use would be contrary to clinical experience with this drug. In support of this position, the comment submitted a controlled study in which the surgical incisions of one group were irrigated before closure with 10 percent povidone-iodine solution, and the surgical incisions of the control group were irrigated before closure with saline solution (Ref. 1). The comment stated that the results of this study showed a significant decrease in infections when povidone-iodine was used, and there were no allergic, adverse, or other deleterious effects following this use of povidone-iodine.

In response to the Commissioner's recommendation for research data (43 FR 1210 at 1235), one comment submitted an extensive review of the extent of scavenging of residual povidone-iodine molecules by the reticuloendothelial system and possible lymph node involvement following use in the abdominal cavity or in large wounds (Ref. 2). The comment stated that, based on these data, povidone-iodine with medium molecular weights should not be limited to use on intact skin, nor should a warning be required. Another comment stated that the average molecular weight of povidone in the povidone-iodine that has been used exclusively in topical antimicrobial products for almost a quarter of a century is 37,900 daltons, and it presents no risk for any of the topical antimicrobial uses covered by the tentative final monograph.

The Panel recognized a relationship between molecular size and nodular lymphatic changes accompanying exposure to povidone-iodine, but made no decision on limiting the molecular size causing such pathology. (See 39 FR 33103 at 33130.) In the previous tentative final monograph, FDA evaluated data provided in a comment (Ref. 3) that contended there should be restrictions on the use of povidone-iodine according to molecular size. Published research cited in that comment indicated that povidone molecules larger than 40,000 daltons cannot be excreted by the kidneys, can cause nodules to appear in the lymphatic system, and may induce cosmetic deformities in the area of healing skin wounds. Based on expert opinion and the data provided in the comment (Ref. 3), the agency proposed that a molecular weight of 35,000 daltons be established as the safe upper limit for povidone-iodine products used parenterally. This calculation assumed that a povidone-iodine molecule with this molecular weight would be too large to pass through the kidney. (See comment 71, 43 FR 1210 at 1221.) FDA also noted its awareness of the inappropriate use of povidone-iodine products in open wounds and in the abdominal cavity during surgery. (See 43 FR 1235.) To promote proper use of povidone-iodine products, FDA proposed to recognize two categories of such products. Products with povidone-iodine molecular weights less than 35,000 daltons would be permitted for general use. Appropriate labeling would place each product in its proper category of use. The professional labeling of povidone-iodine products containing molecules greater than 35,000 daltons would also include warnings against parenteral use of, and exposure of open surgical wounds or deep wounds to, the product.

In this current tentative final monograph, the agency recognizes that the professional uses of povidone-iodine that are proposed as safe and effective are limited to a patient preoperative skin preparation, health-care personnel handwash, and surgical hand scrub. Further examination of the reference cited in the previous tentative final monograph (Ref. 3) reveals that the reported adverse effects were due to intravenous or parenteral use of povidone. Based on the more recent data and comments, the agency now believes that neither medium nor larger molecular weight povidone-iodine molecules present risks when limited to the topical uses included in this tentative final monograph. Larger molecules of povidone-iodine would not be absorbed if the drug is used for these professional uses in accordance with the monograph. Thus, there is no need for the professional labeling to limit the molecular weight of povidone-iodine products or to require special warnings related to the molecular weight of povidone-iodine. Accordingly, such labeling is not being included in this tentative final monograph.

References

(1) Sindelar, W.F., and Mason, G.R., "Irrigation of Subcutaneous Tissue With Povidone-Iodine Solution for Prevention of Surgical Wound Infections," *Surgery, Gynecology and Obstetrics*, 148:227–231, 1979.

(2) Unpublished review of published and unpublished studies regarding lymph node changes and effect on the reticuloendothelial system resulting from use of PVP-iodine on intact skin, mucous membranes, and open wounds, Comment No. C111 (vol. III A), Docket No. 75N–0183, Dockets Management Branch.

(3) Unpublished review of published studies regarding intravenous or parenteral use of polyvinylpyrrolidone (PVP), Comment No. C40, Docket No. 75N–0183, Dockets Management Branch.

19. Several comments contended that there are numerous professional uses for povidone-iodine, particularly uses that involve medical devices, that were not discussed by the Panel or by the agency in the tentative final monograph. These professional uses include catheter care, ostomy hygiene, patient skin scrubbing prior to preoperative prepping, surgical site cleansing after stitching, mouth and throat swabbing, treatment of the skin before covering a fracture with a cast, antiseptic treatment of various scalp problems, and intravenous site preparation. One comment added that a pharmacist or other health professional may recommend the use of povidone-iodine as a douche, perianal wash, or whirlpool concentrate. The comments requested that special labeling be added to the monograph to cover all of these uses, but did not submit data regarding these uses.

One comment also provided professional labeling for povidone-iodine used for urinary or intravenous catheter care procedures. The suggested labeling included the following terms: "antiseptic," "germicide," "microbicidal," and "for hospital and professional use."

Several of the professional uses mentioned by the comments are not covered by this rulemaking, but they will be addressed under other OTC drug rulemakings. For example, the use of povidone-iodine for mouth and throat swabbing is included in the advance notice of proposed rulemaking for OTC oral health care drug products, published in the **Federal Register** of May 25, 1982 (47 FR 22760). The use of povidone-iodine for the treatment of scalp problems is addressed in the final rule for OTC dandruff, seborrheic dermatitis, and psoriasis drug products, published in the **Federal Register** of December 4, 1991 (56 FR 63554). The use of povidone-iodine as a douche is addressed in the advance notice of proposed rulemaking for OTC vaginal drug products, published in the **Federal Register** of October 13, 1983 (48 FR 46694).

The Advisory Review Panel on OTC Hemorrhoidal Drug Products stated that the inclusion of antiseptics in OTC anorectal drug products "is useful in concept," but "that proof of any significant clinical benefit of claimed antiseptic ingredients must be demonstrated in clinical trials" (45 FR 35576 at 35659). That Panel believed that, because of the large numbers of micro-organisms present in feces, there is little likelihood that effective antisepsis could be obtained in the anorectal area with antiseptics any more than with soap and water. Because no data were submitted on povidone-iodine as a perianal wash, the agency did not address this ingredient in the discussion of antiseptics in the tentative final monograph for OTC anorectal drug products when the agency evaluated the Panel's conclusions. Similarly, the ingredient was not included in the final rule for OTC anorectal drug products, published in the **Federal Register** of August 3, 1990 (55 FR 31766). Parties interested in this use of povidone-iodine can submit data and information as part of a citizen petition to amend the final rule for OTC anorectal drug products. (See 21 CFR 10.30.)

Several of the uses suggested by the comments are related to the general category of patient preoperative skin preparation that was discussed by the Panel. (See the **Federal Register** of September 13, 1974, 39 FR 33103 and 33114.) One example is the use "patient skin scrubbing prior to preoperative prepping." The agency believes that this use can more simply be described by the indication "for preparation of the skin prior to surgery," which is being proposed in § 333.460(b)(1)(i) of this tentative final monograph. Other uses are catheter care, ostomy hygiene, and intravenous site preparation. Some uses mentioned by the comments involve postoperative situations (surgical site cleansing after stitching) or do not even involve a surgical procedure (treatment of skin prior to covering a fracture with a cast or use as a whirlpool concentrate). The agency believes that instead of trying to identify in the product's labeling every possible situation where use of the product would reduce the risk of skin infection, this use of the product can best be described by the general indication "Helps to reduce bacteria that potentially can cause skin infection," which is being proposed in § 333.460(b)(1)(ii).

The agency has considered the term "for hospital and professional use only" suggested by one comment and finds it acceptable for professional labeling. (See section I.D., comment 8.) Likewise, the agency has no objection to terms such as "germicide," "germicidal," and "microbicidal" being used in professional labeling because health professionals understand the meaning of these terms. However, the agency does not believe there is a need to include in the monograph every one of these terms that might be used in the professional labeling of these products. These terms will be evaluated by the agency on a product-by-product basis, under the provision of section 502 of the act (21 U.S.C. 352) relating to labeling that is false or misleading.

J. Comments on Quaternary Ammonium Compounds

20. One comment requested that benzalkonium chloride be placed in Category I as a skin antiseptic, a patient preoperative skin preparation, and a skin wound protectant, in addition to its present Category I classification as a skin wound cleanser. In support of its request, the comment cited several surgery textbooks and other references that recommend use of benzalkonium chloride at concentrations ranging from 1:750 to 1:5,000 as a preoperative skin preparation, surgical scrub, skin antiseptic for venipuncture, and in urinary tract procedures, especially in catheterized patients (Ref. 1). The comment also submitted two studies on a product containing benzalkonium chloride at a concentration of 1:1,000: (1) An in vitro study to demonstrate that this product formulation acts as a physical chemical barrier against contamination by micro-organisms, and (2) a study on induced wounds on the arms of 10 healthy subjects to present evidence that this product is nonirritating and neither delays healing nor favors the growth of micro-organisms (Ref. 2).

The agency determined in the tentative final monograph for OTC first aid antiseptic drug products that the safe and effective concentration range for using benzalkonium chloride as a first aid antiseptic has been established as 0.1 percent to 0.13 percent. (See 56 FR 33644 and 33663.) Data submitted to the Antimicrobial I Panel and by the comment were sufficient to establish safety for products intended for short-term use, such as a first aid antiseptic drug product. The data submitted also support safety for use as a patient preoperative skin preparation, based on the short-term use of the drug for this purpose. However, the data reviewed by the Panel and supplemented by the comments to establish the efficacy of benzalkonium chloride for use as a topical antiseptic ingredient in patient preoperative skin preparations are not sufficient. The Antimicrobial I Panel placed this ingredient in Category III for this use. (See 39 FR 33103 and 33115.) The agency finds that the surgery textbooks and other references cited by the comment (Ref. 1) do not contain sufficient information about quantitative and qualitative changes in the microbial flora of the treated skin areas. Before benzalkonium chloride may be generally regarded as effective for use as a patient preoperative skin preparation, additional in vitro and in vivo effectiveness data are needed. The data should include results obtained from both in vitro and in vivo testing procedures as described for patient preoperative skin preparation drug products. (See section I.N., comment 28.)

Accordingly, benzalkonium chloride remains classified in Category III as a topical antiseptic ingredient for use as a patient preoperative skin preparation.

References

(1) Comment No. C116, Docket No. 75N–0183, Dockets Management Branch.

(a) Review of Scientific Literature on the Safety and Effectiveness of Zephiran Chloridé as a "Skin Antiseptic" and "Patient Preoperative Skin Preparation" for the Preoperative Cleansing and Degerming Before Surgery and Use of Medical Devices.

(2) Unpublished Clinical Wound Healing Studies on Medi-Quiké, Comment No. SUP13, Docket No. 75N–0183, Dockets Management Branch.

(a) Statistical Analysis of Data from Efficacy Study of Medi-Quik as a Skin Wound Protectant in Humans.

(b) Studies on Medi-Quik as a Wound Protectant.

21. Two comments objected to the proposed warning statement in § 333.92(c)(6) for concentrated products containing quaternary ammonium compounds, which states, "Dilute with distilled water before use because acidic or hard water may render the product inactive." One comment contended that this proposed warning is prejudicial to the quaternary ammonium products that can act in acidic or hard water and noted that the existence of quaternary ammonium compounds that can act as antimicrobials in acidic or hard water was recognized in the tentative final monograph (43 FR 1210 at 1219). The comment recommended that the labeling of products containing quaternary ammonium compounds include a statement, based on appropriate laboratory tests, about the ability of the product to perform in acidic solutions and the amount of water hardness (described as parts per million (ppm) calcium carbonate) in which the product will continue to be effective.

The other comment stated that several concentrated quaternary ammonium compounds (e.g:, 50 percent benzalkonium chloride, U.S.P.) registered with the Environmental Protection Agency (EPA) conform with the hard-water tolerance requirements and therefore can maintain activity at a water-hardness level of 600 ppm. The comment also stated that pH must be reduced below 3.5 before the effectiveness of quaternary ammonium compounds is decreased to any significant extent (Ref. 1). The comment concluded that, because normal potable water supplies do not approach these levels for either hardness or acidity, the requirement in proposed § 333.92(c)(6) for diluting only with distilled water is inappropriate and needless.

In the tentative final monograph, the agency acknowledged that hard water and acidity reduce the antimicrobial activity of quaternary ammonium compounds, but that there are some newer synthesized quaternary ammonium compounds that are not adversely affected by hard water and acidity (43 FR 1210 at 1218, 1219, and 1236). However, these newer quaternary ammonium compounds (e.g., a mixture of three benzalkonium halide compounds with varying chain lengths), while structurally related to benzalkonium chloride, benzethonium chloride, and methylbenzethonium chloride (the quaternary ammonium compounds which the Antimicrobial I Panel reviewed and which the agency proposed as Category III), were not reviewed or categorized by the Panel or the agency and are not included in this rulemaking. (See comment 58, 43 FR 1210 at 1219.) Further, the agency notes that the 50 percent quaternary ammonium concentrates that conform with EPA standards are intended for germicidal uses and not for the antiseptic uses that are being considered in this rulemaking.

The agency is aware that studies have shown that effects of acidic water on quaternary ammonium compounds occur only at dilutions containing less than the dosage concentration proposed in the tentative final monograph (Ref. 2). Higher concentrations minimize quaternary ammonium compound inactivation due to pH change (Ref. 3). However, it is well known that natural water supplies in different areas differ in acidity and hardness. As a precautionary measure, FDA believes that concentrates of the ingredients considered in this rulemaking should be diluted in distilled water by consumers and health-care professionals, because information about water pH or hardness in any given area is not usually known. Diluting the concentrated quaternary ammonium compound products addressed in this rulemaking with distilled water ensures that inactivating factors are not encountered. Therefore, the agency proposes to retain the warning statement, "Dilute with distilled water before use because acidic or hard water may render the product inactive," for diluting any Category I quaternary ammonium concentrate. However, because all the quaternary ammonium compounds remain in Category III at this time, the warning statement is not being included in this tentative final monograph.

References

(1) Lawrence, C. A., "Surface-Active Quaternary Ammonium Germicides," Academic Press Inc., New York, pp. 76–79, 1950.

(2) Kundsin, R. B., "Investigations on Dynamics of Bactericidal Action of Two Quaternary Ammonium Salts," *Archives of Surgery*, 81:789–797, 1960.

(3) Soike, K. F., D. D. Miller, and P. R. Ellikerr, "Effect of pH of Solution on Germicidal Activity of Quaternary Ammonium Compounds," *Journal of Dairy Science*, 35:764–771, 1952.

K. Comment on Sodium Oxychlorosene

22. One comment requested that sodium oxychlorosene be included in the monograph for use as a topical antiseptic for treating localized infections, to remove necrotic debris in massive infections, as a patient preoperative skin preparation and postoperative irrigant, and for the cleansing and disinfection of fistulae, sinus tracts, empyemas, and wounds. The comment included a number of references that recommended usage of sodium oxychlorosene (Ref. 1). The comment stated that "* * * the 25 years of marketing experience, the almost total absence of complaints, the number of published articles, the unusual spectrum of organisms reported on, all attest to the safety and efficacy of this product."

The agency has reviewed the data submitted and concludes that the available information does not contain any well-controlled clinical studies on the effectiveness of sodium oxychlorosene. In addition, no meaningful scientific information was presented in regard to safety. Clinical use for a period of years may provide corroborative evidence but is inadequate to support safe use. A good example is hexachlorophene; this drug had been used OTC for many years before more thorough safety studies in animals showed that the drug was not as safe as had been assumed. The agency concludes that the data are insufficient to demonstrate the safety and effectiveness of sodium oxychlorosene for OTC topical antiseptic use and therefore places this ingredient in Category III for both safety and effectiveness.

The agency's detailed evaluation of the data and information is on file in the Dockets Management Branch (Ref. 2).

References

(1) Published in vivo and in vitro studies, submitted by Guardian Chemical Corporation, Comment No. C126, Docket No. 75N–0183, Dockets Management Branch.

(2) Letter from W. E. Gilbertson, FDA, to R. Rubinger, Guardian Chemical Corporation, Comment No. ANS3, Docket No. 75N–0183, Dockets Management Branch.

L. Comments on Triclosan

23. A number of comments submitted data and information from microbiological, mutagenicity, metabolism, cross-sensitization, photosensitization, and drug experience studies on triclosan (Ref. 1). The comments stated that the data and information show that triclosan (up to 1.0 percent) is safe and effective and that triclosan should be placed in Category I for use in the categories that were defined in the previous tentative final monograph, i.e., skin antiseptic, skin wound cleanser, skin wound protectant, antimicrobial soap, health-care personnel handwash, patient preoperative skin preparations, and surgical hand scrub. In addition, one comment submitted information on triclosan (0.1 percent) for the treatment of diaper rash and on triclosan (0.1 percent) combined with benzocaine for the treatment of sunburn (Ref. 2).

One comment from the manufacturer of triclosan objected to the agency's expressed concern, as stated in the tentative final monograph (43 FR 1210 at 1231 and 1233), that there is a proliferation of products containing triclosan marketed to the American consumer (Ref. 3). The comment argued that the agency's concerns were without factual basis and submitted sales data, held confidential under 21 CFR 10.20(j)(2)(i)(*d*), showing that overall sales of triclosan in the U.S. have in fact decreased from 1973 to 1977 and that sales for use in bar soaps and deodorants have also declined from 1973 to 1977. The comment pointed out that it has exclusive U.S. patent rights for triclosan and that no license has been, or will be, granted under these patents. The comment added that to the best of its knowledge triclosan is not used in infant clothing, a use mentioned in the tentative final monograph at 43 FR 1231. The comment stated that if triclosan is placed in Category I for use

in antimicrobial soaps, it would limit sales of triclosan to OTC use in antimicrobial and deodorant soaps, underarm deodorants, and registered Environmental Protection Agency (EPA) pesticide products. In the future, sales might be extended to include approved new drug applications. The comment also pointed out that the statement at 43 FR 1233 about the EPA's Office of Special Pesticide Review preparing a report on the proliferation of triclosan-containing products is in error, and that the erroneous statement apparently resulted from a miscommunication between FDA and EPA staff. The comment concluded that the concerns about proliferation raised by the agency in the tentative final monograph should not prevent triclosan from being placed in Category I.

Another comment from the manufacturer of triclosan submitted validation reports and raw data from a 2-year chronic oral toxicity study in rats, and carcinogenicity and reproduction studies conducted in mice, rats, rabbits, and monkeys by Industrial Bio-Test Laboratories (IBT) (Refs. 4, 5, and 6) and asserted that its validation of the studies shows that triclosan is safe.

Several comments objected to the agency's restriction at 43 FR 1229 that antimicrobial soaps containing triclosan can only be formulated in a bar soap to be used with water (Ref. 1). The comments argued that such a restriction was not applied to the other Category III uses of triclosan, *i.e.*, skin antiseptic, skin wound cleanser, and skin wound protectant, and that such a restriction was not recommended by the Panel in the advance notice of proposed rulemaking. The comments suggested that the footnote under "antimicrobial soaps" limiting triclosan to bar soap was probably intended to apply to cloflucarban, which, like triclocarban, is known for its "physical and/or chemical incompatibility."

With regard to safety, the agency evaluated the validation reports to support long-term use of the ingredient (Refs. 4, 5, and 6) and advised the manufacturer of triclosan that the IBT studies were invalid because of numerous problems. The agency's detailed comments and evaluation on the data are on file in the Dockets Management Branch (Ref. 7).

The manufacturer subsequently stated its intent to no longer rely on the 2-year chronic oral toxicity IBT study (Ref. 8), and submitted a final report from a new 2-year chronic oral toxicity study in rats (Ref. 9). The agency has determined that the study data are unacceptable as the sole evidence of the safety of the long-term use of triclosan as a health-care personnel handwash or surgical handscrub based on the marginal survival of the animals in both the control and treated groups and uncertainties about the dose and study conduct. Therefore, data from another chronic exposure study are necessary to assess the safety of the long-term use of triclosan. The agency's detailed comments and evaluation of the data are on file in the Dockets Management Branch (Ref. 10). A subsequent submission from the same manufacturer contained the final report of a two-generation study of the reproductive toxicity of triclosan in rats (Ref. 11). These data are currently being reviewed by the agency and will be discussed in the final rule for these drug products. Triclosan remains classified as Category III for safety for long-term use.

The agency concluded in the amended tentative final monograph for OTC first aid antiseptic drug products (56 FR 33644 at 33665) that triclosan (in concentrations up to 1.0 percent) is safe for short term use as a first aid antiseptic (formerly designated as skin antiseptic, skin wound cleanser, and skin wound protectant). The data reviewed (Ref. 1) also support the safety of triclosan (up to 1.0 percent) for use as a patient preoperative skin preparation. However, with regard to safety for use as an antiseptic handwash or health-care personnel handwash and surgical hand scrub, triclosan remains classified in Category III for safety for long-term use, as stated above.

With regard to effectiveness, in the previous tentative final monograph the agency classified triclosan as Category II for use as a health-care personnel handwash, patient preoperative skin preparation, and surgical hand scrub because triclosan has limited activity against gram-negative bacteria. For example, triclosan is the subject of a patent (patent No. 3,616,256) for use in culture media for isolating *Pseudomonas*. Because human skin is regarded as a superb "culture medium," the possibility was raised (43 FR 1210 at 1232) that triclosan might selectively promote overgrowth of *Pseudomonas* on the hands of health-care personnel. Based upon data reviewed, the agency advised that in vitro data demonstrate that triclosan's antibacterial spectrum can be broadened, to be effective against *Pseudomonas* when triclosan is properly formulated with anionic surfactants to form a "synergistic mixture." Therefore, FDA reclassified triclosan (up to 1.0 percent, with the lower limit to be determined) from Category II to Category III for effectiveness. The agency further advised that additional studies are needed before triclosan can be generally recognized as effective for specific uses, *i.e.*, surgical hand scrub, health-care personnel handwash, patient preoperative skin preparation, and first aid uses (formerly designated as skin antiseptic, skin wound cleanser, and skin wound protectant). The agency's detailed comments are on file in the Dockets Management Branch (Ref. 12).

In response to the agency's comments (Ref. 12), the manufacturer of triclosan requested further guidance, and asserted, "The overall antimicrobial effectiveness of a topically applied product is a function of the total formulation rather than a single ingredient. Although it is impossible to anticipate and test all possible formulations, adequate in vivo evaluations of triclosan-containing formulations for specific end uses are available to fully justify Category I status for triclosan as an active ingredient in surgical hand scrubs, health-care personnel handwashes, and antimicrobial soaps." The comment submitted effectiveness data from four in vivo studies on formulations of triclosan (Ref. 13). These data included three previously unsubmitted studies (RDP/19/23 (June 24, 1981), RDP/19/21 (February 2, 1981), and CAB/AVD (February 2, 1982)), and one previously submitted study (66–D15–W221, OTC Volume 020038) that had been reviewed by the Panel (39 FR 33128). In study *RDP/19/23 (June 24, 1981)*, following modified glove juice test procedures, a test product (0.5 percent triclosan in 60 percent n-propyl alcohol) and a control (60 percent n-propyl alcohol) were compared for reduction of normal baseline flora and persistence of that reduction for 3 hours on the hands of 15 test subjects. The test product (0.5 percent triclosan in 60 percent n-propyl alcohol) and the control (60 percent n-propyl alcohol) immediately reduced approximately 99.5 percent of the baseline number of bacteria. After 3 hours, 0.5 percent triclosan in 60 percent n-propyl alcohol suppressed the baseline count better than the vehicle control; for example the test product allowed about a onefold increase in bacterial count within 3 hours, while the vehicle control (60 percent n-propyl alcohol) allowed an approximately twelvefold increase. Although the test used was not the glove juice test described in the antimicrobial tentative final monograph, alternative methods are acceptable, provided criteria meet those of the glove juice test procedures described in the guidelines. (See "Effectiveness Testing of Surgical Hand Scrub (Glove Juice Test)," 43 FR 1210 at

1242.) The agency has the following comments regarding the protocol for the study: only 15 subjects (an insufficient number) were tested; a baseline count from 3 samplings was not established before the test; the $\log_{10}$ reduction in bacteria from baseline was determined after 3 hours, but not after 6 hours; and the results of the test were not analyzed statistically.

In study *RDP/19/21 (February 2, 1981)*, 2 percent triclosan in a liquid soap vehicle reduced baseline counts of test bacteria *E. coli* ATCC 11229, *P. aeruginosa* ATCC 15442, and Staphylococcus species on the hands of human test subjects by 1 log greater than the water control after 2 minutes of handwashing. In study *CAB/AVD (February 2, 1982)*, triclosan (unknown concentrations) in a liquid soap formulation, compared to a vehicle control, maintained reduction of baseline counts (within 10, 30, 60, 90, and 120 minutes) after artificial contamination with *K. aerogenes*. In study *66–D15–W221 (in OTC Volume 020038)*, 0.5 percent, 1 percent, and 2 percent triclosan in Ivory® soap was compared to Ivory® soap without triclosan, as a control, to show reduction of baseline counts on the hands of five human test subjects after 5 days. Using the Quinn Split-Use Modification of the Price-Cade Method, increased skin-degerming activity was shown after 3 days of repeated (10) applications of triclosan as compared to the control. However, the number of test subjects (5) is not adequate to demonstrate general recognition of effectiveness. (See the "Modified Cade Procedure," 43 FR 1210 at 1243.)

The agency concludes that the data (Ref. 13) discussed above indicate that formulations of triclosan significantly reduce the baseline count of bacterial skin flora. However, before triclosan may be generally recognized as an effective health-care antiseptic for use in antiseptic handwash or health-care personnel handwash, patient preoperative skin preparation, and surgical hand scrub drug products, additional in vivo data, i.e., glove juice test data, are needed. The in vivo data should correlate with data obtained from in vitro studies. Because of the nature of the intended uses of health-care antiseptic drug products, the agency believes it is essential to assure the effectiveness of the active ingredient, triclosan, in final formulations. To demonstrate effectiveness in vitro, information is needed on the germicidal activity of the vehicle alone, so that the germicidal contribution of triclosan attributed to the total effectiveness of the finished formulation can be determined. (See section I.N., comment 28.)

Accordingly, triclosan (up to 1 percent, with the lower limit to be determined) is being classified as Category III for use in health-care antiseptic drug products as a patient preoperative skin preparation, antiseptic handwash or health-care personnel handwash, and surgical hand scrub. The agency's conclusions are summarized below:

Short-term use	Long-term (repeated/daily) uses
Patient Preoperative Skin Preparation IIIE.	Antiseptic Handwash or Health-Care Personnel Handwash IIISE.
	Surgical Hand Scrub IIISE.

S=Safety.
E=Effectiveness.

The agency has communicated further with EPA and has ascertained that there is no specific report on the proliferation of triclosan (Ref. 14). Regarding exclusive patent rights, the agency advises that these are not among the determining criteria to establish general recognition of safety and effectiveness, and therefore cannot be used in the evaluation. However, having reviewed the new data along with the previously submitted data, the agency concludes that there is no proliferation problem with triclosan.

Finally, the agency did not intend to restrict formulations of triclosan to bar soap. The agency has reviewed the Panel's recommendations and the footnotes in the previous tentative final monograph (43 FR 1210 at 1229) and finds that triclosan under "antimicrobial soaps" was erroneously marked with the reference to the footnote "Category III only when formulated in a bar soap to be used with water."

The use of triclosan in products for the treatment of diaper rash was discussed in the tentative final monograph for antimicrobial diaper rash drug products published on June 20, 1990 (55 FR 25246 at 25277 to 25278). The use of triclosan in products for treating sunburn will be addressed in the **Federal Register** at a later date in another OTC drug rulemaking for drug products for this use.

References

(1) Comments No. CP1, SUP19, SUP23, C103, C109, SUP31, SUP39, and C134, Docket No. 75N–0183, Dockets Management Branch.

(2) Comment No. SUP20, Docket No. 75N–0183, Dockets Management Branch.

(3) Comment No. OB15, Docket No. 75N–0183, Dockets Management Branch.

(4) "Two Year Chronic Oral Toxicity Study With Fat 80' 023/A in Albino Rats," Comment No. C109, vol. 1, appendix E, and Comment No. C139, vol. 1–8, Docket No. 75N–0183, Dockets Management Branch.

(5) "Eighteen Month Carcinogenicity Study with Fat 80' 023/A in Albino Mice," Comment No. C109, vol. 3, appendix I, and Comment No. C139, vol. 9, Docket No. 75N–0183, Dockets Management Branch.

(6) "Three Phase Reproduction Study Albino Rats and Rabbits, Bacteriostat CH 3565," Comment No. C134, tab 7, and Comment No. C139, vol. 10–11, Docket No. 75N–0183, Dockets Management Branch.

(7) Letter from W. E. Gilbertson, FDA, to R. Bernegger, Ciba-Geigy Corp., coded LET28/ANS, Docket No. 75N–0183, Dockets Management Branch.

(8) Memorandum of meeting between representatives of Ciba-Geigy Corp. and FDA, Comment No. MM7, Docket No. 75N–0183, Dockets Management Branch.

(9) "FAT 80' 023 2–Year Oral Administration in Rats," vol. XLI, XLII, and XLIII and "Determination of FAT 80' 023 in Blood and Tissue Samples Taken During a Two-Year Chronic Oral Toxicity/Oncogenicity Study in Albino Rats," vol. XLIV, Comment No. RPT2, Docket No. 75N–0183, Dockets Management Branch.

(10) Letter from W. E. Gilbertson, FDA, to Per Stensby, Ciba-Geigy Corp., coded LET100, Docket No. 75N–0183, Dockets Management Branch.

(11) Comment No. RPT7, Docket No. 75N–0183, Dockets Management Branch.

(12) Letter from W. E. Gilbertson, FDA, to R. Bernegger, Ciba-Geigy Corp., coded LET34, Docket No. 75N–0183, Dockets Management Branch.

(13) Comments No. MM3 and C157, Docket No. 75N–0183, Dockets Management Branch.

(14) Letter from A. E. Castillo, EPA, to W. E. Gilbertson, FDA, coded LET33, Docket No 75N–0183, Dockets Management Branch.

M. Comments on Combinations of Active Ingredients

24. One comment stated that the Panel did not review safety and effectiveness data submitted to it on mercufenol chloride (orthohydroxyphenylmercuric chloride) 0.1 percent and secondary amyltricresols 0.1 percent as single ingredients and in combination for use as a patient preoperative skin preparation, skin antiseptic, and skin wound protectant (Ref. 1). The comment added that the agency did not discuss these ingredients alone or in combination in the previous tentative final monograph.

The comment asserted that secondary amyltricresols, mentioned in the previous tentative final monograph under phenol (43 FR 1210 at 1238), is not equivalent to phenol because of chemical differences and differing antimicrobial properties, formulation concentrations, and patterns of use. The comment requested the agency to make decisions on the safety and effectiveness of this ingredient when used alone, or

in combination, as a patient preoperative skin preparation, a skin antiseptic, or a skin wound protectant.

The agency has previously reviewed data for first aid antiseptic uses of 0.1 percent mercufenol chloride and 0.1 percent secondary amyltricresols and found the evidence insufficient to support their safety and effectiveness either as single ingredients or in combination (56 FR 33644 at 33668). Only safety data on animals were submitted by the comment (Ref. 1); in general, these studies were conducted on a very small number of animals, did not detail methodology, and did not adequately describe results (physical condition of the animals). The submitted in vitro studies also lack sufficient detail to establish the effectiveness of mercufenol chloride.

Secondary amyltricresols is a mixture of isomeric secondary amyltricresols, which are derivatives of phenol, and has pharmacological properties similar to phenol. The agency agrees with the comment that the mixture of secondary amyltricresols is not equivalent to phenol and should be categorized separately from phenol. The submitted safety data included a study by Broom (Ref. 2), who reported that amylmetacresol is relatively nontoxic and less toxic than hexylresorcinol in rats and mice.

No toxicity studies in humans were included in the information provided by the comment. However, in the tentative final monograph for OTC external analgesic drug products, published in the **Federal Register** of February 8, 1983 (48 FR 5852 at 5858), the agency proposed that metacresol up to a 3.6-percent concentration be considered safe when combined with camphor and that a 3-to-1 ratio of camphor to metacresol reduces the irritating properties of metacresol. Although cresols may cause some irritation when applied to minor wounds, the agency believes that secondary amyltricresols at the concentration requested (0.1 percent) would not present any safety concerns, particularly considering the short-term use of antiseptics as patient preoperative skin preparation drug products. The submitted data are, however, inadequate to establish the efficacy of secondary amyltricresols.

Data are also needed to determine the safety and effectiveness of the combination of mercufenol chloride and secondary amyltricresols. Only animal safety data are available, and these studies were limited to determinations of the minimum lethal dose by various routes of administration (Ref. 1). The submitted information on marketing history is not sufficient to provide general recognition of the safety of these ingredients. The data contained isolated reports of the combination of mercufenol chloride and secondary amyltricresols causing occasional skin irritation, such as burning and blistering (Ref. 1), adverse effects that need to be more fully studied.

Most of the effectiveness work on the combination of mercufenol chloride and secondary amyltricresols has been in vitro. The combination is reported to combine the antibacterial activity of the single ingredients, that is, mercufenol chloride which is primarily active against gram-negative organisms and secondary amyltricresols which is primarily active against gram-positive organisms (Ref. 3). One in vivo study on the effectiveness of the combination as a patient preoperative skin preparation showed a substantial reduction in the skin microflora (Ref. 4). However, because neutralizers were not used, bacteriocidal activity cannot be differentiated from residual bacteriostatic activity. In addition, the effect of the 50-percent alcohol in the alcohol-acetone vehicle was not taken into consideration. Alcohol, 60 to 95 percent, is in Category I for antiseptic health-care uses.

Under the agency's guidelines for OTC drug combination products (Ref. 5), Category I active ingredients from the same therapeutic category that have different mechanisms of action may be combined to treat the same symptoms or condition if the combination meets the OTC combination policy in all respects and the combination is on a benefit-risk basis, equal to or better than each of the active ingredients used alone at its therapeutic dose. Accordingly, both mercufenol chloride and secondary amyltricresols and the combination of these ingredients are placed in Category III. The combination needs further testing of the combined ingredients compared to each individual active ingredient to establish effectiveness of the combination as a patient preoperative skin preparation.

The agency recommends that in vivo and in vitro effectiveness data be submitted. The data should be based on both in vitro and in vivo testing procedures as described for patient preoperative skin preparation drug products. (See section I.N., comment 28.)

References

(1) OTC Vol. 020093.

(2) Broom, W. A., "A Note on the Toxicity of Amyl-meta-cresol," *British Journal of Experimental Pathology*, 12:327–331, 1931.

(3) Dunn, C. G., "Germicidal Properties of Phenolic Compounds," *Industrial and Engineering Chemistry*, 28:609–612, 1936.

(4) Maddock, W. G., and L. K. Georg, "Further Experience with Mercresin," *American Journal of Surgery*, 45:72–75, 1939.

(5) Food and Drug Administration, "General Guidelines for OTC Drug Combination Products," September 1978, Docket No. 78D–0322, Dockets Management Branch.

25. One comment submitted data on a combination drug product containing calomel (mercurous chloride) 30 percent, oxyquinoline benzoate, and trolamine (triethanolamine) combined with fatty acids to form a soap compound, plus a phenol derivative that is currently marketed over-the-counter and is indicated for use in the prevention of venereal disease (syphilis and gonorrhea) (Ref. 1). The comment included a historical review and information on in vitro activity of one of the ingredients. According to the comment, in 1905 the discovery was made that calomel in combination with fats is an effective germicide against *Treponema pallidum* (*T. pallidum*), the causative organism of syphilis. Later, calomel was stated to be active against *Neisseria gonorrhoeae* (*N. gonorrhoeae*) (the causative organism of gonorrhea).

This combination of ingredients and the indication of prevention of syphilis and gonorrhea have not been reviewed by any OTC advisory review panel. However, because a claim is made indicating antimicrobial activity and the product contains calomel, which is already included in the rulemaking for OTC topical antimicrobial drug products, the agency believes it is appropriate to review this combination and labeling claim in this amended tentative final monograph.

The in vitro effectiveness test described in the comment (Ref. 1) is a zone of inhibition test comparing the germicidal activity of calomel, phenol, and organic silver salts against *S. aureus* as an indicator of activity against syphilis (*T. pallidum*) and gonorrhea (*N. gonorrhoeae*). According to the submission, the causative organisms are not viable in vitro and were not used in the testing. The agency points out that it is possible to isolate and subculture isolates of *N. gonorrhoeae* for in vitro antimicrobial testing (Ref. 2), but *T. pallidum* cannot be grown in vitro (Ref. 3). The agency does not consider the in vitro test against *S. aureus* to be adequate to support a claim of prevention of syphilis and gonorrhea.

In a separate rulemaking for mercury-containing drug products for topical antimicrobial use, calomel was reviewed by the Miscellaneous External Panel (47 FR 436 at 440). That Panel did note that calomel "has been used in the past by inunction (rubbing into the skin)

as a prophylactic against venereal disease * * *" but placed the ingredient in Category II because "calomel may be safe as a topical antimicrobial agent, but it is not effective for this purpose."

Although it is apparent that calomel 30 percent would be considered an active ingredient, it is not clear from the available information whether the other ingredients in the combination (oxyquinoline benzoate, trolamine, and phenol derivative) are also considered active ingredients, nor are the concentrations of these other ingredients stated in the submission and no data have been submitted to the OTC drug review on these ingredients in relation to the prevention of venereal disease. In the absence of any data, none of these ingredients are considered safe and effective for this use.

The comment did not submit any in vivo data from clinical studies to demonstrate that the combination of calomel, oxyquinoline benzoate, trolamine, and phenol derivative is safe and effective for use in the prevention of syphilis and gonorrhea. Preliminary in vitro testing against *N. gonorrhoeae* should be conducted before any human clinical trials are done. Then, favorable results from two well-controlled clinical studies in humans conducted by qualified investigators in two geographic locations (at least one should be within the United States of America) are needed before any drug product can be recognized to be safe and effective in preventing syphilis and gonorrhea. Interested individuals should consult with the agency before initiating any testing. In conclusion, the agency is proposing that this combination of ingredients indicated for the prevention of syphilis and gonorrhea be classified Category II in this amended tentative final monograph.

The agency's detailed comments and evaluation on the data are on file in the Dockets Management Branch (Ref. 4).

References

(1) Comment No. C158, Docket No. 75N–0183, Dockets Management Branch.

(2) Morello, J. A., and M. Bohnhoff, "*Neisseria* and *Branhamella*," in "Manual of Clinical Microbiology," 3rd ed., edited by E. H. Lennette, *American Society for Microbiology*, Washington, pp. 111–122, 1980.

(3) Buchanan, R. E., and N. E. Gibbons, "Bergey's Manual of Determinative Bacteriology," 8th ed., Williams and Wilkins Co., Baltimore, p. 176, 1974.

(4) Letter from W. E. Gilbertson, FDA, to M. Lowenstein, The Sanitube Co., coded LET68, Docket No. 75N–0183, Dockets Management Branch.

N. Comments on Testing

26. Numerous comments addressed the agency's modifications in the Panel's proposed testing guidelines (43 FR 1210 at 1239 to 1240), the agency's statements on final formulation testing (43 FR 1211, 1224, and 1240), and specific protocols for upgrading an antimicrobial ingredient from Category III to Category I (43 FR 1242 to 1246). Stating that the testing guidelines were unclear in some places and pointing out inconsistencies between the guidelines and the agency's responses to comments at 43 FR 1211 and 1223 to 1227, a number of comments requested clarification or proposed modifications of a number of items in the guidelines.

Several comments requested specific information or submitted protocols for testing Category III ingredients. One comment requested that manufacturers be permitted to determine which protocol to follow to establish safety or effectiveness of an ingredient. A number of comments objected to the agency's consideration of the testing guidelines as final, and urged revisions in the guidelines for publication in the Federal Register.

The agency acknowledges that there were some inconsistencies in the testing guidelines for safety and effectiveness proposed in the previous tentative final rule. The agency does not consider the previous testing guidelines as final. The agency is clarifying in this amended tentative final monograph that all final formulations will be required to meet the specifications in the final monograph. As stated in section I.N., comment 28, the agency is proposing testing procedures in § 333.470 for evaluating the active ingredient in pure form as well as in the complete formulation. The agency recommends that manufacturers use these procedures for testing the final formulations of products intended for health-care antiseptic use. Manufacturers may propose other appropriate testing procedures subject to agency evaluation, as requested. The data from these tests are not required to be submitted to FDA by the manufacturer. However, the agency intends to use these procedures for any necessary compliance testing.

27. Two comments pointed out an apparent conflict in the agency's statements concerning safety factor calculations as follows: At 43 FR 1240, the agency concluded that a minimum of a 100-fold safety factor should apply to the exposure dose for ingredients labeled for repeated daily use; at 43 FR 1241, the agency stated that if the safety factor is extrapolated from an animal species to man, considering surface area, the highest no-effect dose should be used for the multiplier, and in the absence of complete data, a 100-fold safety factor should be applied when translating the animal highest no-effect dose to man; and at 43 FR 1213 (see comment 19), the agency stated that modifications of the safety factor will be allowed for specific ingredients where justified by risk-benefit considerations. One comment suggested that a safety factor of less than 100-fold be acceptable when scientific investigation of good quality shows that the test animals used in establishing the no-effect dose are similar to humans with respect to metabolism (biotransformation and pharmacokinetics) and/or tissue susceptibility. Another comment stated that a more reasoned and practical approach would be to require calculation of certain safety factors as recommended, and indicate in a general guideline that risk-benefit ratios based on these factors would determine the relative merits of the product.

The agency does not find any conflict in the various statements included in the previous tentative final monograph. The safety factor calculations were included merely as a general guideline. The agency's response to comment 19 at 43 FR 1213 indicated that the agency would retain a minimum of a 100-fold safety factor applied to the exposure dose for ingredients in products labeled for repeated daily use. However, the agency will consider modifications of the safety factor for specific ingredients where justified by risk-benefit considerations and where requests are based on submitted data. While the 100-fold safety factor was a general guideline in the previous tentative final monograph, the agency does not find a need to include a general guideline in this amended tentative final monograph.

28. Numerous comments requested clarification of the criteria required to establish effectiveness for each antimicrobial product class. One comment stated that the "Testing Guidelines" section seems to indicate that it may be necessary to determine the effect of the vehicle on the active ingredient. The comment contended that this provision is confusing because the preamble discussion in the tentative final monograph indicates that vehicle testing will not be necessary "* * * where adequate data are available on the active ingredients alone." (See 43 FR 1210 at 1224.) Another comment stated that the Cade handwashing test can only be conducted if the antimicrobial is placed in a vehicle and noted that the antimicrobial is never used by consumers in its raw form; therefore, efficacy testing on the raw antimicrobial

ingredient should not be required. A third comment stated that the overall antimicrobial effectiveness of a topically applied product is a function of the total formulation rather than a single ingredient. Another comment added that if an individual product formulation must be tested, and/or the testing of a product vehicle is considered essential, then such testing requirements must be specifically described. Citing the definition of an antiseptic in section 201(o) of the act (21 U.S.C. 321(o)), one comment asserted that the definition requires that the antimicrobial product kill or inhibit the growth of micro-organisms on the skin. The comment proposed that efficacy can be demonstrated by showing that the preparation produces a quantitative reduction in the levels of normal skin flora and/or inhibition of bacterial growth in vitro. Two comments pointed out that the "Modified Cade Procedure" handwashing test (43 FR 1210 at 1243) specifies a one-log reduction of bacteria, but the procedure fails to indicate how many uses or days of use of test product should produce the reduction. Other comments requested that no upper limit be set for bacterial hand counts, that the lower limit of 1.5×10^6 per hand be the only criteria for subject selection, and that minimal hand count reduction be defined in the test protocols for surgical hand scrub and health-care personnel handwash products. Another comment suggested that modification of the "Sampling technique and times" (paragraph 6) of the protocol "Effectiveness Testing of Surgical Hand Scrub (Glove Juice Test)" (43 FR 1243) was needed because the protocol did not indicate the volume of sampling solution but only stated that the volume * * * should be "kept constant" for all tests. The comment recommended that the agency specify a range of 50 to 100 mL of sampling solution in order to provide consistent and reproducible results.

The agency has carefully reviewed the comments, existing data, and other information, and is clarifying the effectiveness criteria for health-care antiseptics in this tentative final monograph.

In order for an antiseptic ingredient to be generally recognized as effective for use as an antiseptic handwash or health-care personnel handwash, patient preoperative skin preparation, and/or surgical hand scrub, it must have existing data from well designed clinical studies demonstrating effectiveness. The agency believes that it is important to correlate effectiveness data from clinical studies with effectiveness data from in vitro studies on the activity of the vehicle and active ingredient individually, so that the germicidal contribution of the antiseptic ingredient to the total formulation can be fully characterized. As stated in the testing guidelines in the previous tentative final monograph, at 43 FR 1240, "* * * there should be demonstration that the formulated product is better than the vehicle alone. Testing of the complete formulation of Category III ingredients * * * is necessary to judge the importance of the vehicle in the release of the active ingredient as well as the influence of formulation on aspects of effectiveness * * *." The agency believes that information on the in vitro activity of the active ingredient alone helps to characterize its antiseptic activity independent of formulation and helps to further define formulation effects on the antimicrobial ingredient. Therefore, the agency is proposing that in vitro studies of the antimicrobial activity of health-care antiseptic drug products covered by § 333.470(a)(1)(i) and (a)(1)(ii) be conducted on the active ingredient, the vehicle, and the final formulation. Manufacturers are to have such data in their files for products containing ingredients included in the monograph.

In this amended tentative final monograph, the agency is proposing that the in vitro antimicrobial activity of the antiseptic ingredient, the vehicle, and the formulated product be characterized by the determination of their antimicrobial spectrum and by minimal inhibitory concentration determinations performed against selected organisms using methodology established by the National Committee for Clinical Laboratories Standards (NCCLS) (Ref. 1). Because the principal intended use of these health-care antiseptic drug products is the prevention of nosocomial or hospital acquired infections, the agency concludes that these products should be able to demonstrate in vitro activity against a microbial spectrum that reflects this use. Since 1970, the National Nosocomial Infection Surveillance System (NNIS) has collected and analyzed data on nosocomial pathogens reported to the Centers for Disease Control by a number of hospitals who perform prospective surveillance on nosocomial infections. These data provide an indication of the most frequently occurring pathogens at four major sites of nosocomial infection—the urinary tract, surgical wounds, lungs (pneumonia), and bloodstream. The agency believes that health-care personnel handwash, surgical hand scrub, and patient preoperative skin preparations should be able to demonstrate in vitro effectiveness against these pathogens as well as the normal resident skin flora. Therefore, the agency is proposing that micro-organisms associated with the most commonly occurring nosocomial infections and those found most often in nosocomial infections of high risk patients as reported by the NNIS, for the period from January 1985 through August 1988 (Ref. 2), be included in the list of micro-organisms to be tested in § 333.470(a)(1)(ii). The agency further concludes that this proposed list identifies a broad spectrum of antimicrobial activity that is also appropriate for home use antiseptic handwash products.

The agency notes that neither filamentous dermatophytic fungi or viruses are included in the NNIS report. More recent studies (Refs. 3 and 4) have reported small numbers of nosocomial infections associated with both of these organisms. However, the new studies do not provide sufficient information to assess the relative importance of these organisms as a cause of nosocomial infection. Therefore, the agency is not proposing to include filamentous dermatophytic fungi in the list of micro-organisms to be tested, as proposed in the previous in vitro effectiveness testing guidelines (43 FR 1210 at 1241) and is continuing to propose that viruses also not be included. The agency recognizes that the list of organisms to be tested may need updating to assure that it remains reflective of current trends in the microbial etiology of nosocomial infections. The agency intends to update the list as new information becomes available. Further, the agency invites the submission of comments and specifically data on the role of other organisms, particularly viruses and filamentous dermatophytic fungi, in nosocomial infections.

In addition to the characterization of the in vitro spectrum of activity, the agency believes that information on how rapidly these antimicrobial drug products achieve their antimicrobial effect is necessary. As a means of indicating how quickly these products achieve their antimicrobial effect, the agency is proposing in vitro time-kill curves of the formulated drug product as part of the testing requirements. The agency acknowledges that there is currently no accepted or standardized method that may be used in conducting this type of study and invites the submission of proposed methods that may be considered as applicable to this test. In § 333.470(a)(1)(iv) of the proposed testing regulations, the agency provides guidance on the development

of such methods. However, any time-kill studies submitted to the agency are to be conducted on a 10-fold dilution of the formulated product against the ATCC strains identified in § 333.470(a)(1)(ii) of the proposed testing regulations and are to include enumeration at times at 0, 3, 6, 9, 12, 15, and 30 minutes.

With regard to proof of clinical effectiveness, the agency is proposing specific criteria for final formulations of antiseptic handwashes or health-care personnel handwashes, patient preoperative skin preparations, and surgical hand scrubs that are based on the recommendations of the Panel and agency experience in evaluating the effectiveness of these types of drug products, as follows.

For antiseptic handwash or health-care personnel handwash products, the agency is proposing the following criteria: (1) A 2-$\log_{10}$ reduction of the indicator organism on each hand within 5 minutes after the first wash and (2) a 3-$\log_{10}$ reduction in the indicator organism on each hand within 5 minutes after the tenth wash, when tested by a modification of the standard procedure for the evaluation of health-care personnel handwash formulations published by the American Society for Testing and Materials (ASTM) (Ref. 5).

For patient preoperative skin preparations, the agency is proposing the following criteria: (1) A 2-$\log_{10}$ reduction of the microbial flora per square centimeter of an abdominal test site, (2) a 3-$\log_{10}$ reduction of the microbial flora per square centimeter of a groin test site within 10 minutes from a matched control area, and (3) the suppression of bacterial growth below baseline for 6 hours, when tested by a modification of the standard procedure for the evaluation of patient preoperative skin preparations published by the ASTM (Ref. 6). The agency believes that the revised effectiveness criteria more closely reflect the conditions of product use, *i.e.*, on a number of different body sites, each supporting different numbers of resident skin flora. In addition, although persistence of effect was not recommended by the Panel as a requirement for these drug products, the agency believes that persistence of antimicrobial effect would suppress the growth of residual skin flora not removed by preoperative prepping as well as transient micro-organisms inadvertently added to the operative field during the course of surgery and reduce the risk of surgical wound infection. Based on the proposed effectiveness criteria for this product class, the agency is proposing a revised definition of a patient preoperative skin preparation drug product in § 333.403(c)(2) of this amended tentative final monograph as follows: "A fast-acting broad-spectrum persistent antiseptic-containing preparation that significantly reduces the number of micro-organisms on intact skin."

As discussed in section I.E., comment 10, the agency is proposing the indication "for the preparation of the skin prior to an injection" for OTC alcohol and isopropyl alcohol drug products. The agency is further proposing that products labeled for such use demonstrate effectiveness by testing according to the same procedure used to demonstrate the effectiveness of patient preoperative skin preparation drug products not labeled for this use. Based on this intended use of alcohol drug products, the agency is proposing a 1-$\log_{10}$ reduction in the microbial flora per square centimeter of a dry skin test site within 30 seconds of product use as the effectiveness criteria for these products.

For surgical hand scrub products, the agency is proposing the following criteria: (1) A 1-$\log_{10}$ reduction of the microbial flora of each hand from the baseline count within 1 minute, (2) suppression of bacterial growth on each hand below baseline for 6 hours on the first day, (3) a 2-$\log_{10}$ reduction of the microbial flora on each hand within 1 minute of product use by the end of the second day, and (4) a 3-$\log_{10}$ reduction of the microbial flora on each hand within 1 minute of product use by the end of the fifth day, when tested by a modification of the standard procedure for the evaluation of surgical hand scrub products published by the ASTM (Ref. 7).

Based on glove juice test data for surgical hand scrub use of povidone-iodine (section I.I., comment 17), alcohol (section I.E., comment 10), chloroxylenol (section I.G., comment 12), and triclosan (section I.L., comment 23), the agency concludes that formulated products containing certain ingredients, *i.e.*, chloroxylenol and triclosan, are substantive in their action and do not produce a high (1-$\log^{10}$) initial reduction, but after repeated use for up to 5 days do reduce the baseline count and suppress the count in the user's glove. In a separate final rule, the agency stated that any product indicated for use as a surgical scrub should meet a standard for initial reduction. A one-log reduction was found acceptable as the minimal level of reduction suitable for a surgical scrub in a handwashing test. (See "New Drugs Containing Hexachlorophene," published in the **Federal Register** of December 20, 1977; 42 FR 63771.)

In that same final rule, the agency acknowledged that hexachlorophene containing surgical scrub drug products are substantive in their action and do not produce an initial high reduction but with repeated use are effective in reducing the resident skin flora and suppressing bacterial growth in the user's glove for up to 6 hours. Based on a lack of available products capable of producing both an initial high reduction in the resident skin flora and a prolonged microbial suppression marketed at the time of the agency's action on the ingredient in 1972, the agency agreed with the recommendations of its Antimicrobial I Panel and concluded that the ingredient should continue to be marketed for use as a surgical scrub and for handwashing as part of patient care. The agency stated its intention to reconsider its criteria for evaluating such products in light of risk-benefit judgments as new products containing both attributes become available (42 FR 63771).

Since that final rule was issued in 1977, data have been submitted to the agency demonstrating the effectiveness of surgical hand scrub formulations capable of producing an initial 1-$\log_{10}$ reduction and a suppression of microbial growth in the wearer's glove for up to 6 hours. (See section I.E., comment 10 on alcohol and section I.I., comment 17 on povidone-iodine.) The agency notes that the persistence of the antimicrobial effect demonstrated by an alcohol-containing surgical hand scrub formulation was provided by a preservative agent in the vehicle. Based on the new data, the agency has concerns about the risk associated with the initial use of substantive surgical hand scrub formulations, and with the use of these formulations after extended lapses in their routine use. Therefore, the agency is proposing that all surgical hand scrub formulations must demonstrate an initial one-log reduction in the bacterial flora. The agency invites comment on the use of substantive antimicrobials in health-care antiseptic drug products. Based on the revised effectiveness criterion for these drug products, the agency is proposing a revised definition of a surgical hand scrub drug product in § 333.403(c)(3) as follows: "An antiseptic containing preparation that significantly reduces the number of micro-organisms on intact skin; it is broad spectrum, fast acting, and persistent."

The agency believes that the modified ASTM procedures for the testing of health-care or antiseptic handwashes, surgical hand scrubs, and patient preoperative skin preps being proposed for inclusion in the testing requirements

provide protocols that are appropriate for the final formulation testing of these drug products. The proposed protocols describe, in detail, study conditions and materials to be used and address the concerns raised by the comments. For instance, the proposed protocol for the testing of surgical hand scrub products includes a baseline criterion for subject selection of equal to, or greater than, 1.5×10^5 bacteria per hand and specifies that a 50 to 100 mL volume of sampling is to be used. The proposed protocols also specify requirements for a number of areas not addressed by the testing guidelines proposed in the previous tentative final monograph. For example, they address statistical aspects of study design and data analysis, and the use of neutralizers. A positive control is included in the protocols as a means of validating the testing procedure, equipment, and facilities. The agency believes that the proposed protocols for the testing of these products provide a consistent approach to the effectiveness testing of health-care personnel handwashes, surgical hand scrubs, and patient preoperative skin preparations. The agency is incorporating the above criteria and testing requirements in proposed § 333.470 of this tentative final monograph and invites specific comment on them at this time. After reviewing any submitted comments or data, the agency may revise the testing requirements and procedures prior to establishing a final monograph. The agency also recognizes that the test procedures may need to be revised periodically to reflect new information and newer techniques that are developed and proven adequate.

References

(1) National Committee for Clinical Laboratory Standards, "Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria that Grow Aerobically—2d ed.; Approved Standard," NCCLS Document M7–A2, 10:8, 1990.

(2) Horan, T. *et al.*, "Pathogens Causing Nosocomial Infections," *The Antimicrobic Newsletter*, 5:65–67, 1988.

(3) Andersen, L. J., "Major Trends in Nosocomial Viral Infections," *The American Journal of Medicine*, 91:107S–111S, 1991.

(4) Jarvis, W. R. *et al.*, "Nosocomial Outbreaks: The Centers for Disease Control's Hospital Infections Program Experience," *The American Journal of Medicine*, 91:101S–106S, 1991.

(5) American Society for Testing and Materials, "Standard Test Method for Evaluation of Health Care Personnel Handwash Formulation, Designation E 1174," in "The Annual Book of ASTM Standards," vol. 11.04, American Society for Testing and Materials, Philadelphia, pp. 209–212, 1987.

(6) American Society for Testing and Materials, "Standard Test Method for Evaluation of a Preoperative Skin Preparation, Designation E 1173," in "The Annual Book of ASTM Standards," vol. 11.04, American Society for Testing and Materials, Philadelphia, pp. 205–208, 1987.

(7) American Society for Testing and Materials, "Standard Test Method for Evaluation of Surgical Hand Scrub Formulation, Designation 1115," in "The Annual Book of ASTM Standards," vol. 11.04, American Society for Testing and Materials, Philadelphia, pp. 201–204, 1986.

II. The Agency's Amended Tentative Final Monograph

A. Summary of Ingredient Categories and Testing of Category II and Category III Conditions

1. Summary of Ingredient Categories

The agency has carefully reviewed the claimed active ingredients submitted to this administrative record (Docket No. 75N–0183), which includes the following: the advance notice of proposed rulemaking (39 FR 33103) and previous tentative final monograph (43 FR 1210) for OTC topical antimicrobial drug products, the advance notice of proposed rulemaking for OTC topical alcohol drug products (47 FR 22324), and the advance notice of proposed rulemaking for OTC topical mercury-containing drug products (47 FR 436). Based upon the available information, including clinical and marketing history, as well as the recommendations of the Miscellaneous External Panel, the agency is proposing a tentative classification for OTC health-care antiseptic active ingredients.

Many of the ingredients included in the tabulation below are in Category II and Category III because of no data or a lack of data on use as a health-care antiseptic. However, all the ingredients have been included as a convenience to the reader. The agency specifically invites comment and additional data on these ingredients.

The advance notice of proposed rulemaking for alcohol drug products for topical antimicrobial OTC human use (47 FR 22324, May 21, 1982) is being incorporated into this amended tentative final monograph. In that proposed monograph, the Miscellaneous External Panel recommended that alcohol 60 to 95 percent by volume in an aqueous solution denatured according to Bureau of Alcohol, Tobacco, and Firearms regulations at 27 CFR part 21 and isopropyl alcohol 50 to 91.3 percent by volume in an aqueous solution be classified as Category I for topical antimicrobial use. The following indications were proposed:

(1) "For first aid use to decrease germs in minor cuts and scrapes."

(2) "To decrease germs on the skin prior to removing a splinter or other foreign object."

(3) "For preparation of the skin prior to an injection." (See the advance notice of proposed rulemaking for OTC alcohol drug products for topical antimicrobial use, in the **Federal Register** of May 21, 1982, 47 FR 22324.)

Based upon submitted data and the conclusions of the Miscellaneous External Panel, the agency is including alcohol as a Category I surgical hand scrub, patient preoperative skin preparation, and antiseptic handwash or health-care personnel handwash (see section I.E., comment 10). While no comments submitted data on health-care uses of isopropyl alcohol, the agency notes that one comment (Ref. 1) from a manufacturer requested that the OTC alcohol drug products monograph provide the labeling indication, "antibacterial handwash." The same manufacturer provided a submission (Ref. 2) to the Miscellaneous External Panel on a combination product containing isopropyl alcohol 50 percent and oxyquinoline sulfate 0.125 percent for use as a germicidal-fungicidal wash. However, the Panel disbanded before it was able to review the submission, which contained labeling for a currently marketed product and in vitro studies of the product's bacteriocidal activity. No in vivo effectiveness data were submitted for the use of isopropyl alcohol as an antiseptic handwash or health-care personnel handwash, patient preoperative skin preparation, or surgical hand scrub.

Based on the lack of data for the use of isopropyl alcohol as an antiseptic handwash or health-care personnel handwash and surgical hand scrub, the agency is placing the ingredient in Category III for these uses. The agency invites data on these uses of isopropyl alcohol. As discussed in section I.E., comment 10, the agency is including the Panel's recommended indication "for the preparation of the skin prior to an injection" as an additional Category I indication for patient preoperative skin preparations containing alcohol. Based on the Panel's recommendations, the agency is also proposing isopropyl alcohol as a Category I patient preoperative skin preparation for this indication. However, based on the lack of data on the use of isopropyl alcohol for more general patient preoperative skin preparation use, the agency is not proposing isopropyl alcohol as Category I for the other patient preoperative skin preparation indications included in § 333.460(b)(1), *i.e.*, "for the preparation of the skin prior to surgery" and "helps

to reduce bacteria that potentially can cause skin infection."

The agency has evaluated standard textbooks and published data on the effectiveness of isopropyl alcohol used topically on the area prior to an injection (Refs. 3, 4, and 5). The minimum effective concentration of isopropyl alcohol for this use is 70 percent. Further, the agency is not aware of any information concerning the use of isopropyl alcohol below 70 percent for this indication. Therefore, the agency is proposing to include isopropyl alcohol 70 to 91.3 percent in Category I for use as a patient preoperative skin preparation for the limited indication "for the preparation of the skin prior to an injection".

The Miscellaneous External Panel recommended that drug products containing alcohol and isopropyl alcohol bear the following warning: "Flammable, keep away from fire or flame," (47 FR 22324 at 22330). The agency concurs with the Panel's recommended warning and is proposing this warning in § 333.450(c)(4) of this tentative final monograph. In order to ensure the warning's prominence, the agency is further proposing that it appear in boldface type and as the first warning immediately following the heading "WARNINGS".

The agency is aware of ten reports (Refs. 6 and 7) of first and second degree burns occurring in patients undergoing electrocautery procedures. The burns were caused by the ignition of the isopropyl alcohol in patient preoperative skin preparations containing chlorhexidine gluconate or povidone-iodine in 70 percent isopropyl alcohol. The reports indicate that these incidents have occurred despite the presence of detailed warnings in the products' labeling cautioning that the products are flammable until dry and should not be allowed to pool on body surfaces or should not be used in conjunction with electrocautery procedures until dry (Refs. 8 and 9). Based on these reports, the agency tentatively concludes that patient preoperative skin preparations containing isopropyl alcohol in concentrations of 70 percent or more cannot be adequately labeled to allow the safe use of these drug products in conjunction with electrocautery procedures. Therefore, the agency is proposing that patient preoperative skin preparations containing isopropyl alcohol in concentrations of 70 percent or more bear the following label warning: "Do not use with electrocautery procedures." The agency is further proposing that the proposed warning immediately follow the flammable warning being proposed in § 333.450(c)(4).

The agency is not currently aware of any similar incidence occurring with other nonemollient patient preoperative skin preparations containing alcohol in similar concentrations. Therefore, at this time the agency is not proposing that patient preoperative skin preparations containing alcohol identified in § 333.412(a) bear a warning concerning the use of these products in conjunction with electrocautery procedures. However, the agency will consider extending the warning to patient preoperative skin preparations containing alcohol if new information indicates that this is necessary. The agency invites specific comment and data on the safety of both alcohol and isopropyl alcohol containing patient preoperative skin preparations in conjunction with electrocautery procedures.

References

(1) Comment No. C00148, Docket No. 75N–0183, Dockets Management Branch.

(2) OTC Vol. 160251.

(3) Lee, S., I. Schoen, and A. Malkin, "Comparison of Use of Alcohol with that of Iodine for Skin Antisepsis in Obtaining Blood Cultures," *American Journal of Clinical Pathology*, 47:646–648, 1967.

(4) Harvey, S.C., "Isopropanol," in "The Pharmacological Basis of Therapeutics," 7th ed., Macmillan Publishing Co., New York, p. 962, 1985.

(5) Harvey, S.C., "Isopropyl Alcohol," in "Remington's Pharmaceutical Sciences," 16th ed., Mack Publishing Co., Easton, PA, pp. 1103–1104, 1980.

(6) Drug Experience Reports No. 184970, 190547, 190548, 190549, 807471, and 851772 in OTC Vol. 230001, Docket No. 75N–183H, Dockets Management Branch.

(7) Transcripts of consumer complaints regarding DuraPrep™ Surgical Solution dated January 31, 1991, April 8, 1992, and April 9, 1992 in OTC Vol. 230001, Docket No. 75N–183H, Dockets Management Branch.

(8) Labeling for DuraPrep Surgical Solution, in OTC Vol. 230001, Docket No. 75N–183H, Dockets Management Branch.

(9) Physicians' Desk Reference, 38th ed., Medical Economics Company, Oradell, NJ, p. 1956, 1984.

The Panel also stated that benzyl alcohol and chlorobutanol were safe, but recommended that the ingredients be categorized as Category II for effectiveness. However, in the first aid antiseptic segment of this rulemaking these alcohol ingredients were reclassified from Category II to Category III for effectiveness as first aid antiseptic ingredients. (See 56 FR 33644 at 33673.) Because no comments, data, or information were received, and because the agency is not aware of any health-care antiseptic uses for these ingredients, benzyl alcohol and chlorobutanol are not being classified in this rulemaking for health-care antiseptic drug products.

The agency published an advance notice of proposed rulemaking for mercury-containing drug products on January 5, 1982 (47 FR 436). That notice, based upon the recommendations of the Miscellaneous External Panel, proposed to classify OTC mercury-containing drug products for topical antimicrobial use as not generally recognized as safe and effective and as being misbranded. The agency received no comments. The Panel classified the mercurial ingredients, as a group, in Category II; some for lack of safety, some for lack of efficacy, and others due to a lack of both safety and efficacy. However, in the first aid antiseptic segment of this amended tentative final monograph, several mercury-containing OTC topical antimicrobials have been reclassified from Category II to Category III for effectiveness. Mercurial ingredients placed in Category II for safety were not reclassified. The ingredients reclassified are calomel, merbromin, mercufenol chloride, and phenylmercuric nitrate. This change was made in keeping with the revised effectiveness criteria for the drug product category "first aid antiseptic," which were not available at the time the Miscellaneous External Panel evaluated the effectiveness of mercurial ingredients. (See 56 FR 33644 at 33672.) The agency is unaware of any clinical data or marketing history for the use of mercury-containing drug products as health-care antiseptics. Consequently, these drugs have not been classified as health-care antiseptics. In addition, the agency has reviewed submitted data on two combinations containing mercurial ingredients and proposes a Category II classification for these combinations. (See section I.M., comments 24 and 25.)

In the previous tentative final monograph, the agency concluded that cloflucarban and triclocarban are not generally recognized as safe and effective for use as a patient preoperative skin preparation, surgical hand scrub, and health-care personnel handwash. The Panel reviewed safety and effectiveness data on these ingredients formulated as a bar soap and classified them in Category III as a health-care personnel handwash when formulated as a bar soap (39 FR 33103 at 33124 and 33126). No safety and effectiveness data for the use of clofucarban in the other health-care antiseptic drug product classes were submitted to the OTC drug review; no data were reviewed by the Panel; and no data were received by the agency.

Cloflucarban is therefore considered to be outside this monograph except as a health-care personnel handwash (formulated as a bar soap). Accordingly, cloflucarban remains Category II as a health-care antiseptic for use as a patient preoperative skin preparation and surgical scrub and Category III as an antiseptic handwash or health-care personnel handwash.

Additional safety data and information were submitted to the agency on triclocarban formulated as a soap. As discussed in the segment of this rulemaking covering first aid antiseptics (56 FR 33644 at 33664), the agency has reviewed a chronic toxicity study and other information and determined that triclocarban can be recognized as safe for OTC daily topical use in a concentration of 1.5 percent. However, no effectiveness data were submitted for any health-care antiseptic uses of this ingredient and the agency is classifying triclocarban in Category III as an antiseptic handwash or health-care personnel handwash, patient preoperative skin preparation, and surgical hand scrub. In the previous tentative final monograph, the agency placed the combination of cloflucarban and triclocarban in Category III (43 FR 1210 at 1239) to be "used in antimicrobial soap * * *". No additional data were submitted on this combination. Therefore, the combination of cloflucarban and triclocarban remains in Category III for antiseptic handwash or health-care personnel handwash uses.

Based upon the Panel's recommendations on phenol, in the previous tentative final monograph, the agency classified phenol less than 1.5 percent as Category III and phenol greater than 1.5 percent as Category II for use as a health-care personnel handwash, patient preoperative skin preparation, and surgical hand scrub (43 FR 1227 and 1229). Hexylresorcinol was also classified in Category III for these uses in the previous tentative final monograph (43 FR 1229). No additional data were submitted on health-care antiseptic uses of phenol and hexylresorcinol and their classifications are unchanged in this amended tentative final monograph. In the previous tentative final monograph, the agency classified triple dye (a combination of gentian violet, brilliant green, and proflavine hemisulfate) in Category II as a health-care personnel handwash, patient preoperative skin preparation, and surgical hand scrub based on a lack of safety data (43 FR 1239). No additional data have been submitted and the ingredient remains in Category II for health-care antiseptic uses.

In comment 85 of the previous tentative final monograph (43 FR 1223), the agency deferred classification of several ingredients to the Miscellaneous External Panel. All of the ingredients have been classified with the exception of methyl alcohol and gentian violet 1 and 2 percent solutions. The Miscellaneous External Panel at its 38th meeting placed methyl alcohol in Category II as an OTC topical antimicrobial ingredient for both safety and effectiveness (Ref. 1). However, this classification was not included in the advance notice of proposed rulemaking for OTC alcohol drug products. The agency agrees with this classification. Further, the agency is not aware of any use of methyl alcohol in OTC drug products, except as a denaturant. Gentian violet was reviewed by the Advisory Review Panel on OTC Oral Cavity Drug Products and placed in Category III based on the lack of effectiveness data for use as a topical antimicrobial on the mucous membranes of the mouth. The agency is not aware of any data on the use of gentian violet as a health-care antiseptic and places this ingredient in Category III for this use.

Reference

(1) Transcript of the Proceedings of the 39th Meeting of the Advisory Review Panel on OTC Miscellaneous External Drug Products, April 20, 1980, pp. 121–123.

Fluorosalan was not classified as an OTC topical antimicrobial ingredient in the previous tentative final monograph because the agency stated that final regulatory action had been taken against "* * * the halogenated salicylanilides, particularly * * * fluorosalan (21 CFR 310.508) * * *" (43 FR 1210 at 1227). Although no comments were received, the agency notes that fluorosalan was not addressed in the final rule for halogenated salicylanilides (21 CFR 310.508), published in the **Federal Register** of October 30, 1975 (40 FR 5027). In reviewing the Antimicrobial I Panel's recommendations, the agency has determined that the Panel did not intend to include fluorosalan in the group of halogenated salicylanilides which it recommended be handled more expeditiously by the agency in a separate **Federal Register** notice. (See the notice of proposed rulemaking for certain halogenated salicylanilides as active or inactive ingredients in drug and cosmetic products (September 13, 1974, 39 FR 33102) and the advance notice of proposed rulemaking for OTC topical antimicrobial drug products (September 13, 1974, 39 FR 33103 at 33120).) The agency affirms the recommendation of the Antimicrobial I Panel (39 FR 33121) that fluorosalan be classified as Category II for use in antiseptic handwash, health-care personnel handwash, patient preoperative skin preparation, and surgical hand scrub drug products.

The following charts are included as a summary of the categorization of health-care antiseptic active ingredients proposed by the agency.

TOPICAL ANTIMICROBIAL INGREDIENTS [1] SUMMARY OF HEALTH-CARE ANTISEPTIC ACTIVE INGREDIENTS

Active ingredient	Patient preoperative skin preparation	Antiseptic handwash or health-care personnel handwash	Surgical hand scrub
Alcohol 60 to 95 percent [2]	I	I	I
Benzalkonium chloride	IIIE	IIISE [4]	IIISE
Benzethonium chloride	IIIE	IIISE	IIISE
Chlorhexidine gluconate [2]	([5])	([5])	([5])
Chloroxylenol	IIIE	IIISE	IIISE
Cloflucarban	II	IIISE	II
Fluorosalan	II	II	II
Hexachlorophene	II	II	II
Hexylresorcinol	IIIE	IIIE	IIIE
Iodine Active Ingredients:			
Iodine complex (ammonium ether sulfate and polyoxyethylene sorbitan monolaurate) [2].	NA	IIIE	IIIE
Iodine complex (phosphate ester of alkylaryloxy polyethylene glycol)	IIIE	IIIE	IIIE
Iodine tincture U.S.P	I	NA	NA

TOPICAL ANTIMICROBIAL INGREDIENTS [1] SUMMARY OF HEALTH-CARE ANTISEPTIC ACTIVE INGREDIENTS—Continued

Active ingredient	Patient preoperative skin preparation	Antiseptic handwash or health-care personnel handwash	Surgical hand scrub
Iodine topical solution U.S.P	I	NA	NA
Nonylphenoxypoly (ethyleneoxy) ethanoliodine	IIIE	IIIE	IIIE
Poloxamer-iodine complex	IIIE	IIIE	IIIE
Povidone-iodine 5 to 10 percent	I	I	I
Undecoylium chloride iodine complex	IIIE	IIIE	IIIE
Isopropyl alcohol 70–91.3 percent [2]	I	IIIE	IIIE
Mercufenol chloride [2]	IIIE	NA	NA
Methylbenzethonium chloride	IIIE	IIISE	IIISE
Phenol (less than 1.5 percent)	IIIE	IIISE	IIISE
Phenol (greater than 1.5 percent)	II	II	II
Secondary amyltricresols [2]	IIISE	IIIE	IIIE
Sodium oxychlorosene [2]	IIISE	IIISE	IIISE
Tribromsalan [3]	II	II	II
Triclocarban	IIIE	IIIE	IIIE
Triclosan	IIIE	IIISE	IIISE
Combinations			
Calomel, oxyquinoline benzoate, triethanolamine, and phenol derivative [2].	II	NA	NA
Mercufenol chloride and secondary amyltricresols in 50 percent alcohol [2].	IIISE	NA	NA
Triple Dye	II	NA	NA

[1]—All ingredients (unless otherwise noted) in Antimicrobial I Drug Products Advance Notice of Proposed Rulemaking (39 FR 33103) and Tentative Final Monograph (47 FR 1210).
[2]—Not categorized in previous tentative final monograph, but categorized in this amended tentative final monograph.
NA=Not Applicable because not evaluated for this use.
[3]—Categorized in Antimicrobial I Drug Products Advance Notice of Proposed Rulemaking (39 FR 33103) and in Certain Halogenated Salicylanilides as Active or Inactive Ingredients in Drug and Cosmetic Products (40 FR 50527).
[4]—S=safety; E=effectiveness
[5]—Determined by the agency to be a "new drug".

SUMMARY OF TOPICAL ANTIMICROBIAL ACTIVE INGREDIENTS NOT ADDRESSED IN THIS RULEMAKING

Ingredients not classified as health-care antiseptic ingredients but generally recognized as safe and effective for OTC first aid use within the established concentration(s) (see 56 FR 33644).

Single ingredients

Alcohol 48 to 59 percent
Hydrogen peroxide topical solution U.S.P.
Isopropyl alcohol 50 to 69 percent

Combinations

Eucalyptol 0.091 percent, menthol 0.042 percent, methyl salicylate 0.055 percent, and thymol 0.063 percent in 26.9 percent alcohol.

Complexes

Camphorated metacresol (3 to 10.8 percent camphor and 1 to 3.6 percent metacresol) in a ratio of 3:1
Camphorated phenol (10.8 percent camphor and 4.7 percent phenol) in light mineral oil, U.S.P. vehicle

Ingredients not classified as Category I as a health-care antiseptic because the agency is not aware of any health-care antiseptic uses for these ingredients.

Single ingredients

Ammoniated mercury
Benzyl alcohol
Calomel (Mercurous chloride)
Chlorobutanol
Gentian violet
Merbromin
Mercuric chloride (Mercury chloride)
Mercuric oxide, yellow
Mercuric salicylate
Mercuric sulfide, red
Mercury
Mercury oleate
Mercury sulfide
Methyl alcohol
Nitromersol

SUMMARY OF TOPICAL ANTIMICROBIAL ACTIVE INGREDIENTS NOT ADDRESSED IN THIS RULEMAKING—Continued

Para-chloromercuriphenol
Phenylmercuric nitrate
Thimerosal
Vitromersol
Zyloxin
Combinations and/or Complexes
None

2. Testing of Category II and Category III Conditions

Required testing procedures for evaluating the effectiveness of the complete formulation of a health-care antiseptic drug product are included in proposed § 333.470. These effectiveness testing procedures can also be used to demonstrate the effectiveness of active ingredients not in a final formulation. Suggested safety testing is described in the previous tentative final monograph. (See 43 FR 1210 at 1240 to 1242.)

Interested persons may communicate with the agency about the submission of data and information to demonstrate the safety or effectiveness of any health-care antiseptic ingredient or condition included in the review by following the procedures outlined in the agency's policy statement published in the **Federal Register** of September 29, 1981 (46 FR 47740) and clarified April 1, 1983 (48 FR 14050). That policy statement includes procedures for the submission and review of proposed protocols, agency meetings with industry or other interested persons, and agency communications on submitted test data and other information.

B. Summary of the Agency's Conclusions Including Changes in the Panel's Recommendations and in the Agency's Previous Recommendations

FDA has considered the comments and other relevant information and is amending the previous tentative final monograph with the changes described in FDA's responses to the comments above and with other changes described in the summary below. A summary of the changes made by the agency in this amended tentative final monograph follows.

1. All of the section numbers for health-care antiseptics in the previous tentative final monograph have been redesignated in this amendment. As a convenience to the reader, the following chart is included to show these redesignations.

REDESIGNATED SECTION NUMBERS OF THE TENTATIVE FINAL MONOGRAPH FOR ANTIMICROBIAL DRUG PRODUCTS

Old section No.	Section name	New section No.
General Provisions:		
333.1	Scope	333.401
333.3	Definitions Active Ingredients	333.403
333.20	Antimicrobial Soap	Deleted
333.30	Patient Preoperative Skin Preparation	333.410
333.50	Surgical Hand Scrub Labeling	333.410
333.80	Antimicrobial Soap	Deleted
333.85	Health-Care Personnel Handwash	333.455
333.87	Patient Preoperative Skin Preparation	333.460
333.97	Surgical Hand Scrub	333.465
333.99	Professional Labeling	Deleted

In addition, a number of format changes have been made that are consistent with the format used in recently published tentative final and final monographs.

2. The agency is proposing the term "antiseptic" as the general statement of identity for the product categories of patient preoperative skin preparation, surgical hand scrub, and health-care personnel handwash drug products. The agency is also providing manufacturers the option to provide alternative statements of identity describing only the specific intended use of the product, e.g., surgical hand scrub. When the term "antiseptic" is used as the only statement of identity on a single-use or a multiple-use product, the intended use(s) is to be included as part of the indications. For multiple use products the agency proposes that a statement of the intended use(s) should also precede the specific directions for each use. (See section I.B., comment 3.)

3. The agency is proposing that the statement of identity "antiseptic handwash" may also be used for a health-care personnel handwash. The agency is proposing to expand the indications proposed for health-care personnel handwash drug products in the previous tentative final monograph to read, "Handwash to help reduce bacteria that potentially can cause disease" or "For handwashing to decrease bacteria on the skin" (which may be followed by one or more of the following: "after changing diapers," "after assisting ill persons," or "before contact with a person under medical care or treatment.") The agency is also proposing "recommended for repeated use" as another allowable indication for this product class. (See section I.B., comment 5.)

4. The agency has replaced the previously proposed definition of an antimicrobial (active) ingredient with a definition of an "antiseptic" drug that is consistent with the definition of an antiseptic in section 201(o) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(o)). The agency is also including a definition for a health-care

antiseptic as follows: "An antiseptic containing drug product applied topically to the skin to help prevent infection or to help prevent cross contamination." The agency has also proposed revised definitions for patient preoperative skin preparations and surgical hand scrubs that reflect the agency's proposed effectiveness criteria for these products. (See section I.N., comment 28.) In addition, the agency has made minor revisions in the definitions of a health-care personnel handwash, patient preoperative skin preparation, and surgical hand scrub to reflect the revised terminology being used in this amended tentative final monograph.

5. The agency is adding to this amended tentative final monograph a definition of broad spectrum activity as follows: A properly formulated drug product, containing an ingredient included in the monograph, that possesses in vitro activity against the micro-organisms listed in § 333.470(a)(1)(ii), as demonstrated by in vitro minimum inhibitory concentration determinations conducted according to methodology established in § 333.470(a)(1)(ii). The agency is proposing to include "broad spectrum" in the definitions of the three product classes included in this tentative final monograph. (See section I.C, comment 6.)

6. The agency has reviewed the *Other Allowable Statements* proposed in the previous tentative final monograph in § 333.85 for health-care personnel handwash, in § 333.87 for patient preoperative skin preparation, and in § 333.97 for surgical hand scrub and determined that statements such as "contains antibacterial ingredient(s)," "contains antimicrobial ingredient(s)," and "non-irritating," are not related in a significant way to the safe and effective use of these products and are not necessary on products intended primarily for health-care professionals. Therefore, the agency is not including these statements in this amended tentative final monograph. The statement "recommended for repeated use," proposed for a health-care personnel handwash, has been included as an "other allowable indication" in proposed § 333.455. The terms "broad spectrum" and "fast acting" are included in the definitions of all three product classes and the agency does not see the need to include this information in the required labeling. (See section I.D., comment 7.)

7. The agency is proposing revised indications for patient preoperative skin preparations in order to more precisely describe the intended uses of these products. The previous indications "kills micro-organisms," "antibacterial," and "antimicrobial" are not being included. Likewise, the indications "kills micro-organisms," "bacteriostatic," and "bactericidal" previously proposed for surgical hand scrubs are not being included in this amended tentative final monograph. The agency believes that these terms are product attributes and not indications for use and should not be included as indications in the labeling of these products.

8. Based on the recommendations of the Miscellaneous External Panel in the advance notice of proposed rulemaking for OTC alcohol drug products (47 FR 22324 at 22332), the agency is proposing "for preparation of the skin prior to an injection" as an indication for OTC alcohol and isopropyl alcohol drug products.

9. The agency is proposing in § 333.450(c) of this amended tentative final monograph the following general warning statements for all health-care antiseptic drug products:

(1) "For external use only."

(2) "Do not use in the eyes."

(3) "Discontinue use if irritation and redness develops. If condition persists for more than 72 hours consult a doctor." The agency is further proposing that the second sentence of the proposed warning in (3) above may be deleted for products labeled "For Hospital and Professional Use Only." (See section I.D., comment 8.) In addition to the general warnings proposed for OTC health-care antiseptic drug products, the agency is proposing the following warning for patient preoperative skin preparations containing isopropyl alcohol identified in § 333.412(d): "Do not use this product with electrocautery procedures." The proposed warning is based on reports of burns associated with the use of isopropyl alcohol containing patient preoperative skin preparations with electrocautery procedures. (See section II.A., paragraph 1—Summary of Ingredient Categories.)

10. Based on its review of the published literature (Refs. 1, 2, and 3), the agency has determined that the way in which health-care antiseptic drug products are used, *e.g.*, method of application, duration of scrub or wash, or use in conjunction with a device (such as a scrub brush), contributes to the effectiveness of these drug products. Therefore, instead of proposing directions for use of these products that include fixed scrub or wash durations or methods of application, the agency is proposing in §§ 333.455(c), 333.460(d), and 333.465(c) directions for use that reflect the conditions used when the antiseptic product was tested according to § 333.470(b). In addition, based on data indicating that the largest bioburden of the hands lies in the subungual region (Ref. 4), the agency is proposing that the directions for use of surgical hand scrub drug products include the following instructions for the trimming and cleansing of the nails: "Clean under nails with a nail pick. Nails should be maintained with a 1 millimeter free edge."

References

(1) Ayliffe, G.A.J., "Surgical Scrub and Skin Disinfection," Infection Control, 5:23–27, 1984.

(2) Maki, D.G., "The Use of Antiseptics for Handwashing by Medical Personnel," *Journal of Chemotherapy*, 1:3–11, 1989.

(3) Ojajarvi, J., "Effectiveness of Hand Washing and Disinfection Methods in Removing Transient Bacteria After Patient Nursing," *Cambridge University Journal of Hygiene*, 85:193–203, 1980.

(4) Leyden, J. *et al.*, "Subungual Bacteria of the Hand: Contribution to the Glove Juice Test; Efficacy of Antimicrobial Detergents," *Infection Control Hospital Epidemiology*, 10:451–454, 1989.

11. The agency is aware that some manufacturers provide technical information relating to the antimicrobial activity of their health-care antiseptic drug products in the form of technical information bulletins. The agency considers such bulletins to be labeling under the provisions of the act. Section 201(m) of the act (21 U.S.C. 321(m)) defines the term "labeling" as "all labels and other written, printed, or graphic matter (1) upon any article or any of the containers or wrappers, or (2) accompanying such article." As labeling, technical information bulletins are subject to the OTC drug review.

The agency has no objection to the inclusion of technical information relating to the antimicrobial activity of these OTC drug products in the labeling of products intended for health-care professionals only. Therefore, in this amended tentative final monograph the agency is proposing that manufacturers have the option of including data derived from the in vitro and clinical effectiveness tests included in § 333.470 of the proposed monograph as additional labeling for products labeled and marketed "For Hospital and Professional Use Only." In order that such additional information provide a standardized comparison of the effectiveness of these OTC drug products, the agency is further proposing that only data on the antimicrobial activity of these OTC drug products derived from the effectiveness tests included in § 333.470 of this

proposed monograph be included in the labeling of these OTC drug products. At the present time, claims of product effectiveness against organisms other than those included in § 333.470(a)(1)(ii) will require an NDA containing information supporting the deviation from the monograph in accord with § 330.11.

12. Based on the wound healing data from studies of test wounds in laboratory animals that were discussed in the first aid antiseptic segment of this amended tentative final monograph (comment 37, 56 FR 33644 at 33662), the agency has reevaluated the labeling for iodine tincture as a patient preoperative skin preparation and is not including the warning "Do not apply this product with a tight bandage, as a burn may result."

13. The agency has determined that data and reports have not provided specific evidence that repeated use of health-care antiseptics has brought about overgrowth of gram-negative bacteria, particularly *Pseudomonas*. Therefore, the previously proposed caution in § 333.99(a) concerning this overgrowth is not being included in this amended tentative final monograph. (See section I.D, comment 9.) The warnings proposed in § 333.99 (b) and (c) of the previous tentative final monograph are not being included in this amendment because these warnings apply to quaternary ammonium compounds which currently are not Category I for health-care antiseptic uses. (See section I.J., comment 20.)

14. The agency is not including the warning proposed by the Miscellaneous External Panel in § 333.98(c)(2) for products containing isopropyl alcohol, "Use only in a well-ventilated area; fumes may be toxic." As discussed in section II.B., paragraph 32 of the segment of this rulemaking covering first aid antiseptics (56 FR 33644 at 33556), the agency invites comment on the need for such a warning, including any reports of adverse reactions due to inhalation that have not yet been brought to the agency's attention.

15. In an effort to simplify OTC drug labeling, the agency proposed in a number of tentative final monographs to substitute the word "doctor" for "physician" in OTC drug monographs on the basis that the word "doctor" is more commonly used and better understood by consumers. Based on comments to these proposals, the agency has determined that final monographs and any applicable OTC drug regulations will give manufacturers the option of using the word "physician" or the word "doctor." This amended tentative final monograph proposes that option in § 333.450(e).

16. Based on the withdrawal of the majority of the comments on chlorhexidine gluconate as a health-care antiseptic, sufficient data upon which to make a safety and effectiveness determination are no longer present in the rulemaking. (See section I.F., comment 11.)

17. The agency has reviewed the data submitted on chloroxylenol and is classifying chloroxylenol 0.24 percent to 3.75 percent as Category I for safety and Category III for effectiveness for short-term use (patient preoperative skin preparation) and Category III for both safety and effectiveness for long-term uses (antiseptic handwash or health-care personnel handwash and surgical hand scrub). (See section I.G., comment 12.)

18. In § 333.30(a) of the previous tentative final monograph, the agency included United States Pharmacopeia (U.S.P.) specifications for iodine tincture and topical solution. In this amended tentative final monograph, the agency is identifying these Category I patient preoperative products as iodine tincture U.S.P. and iodine topical solution U.S.P.

19. The agency has reviewed the submitted data on hexachlorophene and concludes that the data do not address the safety concerns expressed by the Antimicrobial I Panel on this ingredient. Therefore, the agency is proposing that hexachlorophene remain available by prescription only. (See section I.H., comment 13.)

20. The agency has evaluated a "mixed iodophor" consisting of iodine complexed by ammonium ether sulfate and polyoxyethylene sorbitan monolaurate and found it to be safe for use as a surgical hand scrub and health-care personnel handwash, but there are insufficient data available to determine its effectiveness for these uses. Therefore, it is being classified in Category III. (See section I.I., comment 15.) The other iodine-surfactant complexes classified by the Antimicrobial I Panel remain in Category III for health-care uses due to a lack of data.

21. The agency is including povidone-iodine 5 to 10 percent as a Category I health-care antiseptic ingredient for use as a surgical hand scrub, patient preoperative skin preparation, and antiseptic handwash or health-care personnel handwash. (See section I.I., comment 17.) As discussed in section I.I., comment 16, the agency is not including the warning about the interaction of iodophors and starch-containing compounds proposed in comment 66 of the previous tentative final monograph (43 FR 1221). The agency is also not including professional labeling to limit the molecular weight of povidone-iodine or special warnings related to the molecular weight of povidone-iodine. (See section I.I., comment 18.)

22. The agency has evaluated the data submitted on benzalkonium chloride and determined that the data are not sufficient to establish the efficacy of this ingredient as a patient preoperative skin preparation. (See section I.J., comment 20.) No data were received on other health-care uses of this ingredient or health-care uses of the two other quaternary ammonium compounds (benzethonium chloride and methylbenzethonium chloride) classified by the Antimicrobial I Panel. Accordingly, quaternary ammonium compounds remain in Category III as health-care antiseptics.

23. The agency has reviewed data submitted on sodium oxychlorosene, an ingredient not previously classified for OTC topical antiseptic use, and is placing this ingredient in Category III for both safety and effectiveness. (See section I.K., comment 22.)

24. The agency has reclassified triclosan up to 1 percent from Category II to Category III as a health-care antiseptic for use as a patient preoperative skin preparation, antiseptic handwash or health-care personnel handwash, and surgical hand scrub. While submitted data indicate that triclosan—when properly formulated—may be effective, data that meet the criteria described in section I.N., comment 28 are needed to establish effectiveness. In addition, based upon submitted safety data and other information, the agency has reclassified the ingredient from Category III to Category I for safety for short-term use as a patient preoperative skin preparation. Triclosan remains classified in Category III for long-term use (antiseptic handwash or health-care personnel handwash and surgical hand scrub). (See section I.L., comment 23.)

25. The agency is proposing a number of Category I health-care antiseptic ingredients in this document. All of the ingredients included in this proposal as Category I health-care antiseptic ingredients are standardized and characterized for quality and purity and are included as articles in the current United States Pharmacopeia or National Formulary (U.S.P./N.F.) (Ref. 1). However, a number of other ingredients being considered in this rulemaking, *e.g.*, triclosan and triclocarban are not listed in the U.S.P./N.F. For an active ingredient to be included in an OTC

drug final monograph, in addition to information demonstrating safety and effectiveness, it is necessary to have publicly available sufficient chemical information that can be used by all manufacturers to determine that the ingredient is appropriate for use in their products.

The agency believes that it would be appropriate for parties interested in upgrading nonmonograph ingredients to monograph status to develop with the United States Pharmacopeial Convention appropriate standards for the quality and purity of health-care antiseptic ingredients that are not already included in official compendia. However, should interested parties fail to provide necessary information so that appropriate standards may be established, ingredients otherwise eligible for monograph status will not be included in the final monograph.

Reference

(1) "United States Pharmacopeia XXII—National Formulary XVII," United States Pharmacopeial Convention, Inc., Rockville, MD, 1989, pp. 34, 703, 731, and 1119.

26. The agency is proposing testing requirements for patient preoperative skin preparation, antiseptic handwash or health-care personnel handwash, and surgical hand scrub drug products in § 333.470 of this tentative final monograph. As part of the effectiveness criteria for a patient preoperative skin preparation, the agency is proposing new testing requirements for products labeled with the proposed indication "for the preparation of the skin prior to an injection." (See section I.N., comment 28.)

27. The agency acknowledges that deodorancy is considered a cosmetic claim. However, some deodorant soap products also bear antimicrobial claims. The agency stated in comment 10 of the tentative final monograph for OTC first aid antiseptic drug products (56 FR 33644 at 33648) that deodorant soap products making antimicrobial claims are considered to be drugs and that the testing guidelines for antimicrobial claims would be addressed in this rulemaking. Any deodorant soap product containing a monograph ingredient may be labeled with antimicrobial claims provided the product meets the testing requirements for health-care antiseptic drug products or surgical hand scrubs as described under proposed § 333.470.

The agency stated in the previous tentative final monograph for topical antimicrobial drug products (43 FR 1210 at 1244) that actual claims of deodorancy should correlate the microbial reduction achieved in a modified Cade handwashing test to an "adequately designed and executed deodorancy test, such as controlled sniff test." Several comments to that proposal objected to such a correlation of deodorancy and microbial reduction. However, none of the comments provided satisfactory data to enable the agency to include any test in a monograph as a standard for deodorancy due to antimicrobial activity. Specific testing for antimicrobial claims for deodorancy has not yet been developed. The agency intends to review any comments or methods submitted for such a purpose in response to this publication and invites comments and data on this topic.

28. The Panel's evaluation of OTC topical antimicrobial drug products did not include an evaluation of the use of these products by the food industry as hand sanitizers or dips. Historically, hand sanitizers and dips have been marketed as hand cleansers for use by food handlers in federally inspected meat and poultry processing plants and in food handling establishments. Regulation of these products has been under the jurisdiction of the U. S. Department of Agriculture. However, it has come to the agency's attention that many of these products include label claims that the agency considers drug claims, *i.e.*, "antibacterial handwash," "kills germs and bacteria on contact," or "effectively reduces bacterial flora of the skin". (See comment 10 of the tentative final monograph for OTC first aid antiseptic drug products (56 FR 33644 at 33648).) Examination of the labeling of these products (Ref. 1) has led the agency to conclude that the intended use of these products, *i.e.*, the reduction of micro-organisms on human skin for the purpose of the prevention of disease caused by contaminated food, makes them drugs under the provisions of the act. Section 201(g)(1) of the act (21 U.S.C. 321(g)(1)) defines a "drug" as an article "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man * * *."

The safety and effectiveness of active ingredients in these products for drug use needs to be demonstrated. Therefore, the agency is including evaluation of the safety and effectiveness of topical antimicrobial active ingredients indicated for use as hand sanitizers or dips in the rulemaking for OTC topical antimicrobial drug products. Accordingly, the agency invites the submission of data, published or unpublished, and any other information pertinent to the use of topical antimicrobial ingredients in hand sanitizers or dips. The agency also invites comment on applicable effectiveness standards for these products. These data and information will facilitate the agency's review and aid in its determination as to whether these OTC drug products for human use are safe, effective, and not misbranded under their recommended conditions of use. This evaluation will provide all interested parties an opportunity to present for consideration the best data and information available to support the stated claims for these products. The agency suggests that all submissions be in the format described in 21 CFR 330.10(a)(2).

In order to be eligible for review under the OTC drug review procedures, the ingredient must have been marketed in a hand sanitizer or dip to a material extent and for a material time (21 U.S.C. 321(p)(2)). The submission of data should include information that demonstrates that the ingredient(s) has been marketed as a hand sanitizer or dip to a material extent and for a material time. Products with ingredients under consideration in the OTC drug review may be marketed (at the same dosage strength and in the same dosage form) under the manufacturer's good faith belief that the product is generally recognized as safe and effective and not misbranded and in accord with FDA's enforcement policies related to the OTC drug review. (See FDA's Compliance Policy Guides 7132b.15 and 7132b.16.) Such products are marketed at the risk that the agency may adopt a position requiring relabeling, recall, or other regulatory action.

The agency notes that antimicrobial hand sanitizers/dips marketed for use in food handling/processing are typically labeled for a variety of other antimicrobial uses that may include various animal "drug" uses and the disinfection of inanimate objects. These other uses of hand sanitizer or dips will not be included in the agency's evaluation as part of this rulemaking.

Reference

(1) Labeling for hand sanitizer products, in OTC Vol. 230001, Docket No. 75N–183H, Dockets Management Branch.

29. The agency is proposing to remove a portion of § 369.21 applicable to OTC health-care antiseptic drug products when the final monograph eventually becomes effective because a portion of the regulations will be superseded by the final monograph. The item proposed for removal is the entry for "ALCOHOL RUBBING COMPOUND" in § 369.21.

III. Analysis of Impacts

FDA has examined the impacts of this proposed rule under Executive Order

12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and, thus, is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. This proposed rule increases the number of ingredients tentatively classified as generally recognized as safe and effective for use in OTC health-care antiseptic drug products from the previous proposal and, if finalized as proposed, would reduce the need for further safety and effectiveness testing for a number of health-care antiseptic drug products. The detailed testing procedures included in the proposed rule should assist manufacturers of products containing ingredients not included in the proposed monograph, due to a lack of demonstrated effectiveness, in performing the tests that would demonstrate effectiveness so the ingredients can be included in the final rule. The testing procedures will also provide manufacturers guidance on testing requirements for regulatory compliance. Products that contain ingredients for which safety and effectiveness are not established will require reformulation. The proposed monograph includes ingredients that may be used if reformulation becomes necessary. All products will need some relabeling. One year will be provided from the date of publication of the final rule for any necessary relabeling or reformulation. Accordingly, the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

The agency invites public comment regarding any substantial or significant economic impact that this rulemaking would have on OTC health-care antiseptic drug products. Types of impact may include, but are not limited to, costs associated with product testing, relabeling, repackaging, or reformulation. Comments regarding the impact of this rulemaking on OTC health-care antiseptic drug products should be accompanied by appropriate documentation. Because the agency has not previously invited specific comment on the economic impact of the OTC drug review on health-care antiseptic drug products, a period of 180 days from the date of publication of this proposed rulemaking in the **Federal Register** will be provided for comments on this subject to be developed and submitted. The agency will evaluate any comments and supporting data that are received and will reassess the economic impact of this rulemaking in the preamble to the final rule.

The agency has determined under 21 CFR 25.24(c)(6) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Interested persons may, on or before December 14, 1994, submit to the Dockets Management Branch, written comments, objections, or requests for oral hearing before the Commissioner on the proposed regulation. A request for an oral hearing must specify points to be covered and time requested. Written comments on the agency's economic impact determination may be submitted on or before December 14, 1994. Three copies of all comments, objections, and requests are to be submitted, except that individuals may submit one copy. Comments, objections, and requests are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Comments, objections, and requests may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. Any scheduled oral hearing will be announced in the **Federal Register**.

Interested persons, on or before June 19, 1995, may also submit in writing new data demonstrating the safety and effectiveness of those conditions not classified in Category I. Written comments on the new data may be submitted on or before August 17, 1995. These dates are consistent with the time periods specified in the agency's final rule revising the procedural regulations for reviewing and classifying OTC drugs, published in the **Federal Register** of September 29, 1981 (46 FR 47730). Three copies of all data and comments on the data are to be submitted, except that individuals may submit one copy, and all data and comments are to be identified with the docket number found in brackets in the heading of this document. Data and comments should be addressed to the Dockets Management Branch. Received data and comments may also be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

In establishing a final monograph, the agency will ordinarily consider only data submitted prior to the closing of the administrative record on August 17, 1995. Data submitted after the closing of the administrative record will be reviewed by the agency only after a final monograph is published in the **Federal Register**, unless the Commissioner finds good cause has been shown that warrants earlier consideration.

Therefore, the agency is proposing to amend 21 CFR part 333 by adding new subpart E, consisting of §§ 333.401 through 333.470, and to amend 21 CFR part 369 by amending § 369.21 in order to establish conditions under which OTC health-care antiseptic drug products are generally recognized as safe and effective and not misbranded.

List of Subjects

21 CFR Part 333

Labeling, Over-the-counter drugs, Incorporation by reference.

21 CFR Part 369

Labeling, Medical devices, Over-the-counter drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 333 and 369 be amended as follows:

PART 333—TOPICAL ANTIMICROBIAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

1. The authority citation for 21 CFR part 333 is revised to read as follows:

Authority: Secs. 201, 501, 502, 503, 505, 510, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371).

2. New subpart E, consisting of §§ 333.401 through 333.470, is added to read as follows:

Subpart E—Health-Care Antiseptic Drug Products

Sec.

Subpart E—Health-Care Antiseptic Drug Products

§ 333.401 Scope.

(a) An over-the-counter health-care antiseptic drug product in a form suitable for topical administration is generally recognized as safe and effective and is not misbranded if it meets each of the conditions in this subpart and each of the general conditions established in § 330.1 of this chapter.

(b) References in this subpart to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

§ 333.403 Definitions.

As used in this subpart:

(a) *Antiseptic drug.* In accordance with section 201(o) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(o)), "The representation of a drug, in its labeling, as an antiseptic shall be considered to be a representation that it is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body."

(b) *Broad spectrum activity.* A properly formulated drug product, containing an ingredient included in the monograph, that possesses in vitro activity against the micro-organisms listed in § 333.470(a)(1)(ii), as demonstrated by in vitro minimum inhibitory concentration determinations conducted according to methodology established in § 333.470(a)(1)(ii).

(c) *Health-care antiseptic.* An antiseptic containing drug product applied topically to the skin to help prevent infection or to help prevent cross contamination.

(1) *Antiseptic handwash or health-care personnel handwash drug product.* An antiseptic containing preparation designed for frequent use; it reduces the number of transient micro-organisms on intact skin to an initial baseline level after adequate washing, rinsing, and drying; it is broad spectrum, fast acting and, if possible, persistent.

(2) *Patient preoperative skin preparation drug product.* A fast acting, broad spectrum, and persistent antiseptic containing preparation that significantly reduces the number of micro-organisms on intact skin.

(3) *Surgical hand scrub drug product.* An antiseptic containing preparation that significantly reduces the number of micro-organisms on intact skin; it is broad spectrum, fast acting, and persistent.

§ 333.410 Antiseptic handwash or health-care personnel handwash active ingredients.

The active ingredient of the product consists of any of the following within the specified concentration established for each ingredient properly formulated to meet the test requirements in § 333.470, and the product is labeled according to §§ 333.450 and 333.455:

(a) Alcohol 60 to 95 percent by volume in an aqueous solution denatured according to Bureau of Alcohol, Tobacco and Firearms regulations in 27 CFR part 20; or

(b) Povidone-iodine 5 to 10 percent.

§ 333.412 Patient preoperative skin preparation active ingredients.

The active ingredient of the product consists of any of the following within the specified concentration established for each ingredient properly formulated to meet the test requirements in § 333.470, and the product is labeled according to §§ 333.450 and 333.460:

(a) Alcohol 60 to 95 percent by volume in an aqueous solution denatured according to Bureau of Alcohol, Tobacco and Firearms regulations in 27 CFR part 20;

(b) Iodine tincture U.S.P.;

(c) Iodine topical solution U.S.P.;

(d) Isopropyl alcohol 70 to 91.3 percent by volume in an aqueous solution; and

(e) Povidone-iodine 5 to 10 percent.

§ 333.414 Surgical hand scrub active ingredients.

The active ingredient of the product consists of any of the following within the specified concentration established for each ingredient properly formulated to meet the test requirements in § 333.470, and the product is labeled according to §§ 333.450 and 333.465:

(a) Alcohol 60 to 95 percent by volume in an aqueous solution denatured according to Bureau of Alcohol, Tobacco and Firearms regulations in 27 CFR part 20; or

(b) Povidone-iodine 5 to 10 percent.

§ 333.420 Permitted combinations of active ingredients.

[Reserved]

§ 333.450 Labeling of health-care antiseptic drug products.

(a) *Statement of identity.* The labeling of a single-use product contains the established name of the drug, if any, and identifies the product as an "antiseptic" and/or with the appropriate statement of identity described in §§ 333.455(a), 333.460(a), or 333.465(a). The labeling of a multiple-use product contains the established name of the drug, if any, and may use the single statement of identity "antiseptic" and/or the appropriate statements of identity described in §§ 333.455(a), 333.460(a), and 333.465(a). When "antiseptic" is used as the only statement of identity on a single-use or a multiple-use product, the intended use(s), such as patient preoperative skin preparation, is to be included under the indications. For multiple-use products, a statement of the intended use should also precede the specific directions for each use.

(b) *Indications.* The labeling of a single use antiseptic drug product contains the labeling identified in §§ 333.455, 333.460, or 333.465, as appropriate. Multiple-use products contain the labeling from any two or all three of §§ 333.455, 333.460, and 333.465. Indications, warnings, and directions applicable to each intended use of the product may be combined to eliminate duplicative words or phrases so that the resulting indications, warnings, and directions are clear and understandable.

(c) *Warnings.* The labeling of the product contains the following warnings under the heading "Warnings":

(1) "For external use only."

(2) "Do not use in the eyes."

(3) "Discontinue use if irritation and redness develop. If condition persists for more than 72 hours consult a doctor."

(4) *For products containing any ingredient identified in §§ 333.410(a), 333.412(a) and (d), and 333.414(a).* The following statement shall immediately follow the heading "Warnings": "Flammable, keep away from fire or flame." [sentence in boldface type]

(d) The second sentence of the warning in paragraph (c)(3) of this section may be omitted from the labeling of products labeled "For Hospital and Professional Use Only."

(e) The word "physician" may be substituted for the word "doctor" in any of the labeling statements in §§ 333.455, 333.460, and 333.465.

(f) *Optional labeling information.* Technical information relating to the antimicrobial activity of products that is limited to data derived from the in vitro and clinical effectiveness tests included in § 333.470 may be included as

additional labeling for products labeled for "Hospital and Professional Use Only."

§ 333.455 Labeling of antiseptic handwash or health-care personnel handwash drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as an "antiseptic," as stated above under § 333.450(a), and/or "antiseptic handwash," or "health-care personnel handwash."

(b) *Indications.* The labeling of the product states, under the heading "Indications," any of the phrases listed in this paragraph that are applicable to the product. Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in paragraph (b) of this section, may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (the act) relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(1) *For products labeled as a health-care personnel handwash.* "Handwash to help reduce bacteria that potentially can cause disease" or "For handwashing to decrease bacteria on the skin" (which may be followed by one or more of the following: "after changing diapers," "after assisting ill persons," or "before contact with a person under medical care or treatment.")

(2) *For products labeled as an antiseptic handwash.* "For handwashing to decrease bacteria on the skin" (which may be followed by one or more of the following: "after changing diapers," "after assisting ill persons," or "before contact with a person under medical care or treatment.")

(3) *Other allowable indications for products labeled as either antiseptic or health-care handwash.* The labeling of the product may also contain the following phrase: "Recommended for repeated use."

(c) *Directions.* The labeling of the product contains the following statements, under the heading "Directions," that reflect the conditions used when the product was tested according to § 333.470(b)(2):

(1) *For products to be used with water.* "Wet hands and forearms. Apply 5 milliliters (teaspoonful) or palmful to hands and forearms. Scrub thoroughly for" (insert wash duration used when tested according to § 333.470(b)(2)). (Insert any applicable statements about also using a device, such as a scrub brush.) "Rinse and repeat."

(2) *For products to be used without water.* "Place a 'palmful' (5 grams) of product in one hand. Spread on both hands and rub into the skin until dry (approximately 1 to 2 minutes). Place a smaller amount (2.5 grams) into one hand, spread over both hands to wrist, and rub into the skin until dry (approximately 30 seconds)" or "Wet hands thoroughly with product and allow to dry without wiping."

§ 333.460 Labeling of patient preoperative skin preparation drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as an "antiseptic," as stated under § 333.450(a), and/or "patient preoperative skin preparation."

(b) *Indications.* The labeling of the product states, under the heading "Indications," any of the phrases listed in paragraph (b) of this section. Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in this paragraph, may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (the act) relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(1) *For products containing ingredients identified in § 333.412 (a), (b), (c), and (e).* (i) "For preparation of the skin prior to surgery."

(ii) "Helps reduce bacteria that potentially can cause skin infection."

(2) *For products containing alcohol identified in § 333.412(a).* In addition to the indications listed in § 333.460(1), the labeling may also include the statement "For preparation of the skin prior to an injection."

(3) *For products containing isopropyl alcohol identified in § 333.412(d).* "For preparation of the skin prior to an injection."

(c) *Warnings.* For products containing 70 percent or more isopropyl alcohol the following warning shall immediately follow the warning statement in § 333.450(c)(4): "Do not use with electrocautery procedures."

(d) *Directions.* The labeling of the product contains the following statements, under the heading "Directions," that reflect the conditions used when the product was tested according to § 333.470(b)(3):

(1) *For products containing any ingredient identified in § 333.412(a), (d), and (e) that are intended to remain on the skin after application.* "Clean the area. Apply product to the operative site prior to surgery" (insert method of application, including any device used, when tested according to § 333.470 (b)(3).) If appropriate, insert "Dry and repeat procedure."

(2) *For products containing any ingredient identified in § 333.412(b) or (c) that are intended to be removed from the skin after application.* "Apply product to the operative site prior to surgery" (insert method of application, including any device used, when tested according to § 333.470(b)(3).) "When product dries, remove immediately with 70 percent alcohol, or use as directed by a physician."

§ 333.465 Labeling of surgical hand scrub drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as an "antiseptic," as stated above under § 333.450(a), and/or "surgical hand scrub."

(b) *Indication.* The labeling of the product states, under the heading "Indication," the following: "Significantly reduces the number of micro-organisms on the hands and forearms prior to surgery or patient care." Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in paragraph (b) of this section, may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (the act) relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(c) *Directions.* The labeling of the product contains the following statements, under the heading "Directions," that reflect the conditions used when the product was tested according to § 333.470(b)(1):

(1) *For products to be used with water.* "Clean under nails with a nail pick. Nails should be maintained with a 1 millimeter free edge. Wet hands and forearms. Apply 5 milliliters (teaspoonful) or palmful to hands and forearms. Scrub thoroughly for (insert scrub duration used when tested according to § 333.470(b)(1)) "with a sterile" (insert applicable device), "paying particular attention to the nails, cuticles, and interdigital spaces. Rinse and repeat scrub" (if applicable, insert instructions for second scrub used when

tested according to § 333.470(b)(1), if different from the first).

(2) *For products to be used without water.* "Clean under nails with a nail pick. Nails should be maintained with a 1 millimeter free edge. Place a 'palmful' (5 grams) of product in one hand. Spread on both hands, paying particular attention to the nails, cuticles, and interdigital spaces, and rub into the skin until dry (approximately 1 to 2 minutes). Place a smaller amount (2.5 grams) into one hand, spread over both hands to wrist, and rub into the skin until dry (approximately 30 seconds)."

§ 333.470 Testing of health-care antiseptic drug products.

(a) *General testing criteria.* The procedures in this section are designed to characterize the effectiveness of antiseptic drug products formulated for use as an antiseptic handwash or health-care personnel handwash, patient preoperative skin preparation, and surgical hand scrub. Requests for any modifications of the testing procedures in this section or alternative assay methods are to be submitted in accordance with paragraph (d) of this section.

(1) *In vitro testing.* The following tests must be performed using the antiseptic ingredient, the vehicle, and the finished product for all drug product classes:

(i) Determine the in vitro antimicrobial spectrum of the active ingredient, the vehicle, and the final formulation using both standard cultures and recently isolated strains of each species. A series of recently isolated mesophilic strains, including members of the normal flora and cutaneous pathogens (50 isolates of each species, half of which must be fresh clinical isolates), are to be selected.

(ii) Determine the minimal inhibitory concentrations (MIC) using methodology established by the National Committee for Clinical Laboratory Standards and entitled "Methods for Dilution Antimicrobial Susceptibility Test for Bacteria that Grow Aerobically," Document M7–A2, 2d ed., 10:8, 1990, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Committee for Clinical Laboratory Standards, 771 East Lancaster Ave., Villanova, PA 19085, or may be examined at the Center for Drug Evaluation and Research, 7520 Standish Pl., suite 201, Rockville, MD, or the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC. Twenty-five fresh clinical isolates and 25 laboratory strains of the organisms listed in this section are to be included. All in vitro tests must include the American Type Culture Collection (ATCC) reference strains (available from American Type Culture Collection, 12301 Parklawn Dr., Rockville, MD 20852) specified in paragraphs (a)(1)(ii)(A) and (a)(1)(ii)(B) of this section. The agency requires that these organisms be used in testing unless data can be presented to the agency that other organisms are equally representative of organisms associated with nosocomial infection. There must be no claims, either direct or by implication, that a product has any activity against an organism or that it reduces the number of organisms for which it has not been tested. The following organisms are to be included (note: special media and environmental conditions may be required):

(A) *Gram negative organisms: Acinetobacter* species; *Bacteroides fragilis*; *Haemophilus influenza*; *Enterobacter* species; *Escherichia coli* (ATCC Nos. 11229 and 25922); *Klebsiella* species, including *Klebsiella pneumonia*; *Pseudomonas aeruginosa* (ATCC Nos. 15442 and 27853); *Proteus mirabilis*; and *Serratia marcescens* (ATCC No. 14756).

(B) *Gram positive organisms*: Staphylococci: *Staphylococcus aureus* (ATCC Nos. 6538 and 29213); Coagulase-negative Staphylococci: *Staphylococcus epidermidis* (ATCC No. 12228), *Staphylococcus hominis*, *Staphylococcus haemolyticus*, and *Staphylococcus saprophyticus*; *Micrococcus luteus* (ATCC No. 7468); and Streptococci: *Streptococcus pyogenes*, *Enterococcus faecalis* (ATCC No. 29212), *Enterococcus faecium*, and *Streptococcus pneumoniae*.

(C) *Yeast*: *Candida* species and *Candida albicans*.

(iii) Determine the possible development of resistance to the chemical. Two approaches to determining the emergence of resistance to a particular antimicrobial are to be used. The first approach involves a determination of the evolution of a point mutation by the sequential passage of an organism through increasing concentrations of the antimicrobial included in the culture medium. The second approach is a thorough survey of the published literature to determine whether resistance has been reported for the antimicrobial ingredient. The survey is to include information on the microbial contamination of marketed products containing the antimicrobial ingredient in question irrespective of drug concentration. The survey is to cover all countries in which products containing the active ingredient are marketed. Any information submitted in a foreign language should include a translation. Alternate approaches to determining the development of resistance can be submitted as a petition in accord with § 10.30 of this chapter. The petition is to contain sufficient data to show that the alternate approach provides a reliable indication of the development of resistance to a particular antimicrobial ingredient.

(iv) *Time-kill studies.* (A) The assessment of the in vitro spectrum of the antimicrobial provides information on the types of genera and species that may be considered susceptible under the conditions of the test procedure described in paragraph (a)(1)(ii) of this section. However, information is also required that allows an assessment of how rapidly the antimicrobial product produces its effect. Such information may be derived from in vitro time-kill curve studies using a selected battery of organisms and a specified drug concentration.

(B) The satisfactory performance of the test product as assessed by the results of the MIC studies, the time-kill studies, and the simulated in vivo clinical trials of organisms representing the resident microbial flora can then be used to assess the effectiveness of the test product for the transient microbial flora most commonly encountered in the clinical setting. This procedure is required because methods, other than the health-care personnel hand test, do not exist for assessing the in vivo effectiveness of test products versus the transient microbial flora.

(C) It is recognized that a generally accepted or standardized method that may be used in conducting in vitro time-kill studies is not available, but the agency encourages the submission of proposed methods that may be considered applicable to this test. Many variables that should be considered in the development of a method have been addressed for antibiotics and are also applicable to these products. Such variables are described by Schoenknecht, F. D., L. D. Sabath, and C. Thornsberry, "Susceptibility Tests: Special Tests," in the "Manual of Clinical Microbiology," 4th ed., edited by E. H. Lennette et al., American Society for Microbiology, Washington, pp. 1,000–1,008, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the American Society for Microbiology, Washington, DC, or may be examined at the Center for Drug Evaluation and Research, 7520 Standish Pl., suite 201, Rockville, MD, or at the Office of the Federal Register, 800 North

Capitol St. NW., suite 700, Washington, DC.

(D) The procedure to be used is to incorporate the recommendations described on page 1,004 of the chapter in the "Manual of Clinical Microbiology" cited in paragraph (a)(1)(iv)(C) of this section with the following modifications. Because the time frames of greatest interest for antiseptic drug products intended for health-care personnel handwash, surgical hand scrub, and patient preoperative skin preparation use are 1 to 30 minutes, the time-kill studies are to focus on these time frames and are to include enumerations at times 0, 3, 6, 9, 12, 15, 20, and 30 minutes. Enumerate the bacteria in the sampling solution by a standard plate count procedure such as that described in "Standard Methods for the Evaluation of Dairy Products" (available from American Public Health Association, Inc., 1015 15th St. NW., Washington, DC 20005), but using soybean-casein digest agar and a suitable inactivator for the antimicrobial where necessary. The suitability of the inactivator is to be demonstrated using a procedure such as described in E 1054, "Test Methods for Evaluating Inactivators of Antimicrobial Agents Used in Disinfectant, Sanitizer, and Antiseptic Products," in "Annual Book of ASTM Standards," vol. 11.04, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from The American Society for Testing and Materials, 1916 Race St., Philadelphia, PA 19103–1187, or may be examined at the Center for Drug Evaluation and Research (HFD–810), 5600 Fishers Lane, Rockville, MD, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC. The battery of organisms selected is to represent the resident microbial flora most commonly encountered under actual use conditions of the test product and the transient microbial flora most likely to be encountered by health-care professionals in clinical settings. Therefore, the micro-organisms to be used in these time-kill studies are to be the standard ATCC strains identified in paragraph (a)(1)(ii) of this section. The drug concentration to be tested should be a tenfold dilution of the finished product.

(2) *In vivo testing.* The following tests, approximating use conditions for the clinical evaluation of each label claim of the finished product, are to be carried out using the finished product for the product classes specified.

(i) Test method for the evaluation of surgical hand scrub drug products. The procedure to be used (paragraph (b)(1)(iii) of this section) is a modification of the standard testing procedure for the evaluation of surgical hand scrub drug products published by the American Society for Testing and Materials, "Standard Method for Evaluation of Surgical Hand Scrub Formulation, Designation E 1115," in "The Annual Book of ASTM Standards," vol. 11.04, American Society for Testing and Materials, Philadelphia, pp. 201–204, 1986, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from The American Society for Testing and Materials, 1916 Race St., Philadelphia, PA 19103–1187, or may be examined at the Center for Drug Evaluation and Research, 7520 Standish Pl., suite 201, Rockville, MD, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(ii) Test method for the evaluation of health-care antiseptic handwash or health-care personnel handwash drug products. The procedure to be used (paragraph (b)(2)(iii) of this section) is a modification of the standard testing procedure for the evaluation of health-care antiseptic handwash drug products published by the American Society for Testing and Materials, "Standard Method for the Evaluation of Health Care Handwash Formulation, Designation E1174," in "The Annual Book of ASTM Standards," vol. 11.04, American Society for Testing and Materials, Philadelphia, pp. 209–212, 1987, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from The American Society for Testing and Materials, 1916 Race St., Philadelphia, PA 19103–1187, or may be examined at the Center for Drug Evaluation and Research, 7520 Standish Pl., suite 201, Rockville, MD, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(iii) Test method for the evaluation of patient preoperative skin preparation drug products. The procedure to be used (paragraph (b)(3)(iii) of this section) is a modification of the standard testing procedure for the evaluation of patient preoperative skin preparations published by the American Society for Testing and Materials, "Standard Test Method for the Evaluation of a Patient Preoperative Skin Preparation, Designation 1173," in "The Annual Book of ASTM Standards," vol. 11.04, American Society for Testing and Materials, Philadelphia, pp. 205–208, 1987, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from The American Society for Testing and Materials, 1916 Race St., Philadelphia, PA 19103–1187, or may be examined at the Center for Drug Evaluation and Research, 7520 Standish Pl., suite 201, Rockville, MD, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(b) *Specific testing criteria*—(1) *Effectiveness testing of a surgical hand scrub.* A surgical hand scrub drug product in finished form suitable for topical application will be recognized as effective provided that the formulated drug product at its recommended use concentration:

(i) Contains an ingredient in § 333.414 (a) or (b).

(ii) Demonstrates in vitro activity against organisms as described in paragraph (a)(1)(ii) of this section.

(iii) When tested, in vivo, by the test procedure for the evaluation of surgical hand scrub drug products in paragraph (b)(1)(iii) of this section, reduces the number of bacteria 1-$\log_{10}$ on each hand within 1 minute and the bacterial cell count on each hand does not subsequently exceed baseline within 6 hours on the first day, and produces a 2-$\log_{10}$ reduction of the microbial flora on each hand within 1 minute of product use by the end of the second day of enumeration, and a 3-$\log_{10}$ reduction of the microbial flora on each hand within 1 minute of product use by the end of the fifth day when compared to the established baseline.

(A) *Apparatus*—(*1*) *Colony Counter.* Any of several types may be used.

(*2*) *Incubator.* Any incubator capable of maintaining a temperature of 30±2 °C may be used.

(*3*) *Sterilizer.* Any suitable steam sterilizer capable of producing conditions of sterility is acceptable.

(*4*) *Timer (stop clock).* A timer that can be read in minutes and seconds.

(*5*) *Hand washing sink.* A sink of sufficient size to permit panelists to wash without touching hands to sink surface or other panelists.

(*6*) *Water faucet(s).* Water faucets should be located above the sink at a height that permits the hands to be held higher than the elbows during the washing procedure. (It is desirable for the height of the faucets to be adjustable.)

(*7*) *Tap water temperature regulator and temperature monitor.* Device(s) to monitor and regulate water temperature to 40±2 °C.

(B) *Materials and reagents*—(*1*) *Petri dishes.* Petri dishes for performing standard plate count should be 100 by 15 millimeters.

(*2*) *Bacteriological pipets.* Pipets of 10.0 and 2.2 or 1.1 milliliter capacity are recommended.

(*3*) *Water-dilution bottles.* Any sterilizable glass container having a 150 to 200 milliliter capacity and tight closures may be used.

(*4*) *Baseline control soap.* A liquid castile soap or other liquid soap containing no antimicrobial.

(*5*) *Gloves.* Sterile loose fitting gloves of latex, unlined, not possessing antimicrobial properties.

(*6*) *Test formulation.* Directions used to demonstrate the effectiveness of the test formulation are to be the same as those proposed for the use of the product including the use of a nail cleaner and/or brush, if indicated. If no directions are available, use directions provided in paragraph (b)(1)(iii)(J)(*3*) of this section.

(*7*) *Positive control formulation.* Any surgical hand scrub formulation approved by the Food and Drug Administration is acceptable.

(*8*) *Sampling solution.* (*i*) Dissolve 0.4 gram potassium phosphate, monobasic, 10.1 gram sodium phosphate, dibasic, and 1 gram Triton X–100 in 1 liter distilled water. Adjust to pH 7.8 with 0.1 Normal hydrochloric acid or 0.1 Normal sodium hydroxide. Dispense 50 to 100 milliliter volumes into water dilution bottles, or other suitable containers, and sterilize for 20 minutes at 121 °C. Include in the sampling solution used to collect bacterial samples from the hand following the final wash with the test formulation an antimicrobial inactivator specific for the test formulation being evaluated.

(*ii*) A definitive recommendation regarding the inclusion of an inactivator prior to the final wash cannot be made. The questions of whether residual neutralizer on the skin will reduce the effectiveness of the test formulation in subsequent washes and result in higher than expected bacterial counts and whether or not samples can be processed rapidly enough to avoid a decreased bacterial count due to the continued action of the test formulation should be considered when the decision concerning the use of a neutralizer in sampling solutions used for bacterial collection prior to the final wash is made. Whatever the decision, to facilitate the comparison of results across studies, the investigator is to indicate whether or not a neutralizer has been included.

(*9*) *Dilution fluid.* Butterfield's phosphate buffered water adjusted to pH 7.2 and containing an antimicrobial inactivator specific for the test formulation. Adjust pH with 0.1 Normal hydrochloric acid or 0.1 Normal sodium hydroxide.

(*10*) *Soybean-casein digest agar.* Supplemental polysorbate 80 (0.5 to 10 grams/liter) is to be added to the agar to stimulate the growth of lipophilic organisms. A suitable antimicrobial inactivator is also to be added.

(*11*) *Fingernail cleaning sticks.*

(*12*) *Sterile hand brushes (required only if specified for use with test formulation).* Products that specify the use of a device in conjunction with the antimicrobial are to include this information in the product labeling. The device is an integral part of the study. If gauze is to be used, then the product labeling is to reflect this condition of use.

(C) *Test panelists.* Panelists shall consist of healthy adult male and female volunteers who have no evidence of dermatosis, have not received antibiotics or taken oral contraceptives 2 weeks prior to the test, and who agree to abstain from these materials as described in paragraph (b)(1)(iii)(D)(*2*) of this section until the conclusion of the test.

(D) *Preparation of volunteers.* (*1*) At least 2 weeks prior to start of the test, enroll sufficient subjects per product being tested to satisfy the statistical criteria of the clinical trial design.

(*2*) Instruct the volunteers to avoid contact with antimicrobials (other than the test formulation) for the duration of the test. This restriction includes antimicrobial containing antiperspirants, deodorants, shampoos, lotions, soaps, and materials such as acids, bases, and solvents. Bathing in chlorinated pools and hot tubs is to be avoided. Volunteers are to be provided with a kit of nonantimicrobial personal care products for exclusive use during the test and rubber gloves to be worn when contact with antimicrobials cannot be avoided.

(E) *Selection of evaluable subjects.* After panelists have refrained from using antimicrobials for at least 2 weeks, perform wash with baseline control soap. Subjects are not to have washed their hands 2 hours prior to the baseline count determination. After washing, determine the first estimate of the baseline population by sampling both hands and enumerating the bacteria in the sampling solution. This is day 1 of the "baseline period." Repeat this baseline determination on days 3 and 7, days 3 and 5, or days 5 and 7 of the "baseline period" to obtain three estimates of the baseline population. Any subjects exhibiting counts greater than or equal to $1.5X10^5$ after the first and second estimates of the baseline populations are obtained can be assigned to products in accordance with the randomization plan described below. Sufficient evaluable subjects must be enrolled per arm to satisfy the statistical conditions of adequacy with at least 80 percent power and a test level of 5 percent.

(F) *Number of subjects.* The number of subjects required per arm of the study can be estimated from the following equation: $n \geq 2S^2(Z_{a/2}+Z_b)^2/D^2$, where:

S^2 is your estimate of variance;

$Z_{a/2}$ corresponds to the level of the test; for a 5 percent test level = 1.96;

Z_b corresponds to the power of the test; for 80 percent power = .842; and

D is the clinical difference of significance to be ruled out; say 20 percent of the active control's mean reduction from baseline at a specific time. For example, data from a number of glove juice studies submitted over the past few years to the agency as part of applications under part 314 of this chapter were reviewed to obtain information relative to the variance of the difference from baseline for count reduction data. For 128 standard deviations extracted, it was noted that 50 percent of the values are between .90 and 1.12; 25 percent are less than .90; and 25 percent are greater than 1.12. The range is from .49 to 1.73, the 25th percentile standard deviation is 0.66, the median standard deviation is 1.01, and the 75th percentile standard deviation is 1.20. The larger the standard deviation, the larger the sample size required to rule out a difference of clinical importance. Assuming that the active control surgical hand scrub produces a mean log reduction of 2.5 at hour 3 and the test hand scrub is to be within 20 percent of this, *i.e.*, D=0.5, and if S^2= 1.02, then n=64 subjects per arm of the study. Because blocks of six are recommended, the sample size per arm is 66. The S_2=1.44 corresponds to the 75th percentile in the data set. This gives a sample size of 90 subjects per arm. The total number of evaluable subjects required for a successful trial will depend upon the estimate of variance available and the number of products that need testing.

(G) *Study design.* A randomized, blinded, parallel arm design is to be used to test the products. Due to the nature of their constituents, some test surgical hand scrubs will require not only the use of an active control arm but also use of a vehicle control arm and perhaps a placebo control arm to demonstrate efficacy. The schematic layout of sampling times is given in Table 1 as follows:

TABLE 1.—SAMPLING TIMES FOR SURGICAL HAND SCRUB EFFECTIVENESS TEST

Days	Hours			
	Baseline period	1/60	3	6
Day 0	X			
Day 1		X	X	X
Day 3 or 5		X	X	X
Day 5 or 7		X	X	X

The schematic layout of randomization of subjects in blocks of 6 is given in Table 2; in Table 2, R refers to right hand and L refers to left hand as follows:

TABLE 2.—RANDOMIZATION OF SUBJECTS FOR SURGICAL HAND SCRUB EFFECTIVENESS TEST

Subjects	Hours		
	1/60	3	6
A	R	L	
B	L	.....	R
C	.....	L	R
D	L	R	
E	R	.....	L
F	.....	R	L
Total Observations.	4	4	4

Assume N evaluable subjects are enrolled (the issue of determining N, the sample size, is discussed in paragraph (b)(1)(iii)(F) of this section). First, randomly divide the N subjects into as many treatment groups as there are products to be tested (n_t). Secondly, randomize the n_t subjects within each treatment group in blocks of six subjects in accordance with the subject allocation scheme in Table 2 of paragraph (b)(iii)(G) of this section until all n_t patients are randomized to 6 hours. Repeat this process for each of the other treatment groups.

(H) *Count determinations.* No sooner than 12 hours, nor longer than 4 days after completion of their baseline determination, subjects perform the initial scrub with the test formulations. Determine the bacterial population on the randomly designated hand of all subjects assigned to hour 1/60 in Table 2 of paragraph (b)(iii)(G) of this section immediately (within 1 minute) after scrub with the appropriate scrub formulation. Determine the bacterial counts on the designated hands at 3 and 6 hours after scrub. Determine bacterial population by sampling hands and enumerating the bacteria in the sampling solution as specified in paragraphs (b)(1)(iii)(K) and (b)(1)(iii)(L) of this section. Repeat this scrubbing and sampling procedure the next day (day 2). On day 5, repeat the sampling procedure after scrubbing with the formulations two additional times on day 2 and three times per day on day 3 and day 4, with at least a 1-hour interval between scrubs. Perform one scrub on day 5, prior to sampling. In summary, the subjects scrub a total of 11 times with each formulation, once on days 1 and 5 and 3 times per day on days 2, 3, and 4. Collect bacterial samples following the single scrubs of days 1 and 5 and following the first scrub on day 2. This procedure mimics typical usage and permits determination of both immediate and longer-term reductions.

(I) *Washing technique for baseline determinations.* (*1*) Volunteers clean under fingernails with nail stick and clip fingernails to less than or equal to 2 millimeter free edge. Remove all jewelry from hands and arms.

(*2*) Rinse hands including two thirds of forearm under running tap water 38 to 42 °C for 30 seconds. Maintain hands higher than elbows during this procedure and steps outlined in paragraphs (b)(1)(iii)(I)(*3*), (b)(1)(iii)(I)(*4*), and (b)(1)(iii)(I)(*5*) of this section.

(*3*) Wash hands and forearms with baseline control soap for 30 seconds using water as required to develop lather.

(*4*) Rinse hands and forearms for 30 seconds under tap water to thoroughly remove all lather.

(*5*) Don rubber gloves used in sampling hands and secure gloves at wrist.

(J) *Surgical scrub technique to be used prior to bacterial sampling.* (*1*) Repeat procedure outlined in paragraphs (b)(1)(iii)(I)(*1*) and (b)(1)(iii)(I)(*2*) of this section.

(*2*) Perform surgical scrub with test formulation in accordance with directions furnished with the test formulation. If no instructions are provided with the test formulation, use the 10-minute scrub procedure described in paragraph (b)(1)(iii)(J)(*3*) of this section.

(*3*) Perform 10-minute scrub procedure as follows:

(*i*) Dispense formulation into hands.

(*ii*) Set and start timer for 5 minutes (time required for the steps described in paragraphs (b)(1)(iii)(J)(*3*)(*iii*) through (b)(1)(iii)(J)(*3*)(*vii*) of this section.

(*iii*) With hands, distribute formulation over hands and lower two-thirds of forearms.

(*iv*) If scrub brush is to be used, pick up with finger tips and pass under tap to wet without rinsing formulation from hands.

(*v*) Alternatively, scrub right hand and lower two-thirds of forearm and left hand and lower two-thirds of forearm.

(*vi*) Rinse both hands, the lower two-thirds of forearms, and the brush for 30 seconds.

(*vii*) Place brush in sterile dish within easy reach.

(*viii*) Repeat the timed 5 minute scrub in paragraphs (b)(1)(iii)(J)(*3*)(*iii*) through (b)(1)(iii)(J)(*3*)(*vii*) of this section so that each hand and forearm is washed twice. The second wash and rinse should be limited to the lower one-third of the forearms and the hands.

(*ix*) Perform final rinse. Rinse each hand and forearm separately for 1 minute per hand.

(*x*) Don rubber gloves used in sampling hands and secure at wrist.

(K) *Sampling techniques.* (*1*) At specified sampling times, aseptically add 50 to 100 milliliters of sampling solution to glove and hand to be sampled, and fasten glove securely above wrist.

(*2*) After adding sampling solution, uniformly massage all surfaces of hand for 1 minute, paying particular attention to the area under the nails.

(*3*) After massaging, aseptically sample the fluid of the glove. Transfer immediately a measured volume of the sample to a serial dilution tube containing a suitable antimicrobial inactivator.

(L) *Enumeration of bacteria in sampling solution.* Enumerate the bacteria in the sampling solution by a standard plate count procedure such as that described in "Standard Methods for the Evaluation of Dairy Products" (available from American Public Health

Association, Inc., 1015 15th St. NW., Washington, DC 20005) but using soybean-casein digest agar and a suitable inactivator for the antimicrobial where necessary. The suitability of the inactivator is to be demonstrated using a procedure such as described in E 1054, "Test Methods for Evaluating Inactivators of Antimicrobial Agents Used in Disinfectant, Sanitizer, and Antiseptic Products," in "Annual Book of ASTM Standards," vol. 11.04, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from The American Society for Testing and Materials, 1916 Race St., Philadelphia, PA 19103–1187, or may be examined at the Center for Drug Evaluation and Research, 7520 Standish Pl., suite 201, Rockville, MD, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC. Prepare sample dilutions in dilution fluid. Plate in duplicate. Incubate plated sample at 30 ± 2 °C for 48 hours before reading.

(M) *Determination of reduction obtained.* (*1*) At each sampling interval, determine changes from baseline counts obtained with test material.

(*2*) For a more realistic appraisal of the activity of products, all raw data should be converted to common (base 10) logarithms. Reductions should be calculated from average of the logarithms. This will also facilitate statistical analysis of data.

(N) *Comparison of test materials with a positive control material.* (*1*) In order to validate the testing procedure, equipment, and facilities, it is required that the test formulation be compared with an active control formulation. This will require an equivalent number of panelists to be assigned to the control formulation on a random basis. All test parameters will be equivalent for both formulations, except that the scrub procedure for the established formulation may be different from that of the test formulation. Both test and control formulations are to be run concurrently. Identity of the formulations used by panelists are to be blinded from those individuals counting plates and analyzing data.

(*2*) To validate the assay, compare changes from baseline counts obtained with control material at each sampling interval.

(O) *Statistical analyses.* Either of the statistical approaches to the evaluation of the data detailed in paragraph (b)(1)(iii)(O) of this section is acceptable.

(*1*) Treat data as a binomial response. That is, if a subject achieves the target reduction, it is judged a success; if not it is a failure. A potential problem to this approach is that information may be lost. For example, if at the 1 minute time frame, a large number of subjects using one skin scrub achieve a 2-log reduction and those on the other scrub attain only a 1-log reduction, the binomial procedure will indicate both scrubs achieve the same degree of reduction. If it is believed that the binomial approach causes loss of information by not including numerical response data, then the alternate statistical analysis described in paragraph (b)(1)(iii)(0)(*2*) of this section is applicable. If the success rate is in the 90 percent range, then the variance is relatively small, sample size requirements are relatively small, and confidence intervals are reasonable. However, if the success rates drop to the 70 percent range, then relatively large sample sizes are required to obtain the same power as one gets for 90 percent success rates.

(*2*) Another option is to treat the log counts as numerical data and evaluate using the Student's t-test or similar procedure. The large variance that usually occurs with this type of data may cause problems with tests of significance and construction of confidence intervals. However, Monte Carlo techniques indicate that if entry is limited to subjects that exhibit 1.5×10^5 to 10^6 counts, then the reductions are rather homogeneous and the large variance problem is alleviated. If the variances are large, the sample size must be increased considerably to retain the same level of the test, same power, and same difference to be ruled out.

(2) *Effectiveness testing of an antiseptic handwash or health-care personnel handwash.* An antiseptic handwash or health-care personnel handwash drug product in finished form suitable for topical application will be recognized as effective provided that the formulated drug product at its recommended use concentration:

(i) Contains an ingredient in § 333.410 (a) or (b).

(ii) Demonstrates in vitro activity against organisms as described in paragraph (a)(1)(ii) of this section.

(iii) When tested, in vivo, by the test method for the evaluation of antiseptic or health-care personnel handwash drug products described in paragraph (b)(2)(iii) of this section, reduces the number of the indicator organism on each hand 2 $\log_{10}$ within 5 minutes after the first wash and demonstrates a 3-$\log_{10}$ reduction of the indicator organism on each hand within 5 minutes after the tenth wash.

(A) *Apparatus.*—(*1*) *Colony Counter.* Any of several types may be used.

(*2*) *Incubator.* Any incubator capable of maintaining a temperature of 25±2 °C may be used. This temperature is required to assure pigment production by the *Serratia marcescens.*

(*3*) *Sterilizer.* Any suitable steam sterilizer capable of producing conditions of sterility is acceptable.

(*4*) *Timer (stop clock).* A timer that can be read in minutes and seconds.

(*5*) *Hand washing sink.* A sink of sufficient size to permit panelists to wash without touching hands to sink surface or other panelists.

(*6*) *Water faucet(s).* Water faucet(s) should be located above the sink at a height that permits the hands to be held higher than the elbows during the washing procedure. (It is desirable for the height of the faucet(s) to be adjustable.)

(*7*) *Tap water temperature regulator and temperature monitor.* Device(s) to monitor and regulate water temperature to 40±2 °C.

(B) *Materials and reagents.*—(*1*) *Bacteriological pipets.* Pipets of 10.0 and 2.2 or 1.1 milliliter capacity are recommended.

(*2*) *Water-dilution bottles.* Any sterilizable glass container having a 150 to 200 milliliter capacity and tight closures may be used.

(*3*) *Erlenmeyer flask.* A 2-liter capacity for culturing test organism is recommended.

(*4*) *Baseline control soap.* A liquid castile soap or other liquid soap containing no antimicrobial.

(*5*) *Test formulation.* Directions used to demonstrate the effectiveness of the test formulation are to be the same as those proposed for the use of the product. If no directions are available, use directions provided in paragraph (b)(2)(iii)(H)(*5*) of this section.

(*6*) *Positive control formulation.* Any health-care personnel handwash formulation approved by the Food and Drug Administration is acceptable.

(*7*) *Gloves/bags.* Sterile loose fitting gloves of latex, unlined, possessing non-antimicrobial properties or sterile polyethylene bags are to be used.

(*8*) *Sampling solution.* Dissolve 0.4 gram potassium phosphate, monobasic, 10.1 gram sodium phosphate, dibasic, and 1 gram Triton X–100 in 1 liter distilled water. Adjust to ph 7.8 with 0.1 Normal hydrochloric acid or 0.1 Normal sodium hydroxide. Dispense 50 to 100 milliliter volumes into water dilution bottles, or other suitable containers, and sterilize for 20 minutes at 121 °C.

(*9*) *Dilution fluid.* Butterfield's phosphate buffered water adjusted to pH 7.2 and containing an antimicrobial inactivator specific for the test formulation. Adjust pH with 0.1 Normal

hydrochloric acid or 0.1 Normal sodium hydroxide.

(*10*) *Plating medium.* Soybean-casein digest agar plus a suitable inactivator.

(*11*) *Broth.* Soybean-casein digest: 1,000 milliliters per 2-liter flask is recommended.

(C) *Test Organism.* (*1*) *Serratia marcescens* ATCC No. 14756 (available from American Type Culture Collection, 12301 Parklawn Dr., Rockville, MD 20852) is to be used as a marker organism. This is a strain having stable pigmentation.

(*2*) The application of micro-organisms to the skin may involve a health risk. Prior to applying the *Serratia marcescens* strain to the skin, the antimicrobial sensitivity profile of the strain should be determined. If the strain is not sensitive to Gentamicin, do not use it. If an infection occurs, the antibiotic sensitivity profile should be made available to the attending clinician.

(*3*) Following the last contamination and wash with the test formulation, the panelists' hands are to be sanitized by scrubbing with a 70 percent ethanol solution. The purpose of this alcohol scrub is to destroy any residual *Serratia marcescens.*

(*4*) *Preparation of marker culture suspension.* From stock culture inoculate *Serratia marcescens* ATCC No. 14756 in a 2-liter flask containing 1,000 milliliters of Soybean-casein digest broth. Incubate for 24 ± 4 hours at 25 °C. Stir or shake the suspension before each aliquot withdrawal. Assay the suspension for number of organisms by membrane filtration technique or surface inoculation at the beginning and end of the use period. Do not use a suspension for more than 8 hours.

(D) *Test panelists.* Recruit a sufficient number of healthy adult male and female human volunteers who have no clinical evidence of dermatosis, open wounds, hangnail, or other skin disorders that may affect the integrity of the test, and enroll sufficient subjects per product being tested to satisfy the statistical criteria of the clinical trial design.

(E) *Preparation of volunteers.* Instruct the volunteers to avoid contact with antimicrobials (other than the test formulation) for the duration of the test. This restriction includes antimicrobial containing antiperspirants, deodorants, shampoos, lotions, soaps, and materials such as acids, bases, and solvents. Bathing in chlorinated pools and hot tubs is to be avoided. Volunteers are to be provided with a kit of nonantimicrobial personal care products for exclusive use during the test and rubber gloves to be worn when contact with antimicrobials cannot be avoided.

(F) *Number of subjects required.* The standard deviations for antiseptic handwash or health-care personnel handwash obtained when an inoculant such as *Serratia marcescens* is used are more homogeneous than those for surgical hand scrub products discussed in paragraph (b)(1)(iii)(F) of this section. The standard deviations extracted from data submitted to the agency as part of applications under part 314 of this chapter for these drug products range from 0.31 to 0.92; the median standard deviation is 0.71. The sample size estimation equation in paragraph (b)(1)(iii)(F) of this section may be used to estimate sample sizes required. For example, assume the active control hand scrub produces an immediate mean log reduction of 2.0 and the test hand scrub is to be within 20 percent of this, i.e., D=0.4. If S^2=0.71, then n=50 subjects per arm of the study. Because blocks of 6 are recommended, the sample size per treatment arm is 54 subjects.

(G) *Study design.* Randomization of subjects to time periods and treatment to hands will be accomplished in accordance with the plan presented previously.

(H) *Procedure.* (*1*) *Initial wash.* After panelists have refrained from using antimicrobials for at least 7 days, perform a 30-second practice wash in the same manner as is described for the test and control formulations, except that a solution of nonantimicrobial bland soap is used. This procedure removes oil and dirt and familiarizes the panelists with the washing technique.

(*2*) *Contaminant suspension and hand contamination.* The contaminant is a liquid suspension of *Serratia marcescens* containing at least 10^8 organisms per milliliter. Five milliliters of the contaminant culture are dispensed onto the hands then rubbed over the surfaces of the hands, not reaching above the wrist. Application and spreading should involve about 45 seconds. The hands are then held still away from the body and allowed to air dry for 2 minutes.

(3) *Contamination schedule.* The panelists' hands are contaminated with the marker organism according to the following schedule:

(*i*) Prior to the baseline bacterial sample collection.

(*ii*) Prior to all 10 washes with the test material.

(*4*) *Baseline recovery.* Baseline sample is taken after contamination of the hands to determine the number of marker organisms surviving on the hands after washing with a baseline control soap as described in paragraph (b)(2)(iii)(H)(*1*) of this section. Bacterial sampling will follow the procedures outlined in paragraph (b)(2)(iii)(H)(*6*) of this section.

(*5*) *Wash and rinse procedure.* The wash and rinse procedure described as follows is for all washes with the test formulation. A specified volume of the test formulation is dispensed onto the hands and rubbed over all surfaces, taking caution not to lose or dilute the substance. After the material is spread, a small amount of water is added from the tap and the hands are completely lathered for a specified time period. The lower third of the forearm is also washed. After completion of the wash, hands and forearms are rinsed under tap water at 40 ±2 °C for 30 seconds. A total of 10 washes with the test formulation is involved. Bacterial samples are taken following the 1st, 3rd, 7th, and 10th washes.

(*6*) *Bacterial sampling.* After the 1st, 3rd, 7th, and 10th washes, place rubber gloves or polyethylene bags used for sampling on the right and left hand. Sampling should occur within 5 minutes after each of these washes. Add 50 to 100 milliliters of sampling solution to each glove and secure gloves above the wrist. After adding sampling solution, uniformly massage all surfaces of the hand for 1 minute, paying particular attention to the area under the nails. After massaging aseptically, sample the fluid of the glove. Transfer immediately a measured volume of the sampling fluid to a test tube containing a suitable antimicrobial inactivator.

(*i*) Because contamination, product use, and enumeration are conducted sequentially within a time period of less than a day, an inactivator included in the sampling solution prior to the final wash may affect the test results. Therefore, no inactivator for the antimicrobial in the handwash formulation is to be included in the sampling solution prior to the final wash. The 50 to 100 milliliters of sampling fluid may be sufficient to dilute out the activity of the antimicrobial; however, this should be demonstrated using a procedure such as the one described in E 1054, "Test Methods for Evaluation Inactivators of Antimicrobial Agents Used in Disinfectants, Sanitizer, and Antiseptic Products," in "Annual Book of ASTM Standards," vol. 11.04, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from The American Society of Testing and Materials, 1916 Race St., Philadelphia, PA 19103–1187, or may be examined at the Center for Drug Evaluation and

Research, 7520 Standish Pl., suite 201, Rockville, MD, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(*ii*) If neutralization is not accomplished by dilution, include in the sampling solution used to collect the bacterial samples from the hand following the final wash with the test formulation an antimicrobial inactivator specific for the test formulation being evaluated.

(I) *Enumeration of bacteria in sampling solution.* (*1*) Enumerate the *Serratia marcescens* in the sampling solution using standard microbiological techniques, such as membrane filter technique or surface inoculation technique. Prepare sample dilutions in dilution fluid. Use Soybean-casein digest agar with suitable inactivator as recovery medium. The suitability of the inactivator for the antimicrobial should be demonstrated using a procedure such as described in E 1054, "Test Methods for Evaluating Inactivators of Antimicrobial Agents Used in Disinfectant, Sanitizer, and Antiseptic Products," in "Annual Book of ASTM Standards," vol. 11.04, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from The American Society of Testing and Materials, 1916 Race St., Philadelphia, PA 19103–1187, or may be examined at the Center for Drug Evaluation and Research, 7520 Standish Pl., suite 201, Rockville, MD, or at the Office of the **Federal Register**, 800 North Capitol St. NW., suite 700, Washington, DC. Incubate prepared plates 48 hours at 25±2 °C. Standard plate counting procedures are used to count only the red pigmented *Serratia marcescens*.

(*2*) [Reserved]

(J) *Determination of reduction.* Determine at each sampling interval changes from baseline counts obtained with test material.

(K) *Comparison with a positive control material.* (*1*) In order to validate the testing procedure, equipment, and facilities, it is required that the test formulation be compared with an active control formulation. This will require an equivalent number of panelists to be assigned to the control formulation on a random basis. All test parameters will be equivalent for both formulations, although the handwash procedure for the established formulation may be different from that of the test formulation. Both test and control formulations are to be run concurrently. The identity of the formulations used by panelists is to be blinded from those individuals counting plates and analyzing data.

(*2*) To validate the assay, compare, at each sampling interval, changes from baseline counts obtained with test material to changes obtained with control material.

(L) *Statistical analysis.* Because the hands are inoculated prior to sampling it is possible to generate counts of 1.5×10^5 to 10^6 organisms. Therefore, reductions are less variable and evaluation of the log counts using the Student's t- test or similar procedure is recommended.

(3) *Effectiveness testing of a patient preoperative skin preparation.* A patient preoperative skin preparation drug product in finished form suitable for topical applications will be recognized as effective provided that the formulated drug product at its recommended use concentration:

(i) Contains an ingredient in § 333.412 (a), (b), (c), (d), or (e).

(ii) Demonstrates in vitro activity against organisms as described in paragraph (a)(1)(ii) of this section.

(iii) When tested, in vivo, by the standard testing procedure for the evaluation of patient preoperative skin preparation drug products described in paragraph (b)(3)(iii) of this section and labeled according to § 333.460(b)(1) of this section, reduces the number of bacteria 2 $\log_{10}$ per square centimeter on an abdomen test site and 3 $\log_{10}$ per square centimeter on a groin test site within 10 minutes after product use and the bacterial cell count for each test site does not subsequently exceed baseline 6 hours after product use. When labeled according to § 333.460(b)(2) and tested, in vivo, by the standard testing procedure described in paragraph (b)(3)(iii) of this section, reduces the number of bacteria 1 $\log_{10}$ per centimeter squared on a dry skin test site within 30 seconds of product use.

(A) *Apparatus.*—(*1*) *Colony Counter.* Any of several types may be used.

(*2*) *Incubator.* Any incubator capable of maintaining a temperature of 30±2 °C may be used.

(*3*) *Sterilizer.* Any suitable steam sterilizer capable of producing conditions of sterility is acceptable.

(*4*) *Timer (stop clock).* A timer that can be read in hours and minutes.

(*5*) *Examining table.* Any elevated surface such as a 3-by- 6-foot table with mattress or similar padding to allow subject to recline.

(B) *Materials and reagents.*—(*1*) *Bacteriological pipets.* Pipets of 10.0 and 2.2 or 1.1 milliliter capacity are recommended.

(*2*) *Water-dilution bottles.* Any sterilizable glass container having a 150 to 200 milliliter capacity and tight closures may be used.

(*3*) *Scrubbing cups.* Sterile glass cylinders, height approximately 2.5 centimeter, inside diameter of convenient size to place on anatomical area to be sampled. Useful sizes range from approximately 2.5 to 4.0 centimeters. Sampling should be conducted as described in paragraph (b)(3)(iii)(J) of this section.

(*4*) *Rubber policeman.* These can be fashioned in the laboratory or purchased from most laboratory supply houses.

(*5*) *Test formulation.* Directions used to demonstrate the effectiveness of the test formulation are to be the same as those proposed for the use of the product.

(*6*) *Positive control formulation.* Any patient preoperative skin preparation formulation approved by the Food and Drug Administration is acceptable.

(*7*) *Sterile Drape or dressing.* A sterile drape or dressing should be used to cover treated skin sites.

(*8*) *Sampling solution.* Dissolve 0.4 gram potassium phosphate, monobasic, 0.1 gram sodium phosphate, dibasic and 1 gram Triton X–100 in 1 liter distilled water. Include in this formulation an inactivator specific for the antimicrobial in the test formulation. Adjust to pH 7.8 with 0.1 Normal hydrochloric acid or 0.1 Normal sodium hydroxide. Dispense 50 to 100-milliliter volumes into water dilution bottles, or other suitable containers, and sterilize for 20 minutes at 121 °C.

(*9*) *Dilution fluid.* Butterfield's phosphate buffered water adjusted to pH 7.2 and containing an antimicrobial inactivator specific for the test formulation. Adjust pH with 0.1 Normal hydrochloric acid or 0.1 Normal sodium hydroxide.

(*10*) *Plating medium.* Soybean-casein digest agar plus a suitable inactivator.

(C) *Test and control skin sites.* (*1*) The skin sites selected for use in evaluating the effectiveness of the pre-operative skin preparation are to represent body areas that are common surgical sites and are to include both dry and moist skin areas. The sites are to possess bacterial populations large enough to allow demonstrations of bacterial reduction of up to 2 $\log_{10}$ per square centimeter on dry skin sites and up to 3 $\log_{10}$ per square centimeter on moist sites. A suitable dry skin area is the abdomen and a suitable moist area is the groin. For the effectiveness testing of patient preoperative skin preparation antiseptic drug products labeled according to § 333.460(b)(2), a dry skin site such as the arm, from the shoulder to the elbow, or the posterior surface of the hand below the wrist is to be selected. The sites to be tested are to have a bacterial

population of 3 $\log_{10}$ organisms per square centimeter of skin.

(*2*) Treatment and control sites are to be located contralateral to each other. Each site is to be 5 by 5 centimeters.

(D) *Test panelists.* Recruit healthy adult male and female human volunteers who have no clinical evidence of dermatosis, open wounds, or other skin disorders that may affect the integrity of the study, and in sufficient numbers per formulation being tested to satisfy the statistical criteria of the clinical trial design.

(E) *Preparation of volunteers.* (*1*) Instruct the volunteers to avoid contact with antimicrobials (other than the test formulation) for the duration of the test. This restriction includes antimicrobial containing antiperspirants, deodorants, shampoos, lotions, soaps, and materials such as acids, bases, solvents. Bathing in chlorinated pools and hot tubs should be avoided.

(*2*) Volunteers are to be provided with a kit of nonantimicrobial personal care products for exclusive use during the test. Volunteers are not to shower or tub bathe in the 24-hour period prior to the application of test material or microbial sampling. Sponge baths may be taken but the skin sites to be used in the study are to be excluded.

(*3*) If the skin sites to be used include areas that would require shaving prior to surgery, for example, the groin site, these sites should be shaved no later than 48 hours prior to the application of test formulation or microbial sampling.

(*4*) After volunteers have refrained from using antimicrobials for at least 2 weeks, obtain an estimate of baseline bacterial population from one groin and one abdominal site at least 72 hours prior to entering subjects into the study. Sampling and enumeration techniques described in paragraphs (b)(3)(iii)(J) and (b)(3)(iii)(K) of this section are to be used.

(*5*) Based on the initial estimate of baseline bacterial population, select sufficient numbers of subjects with high bacterial counts per formulation being tested to satisfy the statistical criteria of the clinical trial design.

(F) *Study design and randomization.* Subjects admitted to the study are to be identified as to whether they meet the groin portion or abdomen portion of the study, or both. Once a subject is admitted to the study, treatments are to be randomly assigned to one contralateral groin site, for subjects identified as belonging to this study group and similar treatments are to be randomly assigned to left or right side of the abdominal area, for subjects identified as belonging to the abdominal study group. This method of choosing subjects and sampling sites fits the paired comparison statistical design. Randomization of subjects to time periods and treatment to left or right side is to be accomplished in accordance with the plan similar to that presented for surgical hand scrub products.

(G) *Number of subjects required and statistical analysis of data.* (*1*) Two ways to statistically evaluate effectiveness of a preoperative scrub product are presented. The first depends upon calculating the average $\log_{10}$ reduction from baseline. This is accomplished by obtaining the difference in log counts for each paired sample for each subject in the appropriate sampling time frame. This will facilitate subsequent statistical evaluation of resulting data. It is usually fairly easy to enroll subjects with counts 1×10^5 or greater when working with the groin areas. It is anticipated this method will primarily be used to evaluate data collected from the groin areas. The sample size estimation equation given earlier may be used to estimate sample sizes required for this case. Standard deviations for preoperative scrub products are relatively homogeneous when inclusion criterion require counts of 1×10^5 or greater. The standard deviations extracted from files range from 0.82 to 1.72; the median standard deviation was 0.98. When counts in the range of 1×10^5 to 1×10^6 were used, the standard deviation ranged from 0.78 to 1.22, with a median value of 0.99. Using the sample size estimation equation given in paragraph (b)(1)(iii)(F) of this section and assuming the active control preoperative scrub produces an immediate mean log reduction of 2.0 and test scrub is to be within 20 percent of this, i.e., D=0.4, and S^2=0.98, gives n=97 subjects per arm of the study. Because blocks of 6 are recommended, the sample size per treatment arm is 96 subjects.

(*2*) The second method for evaluating the data depends upon establishing an entry target bacterial population of greater than 250 colony forming units per square centimeter and a target reduction criterion that a successful scrub reduces bacterial counts to below 25 colony forming units per square centimeter. A successful scrub product is to provide this degree of reduction in at least 90 percent of the subjects tested. Using the normal binomial confidence interval approach, it can be shown that if the standard preoperative scrub product achieves a 90 percent success rate and it is desired to rule out success rates less than 85 percent for the new product with power of 80 percent then 340 subjects per arm are required. If it is desired to rule out success rates less than 80 percent, then the sample size is only 100 per arm. Again, since blocks of 6 or some multiple thereof, are recommended, the sample size is 102 subjects per study arm.

(*3*) In both cases described in paragraphs (b)(3)(iii)(G)(*1*) and (b)(3)(iii)(G)(*2*) of this section, effectiveness is judged based on calculation of 95 percent confidence intervals on the difference of the "success rate for standard scrub product minus success rate for test scrub product."

(H) *Treatment application procedure.* Apply treatment according to label directions or as stated in the proposed directions for test formulation. The control product is to be used according to the labeling directions.

(I) *Sampling schedule.* (*1*) For patient preoperative skin preparation antiseptic drug products labeled according to § 333.460(b)(1), the treatment is randomly assigned to one contralateral groin site and one contralateral abdominal site on each of the subjects. The assignment is to be balanced such that an equal number of right and left sites in each anatomical area receive treatment. The untreated contralateral sites serve as control sites to establish baseline populations. Collect a baseline bacterial sample from one untreated groin site and from one abdominal site on each subject using the scrub cup technique just prior to application of the preoperative skin treatment to the corresponding contralateral site. Ten minutes after treatment, sample one treated groin site and one treated abdominal site on one-third of the subjects using the same sampling technique. Thirty minutes posttreatment, sample another one-third of the subjects as before, and 6 hours posttreatment, sample the remaining one-third of the subjects.

(*2*) Between the time of treatment allocation and the 6-hour sampling interval, the subjects movements should be restricted. Subjects treated in the groin area should avoid activities or positions that would cause untreated skin sites to contact treated sites or clothing. Positions that might be appropriate are lying on the back or sitting with the legs extended without flexing from the trunk. To allow subjects some degree of mobility between the time of treatment and the 4-hour posttreatment sampling, the treated skin areas should be loosely draped with a sterile nonocclusive dressing. This material is to be applied in such a manner as to protect the treated skin sites from contact with untreated skin.

(3) For patient preoperative skin preparation antiseptic drug products labeled according to § 333.460(b)(2), the treatment is randomly assigned to contralateral dry skin sites on each of the subjects. The assignment is to be balanced such that an equal number of right and left sites in each anatomical area receive treatment. The untreated contralateral site serves as a control site to establish baseline populations. Collect a baseline bacterial sample from an untreated site on each subject using the scrub cup technique just prior to application of the preoperative skin preparation to the corresponding contralateral site. Thirty seconds after application, sample the treated site using the same sampling technique.

(J) *Microbiological methods.* Samples for bacterial enumeration are obtained by the detergent scrub cup technique. Hold a sterile scrubbing cup firmly to the skin. Aseptically pipet 2.5 milliliters of sterile sampling solution into the scrubbing cup and rub the skin with a sterile rubber policeman for 1 minute using moderate pressure. Aspirate the wash fluid and place in a sterile test tube. Place a second 2.5-milliliter aliquot of sampling solution in the scrub cup and rub the skin again for 1 minute with the rubber policeman. Pool the two washes and enumerate the bacteria.

(K) *Enumeration of bacteria in sampling solution.* (1) Enumerate the bacteria in the sampling solution by a standard plate count procedure such as that described in "Standard Methods for the Evaluation of Dairy Products" (available from American Public Health Association, Inc., 1015 15th St. NW., Washington, DC 20005) but using soybean-casein digest agar and a suitable inactivator for the antimicrobial where necessary. The suitability of the inactivator is to be demonstrated using a procedure such as described in E 1054, "Test Methods for Evaluating Inactivators of Antimicrobial Agents Used in Disinfectant, Sanitizer, and Antiseptic Products," in "Annual Book of ASTM Standards," vol. 11.04, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from The American Society for Testing and Materials, 1916 Race St., Philadelphia, PA 19103–1187, or may be examined at the Center for Drug Evaluation and Research, 7520 Standish Pl., suite 201, Rockville, MD, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC. Prepare sample dilutions in dilution fluid. Plate in duplicate. Incubate plated sample at 30 ± 2 °C for 48 hours before reading.

(2) Determine changes from baseline counts obtained with the test material at each sampling interval for each anatomical site. For a more realistic appraisal of the activity of products, all raw data should be converted to common (base 10) logarithms. Reduction should be calculated from the average of the logarithms. This will also facilitate statistical analysis of data.

(L) *Comparison of test material with control material.* (1) In order to validate the testing procedure, equipment, and facilities, it is required that the test material be compared with an active control material. The number of test subjects will depend upon the number of control posttreatment sampling intervals chosen and the level of statistical significance desired for the test results. The identity of the formulations used by panelists should be blinded from those individuals counting plates and analyzing data.

(2) To validate the assay, compare, at each sampling interval, changes from baseline counts obtained with the test material to changes obtained with the control materials.

(c) *Effects on microbial flora.* The agency notes that, if there is some reasonable scientific indication that the activity of an ingredient will affect the microbial flora, and thereby cause a shift in the composition of this flora, e.g., an increase in the fungus or virus level that might result in greater harm, then further safety and effectiveness testing will be required.

(d) *Test modifications.* The formulation or mode of administration of certain products may require modifications of the testing procedures in this section. In addition, alternative assay methods (including automated procedures) employing the same basic chemistry and microbiology as the methods included in this section may be used. Any proposed modification or alternative assay method shall be submitted as a petition under the rules established in § 10.30 of this chapter. The petition should contain data to support the modification or data demonstrating that an alternative assay method provides results of equivalent accuracy. All information submitted will be subject to the disclosure rules in part 20 of this chapter.

PART 369—INTERPRETATIVE STATEMENTS RE WARNINGS ON DRUGS AND DEVICES FOR OVER-THE-COUNTER SALE

3. The authority citation for 21 CFR part 369 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 371).

§ 369.21 [Amended]

4. Section § 369.21 *Drugs; warning and caution statements required by regulations* is amended by removing the entry for "Alcohol Rubbing Compound."

Dated: May 24, 1994.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 94–14503 Filed 6–16–94; 8:45 am]

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Friday
June 17, 1994

Part IV

Department of Housing and Urban Development

Office of the Assistant Secretary for Housing-Federal Housing Commissioner

NOFA for Capital Improvement Loans Under the Flexible Subsidy Program Awarded as Incentives Pursuant to Preservation Plans of Action; Notice

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Housing-Federal Housing Commissioner

[Docket No. N–94–3764; FR–3681–N–01]

NOFA for Capital Improvement Loans Under the Flexible Subsidy Program Awarded as Incentives Pursuant to Preservation Plans of Action

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

ACTION: Notice of Fund Availability for Fiscal Year 1994.

SUMMARY: This notice announces HUD's funding for that portion of the Capital Improvement Loan component of the Flexible Subsidy Program set aside for Fiscal Year 1994 to support approved plans of action under the Emergency Low-Income Housing Preservation Act of 1987 (ELIHPA). This document includes information concerning the following:

(a) The purpose of the NOFA and information regarding eligibility, available amounts, and selection criteria;

(b) Application processing, including how to apply and how selections will be made; and

(c) A checklist of steps and exhibits involved in the application process.

DATES: Applications may be submitted beginning June 17, 1994. There is no deadline for an application. An application may be submitted as soon as a HUD Field Office has issued preliminary approval of a plan of action under ELIHPA and as long as funds remain available.

ADDRESSES: Applications are to be submitted to the HUD Field Office by which the owner has had a plan of action approved under ELIHPA.

FOR FURTHER INFORMATION CONTACT: Frank Malone, Director, Multifamily Housing Preservation and Property Disposition, Department of Housing and Urban Development, Room 6164, 451 Seventh Street, NW, Washington, DC 20410; telephone (202) 708–3555. To provide service for persons who are hearing or speech-impaired, this number may be reached via TDD by dialing the Federal Information Relay Service on 1–800–877–TDDY (1–800–877–8339) or (202) 708–9300. (Except for the TDD number, telephone numbers are not toll free.)

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Statement

The Office of Management and Budget has approved the use of the Flexible Subsidy forms under OMB control number 2502–0395.

I. Purpose and Substantive Description

A. Statutory Background and Authority

Section 201 of the Housing and Community Development Amendments (HCDA) of 1978 created the Flexible Subsidy Program to provide Operating Assistance to eligible projects experiencing financial difficulty. Operating Assistance is provided in the form of a deferred loan and, in conjunction with other resources, is designed to restore or maintain the physical and financial soundness of eligible projects. The 1983 amendments to section 201 of the HCDA expanded the universe of eligible projects and clarified that a project need not have an FHA-insured mortgage to be eligible for Flexible Subsidy assistance (e.g., a non-insured section 236 project is eligible).

The Housing and Community Development Act of 1987 amended section 201 of HCDA to create a new category of assistance to be provided under the Flexible Subsidy Program for projects that needed capital improvements to achieve physical soundness that cannot be funded from project reserve funds without jeopardizing other major repairs or replacements that are reasonably expected to be required in the near future.

The 1987 amendments to the Flexible Subsidy statute (Sections 185 and 186 of the Housing and Community Development Act of 1987) also recognized the need to coordinate assistance under the Flexible Subsidy Program with the initiative to preserve low- and moderate-income housing, enacted in Title II of that Act. (In its comprehensive revision of the 1987 Act, Title VI of the 1990 Cranston-Gonzalez National Affordable Housing Act, at the new section 219, repeated the listing of incentives the Secretary could agree to provide an owner as part of a plan of action to prevent prepayment of a mortgage on a project serving low- and moderate-income tenants. A capital improvement loan was included as an incentive to owners.)

Section 405 of the Housing and Community Development Act of 1992, in addition to making other amendments, removed the priority for ELIHPA-eligible projects and imposed certain exclusivity restrictions on Flexible Subsidy-assisted and ELIHPA- and LIHPRHA-eligible projects. These provisions have been repealed by section 103(b) of the Multifamily Housing Property Disposition Reform Act of 1994 (the 1994 Act).

Section 201(n)(1) of the HCDA, as amended by section 103(b)(3) of the 1994 Act, authorizes the Department to set aside assistance for Capital Improvement Loans for projects that are eligible for incentives under ELIPHA. In addition, under section 201(n)(1), the Department is authorized to make this assistance available on a noncompetitive basis.

This notice supports preservation efforts by announcing a set-aside of $20 million for Flexible Subsidy Capital Improvement funding to insured projects that are eligible under ELIHPA to receive incentives in exchange for extending the low- to moderate-income use of the projects under plans of action approved in accordance with 24 CFR part 248, subpart C.

B. Allocation Amounts

The Flexible Subsidy Fund is comprised of excess rental receipts paid to HUD from owners of Section 236 projects, interest earned on the fund, repayment of Operating Assistance loans made by the Department in past fiscal years, and amounts appropriated by Congress, if any, to carry out the purposes of the Flexible Subsidy Program.

The Capital Improvement Loan portion of the program is required by statute (Section 201(j)(4)) to be funded at a minimum level of $30 million or 40 percent of the amount in the Flexible Subsidy fund, whichever is less. This year, $30 million is less than 40 percent of the fund, and therefore, is the amount designated for Capital Improvement Loans. Of the $30 million set aside for Capital Improvement funding, $20 million is available under this NOFA for preservation projects. The remaining $10 million was made available under the Flexible Subsidy NOFA, published on January 13, 1994, at 59 FR 2270.

C. Eligibility.

1. Types of Projects. The following types of rental or cooperative housing are eligible for Capital Improvement Loans:

a. A project which meets the definition of "eligible low-income housing" as set forth at 24 CFR 248.201; *and*

b. Has received preliminary approval of a plan of action pursuant to 24 CFR 248.233 which provides for a sale to a nonprofit or a limited equity cooperative.

2. Conditions. Flexible Subsidy assistance will be made available in accordance with Section 201 of the Housing and Community Development Amendments (HCDA) of 1978, as amended by Section 103 of the Multifamily Housing Property Disposition Reform Act of 1994. Assistance can be provided only if the following conditions are determined to exist when a plan of action is approved:

a. The assistance is necessary, when considered with other resources available to the project; it will restore or maintain the financial or physical soundness of the project; and it will preserve the low- and moderate-income character of the project.

b. The owner has agreed to maintain the low- and moderate-income character of the project for a period at least equal to the remaining term of the project mortgage.

c. The assistance will be less costly to the Federal Government over the useful life of the project than other reasonable alternatives of preserving the occupancy character of the project.

d. The project is or can reasonably be made structurally sound, as determined in accordance with an on-site inspection.

e. All reasonable attempts have been made to take all appropriate actions and provide suitable housing for project residents.

f. There is evidence of the existence of a feasible plan to involve the residents in project decisions.

g. The project will be operated competently, as determined by HUD in a management review.

h. Project management is in accordance with any management improvement and operating plan approved by HUD for the project.

i. The Affirmative Fair Housing Marketing plan meets applicable requirements.

j. The purchaser certifies that it will comply with all applicable equal opportunity statutes, including the provisions of the Fair Housing Act, Title VI of the Civil Rights Act of 1964, Executive Orders 11063, 11246 and 11375, Section 504 of the Rehabilitation Act of 1973, the Age Discrimination Act of 1975, the Americans with Disabilities Act, Section 3 of the Housing and Urban Development Act of 1968, and all regulations issued pursuant to these authorities.

k. The purchaser has funded the reserve for replacements account in accordance with HUD requirements, and yet the reserve account (and any other project funds available to fund the reserve account) is insufficient to finance both the capital improvements for which assistance is being requested and other capital improvements that are reasonably expected to be required within the next 24 months.

D. Selection Criteria and Ranking Factors

Each application for a Capital Improvement Loan will be reviewed by the HUD Field Office having jurisdiction over the project in question. Field Offices will recommend applications for funding to HUD Headquarters.

Under section 201(n)(1), as amended by section 103(b) of the 1994 Act, Capital Improvement Loans for ELIHPA projects that are eligible for incentives may be made available on a noncompetitive basis. Submission and approval of the notices of intent and plans of action are subject to the eligibility of the owner filing them.

E. Other Loan Terms and Conditions

Repair items eligible for funding as a Capital Improvement Loan include any major repair or replacement of building components or other on-site improvements included in allowable costs when the project was built, (e.g., sewer laterals, roof structures, ceilings, wall or floor structures, foundations, plumbing, heating, cooling, electrical systems and major equipment), as well as any major repair or replacement of any short-lived building equipment or component before the expiration of its useful life.

Improvements eligible for funding may also include limited supplements or enhancements to mechanical equipment, to the extent they are needed for the health and safety of the residents (e.g., air conditioning, heating equipment, and building sprinkler systems), where they do not exist; improvements necessary to comply with HUD's standards in 24 CFR part 8 for accessibility to individuals with handicaps; and cost effective energy efficiency improvements. Improvements eligible for funding as a Capital Improvement Loan do not include maintenance of any building components or equipment.

Capital Improvement assistance may be provided in the form of an amortizing loan. The interest rate on the loan may not be less than three (3) percent (unless HUD determines that a lower rate is necessary to maintain rental rates, in accordance with Chapter 12 of HUD Handbook 4350.6, Processing Plans of Action Under the Low-Income Housing Preservation and Resident Homeownership Act of 1990 and Form HUD–90010, Owner's Calculation of Tenant Rent Phase-In Due to POA approval, but in no case less than one percent) nor more than six (6) percent. The rate is determined taking into consideration the project's ability to absorb the rent increase and the percentage of the tenants receiving rental assistance. Interest on the Capital Improvement Loan starts to accrue and the loan amortization period begins immediately upon disbursement of loan proceeds.

A Capital Improvement Loan to a nonprofit organization may be in the form of a deferred note with a term coincident with the expiration of the project's insured mortgage note, accruing interest at a rate of one (1) percent. The deferred note will become due and payable upon a sale or refinancing of the project or at the expiration of the insured mortgage note.

II. Application and Funding Award Process

A. Obtaining and Preparing Applications

Applicants may obtain application packages from the local HUD Field Office.

An application must reflect the improvements required as a condition of approval of the plan of action. In addition, all other deficiencies, which are to be corrected with funds from sources other than Flexible Subsidy, must be identified on the work write-up and cost estimate and Management Improvement and Operation (MIO) plan Part II (Forms HUD–9835, HUD–9835–A, and HUD–9835–B) as if Flexible Subsidy were being requested.

B. Submitting Applications

Complete applications for a Flexible Subsidy Capital Improvement Loan pursuant to plans of action receiving preliminary approval under ELIHPA must be received in the HUD field office not more than 30 days following the issuance of preliminary approval. Timeliness of submission will allow the Department to review the application within the 30-day mandatory review period and in time to issue final approval of the plan of action in the period required by Part 248.219.

After HUD receives the application, it will review it against the improvements agreed upon in the plan of action. HUD may also conduct a comprehensive management review to ensure that all management issues are addressed as part of the MIO plan requirements.

C. Funding Award Process: Compliance with HUD Reform Act.

1. Section 103. In accordance with the requirements of section 103 of the

Department of Housing and Urban Development Reform Act of 1989 (HUD Reform Act) and HUD's implementing regulations at 24 CFR part 4, no selection information will be made available to applicants or other persons not authorized to receive this information during the period of HUD review and evaluation of the applications. However, applicants that are declared ineligible will be notified of their ineligibility at the time such determination is made.

Noncompetitive individual funding allocations and announcements will be made, as funding determinations are completed, through the HUD Regional or Field Offices after notification to the Congressional delegation. No information regarding any unfunded application will be made available to the public. All awards will be disclosed publicly at the conclusion of each selection.

2. Section 102. Section 102 contains a number of provisions that are designed to ensure greater accountability and integrity in the provision of certain types of assistance administered by HUD. The following requirements concerning documentation and public access, disclosures, and subsidy layering determinations are applicable to assistance awarded under this NOFA.

a. *Documentation and public access.* HUD will ensure that documentation and other information regarding each application submitted pursuant to this NOFA are sufficient to indicate the basis upon which assistance was provided or denied. This material, including any letters of support, will be made available for public inspection for a five-year period beginning not less than 30 days after the award of the assistance. Material will be made available in accordance with the Freedom of Information Act (5 U.S.C. 552) and HUD's implementing regulations at 24 CFR part 15. In addition, HUD will include the recipients of assistance pursuant to this NOFA in a **Federal Register** notice of recipients of HUD assistance awarded. (See 24 CFR 12.14(a) and 12.16(b), and the notice published in the **Federal Register** on January 16, 1992 (57 FR 1942), for further information on these requirements.)

b. *Disclosures.* HUD will make available to the public for five years all applicant disclosure reports (Form HUD–2880) submitted in connection with this NOFA. Update reports (also Form HUD–2880) will be made available along with the applicant disclosure reports, but in no case for a period generally less than three years. All reports—both applicant disclosures and updates—will be made available in accordance with the Freedom of Information Act (5 U.S.C. 552) and HUD's implementing regulations at 24 CFR part 15. (See 24 CFR subpart C, and the notice published in the Federal Register on January 16, 1992 (57 FR 1942), for further information on these disclosure requirements.)

c. *Subsidy-layering determinations.* 24 CFR 12.52 requires HUD to certify that the amount of HUD assistance is not more than is necessary to make the assisted activity feasible after taking into account other government assistance. HUD will make the decision with respect to each certification available to the public free of charge, for a three-year period. (See the notice published on February 25, 1994 at FR 59 9332 for further information on requesting these decisions.) Additional requests for information about applications, HUD certifications, and assistance adjustments, either before assistance is provided or subsequently, are to be made under the Freedom of Information Act (24 CFR part 15).

III. Checklist of Application Submission Requirements

The following items are required as part of each application:

A. A work write-up and cost estimates listing the major project components that have failed, or are likely to fail or seriously deteriorate within the next 24 months; capital items that can be upgraded to meet cost-effective energy efficiency standards approved by HUD; supplements or enhancements to mechanical equipment and the extent they are needed for health or safety reasons; and amounts needed to comply with the Department's standards as set forth in 24 CFR part 8, dealing with accessibility to individuals with handicaps.

B. All documentation required by HUD Notice, published on February 25, 1994, at FR59 9332, Combining Low-Income Housing Tax Credits (LIHTC) with HUD Programs, and by the Notice of Administrative Guidelines to be applied to assistance programs of the Office of Housing, published on April 9, 1991 (56 FR 14436).

C. Anti-lobbying Certification for Contracts, Grants, Loans and Cooperative Agreements for grants exceeding $100,000; and, if warranted, Disclosure of Lobbying Activities (Standard Form-LLL) if other than federally appropriated funds will be or have been used to lobby the Executive or Legislative branches of the Federal Government regarding specific contracts, grants, loans or Cooperative agreements. Form SF-LLL, Byrd Amendment Disclosure and Certification Regarding Lobbying should be submitted *only if the applicant* determines it is applicable. The SF-LLL form may not need to be submitted with all applications.

D. *Environmental Requirements.* A comprehensive technical energy analysis which includes a review of all capital improvements for which assistance is requested, and related capital items whose improvement or upgrading will result in cost-effective energy efficiency improvements. The results of the analysis will be a list of specified improvements, their costs and evidence of their cost effectiveness. An energy analysis that is provided by a local utility company and that contains a measure of cost-effectiveness information may be acceptable in meeting this requirement. All applications will be reviewed for compliance with 24 CFR 219.125, Environmental requirements as applicable.

E. *MIO Plan Part II, Management Objectives, Action Items, and Sources and Uses of Funds (Forms HUD–9835, 9835–A, and HUD–9835–B).* Refer to Section 5–4 of HUD HANDBOOK 4355.1, Rev. 1, *Flexible Subsidy*, for further discussion of MIO Plan Part II. Management Objectives must be specific, measurable, and must address all management deficiencies including actions which will be performed to improve management and personnel and upgrade tenant services, as appropriate.

Action Items must address all project deficiencies, including those which are to be corrected using resources other than Flexible Subsidy assistance. Action Items must be written in a manner which specifically describes the scope of the work and provides an estimate of the cost of the work to be performed. In addition, they must be structured so as to be highly visible items for which expenditures and work progress can be easily monitored. For example, if boilers are to be replaced, the description should identify the malfunctioning unit, its age, and its location, e.g., building number, basement/roof. A further explanation should identify the replacement unit, the estimated cost per unit and the labor cost associated with the entire replacement.

F. Form HUD–2530, Previous Participation Certificate, for all principals requiring clearance under these procedures.

G. Certification of compliance with the requirements of the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970, as amended (42 U.S.C. 4601–4655), and its

implementing regulations at 49 CFR part 24, and HUD Handbook 1378, Tenant Assistance, Relocation and Real Property Acquisition.

I. Affirmative Fair Housing Marketing plan (Form HUD–935.2).

J. Certification that the applicant will comply with the provisions of the Fair Housing Act, Title VI of the Civil Rights Act of 1964, Executive Orders 11063, 11246 and 11375, the American with Disabilities Act, Section 504 of the Rehabilitation Act of 1973, the Age Discrimination Act of 1975, Section 3 of the Housing and Urban Development Act of 1968, and all regulations issued pursuant to these authorities.

K. Form HUD–2880, Applicant/Recipient Disclosure/Update Report, as required under subpart C of 24 CFR part 12, Accountability in the Provision of HUD Assistance.

IV. Deficient Applications

A. Application Review

Within 30 days of receipt by HUD of the application from the owner, HUD will advise the owner, in writing, whether or not the application meets the submission requirements as stated in Part III above. Should HUD fail to inform the owner of its disapproval within the 30-day time frame, the application shall be considered to be approved. If HUD disapproves the application, an ELIHPA plan of action may not receive final approval.

B. Submission of Substantive Changes

Substantive changes or supplements to the application may be submitted by the applicant at any time. These include changes to the work write up, cost estimates or Form HUD–9835. However, submission of substantive changes will cause HUD's 30-day mandatory review time to recommence upon resubmission and will delay consideration of approval of a plan of action.

V. Other Matters

Prohibition Against Lobbying Activities

The use of funds awarded under this NOFA is subject to the disclosure requirements and prohibitions of section 319 of the Department of Interior and Related Agencies Appropriations Act for Fiscal Year 1990 (31 U.S.C. 1352), and the implementing regulations at 24 CFR part 87. These authorities prohibit recipients of Federal contracts, grants, or loans from using appropriated funds for lobbying the Executive or Legislative Branches of the Federal Government in connection with a specific contract, grant, or loan. The prohibition also covers the awarding of contracts, grants, cooperative agreements, or loans unless the recipient has made an acceptable certification regarding lobbying. Under 24 CFR part 87, applicants, recipients, and subrecipients of assistance exceeding $100,000 must certify that no Federal funds have been or will be spent on lobbying activities in connection with the assistance.

Prohibition Against Lobbying of HUD Personnel

Section 13 of the Department of Housing and Urban Development Act (42 U.S.C. 3537b) contains two provisions dealing with efforts to influence HUD's decisions with respect to financial assistance. The first imposes disclosure requirements on those who are typically involved in these efforts—those who pay others to influence the award of assistance or the taking of a management action by the Department *and* those who are paid to provide the influence. The second restricts the payment of fees to those who are paid to influence the award of HUD assistance, if the fees are tied to the number of housing units received or are based on the amount of assistance received, or if they are contingent upon the receipt of assistance.

Section 13 was implemented by final rule published in the **Federal Register** on May 17, 1991 (56 FR 29912). See 24 CFR Part 86. If readers are involved in any efforts to influence the Department in these ways, they are urged to read 24 CFR Part 86, particularly the examples contained in Appendix A.

Any questions concerning Part 86 should be directed to Garry L. Phillips, Acting Director, Office of Ethics, Room 2158, Department of Housing and Urban Development, 451 Seventh Street, SW, Washington, DC 20410–3000. Telephone: (202) 708–3815 (TDD Voice). (This is not a toll-free number.) Forms necessary for compliance with the rule may be obtained from the local HUD office.

Prohibition Against Advance Information on Funding Decisions

Section 103 of the Reform Act proscribes the communication of certain information by HUD employees to persons not authorized to receive that information during the selection process for the award of assistance that entails a competition for its distribution. HUD's regulations implementing section 103 are codified at 24 CFR part 4 (see 56 FR 22088, May 13, 1991). (See also Section II.C. of this NOFA.) In accordance with the requirements of Section 103, HUD employees involved in the review of applications and in the making of funding decisions under a competitive funding process are restrained by 24 CFR part 4 from providing advance information to any person (other than an authorized employee of HUD) concerning funding decisions, or from otherwise giving any applicant an unfair competitive advantage. Persons who apply for assistance in this competition should confine their inquiries to the subject areas permitted by 24 CFR part 4. Applicants who have questions should contact the HUD Office of Ethics (202) 708–3815. (This is not a toll-free number.)

Environmental Impact

A Finding of No Significant Impact with respect to the environment has been made in accordance with HUD regulations that implement Section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332). The Finding of No Significant Impact is available for public inspection during business hours in the Office of the Rules Docket Clerk, Office of General Counsel, Room 10276, Department of Housing and Urban Development, 451 Seventh Street, SW, Washington, DC 20410.

Federalism Executive Order

The General Counsel, as the Designated Official under Section 6(a) of Executive Order 12612, Federalism, has determined that this Notice of Fund Availability will not have substantial, direct effects on States, on their political subdivisions, or on their relationship with the Federal Government, or on the distribution of power and responsibilities between them and other levels of government.

Family Executive Order

The General Counsel, as the Designated Official under Executive Order 12606, the Family, has determined that this Notice of Fund Availability will not have a significant impact on family formation, maintenance or well being, and therefore, is not subject to review under the order. The NOFA, insofar as it funds emergency repairs to multifamily housing projects, will assist in preserving decent housing stock for families residing there. Catalog. The Catalog of Federal Domestic Assistance Program number is 14.164.

Dated: June 13, 1994.

Nicolas P. Retsinas,

Assistant Secretary for Housing-Federal Housing Commissioner.

[FR Doc. 94–14746 Filed 6–16–94; 8:45 am]

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federal register

Friday
June 17, 1994

Part V

Environmental Protection Agency

Solicitation Notice for Fiscal Year 1995; Environmental Education Grants Program

ENVIRONMENTAL PROTECTION AGENCY

[FRL–4895–7]

Solicitation Notice for Fiscal Year 1995; Environmental Education Grants Program

Section I. Important Pre-Application Information

A. What is the purpose of this solicitation notice:

This notice solicits pre-applications from eligible organizations and institutions for grants to support projects to design, demonstrate, or disseminate practices, methods, or techniques related to environmental education as specified under Section 6 of the National Environmental Education Act of 1990 (the Act). The Section 6 Environmental Education Grants Program is separate from the Environmental Education and Training Program authorized under Section 5 of the Act in which EPA awards a cooperative agreement on a three year basis to support a national teacher training program. For information on the teacher training program, contact the EPA representative listed at the end of this notice.

B. When is my pre-application due to EPA and when will EPA announce the grant awards?

Pre-applications (a signed original plus two copies of the original) must be mailed to EPA postmarked no later than Friday, October 14, 1994. Pre-applications which are postmarked after October 14, 1994 will not be considered for funding. EPA expects to announce the grant awards in the Spring of 1995.

C. Do I mail my pre-application to EPA headquarters or an EPA regional office? Is there a difference between the type of project that is funded by EPA headquarters as opposed to EPA's regional offices?

Pre-applications requesting between $25,001 and $250,000 in federal environmental education grant funds must be mailed to EPA headquarters in Washington, DC. Pre-applications requesting $25,000 or less in federal environmental education grant funds must be mailed to the EPA regional office where the project will take place (rather than to the regional office where the applicant is located, if these locations are different). A list of addresses is included at the end of this notice. The EPA headquarters and regional grants will be evaluated using the same criteria as defined in this solicitation. The only difference between grants that are awarded by EPA headquarters and by EPA's regional offices is the size of the grant.

D. Where do I get the information and forms needed to prepare my pre-application?

EPA strongly encourages applicants to read the solicitation notice carefully. This notice contains all the information and forms necessary to prepare a pre-application. If your project is selected as a finalist after the evaluation process is concluded, EPA will provide you with additional forms that must be completed in order to process your pre-application further.

E. How much money can I request and how does the dollar amount requested affect my chance of being funded?

Applicants may request up to the statutory ceiling of $250,000 in environmental education grant funds for any one grant. However, pre-applications which request relatively small amounts of funding have a much better chance of being funded because EPA awards a much greater number of grants at lower funding levels. A significant number of small awards are made because EPA is required, under Section 6(i) of the Act, to award 25% of funds for grants of $5,000 or less. In addition, EPA has chosen to award very few of the largest grants (e.g., those over $100,000) so that we may support a greater number of efforts. Thus, your chance of being funded increases dramatically as the amount of money you request decreases as illustrated below.

EPA has awarded grants under the Environmental Education Grants Program in Fiscal Years 1992, 1993, and 1994. Individual awards have ranged from less than $5,000 up to $250,000. During this three year period, EPA has funded only about 10 proposals annually for projects requesting between $25,001 and $250,000; only 1 proposal each year has been funded at or near the $250,000 level. By contrast, EPA has funded about 30 proposals annually for projects requesting between $5,001 and $25,000. Furthermore, EPA has funded about 200 proposals annually for projects requesting $5,000 or less. EPA has received between 1,500 and 3,000 pre-applications each year. To increase your chance of obtaining funding in FY 1995, EPA strongly encourages applicants to request regional grants of $5,000 or less. If larger sums are needed, EPA strongly encourages applicants to request a headquarters grant closer to $25,000 rather than the maximum of $250,000.

Section II. Laws and Regulations Governing Grants Program

F. Under what authority has this grants program been established and what laws and regulations do I need to follow in applying for a grant?

On November 16, 1990, the President signed the National Environmental Education Act (Pub. L. 101–619) into law. Section 6 of the Act requires that the U.S. Environmental Protection Agency (EPA) administer an environmental education grants program to support projects that design, demonstrate, or disseminate practices, methods, or techniques related to environmental education. The Act also requires that EPA establish a program which includes a process for soliciting, selecting, supervising, evaluating results, and disseminating information on the effectiveness of projects funded under this program.

EPA published the Environmental Education Grant Program Regulations in the **Federal Register** on March 9, 1992 which provides additional information on how EPA is administering this program (57 FR 8390; Title 40 of the Code of Federal Regulations, Part 47 (40 CFR part 47). In addition to the requirements of the Act and part 47, recipients of section 6 grants must comply with EPA's general assistance regulations at 40 CFR part 31 for states, local governments, and Indian tribes and Part 30 for all others.

G. How much money has Congress appropriated for this grants program?

The Act requires that 38% of the total funds Congress appropriates in a given fiscal year under the National Environmental Education Act be awarded as grants under the section 6 environmental education grants program. Based on this percentage, EPA has awarded approximately $8.1 million in grants under section 6 of the Act over the past three years (approximately $2.5 in Fiscal Year 1992, $2.7 in Fiscal Year 1993, and $2.9 in Fiscal Year 1994). EPA will award grants in Fiscal Year 1995 subject to the amount of funds appropriated by Congress. EPA may use up to 15% of these funds to support environmental education projects which meet the requirements under section 6, but are outside of the competitive process established under the solicitation notice. If funds are used in this manner, EPA will publish a separate solicitation notice in the **Federal Register** to cover the award of these funds.

Section III. Eligible Applicants

H. Who is eligible to submit pre-applications?

Any local or tribal education agency, college or university, state education or environmental agency, not-for-profit organization, or noncommercial educational broadcasting entity may submit a pre-application. These terms are defined in Section 3 of the Act and 40 CFR 47.105.

I. May an organization submit more than one pre-application for Fiscal Year 1995?

Yes, an organization may submit more than one pre-application for Fiscal Year 1995, but only if the pre-applications are for completely different projects. For example, a national non-profit organization or a large university may wish to submit pre-applications from different chapters or departments for different projects. No organization will be awarded more than one grant for the same project during the same fiscal year.

J. May I submit a pre-application for Fiscal Year 1995 even though I have been awarded funding under this program for Fiscal Years 1992, 1993, and/or 1994?

Yes, applicants who were awarded funding previously may submit a pre-application for Fiscal Year 1995. The Fiscal Year 1995 pre-application may or may not have any relationship to the project funded in a previous year. Every pre-application for Fiscal Year 1995 will be evaluated based upon the merit of the proposed project in relation to the other Fiscal Year 1995 pre-applications and the new criteria set forth in this solicitation, regardless of whether the proposal would expand a project funded in a previous year.

K. May a teacher or educator apply?

No, an individual teacher or educator cannot apply. Only education agencies and organizations—not individuals—are eligible to apply for grants. For example, a teacher's school, school district, or state or local education agency or organization may apply.

Section IV. Eligible Activities and Funding Priorities

L. What type of activities are eligible for funding under this program?

As specified in the Act, the environmental education activities that are eligible to receive funding under this program must include at least one of, but are not limited to, the following:

1. The design, demonstration, or dissemination of environmental curricula, including development of educational tools and material;
2. The design and demonstration of field methods, practices, and techniques, including assessment of environmental and ecological conditions and analysis of environmental pollution problems;
3. The assessment of a specific environmental issue or a specific environmental problem;
4. The provision of training or related education for teachers, faculty, or related personnel in a specific geographic area or region; and
5. The design and demonstration of projects to foster international cooperation in addressing environmental issues and problems involving the United States and Canada or Mexico.

In reference to Section IV.L.1. above, EPA strongly encourages applicants to focus on the demonstration or dissemination of existing environmental curricula rather than the design or development of new curricula. Environmental educators and other experts have conveyed to EPA that the field needs to improve its use and dissemination of existing curricula more than it needs to develop new curricula. Focusing on demonstrating or disseminating existing curricula will also help ensure that federal funds are not used to duplicate already existing curricula.

Nonetheless, EPA does recognize that there are gaps in the types of curricula that presently exist and that there is some difficulty in gaining access to quality materials. Thus, applicants who propose to design new curricula in their pre-applications must demonstrate that there is a need to develop these new materials.

For example, the applicant may show that the curriculum proposed for development has not been designed for a particular target audience, that existing curricula cannot be adapted well to a particular local environmental concern, or that existing curricula are not otherwise readily accessible. In demonstrating the need for new curricula, the applicant must specify what steps they have taken to determine this need (e.g., the applicant may cite a conference where this need was discussed, the results of inquiries made within the community or with various educational institutions or organizations, or a published survey or research document).

M. What activities are not eligible for funding under this program?

Funds cannot be used for:

1. construction projects;
2. technical training of environmental management professionals;
3. non-educational research and development; and/or
4. environmental information projects.

In reference to Section IV.M.1., EPA will not fund construction activities such as the acquisition of real property (including buildings) or the construction or modification of any building. EPA may, however, fund activities such as creating a nature trail or building a bird watching station as long as these items are an integral part of the proposed project.

In reference to Section IV.M.4., EPA will fund only environmental education projects as opposed to projects that are solely designed to develop or disseminate environmental information. The long term goal of environmental education is to increase public awareness and knowledge about environmental issues as well as provide the public with the skills necessary to make informed decisions and the motivation to take responsible actions. Environmental education enhances critical-thinking, problem-solving, and effective decision-making skills and may take place in formal or informal settings. Environmental education engages and motivates individuals, and enables them to weigh various sides of an environmental issue to make informed and responsible decisions.

Environmental information provides facts or opinions about environmental issues or problems, but does not enhance critical-thinking, problem-solving, or effective decision-making skills. Although information is an essential element of an educational effort, environmental information is not, by itself, environmental education.

N. What kind of projects will EPA consider funding?

EPA will consider funding only those proposed projects which meet the criteria specified under #1 and #2 below Any proposed project which does not meet these criteria will not be funded.

1. As required under the Act, all projects must develop an environmental education practice, method, or technique which meets all three of the following criteria:

a. Is new or significantly improved;

b. Demonstrates the potential for wide application; and

c. Addresses a high priority environmental issue.

EPA defined the terms "new or significantly improved," "wide application," and "a high priority environmental issue" in "relative terms" (i.e., applicants must define

these terms as they relate to their individual projects). For example, in reference to Section IV.N.1.a., EPA may consider a project new or significantly improved if it reaches a specific community or audience for the first time, develops a new or improved teaching strategy, or uses a new or improved method of applying existing materials.

In reference to Section IV.N.1.b., EPA may consider a project to have wide application if it targets a large and diverse audience in terms of numbers and demographics. It may also have wide application if it can serve as a model program elsewhere such as another school, community, state, or region.

In reference to Section IV.N.1.c., EPA may consider that a project addresses a high priority environmental issue if the applicant demonstrates that a particular issue is important to the community, state, or region being targeted by the project. For example, one community may have significant air pollution problems which would make teaching about solutions to air pollution important to that community. In another community, unplanned development may threaten a nearby wildlife habitat, thus, making habitat or ecosystem protection a high priority issue. In still another community, urban decay may make education about lead poisoning from paint or lead pipes important, especially for culturally diverse or low-income residents who often live in inner-city communities.

2. *All proposals must also focus on one of the following types of projects:*

a. Projects that improve educators' environmental education teaching skills (e.g., through workshops);

b. Projects that build state, local, or tribal capacity to develop and deliver environmental education programs;

c. Projects that educate members of a community through a grassroots community-based organization; or

d. Projects that motivate the general public to be more environmentally conscious in making informed decisions and taking responsible actions through vehicles such as print, film, or broadcast media.

All pre-applications must clearly identify which type of project, described under Section IV.N.2.a, b, c, or d above, the proposal will focus on. Note that these types of projects have been chosen precisely because they reach different audiences through different means. EPA believes that requiring you to focus on one of the above types of projects will help ensure that your proposal has a clear target audience and a well defined vehicle for reaching that audience. Although your proposal may include more than one of the types of projects described above, doing so will not likely improve your chance of being funded (unless focusing on more than one strengthens rather than dilutes the focus of your proposal). EPA's overall goal is to fund a balanced range of projects to increase environmental literacy throughout the country as described under Section VI.V.1–6.

In reference to Section IV.N.2.a., the term *workshop* refers to training activities that better prepare educators to utilize existing or new environmental education materials. Such workshops may be directed toward young people and/or adults in formal and/or informal settings. A formal setting is a school or other similar institution devoted to learning and an informal setting includes institutions such as museums, nature centers, parks, and community centers.

Workshops should emphasize the process, problem-solving, and investigative approach to learning that is a fundamental aspect of most established environmental education materials and curricula. Workshops should, in all cases, use a "hands-on" process approach to learning that leads to the development of problem-solving and critical-thinking skills. Workshops may be specific to a particular set of environmental education materials and may include youth leaders and other professionals who work in the environmental education field.

In reference to Section IV.N.2.b., the term *building state, local, or tribal capacity* refers to the development and implementation of plans designed to improve the coordinated delivery of environmental education at the state, local, or tribal level. Pre-applications addressing this priority should involve a coordinated effort by the primary environmental education providers from the respective state, local, or tribal government in the planning and implementation of the project. Examples of primary environmental education providers includes State Departments of Education or Natural Resources, local school districts, and state, local, and tribal environmental education coordinating councils or associations. Examples of how an applicant may propose to build state, local, or tribal capacity includes the development of plans for:

- Identifying and assessing needs as well as setting priorities for environmental education;
- Creating grant programs or identifying funding sources for environmental education providers; and/or
- Identifying environmental education teacher training needs.

In reference to Section IV.N.2.c., the term *grassroots community-based organization* refers to organizations in which local problems are addressed by individuals who reside in the community being served.

Section V. The Pre-Application

O. What is a pre-application?

The pre-application contains three parts: (1) The "Application for Federal Assistance" (Standard Form 424/SF 424, attached), (2) the "Budget Information: Non-Construction Programs" (Standard Form 424A/SF 424A, attached), and (3) a work plan (described below). To ensure your pre-application is completed properly, carefully follow the instructions on the SF 424, SF 424A, and those provided below. The SF 424, SF 424A, and the completed work plan contain all the information EPA will use to evaluate the merits of your pre-application. Applicants will not be asked to submit additional information to support their projects unless applicants are identified as finalist. Finalists will be asked to submit various other forms necessary to complete formal application.

P. Are matching funds required?

Yes, non-federal matching funds of at least 25% of the total cost of the project are required, although EPA encourages matching funds of greater than 25%. Federal funds to support the project must not exceed 75% of the total cost of the project. The 25% match may be provided by the applicant or any other organization or institution, except that no portion of the 25% match can include federal funds (unless specifically authorized by statute). The 25% match may be provided in cash or by in-kind contributions and other non-cash support. In-kind contributions often include salaries or other verifiable costs. In the case of salaries, applicants may use either minimum wage or fair market value. The proposed match, including the value of in-kind contributions, is subject to negotiation with EPA. All grants are subject to audit, so the value of in-kind contributions must be carefully documented.

The matching non-federal share is a percentage of the entire cost of the project. For example, if the 75% federal portion is $5,000, then the entire project should, at a minimum, have a budget of $6,667, with the recipient providing a contribution of $1,667. The amount of non-federal funds, including in-kind contributions, must be briefly itemized

in Block 15 of the SF 424 included at the end of this notice.

Q. Can I use federal funds other than those provided by this program to support the same project?

Yes, you may use federal funds other than those provided by the Environmental Educational Grants Program to support the same project, but only for different activities. Furthermore, you may not use any federal funds to meet all or any part of the required 25% match as stated in Section V.P. above. If you have already been awarded federal funds for a project in which you are seeking additional support from this program, you must indicate in the budget section of the work plan that you have been awarded other federal support for this project. You must also identify the project officer, agency, office, address, phone number, and the amount of the award.

R. Can I request funding for any budget category on the SF 424A (i.e., personnel/ salaries, fringe benefits, travel, equipment, supplies, contractual, construction, and indirect charges)?

Yes, you may request funding for any of the budget categories identified above with the following exceptions. First, as indicated under Section VI.M.1. above, EPA will not fund the acquisition of real property (including buildings) or the construction or modification of any building under this program.

Second, you may request funds to pay for salaries, but only for those personnel who are directly involved in implementing the proposed project and whose salaries are directly related to specific products or outcomes of the proposed project. EPA also strongly encourages applicants to request reasonable amounts of funding for salaries. Third, you may include a request for indirect costs if your organization has already negotiated and received an indirect cost rate from the federal government.

S. What must the pre-application contain and how must the information be presented in the pre-application?

The pre-application must contain an SF 424, and SF 424A, and a work plan as described below:

1. *Application for Federal Assistance (SF 424).* The SF 424 is an official form required for all federal grants. A completed SF 424 must be submitted as part of your pre-application. This form, along with instructions and a sample, are included at the end of this notice. Please carefully review the instructions and the sample.

2. *Budget Information: Non-Construction Programs (SF 424A).* The SF 424A is an official form required for all federal grants. A completed SF 424A must be submitted as part of your pre-application. This form, along with instructions and a sample, are included at the end of this notice. Please carefully review the instructions and the sample. Refer to Section V.R. above for information on what types of activities can and cannot be funded.

3. *Work Plan.* A work plan describes the applicant's proposed project. Work plans must contain all four sections (a–d) submitted in the format described below. Each section of the work plan is assigned points which indicate how your proposal will be scored. Note that certain sections and subsections are given more points than others. Work plans *must* contain the following four sections:

a. *Project Summary:* A synopsis of no more than one page stating:

(1) The nature of the organization requesting funds;

(2) The type of project proposed as described under Section IV.N.2;

(3) The overall purpose and specific objective of the project;

(4) The target audience as well as the total number of individuals to be reached and their demographics;

(5) The expected results of the project; *and*

(6) How the funds will be used. (Do not include a detailed budget in the summary section).

The project summary will be scored on its overall clarity and the extent to which all six of the subsections identified above are addressed.

Project Summary Maximum Score: 12 points (2 points for each of the six subsections identified above)

b. *Project Description:* A concise description which explains how the proposed project meets #1 and #2 below.

(1) Explain how the proposed project (a) is new or significantly improved, (b) has wide application, *and* (c) addresses a priority issue as described under Section IV.N.1.a, b, and c.

This subsection will be scored on the extent to which you clearly, fully, and effectively explain how your proposal meets the three elements identified above. Subsection maximum score: 15 points (5 points for each of the three elements identified above)

(2) Explain how the proposed project (a) improves teaching skills; (b) builds state, local, or tribal capacity; (c) reaches a community through a grassroots community-based organization; or (d) motivates the general public as described under section IV.N.2.a, b, c, or d.

This subsection will be scored on the extent to which you clearly, fully, and effectively: (a) Identify which type of project you have chosen from among the four types identified above, (b) establish realistic goals and objectives, (c) identify an effective means to implement your project, and (d) demonstrate how your project enhances critical-thinking, problem-solving, and decision-making skills. Subsection maximum score: 44 points (11 points for each of the four elements identified in this paragraph)

Project Description Maximum Score: 59 Points

c. *Project Evaluation and Sustainability:* A discussion of the following:

(1) The anticipated strengths and challenges in implementing your project;

(2) The expected outcome of your project (i.e., how you will know whether your project is successful); *and*

(3) The sustainability of your project over the long-term (i.e., how the benefits of your project will be sustained over the long-term after the EPA budget period is completed).

Project Evaluation and Sustainability Maximum Score: 9 points (3 points for each of the three elements identified above)

d. *Appendices:* Attachments to the work plan which contain information on the budget, key personnel, and letters of commitment.

(1) Budget: An appendix with a budget describing how funds will be used for personnel/salaries, fringe benefits, travel, equipment, supplies, contract costs, and indirect costs. You must include budget milestones for each major proposed activity and a timetable showing the month/year they will be completed.

This subsection will be scored on the extent to which (a) the budget information clearly and accurately shows how funds will be used, and (b) the funding request is reasonable given the activities proposed. Subsection maximum score: 10 points (5 points for each of the two elements described in this paragraph)

(2) Key Personnel and Letters of Commitment: An appendix with one or two page resumes for up to three key personnel implementing the project. Also, you are required to include one page letters of commitment from any partner with a significant role in the proposed project. Letters of endorsement will not be considered in evaluating pre-applications.

This subsection will be scored based upon whether resumes of key personnel

are included and the extent to which the resumes show that the key personnel are qualified to implement the proposed project. In addition, the score will reflect whether letters of commitment are included (if partners are used) and the extent to which a firm commitment is made. Subsection maximum score: 10 points

Appendices Maximum Score: 20 Points

Work plans must be no more than 10 pages for requests for federal funds of more than $5,000 from this environmental education grants program and no more than 5 pages for requests of $5,000 or less. These page limits apply only to Section V.S.3.a, b, and c. of the work plan (i.e., the "summary," "project description," and "project evaluation and sustainability"). These page limits do not apply to Section V.S.3.d. (i.e., the "appendices"). "One page" refers to one side of a single-spaced typed page. The pages must be letter sized (8½ × 11 inches), with normal type size (10 or 12 cpi) and at least 1 inch margins. To conserve paper, please provide double-sided copies of the pre-application.

The only appendices EPA will accept are a budget, resumes of key personnel, and commitment letters from organizations with a significant role in the project. EPA will not accept brochures, video tapes, notebooks, photographs, curriculum samples, or any other supporting material not described as part of the work plan under Section V.S.3.a, b, c, and d.

T. How Must the Pre-Application Be Submitted?

The applicant must submit one original and two copies of the preapplication (a signed SF 424, an SF 424A, and a work plan). The pre-application must be signed by a person authorized to receive funds. Please sign the original pre-application in blue ink to help EPA distinguish which document is the signed original and which documents are copies. Pre-applications must be reproducible. They should be stapled once in the upper left hand corner, on white paper, and with page numbers in the upper right hand corner.

Section VI. Review and Selection Process

U. How will pre-applications be reviewed and who will conduct the reviews?

Pre-applications will be reviewed in two phases—the screening phase and the evaluation phase. During the screening phase, pre-applications will be reviewed to determine whether they are consistent with the requirements described in Section IV.L.1–5., Section IV.M.1–4., and Section V.S.3.a-d. Only those pre-applications which meet all of these requirements will enter the evaluation phase of the review process. During the evaluation phase, pre-applications will be evaluated based upon the quality of their work plans, especially the degree to which the work plan meets the requirements set forth in Section IV.N.1.a-c. and Section IV.N.2.a-d.

Reviewers conducting the screening and evaluation phases of the review process will include EPA officials and external environmental educators approved by EPA. At the conclusion of the evaluation phase, the reviewers will rank each applicant's work plan based upon the scoring system identified in Section V.S.3.a, b, c, and d.

V. How will the final selections be made?

After individual projects are evaluated and ranked by the reviewers as described under Section VI.U. above, EPA officials in the regions and at headquarters will identify finalists among the highest ranking pre-applications. In identifying finalists and making final selections, EPA's goal is to fund projects that, when viewed together, provide a balance among the types of projects being funded, by taking into account the following:

1. The target audience and their socioeconomic status;
2. The methods used to reach the target audience;
3. The type of organization submitting the proposal and/or whether the proposal makes effective use of partnerships;
4. The type of environmental issue addressed;
5. The geographic location of the project; and
6. The cost.

In reference to *socioeconomic status*, under Section VI.V.1. above, EPA's goal is to encourage applicants to submit proposals that promote environmental justice for culturally-diverse and low-income populations. EPA hopes to fund many proposals which score high in the evaluation process and which promote environmental justice. The term *environmental justice* refers to the fair treatment of people of all races, cultures, and income with respect to the development, implementation and enforcement of environmental laws, regulations, and policies. Fair treatment means that no racial, ethnic, or socioeconomic group should bear a disproportionate share of the negative environmental consequences resulting from the operation of industrial, municipal, and commercial enterprises and from the execution of federal, state, local, and tribal programs and policies.

Efforts to address environmental justice through environmental education may include educational programs that provide culturally-diverse and low-income populations with critical-thinking, problem-solving, and decision-making skills to identify, assess, and address an environmental problem that has a disproportionately high and adverse human health or environmental impact in their community.

In reference to the *effective use of partnerships*, under Section VI.V.3. above, EPA's goal is to encourage applicants to submit proposals which form partnerships, where possible. EPA hopes to fund many proposals which score high in the evaluation process and which promote the effective use of partnerships between organizations. The term *partnerships* refers to forming a collaborative working relationship between two or more organizations such as governmental agencies, non-profit organizations, educational institutions, and/or the private sector.

In reference to the *type of environmental issue*, under Section VI.V.4. above, EPA's goal is to encourage applicant to submit proposals which use pollution prevention concepts or techniques to address a high priority environmental issue (as discussed under Section IV.N.1.c.). EPA hopes to fund many proposals which score high in the evaluation process and which convey the importance of pollution prevention. The term pollution prevention refers to reducing or eliminating waste or pollution at the source. It means not creating waste or pollution in the first place, instead of deciding how to recycle, treat, or dispose of waste and pollution that has already been created. Pollution prevention may include increasing energy efficiency and resource conservation efforts, as well as finding non-polluting substitutes for existing products and activities.

Pollution prevention is not the only strategy that EPA uses to reduce risk to public health and the environment, but it is EPA's preferred approach. Efforts to promote pollution prevention through environmental education may include projects that educate the public about the value of preventive approaches to environmental problems and the choices they can make in their everyday lives to minimize adverse effects of human activities on the environment

(e.g., in the home, work place, market place, and/or community).

EPA Regional Administrators will select grant recipients for projects with federal environmental education grant funding of $25,000 or less, taking into account the recommendations of the regional environmental education coordinators who will base their recommendations on the factors discussed above. The Associate Administrator for Communications, Education, and Public Affairs at EPA headquarters will select the grant recipients for projects with federal environmental education grant funding of more than $25,000 and up to $250,000, taking into account the recommendations of the Environmental Education Division Director who will base the recommendations on the factors discussed above.

W. How and when will I be notified about the status of my proposal?

Headquarters and each regional office set up their own processes for notifying applicants about the status of their proposals. Our goal is to keep applicants informed as much as possible about the status of their proposals and to assist those applicants who do not receive funding to successfully compete in future years. To this end, all applicants will be notified (in mid-December 1994) after their pre-applications have been received and entered into a computerized data base, and again (in late April to early May 1995) after awards have been announced. To the extent possible, EPA will also provide applicants with feedback on those proposals which were screened out of the process early and on how proposals were evaluated. The degree to which EPA can provide such feedback will vary among EPA offices depending upon the availability of resources to conduct these activities.

X. Where may I obtain more information on possible sources of funding other than this program?

The large number of pre-applications EPA received in Fiscal Years 1992, 1993, and 1994 demonstrates the strong demand for funding environmental education projects. EPA expects an equally large demand for funding for Fiscal Year 1995. Unfortunately, EPA alone cannot meet this demand. Thus, in cooperation with EPA, the North American Association for Environmental Education (NAAEE) has developed a publication called "Grant Funding For Your Environmental Education Program" which provides strategies for identifying potential sources of funding. This publication can be purchased for a $5.00 fee by writing to NAAEE, Publications and Member Services, P.O. Box 400, Troy, Ohio, 45373.

Section VII. Grant Recipient Activities

Y. When can I begin incurring costs?

Grant recipients may begin incurring costs on the start date that is identified in your grant agreement with EPA. Since EPA plans to announce awards in the Spring of 1995, EPA recommends that you do not plan to begin incurring costs until June of 1995.

Z. When must proposed activities be completed?

EPA strongly encourages grant recipients to complete their projects within the time period specified in the pre-application. Extensions may be granted only in extenuating circumstances.

AA. May an applicant request Fiscal Year 1995 funds for a project that extends beyond a one-year budget period?

Pre-applications submitted to EPA regional offices for up to $5,000 may request funds for only a one-year budget period. Pre-applications submitted to EPA regional offices or headquarters requesting funds of more than $5,000 may request funds for up to a two-year budget period, although EPA strongly encourages applicants to request funds for only a one-year budget period.

BB. Who will perform projects and activities?

The Act requires that projects be performed by the applicant or by a person satisfactory to the applicant and EPA. All pre-applications must identify any person other than the applicant that will assist in carrying out the project.

CC. What reports and work products must grant recipients submit to EPA and when are they due?

All grant recipients must submit three copies of their final report and three copies of all work products to the EPA project officer within 30 days after the expiration of the budget period. This report will be accepted as the final report unless the EPA project officer notifies you, within 30 days of your submittal date, that changes must be made. Grant recipients with projects that have a two-year budget period must also submit a progress report at the end of the first year. Grant recipients with a federal environmental education grant share greater than $5,000 may also be required to submit a quarterly or semi-annual progress report. Specific report requirements will be identified in your award agreement with EPA.

DD. What does EPA plan to do with the grant recipients' final reports and final work products?

Copies of all final reports and final work products will be assembled in a central library at EPA headquarters. EPA will evaluate these final reports and final work products and may disseminate these items to others to serve as model programs.

Section VIII—Additional Information on Preparing Pre-Applications and for Fiscal Year 1996 Program

EE. Where can I get additional information in preparing my pre-application?

EPA strongly encourages applicants to carefully read the solicitation notice. Many questions, such as when is the deadline for submitting pre-applications and what activities can be funded under this program, are answered in this solicitation. Nonetheless, if you need more information about this grant program or clarification about specific requirements in this solicitation notice, you may contact the EPA Environmental Education Division in Washington, DC for grant requests of more than $25,000 or your EPA regional office for grant requests of $25,000 or less. A list of the names and telephone numbers of EPA representatives are listed at the end of this notice.

In addition, you may contact the National Consortium for Environmental Education and Training (NCEET) at the University of Michigan for general information on current environmental education activities and recent developments in the field (*e.g.*, information about current in-service teacher education needs and opportunities as well as resources that identify environmental education organizations, curricula, and research). NCEET can also provide you with a list of all environmental education grants awarded by EPA in FY 1992, FY 1993, and FY 1994 as well as summaries of those projects completed under the FY 1992 program. NCEET will not provide sample curricula nor will they evaluate products or funding proposals. NCEET was established in 1992 with financial support from EPA to facilitate teacher training opportunities. You may contact NCEET by writing to NCEET, School of Natural Resources, University of Michigan, Dana Building Ann Arbor, Michigan 48109–1115 or by calling 313–998–6726.

FF. How can I get information on the Fiscal Year 1996 EPA Environmentol Educotion Grants Program?

After the Fiscal Year 1995 grants process is completed, EPA will develop an entirely new mailing list for the Fiscal Year 1996 solicitation. The Fiscal Year 1996 mailing list will include all applicants who submitted pre-applications for Fiscal Year 1995 as well as anyone else who specifically requests to be placed on the mailing list. If you did not submit a pre-application for Fiscal Year 1995 and you wish to be added to our mailing list to receive information on the Fiscal Year 1996 Environmental Education Grants Program, you must mail your request—please do not telephone—along with your name, organization, address, and phone number to: U.S. Environmental Protection Agency, Environmental Education Division (1707), FY 1996 Environmental Education Grants Program, 401 M Street SW., Washington, DC 20460.

Approved by:

Loretta M. Ucelli,

Associate Administrator; Office of Communications, Education and Public Affairs.

U.S. EPA Representatives and Mailing Addresses

U.S. EPA Heodquarters—For Grants Over $25,000

Mail pre-applications to: U.S. EPA, Env Ed Grants, Environmental Education, Division (1707/Room 333WT), Office of Communications, Education, and Public Affairs, 401 M Street, SW. Washington, DC 20460

Information: George Walker or Kathleen MacKinnon, Environmental Education Specialists, 202–260–8619 or 202–260–4951

U.S. EPA Regional Offices—For Grants of $25,000 or Less

EPA Region I—Ct, ME, MA, NH, RI, VT

Mail pre-applications to: U.S. EPA, Region I, Env Ed Grants, Henry Gurrell, Chief, Grants Information and Management Section, JFK Federal Building (PGI), Boston, MA 02203

Hand-deliver to: One Congress Street, 11th Floor, Mail Room, Boston, MA 02114 (8am–4pm), Information: Maria Pirie, Environmental Education Coordinator, 617–565–9447

EPA Region II—NJ, NY, PR, VI

Mail pre-applications to: U.S. EPA, Region II, Env Ed Grants, Grants Administration Branch, 26 Federal Plaza (room 1714), New York, NY 10278

Information: Teresa Ippolito, Environmental Education Coordinator, 212–264–2980

EPA Region III—DC, DE, MD, PA, VA, WV

Mail pre-applications to: U.S. EPA, Region III, Env Ed Grants, Grants Management Chief (3PM71), Grants Management Section, 841 Chestnut Street, Philadelphia, PA 19107

Information: Bonnie Smith or Amelia Libertz, Environmental Education Coordinators, 215–597–9076 or 215–597–9817

EPA Region IV—AL, FL, GA, KY, MS, NC, SC, TN

Mail pre-applicotions to: U.S. EPA, Region IV, Env Ed Grants, Office of Public Affairs (E2), 345 Courtland Street, NE., Atlonta, GA 30365

Information: Rae Hallisey, Environmental Education Office, 404–347–3004

EPA Region V—IL, IN, MI, MN, OH, WI

Mail pre-applications to: U.S. EPA, Region V, Env Ed Grants, Grants Management Section (MC–10J), 77 West Jackson Boulevard, Chicago, IL 60604

Information: Suzanne Saric, Environmental Education Coordinator, 312–353–3209

Region VI—AR, LA, NM, OK, TX

Mail pre-applications to: U.S. EPA, Region VI, Env Ed Grants, Environmental Education Coordinator (6X), 1445 Ross Avenue, Dallas. TX 75202

Information: Sandy Sevier, Environmental Education Coordinator, 214–655–2204

Region VII—IA, KS, MO, NE

Mail pre-application to: U.S. EPA, Region VII, Env Ed Grants, Grants Administration Division, 726 Minnesota Avenue, Kansas City, KS 66101

Information: Rowena Michaels, Environmental Education Coordinator, 913–551–7003

Region VIII—CO, MT, ND, SD, UT, WY

Mail pre-applications to: U.S. EPA, Region VIII, Env Ed Grants, 999 18th Street (80EA), Denver, CO 80202–2466

Information : Cece Forget, Environmental Education Coordinator, 303–294–1113

Region IX—AZ, CA, HI, NV, Americon Somoo, Guam, Northern Marianos, Republic of Polou

Mail pre-applications to: U.S. EPA, Region IX, Env Ed Grants, Office of Public Affairs (E2), 75 Hawthorne Street, San Francisco, CA 94105

Information: Ida Tolliver, Environmental Education Coordinator, 415–744–1581 or 1582

Region X—AK, ID, OR, WA

Mail pre-applications to: U.S. EPA, Region X, Env Ed Grants, Public Information Center (SO–143), 1200 Sixth Avenue, Seattle, WA 98101

Information: Sally Hanft, Environmental Education Coordinator, 206–553–1207

BILLING CODE 6560–60–M

OMB Approval No. 0348-0043

APPLICATION FOR FEDERAL ASSISTANCE

1. TYPE OF SUBMISSION: Application ☐ Construction ☒ Non-Construction; Preapplication ☐ Construction ☐ Non-Construction	2. DATE SUBMITTED	Applicant Identifier
	3. DATE RECEIVED BY STATE	State Application Identifier
	4. DATE RECEIVED BY FEDERAL AGENCY	Federal Identifier

5. APPLICANT INFORMATION

Legal Name	Organizational Unit
Address (give city, county, state, and zip code)	Name and telephone number of the person to be contacted on matters involving this application (give area code)

6. EMPLOYER IDENTIFICATION NUMBER (EIN): ☐☐ – ☐☐☐☐☐☐☐

7. TYPE OF APPLICANT: (enter appropriate letter in box) ☐
A State; B County; C Municipal; D Township; E Interstate; F Intermunicipal; G Special District; H Independent School Dist; I State Controlled Institution of Higher Learning; J Private University; K Indian Tribe; L Individual; M Profit Organization; N Other (Specify) _____

8. TYPE OF APPLICATION: ☐ New ☐ Continuation ☐ Revision
If Revision, enter appropriate letter(s) in box(es) ☐ ☐
A Increase Award; B Decrease Award; C Increase Duration; D Decrease Duration; Other (specify) _____

9. NAME OF FEDERAL AGENCY:

10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER: 6 6 . 9 5 1
TITLE: Environmental Educational Grants

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT

12. AREAS AFFECTED BY PROJECT (cities, counties, states, etc.)

13. PROPOSED PROJECT		14. CONGRESSIONAL DISTRICTS OF	
Start Date	Ending Date	a. Applicant	b. Project

15. ESTIMATED FUNDING		
a. Federal	$	00
b. Applicant	$	00
c. State	$	00
d. Local	$	00
e. Other	$	00
f. Program Income	$	00
g. TOTAL	$	00

16. IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?
a. YES THIS 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

17. IS THE APPLICANT DELINQUENT ON ANY FEDERAL DEBT?
☐ Yes If "Yes," attach an explanation ☐ No

18. TO THE BEST OF MY KNOWLEDGE AND BELIEF, ALL DATA IN THIS APPLICATION/PREAPPLICATION 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 AWARDED

a. Typed Name of Authorized Representative	b. Title	c. Telephone number
d. Signature of Authorized Representative		e. Date Signed

Previous Editions Not Usable

Standard Form 424 (REV 4-88)
Prescribed by OMB Circular A-102

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BILLING CODE 6560-50-C

Instructions for the SF 424

This is a standard form used by applicants as a required facesheet for preapplications and applications submitted for Federal assistance. It will be used by Federal agencies to obtain applicant certification that States which have established a review and comment procedure in response to Executive Order 12372 and have selected the program to be included in their process, have been given an opportunity to review the applicant's submission.

Item and Entry

1. Self-explanatory.

2. Date application submitted to Federal agency (or State if applicable) & applicant's control number (if applicable).

3. State use only (if applicable).

4. If this application is to continue or revise an existing award, enter present Federal identifier number. If for a new project, leave blank.

5. Legal name of applicant, name of primary organizational unit which will undertake the assistance activity, complete address of the applicant, and name and telephone number of the person to contact on matters related to this application.

6. Enter Employer Identification Number (EIN) as assigned by the Internal Revenue Service.

7. Enter the appropriate letter in the space provided.

8. Check appropriate box and enter appropriate letter(s) in the space(s) provided:

—"New" means a new assistance award.

—"Continuation" means an extension for an additional funding/budget period for a project with a projected completion date.

—"Revision" means any change in the Federal Government's financial obligation or contingent liability from an existing obligation.

9. Name of Federal agency from which assistance is being requested with this application.

10. Use the Catalog of Federal Domestic Assistance number and title of the program under which assistance is requested.

11. Enter a brief descriptive title of the project. If more than one program is involved, you should append an explanation on a separate sheet. If appropriate (e.g., construction or real property projects), attach a map showing project location. For preapplications, use a separate sheet to provide a summary description of this project. Also circle a b c or d to indicate the focus of project as described in Section I.2 of Solicitation Notice.

12. List only the largest political entities affected (e.g., State, counties, cities).

13. Self-explanatory.

14. List the applicant's Congressional District and any District(s) affected by the program or project.

15. Amount requested or to be contributed during the first funding/budget period by each contributor. Value of in-kind contributions should be included on appropriate lines as applicable. If the action will result in a dollar change to an existing award, indicate *only* the amount of the change. For decreases, enclose the amounts in parentheses. If both basic and supplemental amounts are included, show breakdown on an attached sheet. For multiple program funding, use totals and show breakdown using same categories as item 15.

16. Applicants should contact the State Single Point of Contact (SPOC) for Federal Executive Order 12372 to determine whether the application is subject to the State intergovernmental review process.

17. This question applies to the applicant organization, not the person who signs as the authorized representative. Categories of debt include delinquent audit disallowances, loans and taxes.

18. To be signed by the authorized representative of the applicant. A copy of the governing body's authorization for you to sign this application as official representative must be on file in the applicant's office. (Certain Federal agencies may require that this authorization be submitted as part of the application.)

BILLING CODE 6560-50-M

OMB Approval No. 0348-0043

APPLICATION FOR FEDERAL ASSISTANCE

2. DATE SUBMITTED: 10/10/94	Applicant Identifier
3. DATE RECEIVED BY STATE	State Application Identifier
4. DATE RECEIVED BY FEDERAL AGENCY	Federal Identifier

1. TYPE OF SUBMISSION:
Application: ☐ Construction ☒ Non-Construction
Preapplication: ☐ Construction ☐ Non-Construction

5. APPLICANT INFORMATION

Legal Name: Clean-Up School
Organizational Unit: Environmental Office
Address (give city, county, state, and zip code): 100 State Street, Belle View, Green County, Any State 12345
Name and telephone number of the person to be contacted on matters involving this application (give area code): Willie Doitt (123)456-7890

6. EMPLOYER IDENTIFICATION NUMBER (EIN): 12-3456789

7. TYPE OF APPLICANT (enter appropriate letter in box): H
A State; B Cr...; ... Municipal; ... Special District
H Independent School Dist
I State Controlled Institution of Higher Learning
J Private University
K Indian Tribe
L Individual
M Profit Organization
N Other (Specify): _____

8. TYPE OF APPLICATION:
☒ New ☐ Continuation ☐ Re...
If Revision, enter appropriate letter(s) in box(es): ☐ ☐
A Increase Award B Decrease Award
D Decrease Duration Other (specify): _____

SAMPLE

9. NAME OF FEDERAL AGENCY: U.S. EPA

10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER: 66.951
TITLE: Environmental Educational Grants

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:
Teacher environmental workshop: behavioral changes in setting positive influences on students

12. AREAS AFFECTED BY PROJECT (cities, counties, states, etc.): Green and Surrounding Counties

13. PROPOSED PROJECT: Start Date 06/01/95; Ending Date 05/31/96

14. CONGRESSIONAL DISTRICTS OF: a Applicant 02; b Project 01, 02, 03

15. ESTIMATED FUNDING:

a Federal	$	5,000.00
b Applicant	$	1,667.00
c State	$	.00
d Local	$	.00
e Other	$	.00
f Program Income	$	.00
g TOTAL	$	6,667.00

16. IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?
a YES THIS 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

17. IS THE APPLICANT DELINQUENT ON ANY FEDERAL DEBT?
☐ Yes If "Yes," attach an explanation ☒ No

18. TO THE BEST OF MY KNOWLEDGE AND BELIEF ALL DATA IN THIS APPLICATION/PREAPPLICATION 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 AWARDED

a Typed Name of Authorized Representative: Gertrude Smith	b Title: Superintendent	c Telephone number: 123-456-0987
d Signature of Authorized Representative: Gertrude Smith		e Date Signed: 10/10/94

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Standard Form 424 (REV 4-88)
Prescribed by OMB Circular A-102

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BUDGET INFORMATION — Non-Construction Programs

Section A- Budget Summary

Grant Program Function or Activity (a)	Catalog of Federal Domestic Assistance Number (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 (5)
	(1)	(2)	(3)	(4)	
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 (sum of 6i and 6j)	$	$	$	$	$
Program Income	$	$	$	$	$

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Standard Form 424A (4-88)
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BILLING CODE 6560-50-C

Instructions for the SF–424A

All applications should contain a breakdown by the object class categories shown in Lines a–k if Section B.

Section B Budget Categories

In the column headings (1) through (4), enter the titles of the same programs, functions, and activities shown on Lines 1–4, Column (a), Section A. When additional sheets are prepared for Section A, provide similar column headings on each sheet. For each program, function or activity, fill in the total requirements for funds (both Federal and non-Federal) by object class categories.

Lines 6a–i—Show the totals of lines 6a to 6h in each column.

Line 6j—Show the amount of indirect cost.

Line 6k—Enter the total of amounts on Lines 6i and 6j. For all applications for new grants and continuation grants the total amount in column (5), Line 6k, should be the same as the total amount shown in Section A, Column (g), Line 5. For Supplemental grants and changes to grants, the total amount of the increase or decrease as shown in Columns (1)–(4), Line 6k should be the same as the sum of the amounts in Section A, Columns (e) and (f) on Line 5.

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 under the program narrative statement the nature and source of income. The estimated amount of program income may be considered by the Federal grantor agency in determining the total amount of the grant.

BILLING CODE 6560–50–M

BUDGET INFORMATION — Non-Construction Programs

Section A- Budget Summary

Grant Program Function or Activity (a)	Catalog of Federal Domestic Assistance Number (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 (1)	(2)	(3)	(4)	Total (5)
a. Personnel	$ 2,000	$	$	$	$ 2,000
b. Fringe Benefits	500				500
c. Travel	2,000				2,000
d. Equipment	0				0
e. Supplies	667				667
f. Contractual	1,000				1,000
g. Construction	xxxxxxx				xxxxxxx
h. Other	500				500
i. Total Direct Charges	6,667				6,667
j. Indirect Charges					
k. Totals (sum of 6i and 6j)	$ 6,667	$	$	$	$ 6,667
Program Income	$	$	$	$	$

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Friday
June 17, 1994

Part VI

Department of Health and Human Services

Administration for Children and Families

Fiscal Year 1994 Family Violence Prevention and Services Discretionary Funds Program; Availability of Funds and Request for Applications; Notice

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[Program Announcement No. OCS 94–08]

Fiscal Year 1994 Family Violence Prevention and Services Discretionary Funds Program; Availability of Funds and Request for Applications

AGENCY: Office of Community Services, Administration for Children and Families (ACF), Department of Health and Human Services.

ACTION: Announcement of the availability of funds and request for applications under the Office of Community Services Family Violence Prevention and Services Program.

SUMMARY: The Office of Community Services (OCS) announces its Family Violence Prevention and Services discretionary funds program for fiscal year (FY) 1994. Funding for grants under this announcement is authorized by the "Child Abuse, Domestic Violence, Adoption, and Family Services Act of 1992," Public Law 102–295, governing discretionary programs for family violence prevention and services. This announcement contains all forms and instructions for submitting an application.

DATES: The closing date for submission of applications is August 1, 1994.

ADDRESSES: Applications may be mailed to the Department of Health and Human Services, Administration for Children and Families, Division of Discretionary Grants, 370 L'Enfant Promenade, SW., 6th Floor (OCS 94–08), OFM/DDG, Washington, DC 20447

Hand delivered applications are accepted during the normal working hours of 8 a.m. to 4:30 p.m., Monday through Friday, on or prior to the established closing date at: Administration for Children and Families, Division of Discretionary Grants, 901 D Street, SW., 6th Floor (OCS 94–08), OFM/DDG, Washington, DC 20447.

FOR FURTHER INFORMATION CONTACT: Administration for Children and Families, Office of Community Services, Division of State Assistance, 370 L'Enfant Promenade, SW., Washington, DC 20447. Telephone (202) 401–9233.

SUPPLEMENTARY INFORMATION: The Office of Community Services, Administration for Children and Families, announces that applications are being accepted for funding for FY 1994 projects on Public Information/ Community Awareness for the Prevention of Domestic Violence; Historical Black Colleges and Universities (HBCUs) Institutional Outreach Activities in Support of Comprehensive Family Violence Prevention Activities (Outreach and Prevention); and Domestic Violence/ Child Welfare Services Collaboration:

This program announcement consists of four parts. Part I provides information on the family violence program and the statutory funding authority applicable to this announcement.

Part II describes the priority areas under which applications for FY 1994 family violence funding are being requested.

Part III describes the review process.

Part IV provides information and instructions for the development and submission of applications.

The forms to be used for submitting an application follow Part IV. Please copy and use these forms in submitting an application under this announcement. No additional application materials are available or needed to submit an application.

Applicants should note that grants to be awarded under this program announcement are subject to the availability of funds.

Part I. Introduction

Title III of the Child Abuse Amendments of 1984, (Pub. L. 98–457, 42 U.S.C. 10401, *et seq.*) is entitled the Family Violence Prevention and Services Act (the Act). It was first implemented in FY 1986 and reauthorized and amended for fiscal years 1993 through 1995 by Congress on May 28, 1992 by Public Law 102–295. Funds under the Act are awarded to States and Indian Tribes to assist in supporting programs and projects to prevent incidents of family violence and to provide immediate shelter and related assistance for victims of family violence and their dependents.

Family violence prevention funds have served to supplement many already established community-based family violence prevention and service activities. These funds also have allowed States and Tribes to expand current service programs and establish additional new centers in rural and underserved areas, on Native American Reservations, and in Alaskan Native Villages and Regional Corporation areas. In most areas, there is private sector as well as State and local funding for these emergency shelters.

The Department, through the Family Violence Prevention and Services Act, has provided technical assistance grants to several State Coalitions Against Domestic Violence, and to several nonprofit organizations to assist shelter operators and service providers to improve their service delivery, and also to support better planning, coordination and information exchange.

In addition to the grants that were initially made available in FY 1986, the Department also has supported: The operation of the Clearinghouse on Family Violence Information; research activities with the Department of Justice; regionally based training and technical assistance for State and local law enforcement personnel through the Department of Justice; and grants for technical assistance and training for State and local public and private nonprofit agencies administering the family violence program.

During FY 1993, the Department continued to make grant awards that enhanced public information and community awareness strategies and activities. Twenty-one grant awards for public information and community awareness were made during FY 1993 to private non-profit organizations representing Native Americans, Haitian Americans, Asian Americans, and community coalitions. These grant awards provided support to various organizations in their efforts to prevent family violence and to make their communities aware of the nature and prevalence of domestic violence as well as the services available for prevention activities.

Six grant awards were made during FY 1993 to demonstrate model training for domestic violence prosecutors that would provide improved access and legal representation for domestic violence victims. A national resource center for domestic violence and three special issue resource centers also were established during FY 1993. The national resource center and the special-issue resource centers will provide resource and service information, training, and technical assistance to Federal, State, and Indian tribal agencies, as well as to local domestic violence programs and to professionals and other individuals who provide services to victims of domestic violence.

Part II. Fiscal Year 1994 Family Violence Projects

1. Priority Area Number FV01–94:

Public Information/Community Awareness Campaign Projects for the Prevention of Family Violence

Purpose: To assist in the development of public information and community awareness campaign projects and activities that will serve as information models for the prevention of family violence. These projects should provide information on resources, facilities, and

service alternatives available to family violence victims and their dependents, community organizations, local school districts, and other individuals seeking assistance.

Eligible Applicants: State and local agencies, Territories, and Native American Tribes and Tribal Organizations who are, or have been, recipients of Family Violence Prevention and Services Act grants; State and local private non-profit agencies experienced in the field of family violence prevention; and public and private non-profit educational institutions, community organizations and community-based coalitions, and other entities that have designed and implemented family violence prevention information activities or community awareness strategies.

Background: Based on the encouraging response to the announcement for public information and community awareness grants for family violence prevention in Federal fiscal years 1992 and 1993, ACF plans to again make these grants available in FY 1994.

The public information/community awareness grant awards have spawned very effective informational activities at the local levels. These grants have assisted community organizations to focus on and emphasize prevention, helped to make available public service announcements and legal brochures in several different languages, including Russian and Vietnamese, and have assisted in the implementation of conflict resolution activities in elementary, middle and high school curricula.

The goal of this priority area is to continue to add credible and persuasive information to the arsenal of weapons necessary and available to community organizations to help break the so-called "cycle of family violence." The continuation of these efforts will help assure that individuals, particularly within minority communities, are aware of available resources and alternative responses for the resolution and the prevention of violence. The proposed grant awards will provide support for a model that provides for a more informed individual and thus, more effective prevention strategies on the part of that individual.

The focus of this priority area requires the development and implementation of an innovative public information campaign model that may be used, for example, by public and private agencies, schools, churches, boys and girls clubs, community organizations, and individuals. The ACF support for the continued increase of information on services and other alternatives for the prevention of family violence promotes the concepts that this behavior is unacceptable and that victims, their dependents, and perpetrators need to be provided with remedial and service options for their particular situations.

Accurate information is critical to any community awareness strategy and activity. How information is communicated must be modified where communication barriers may exist because of perceived or real language differences and cultural insensitivities.

Minimum Requirements for Project Design: In order to successfully compete under the priority area, the applicant should:

- Present a plan for community awareness and public information activities that clearly reflect how the applicant will coordinate with public agencies and with other community organizations and institutions active in the field of family violence prevention.
- Describe, as an element of the plan, a proposed model approach to the development of a public information campaign and identify the specific audience(s), community(ies), and groups with the highest prevalence of domestic violence that will be educated in the prevention of family violence.
- Include, as critical elements in the plan:
- A set of achievable objectives and a description of the population groups, relevant geographic area, and the evaluation components to be used to measure progress and the overall effectiveness of the campaign;
- Applicants must also describe their intended strategies for test marketing their development plans and give assurances that effectiveness criteria will be implemented prior to finalizing the plan;
- The development and use of non-traditional sources as information providers (applicants should present specific plans for the use of local organizations, businesses and individuals in the distribution of information and materials);
- The identification of the media to be used in the campaign and the geographic distribution of the campaign;
- How the applicant would be responsive to and demonstrate its sensitivity towards minority communities and their cultural perspectives; and
- Provide a description of the kind, volume, distribution, and timing of the proposed information with assurances that the public information campaign activities will not supplant or lower the current frequency of public service announcements.

Project Duration: The length of the project should not exceed 12 months.

Federal Share of the Project: The maximum Federal share of the project is not to exceed $35,000 for the 1-year project period. Applications for lesser amounts also will be considered under this priority area.

Matching Requirement: Grantees must provide at least 25 percent of the total cost of the project. The total approved cost of the project is the sum of the ACF share and the non-Federal share. The non-Federal share maybe met by cash or in-kind contributions, although applicants are encouraged to meet their match requirements through cash contributions. Therefore, a project requesting $35,000 in Federal funds (based on an award of $35,000 per budget period), must include a match of at least $11,660 (25% of total project cost).

Anticipated Number of Projects to be Funded: It is anticipated that three projects will be funded at the maximum level; more than three projects may be funded depending on the number of acceptable applications for lesser amounts which are received.

CFDA: 93.671 Family Violence Prevention and Services: Family Violence Prevention and Services Act, as amended.

2. Priority Area Number FV02–94:

Historical Black Colleges and Universities (HBCUs) Institutional Outreach Activities in Support of Comprehensive Family Violence Prevention Activities (Outreach and Prevention);

Purpose: To assist in the development of public information materials, educational strategies, and community activities for families that will focus on family violence prevention as a part of a comprehensive approach to improve and enable family-focused interventions. It is expected that these interventions which are directed towards families will increase the awareness of violence and decrease its incidence and impact in minority communities. In these efforts the responding institutions should enlist the energy and cooperation of significant community institutions, community organizations, and individuals to serve as models and to provide information on resources, services, facilities, and alternatives to violence in the family.

Eligible Applicants: The Office of Community Services, Administration for Children and Families invites Historically Black Universities and Colleges to submit applications for

projects that will provide for the development, implementation and operation of comprehensive family violence prevention strategies and for the dissemination of informational and rescurce materials for the prevention of family violence in our minority communities. Successful applicants for this priority area will not be precluded from applying in response to a subsequent announcement.

Background: The goal of this priority area is to provide support for the inclusion of "family violence prevention" in a comprehensive approach which considers environmental and cultural factors in plans for intervention and violence prevention strategies in minority communities. Historical Black Colleges and Universities in their relationships with minority communities and their residents offer an opportunity for the exchange and development of innovative ideas and approaches to the prevention of violence in general. This effort will make it possible to capture, consider and utilize the ideas for violence prevention that exist in the minority communities, particularly in response to the problems of racism and poverty. The utilization of HBCUs in this effort will make available the considerable expertise, experience, and resources to be found in these institutions.

Family violence prevention activities encompass a wide range of activities that include the teaching of conflict resolution skills, the implementation of intervention strategies, and the development of informational materials on available resources and services. Family violence prevention may be viewed as the sum of activities which are guides to acceptable behavior. For example, activities that may be a part of the family violence prevention equation provide parenting skills and techniques, emphasize self-esteem for our youth, stress the importance of higher education as a conduit to a better lifestyle, and identify the means of avoiding negative health consequences such as AIDS and other sexually transmitted diseases.

Family violence prevention needs to be considered as a part of an overall violence prevention strategy. With this particular perspective the Administration for Children and Families is interested in applications that address:

Overall strategies for violence prevention activities that focus on educational and training efforts, outreach activities and supportive services, and the role and impact of community institutions;

Cooperative networks and collaborative approaches within the minority communities for the prevention of anti-social and violent behavior and that facilitate the implementation of family violence preventive efforts;

Intervention approaches concerned with building upon family values within minority families;

Institutional intervention strategies utilizing resources such as alumni, fraternities and sororities, the African American religious community, and volunteers from the community in general; and

The identification of data gathering, informational and research activities that are needed to identify, support, and implement the long-term strategic interventions to reduce "Black on Black" crime in general and family violence in the African American community in particular.

Minimum Requirements for Project Design:

In order to successfully complete under this priority area, the applicant should:

- Prepare and submit an application that clearly reflects how the applicant will coordinate with other community organizations, agencies, institutions, and individuals active in the field of family violence prevention;
- Describe, as a major element, the significant prevention efforts that are a part of the educational and training, outreach, and supportive service strategies; and
- Describe, as an element of the plan, the proposed approach to a public information/community awareness strategy and identify the specific audience, community(s), and target group(s) on which the efforts will be focused.
- Describe, as an element of the plan, the intended strategies for test marketing the development plans and give assurances that effectiveness criteria will be implemented prior to finalizing the plan;
- Include as critical elements in the plan:
- The development and use of non-traditional sources as information providers and in outreach efforts;
- The specific interventions to be modeled and their responsiveness and sensitivity to the general violence in the African American community;
- A set of achievable objectives and the evaluation components that are to be used to measure the degree of success in achieving the objectives as well as the assessment of the programs impact.

Project Duration: The length of the project should not exceed 17 months.

Federal Share of the Project: The maximum Federal share of the project is not to exceed $40,000 for the 17-month project period. Applications for lesser amounts also will be considered under this priority area.

Matching Requirement: Grantees must provide at least 25 percent of the total cost of the project. The total approved cost of the project is the sum of the ACF share and the non-Federal share. The non-Federal share maybe met by cash or in-kind contributions, although applicants are encouraged to meet their match requirements through cash contributions. Therefore, a project requesting $40,000 in Federal funds (based on an award of $40,000 per budget period), must include a match of at least $13,333 (25% of total project cost).

Anticipated Number of Projects to be Funded: It is anticipated that three projects may be funded at the maximum level; more than three projects may be funded depending on the number of acceptable applications for lesser amounts which are received.

CFDA: 93.671 Family Violence Prevention and Services: Family Violence Prevention and Services Act, as amended.

3. Priority Area Number FV03–94:

Domestic Violence/Child Protective Services Collaboration:

Eligible Applicants: State and local child protection agencies; Other State and local agencies, Territories, and Native American Tribes and Tribal Organizations who are recipients, or have been recipients, of Family Violence Prevention and Services Act grants; private nonprofit child welfare agencies; domestic violence advocacy organizations; and domestic violence State coalitions. Applicants must submit a signed Letter of Agreement between the public agency representing the child welfare/child protection responsibilities and the organization or coalition representing domestic violence advocacy organizations and their concerns. Either signatory to the Agreement may be the principal grantee. The Agreement to be submitted will specifically indicate the role each participant organization has in the implementation of the proposed project. Because the successful implementation of a proposed project would have implications for systemic/procedural change in the child welfare and/or the domestic violence community, the Letter of Agreement is mandatory.

Purpose: To develop effective strategies for domestic violence services

integration into child protection systems and strategies. To offer the applicant organizations an opportunity to design, develop, and collaborate on one of several issues or areas of concern between the child protection system and the domestic violence community. Efforts are to be focused on the development of curricula and materials and the implementation of training to be available. The training of child protection representatives and domestic violence advocates will be to enable the most efficient and effective response when encountering woman abuse in the course of child abuse and neglect investigations. Protocols for effective strategies of intervention need to be designed, developed and put in place to allow for the child protection system to assist and utilize the non-offending parent to protect her children.

Applicants may propose to do one or more of the following: Plan and implement the training of child protection service workers, supervisors and social services providers on the relationship of domestic violence and child abuse and neglect; develop and implement domestic violence responsive policies to be adopted by the Statewide child protection services system; develop and implement through the child protection system a domestic violence specific curriculum which will become part of a mandatory training program; develop and implement Memoranda of Understanding between the child protection system and the domestic violence statewide system; and gather and submit data correlating abuse between adult partners and child abuse and neglect.

Background: Based on a recent review of the literature, it has become evident that in the homes where the woman is battered the children were themselves more likely to be victims of child abuse and neglect. Domestic violence is surfacing as one of the highest risks to children. Domestic violence represents physical endangerment to the child as well as the possibility for developmental delay.

In 1985, there were an estimated 795,000 abused children between the ages of 3 and 17 living in two-parent households (Gelles, Strauss, 1987). According to these studies, men are the main perpetrators of domestic violence and commit 95 percent of all assaults on women. In 70 percent of households in which women are abused, the men also commit child abuse (Schecter, 1982). Also, in 70 percent of child abuse cases treated at Boston Children's Hospital in 1991, the mother was abused as well.

In an attempt to establish the actual relationship between child abuse and battering in families, 116 mothers of children "darted" or flagged in a single year for abuse or neglect at a metropolitan hospital were studied by Stark and Flitcraft (1984). These examinations revealed that 45 percent of the abused children had mothers who themselves were being physically abused and another 5 percent had mothers whose relationships were "full of conflict," although abuse was not verified. Bowker, Arbitell and McFerron (1988) reported that children whose mothers had been battered were more likely to be physically abused and less likely to be "neglected" than children whose mothers had not been battered. In Hilberman and Munson's (1987) research, they found evidence of physical and/or sexual abuse of children in 20 of the 60 cases they studied. They concluded: "There seems to be two styles of abuse: the husband beats the wife who beats the children, and/or the husband beats both his wife and children."

Project Duration: The length of the project should not exceed 17 months.

Federal Share of the Project: The maximum Federal share of the project is not to exceed $50,000 for the 17 month project period. Applications for lesser amounts also will be considered for this project.

Matching Requirement: Grantees must provide at least 25 percent of the total cost of the project. The total approved cost of the project is the sum of the ACF share and the non-Federal share. The non-Federal share maybe met by cash or in-kind contributions, although applicants are encouraged to meet their match requirements through cash contributions. Therefore, a project requesting $50,000 in Federal funds (based on an award of $50,000 per budget period), must include a match of at least $16,666 (25% of total project cost).

Anticipated Number of Projects to be Funded: It is anticipated that five projects may be funded at the maximum level; more than five projects may be funded depending on the number of acceptable applications for lesser amounts which are received.

CFDA: 93.671 Family Violence Prevention and Services: Family Violence Prevention and Services Act, as amended.

Part III—The Review Process

A. Eligible Applicants

Before applications are reviewed, each application will be screened to determine that the applicant organization is an eligible applicant as specified under the selected priority area. Applications from organizations which do not meet the eligibility requirements for the priority area will not be considered or reviewed in the competition, and the applicant will be so informed.

Each priority area description contains information about the types of agencies and organizations which are eligible to apply under that priority area. Since eligibility varies among priority areas, it is critical that the "Eligible Applicants" section under each specific priority area be read carefully.

Only agencies and organizations, not individuals, are eligible to apply under any of the priority areas. On all applications developed jointly by more than one agency or organization, the applications must identify only one organization as the lead organization and official applicant. The other participating agencies and organizations can be included as co-participants, subgrantees or subcontractors.

Any non-profit agency which has not previously received an award from the U. S. Department of Health and Human Services must submit proof of non-profit status with its grant application.

The non-profit agency can accomplish this by either making reference to its listing in the Internal Revenue Service's (IRS) most recent list of tax-exempt organizations or submitting a copy of its letter from the IRS under IRS Code Section 501(c)(3). ACF cannot fund a non-profit applicant without acceptable proof of its non-profit status.

B. Review Process and Funding Decisions

Timely applications will be reviewed and scored competitively. Experts in the field, generally persons from outside of the Federal government, will use the appropriate evaluation criteria listed later in this Part to review and score the applications. The results of this review are a primary factor in making funding decisions.

OCS reserves the option of discussing applications with, or referring them to, other Federal or non-Federal funding sources when this is determined to be in the best interest of the Federal government or the applicant. It may also solicit comments from ACF Regional Office staff, other Federal agencies, interested foundations, national organizations, specialists, experts, States and the general public. These comments, along with those of the expert reviewers, will be considered by OCS in making funding decisions.

In making decisions on awards, OCS may give preference to applications which focus on or feature: Minority

populations; a substantially innovative strategy with the potential to improve theory or practice in the field of human services; a model practice or set of procedures that holds the potential for replication by organizations involved in the administration or delivery of human services; substantial involvement of volunteers; substantial involvement (either financial or programmatic) of the private sector; a favorable balance between Federal and non-Federal funds available for the proposed project; the potential for high benefit for low Federal investment; a programmatic focus on those most in need; and/or substantial involvement in the proposed project by national or community foundations.

To the extent possible, efforts will be made to ensure that funding decisions reflect an equitable distribution of assistance among the States and geographical regions of the country, rural and urban areas, and ethnic populations. In making these decisions, OCS may also take into account the need to avoid unnecessary duplication of effort.

C. Evaluation Criteria

Using the appropriate evaluation criteria below, a panel of at least three reviewers (primarily experts from outside the Federal government) will review each application. Applicants should ensure that they address each minimum requirement in the priority area description under the appropriate section of the Program Narrative Statement.

Reviewers will determine the strengths and weaknesses of each proposal in terms of the appropriate evaluation criteria listed below, provide comments and assign numerical scores. The point value following each criterion heading indicates the maximum numerical weight that each section may be given in the review process.

Review Criteria for All Priority Areas

Applications under all priority areas will be evaluated against the following criteria.

1. *Objectives and Need for the Project (20 points).* State the specific objectives and needs addressed by the project in terms of its national or regional significance, its theoretical importance, its applicability to policy and practice. Provide a detailed discussion of the "state-of-the-art" relative to the problem or area addressed by the proposal and indicate how the proposed effort will impact on it. State the goals or service objectives of the proposal. Provide supporting documentation or other testimonies from concerned interests other than the applicant. Summarize, evaluate and relate relevant data, based on planning or demonstration studies to the proposed project. The application must identify the specific topics or program areas to be served by the proposed project.

2. *Results or Benefits Expected (20 points).* The extent to which the application identifies the results and benefits to be derived, the extent to which they are consistent with the objectives of the proposal, the extent to which the application indicates the anticipated contributions to policy, practice, and theory, and the extent to which the proposed project costs are reasonable in view of the expected results. Identify, in specific terms, the results and benefits, for target groups and human service providers, to be derived from implementing the proposed project. Describe how the expected results and benefits will relate to previous demonstration efforts. Describe in detail evaluation plans and procedures which are capable of measuring the degree to which the project objectives have been accomplished.

3. *Approach (35 points).* The extent to which the application outlines a sound and workable plan of action pertaining to the scope of the project, and details how the proposed work will be accomplished; relates each task to the objectives and identifies the key staff member who will be the lead person; provides a chart indicating the timetable for completing each task, the lead person, and the time committed; cites factors which might accelerate or decelerate the work, giving acceptable reasons for taking this approach as opposed to others; describes and supports any unusual features of the project, such as design or technological innovations, reductions in cost or time, or extraordinary social and community involvements; and provides for projections of the accomplishments to be achieved.

The extent to which, when applicable, the application describes the evaluation methodology that will be used to determine if the needs identified and discussed are being met and if the results and benefits identified are being achieved. The application also lists each organization, agency, consultant, or other key individuals or groups who will work on the project, along with a description of the activities and nature of their effort or contribution.

4. *Level of Effort: (25 Points). Staffing pattern*—Describe the staffing pattern for the proposed project, clearly linking responsibilities to project tasks and specifying the contributions to be made by key staff.

Competence of staff—Describe the qualifications of the project team including any experiences working on similar projects. Also, describe the variety of skills to be used, relevant educational background and the demonstrated ability to produce final results that are comprehensible and usable. One or two pertinent paragraphs on each key member are preferred to vitae/résumés. However, vita/résumés may be included in the ten pages allowed for attachments/appendices.

Adequacy of resources—Specify the adequacy of the available facilities, resources and organizational experience with regard to the tasks of the proposed project. List the financial, physical and other sources to be provided by other profit and nonprofit organizations. Explain how these organizations will participate in the day to day operations of the project.

Budget—Relate the proposed budget to the level of effort required to obtain project objectives and provide a cost/benefit analysis. Demonstrate that the project's costs are reasonable in view of the anticipated results.

Collaborative efforts—Discuss in detail and provide documentation for any collaborative or coordinated efforts with other agencies or organizations. Identify these agencies or organizations and explain how their participation will enhance the project. Letters from these agencies and organizations discussing the specifics of their commitment must be included in the application.

Authorship—The authors of the application must be clearly identified together with their current relationship to the applicant organization and any future project role they may have if the project is funded.

Applicants should note that non-responsiveness to the section *"Minimum Requirements for Project Design"* will result in a low evaluation score by the panel of expert reviewers. Applicants must clearly identify the specific priority area under which they wish to have their applications considered, and tailor their applications accordingly. Previous experience has shown that an application which is broader and more general in concept than outlined in the priority area description is less likely to score as well as one which is more clearly focused on and directly responsive to the concerns of that specific priority area.

D. Available Funds

OCS intends to award grants resulting from this announcement during the fourth quarter of FY 1994. The size of

the actual awards will vary. Each priority area description includes information on the maximum Federal share of the project costs and the anticipated number of projects to be funded.

The term "project period" refers to the total time a project is approved for support, including any extensions.

Where appropriate, applicants may propose project periods which are shorter than the maximums specified in the various priority areas. Non-Federal share contributions may exceed the minimums specified in the various priority areas when the applicant is able to do so.

E. Grantee Share of Project Costs

Federal funds will be provided to cover up to 75% of the total allowable project costs. Therefore, the non-Federal share must amount to at least 25% of the total (Federal plus non-Federal) project cost. This means that, for every $3 in Federal funds received, up to the maximum amount allowable under each priority area, applicants must contribute at least $1.

For example, the cost breakout for a project with a total cost of $56,666 to implement would be:

Federal request	Non-Federal share	Total cost
$50,000	$16,666	$56,666
75%	25%	100%

Part IV—Instructions for the Development and Submission of Applications

This Part contains information and instructions for submitting applications in response to this announcement. Application forms are provided as part of this publication along with a checklist for assembling an application package. Please copy and use these forms in submitting an application.

Potential applicants should read this section carefully in conjunction with the information contained within the specific priority area under which the application is to be submitted. The priority area descriptions are in part II.

A. Required Notification of the State Single Point of Contact

This program is covered under Executive Order 12372, (E.O.) "Intergovernmental Review of Federal Programs," and 45 CFR part 100, "Intergovernmental Review of Department of Health and Human Services Program and Activities." Under the E.O., States may design their own processes for reviewing and commenting on proposed Federal assistance under covered programs.

All States and territories, except Alabama, Alaska, Connecticut, Hawaii, Idaho, Kansas, Louisiana, Minnesota, Montana, Nebraska, Oklahoma, Oregon, Pennsylvania, South Dakota, Virginia, Washington, American Samoa and Palau, have elected to participate in the E.O. process and have established a Single Points of Contact (SPOCs). Applicants from these eighteen jurisdictions need take no action regarding E.O. 12372. Applicants for projects to be administered by Federally-recognized Indian tribes are also exempt from the requirements of E.O. 12372. Otherwise, applicants should contact their SPOCs as soon as possible to alert them of the prospective applications and receive any necessary instructions. Applicants must submit any required material to the SPOCs as soon as possible so that OCS can obtain and review SPOC comments as part of the award process. It is imperative that the applicant submit all required materials, if any, to the SPOC and indicate the date of this submittal (or the date of contact if no submittal is required) on the Standard Form 424, item 16a.

Under 45 CFR 100.8(a)(2), a SPOC has 60 days from application deadline to comment on proposed new or competing continuation awards.

SPOCs are encouraged to eliminate the submission of routine endorsements as official recommendations. Additionally, SPOCs are requested to differentiate clearly between mere advisory comments and those official State process recommendations which may trigger the "accommodate or explain" rule.

When comments are submitted directly to ACF, they should be addressed to: Department of Health and Human Services, Administration for Children and Families, Division of Discretionary Grants, 370 L'Enfant Promenade, SW., 6th Floor, Washington, DC 20447.

A list of the Single Points of Contact for each State and Territory is included at the end of this announcement.

B. Deadline for Submittal of Applications

The closing date for submittal of applications under this program announcement is found at the beginning of this program announcement under DATES. Applications shall be considered as meeting the announced deadline if they are either:

1. Received on or before the deadline date at: Administration for Children and Families, Division of Discretionary Grants, 6th Floor, OFM/DDG, 370 L'Enfant Promenade, SW, Washington, DC 20447, or

2. Sent on or before the deadline date and received by ACF in time for the independent review under DHHS GAM Chapter 1 62. (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 the criteria stated above are considered late applications. The ACF shall notify each late applicant that its application will not be considered in the current competition.

Extension of deadlines: The ACF may extend the deadline for all applicants due to acts of God, such as floods, hurricanes or earthquakes, etc., or when there is widespread disruption of the mail. However, if ACF does not extend the deadline for all applicants, it may not waive or extend the deadline for any applicant.

C. Instructions for Preparing the Application and Completing Application Forms

The SF 424, SF 424A, Page 2 and certifications have been reprinted for your convenience in preparing the application. You should reproduce single-sided copies of these forms from the reprinted forms in the announcement, typing your information onto the copies. Please do not use forms directly from the **Federal Register** announcement, as they are printed on both sides of the page.

In order to assist applicants in correctly completing the SF 424 and SF 424A, instructions for these forms have been included at the end of Part IV of this announcement.

Where specific information is not required under this program, NA (not applicable) has been preprinted on the form.

Please prepare your application in accordance with the following instructions:

1. SF 424 Page 1, Application Cover Sheet

Please read the following instructions before completing the application cover sheet. An explanation of each item is included. Complete only the items specified.

Top of Page. Enter the single priority area number under which the application is being submitted. An application should be submitted under only one priority area.

Item 1. "Type of Submission"—Preprinted on the form.

Item 2. "Date Submitted" and "Applicant Identifier"—Date application is submitted to ACF and applicant's own internal control number, if applicable.

Item 3. "Date Received By State"—State use only (if applicable).

Item 4. "Date Received by Federal Agency"—Leave blank.

Item 5. "Applicant Information"

"Legal Name"—Enter the legal name of applicant organization. For applications developed jointly, enter the name of the lead organization only. There must be a single applicant for each application.

"Organizational Unit"—Enter the name of the primary unit within the applicant organization which will actually carry out the project activity. Do not use the name of an individual as the applicant. If this is the same as the applicant organization, leave the organizational unit blank.

"Address"—Enter the complete address that the organization actually uses to receive mail, since this is the address to which all correspondence will be sent. Do not include both street address and P.O. box number unless both must be used in mailing.

"Name and telephone number of the person to be contacted on matters involving this application (give area code)"—Enter the full name (including academic degree, if applicable) and telephone number of a person who can respond to questions about the application. This person should be accessible at the address given here and will receive all correspondence regarding the application.

Item 6. "Employer Identification Number (EIN)"—Enter the employer identification number of the applicant organization, as assigned by the Internal Revenue Service, including, if known, the Central Registry System suffix.

Item 7. "Type of Applicant"—Self-explanatory.

Item 8. "Type of Application"—Preprinted on the form.

Item 9. "Name of Federal Agency"—Preprinted on the form.

Item 10. "Catalog of Federal Domestic Assistance Number and Title"—Enter the Catalog of Federal Domestic Assistance (CFDA) number, 93.671, assigned to the program under which assistance is requested and its title, as indicated in the relevant priority area description.

Item 11. "Descriptive Title of Applicant's Project"—Enter the project title. The title is generally short and is descriptive of the project, not the priority area title.

Item 12. "Areas Affected by Project"—Enter the governmental unit where significant and meaningful impact could be observed. List only the largest unit or units affected, such as State, county, or city. If an entire unit is affected, list it rather than subunits.

Item 13. "Proposed Project"—Enter the desired start date for the project and projected completion date.

Item 14. "Congressional District of Applicant/Project"—Enter the number of the Congressional district where the applicant's principal office is located and the number of the Congressional district(s) where the project will be located. If statewide, a multi-State effort, or nationwide, enter "00."

Items 15 "Estimated Funding Levels"—In completing 15a through 15f, the dollar amounts entered should reflect, for a 17 month or less project period, the total amount requested.

Item 15a. Enter the amount of Federal funds requested in accordance with the preceding paragraph. This amount should be no greater than the maximum amount specified in the priority area description.

Items 15b-e. Enter the amount(s) of funds from non-Federal sources that will be contributed to the proposed project. Items b-e are considered cost-sharing or "matching funds." The value of third party in-kind contributions should be included on appropriate lines as applicable. For more information regarding funding as well as exceptions to these rules, see Part III, Sections E and F, and the specific priority area description.

Item 15f. Enter the estimated amount of income, if any, expected to be generated from the proposed project. Do not add or subtract this amount from the total project amount entered under item 15g. Describe the nature, source and anticipated use of this income in the Project Narrative Statement.

Item 15g. Enter the sum of items 15a-15e.

Item 16a. "Is Application Subject to Review By State Executive Order 12372 Process? Yes."—Enter the date the applicant contacted the SPOC regarding this application. Select the appropriate SPOC from the listing provided at the end of Part IV. The review of the application is at the discretion of the SPOC. The SPOC will verify the date noted on the application. If there is a discrepancy in dates, the SPOC may request that the Federal agency delay any proposed funding until September 30, 1994.

Item 16b. "Is Application Subject to Review By State Executive Order 12372 Process? No."—Check the appropriate box if the application is not covered by E.O. 12372 or if the program has not been selected by the State for review.

Item 17. "Is the Applicant Delinquent on any Federal Debt?"—Check the appropriate box. This question applies to the applicant organization, not the person who signs as the authorized representative. Categories of debt include audit disallowances, loans and taxes.

Item 18. "To the best of my knowledge and belief, all data in this application/preapplication 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 awarded."—To be signed by the authorized representative of the applicant. A copy of the governing body's authorization for signature of this application by this individual as the official representative must be on file in the applicant's office, and may be requested from the applicant.

Item 18a-c. "Typed Name of Authorized Representative, Title, Telephone Number"—Enter the name, title and telephone number of the authorized representative of the applicant organization.

Item 18d. "Signature of Authorized Representative"—Signature of the authorized representative named in Item 18a. At least one copy of the application must have an original signature. Use colored ink (not black) so that the original signature is easily identified.

Item 18e. "Date Signed"—Enter the date the application was signed by the authorized representative.

2. SF 424A—Budget Information—Non-Construction Programs

This is a form used by many Federal agencies. For this application, Sections A, B, C, E and F are to be completed. Section D does not need to be completed.

Sections A and B should include the Federal as well as the non-Federal funding for the proposed project covering the total project period of 17 months or less.

Section A—Budget Summary. This section includes a summary of the budget. On line 5, enter total Federal costs in column (e) and total non-Federal costs, including third party in-kind contributions, but not program income, in column (f). Enter the total of (e) and (f) in column (g).

Section B—Budget Categories. This budget, which includes the Federal as well as non-Federal funding for the proposed project, covers the total project period of 17 months or less. It should relate to item 15g, total funding, on the SF 424. Under column (5), enter

the total requirements for funds (Federal and non-Federal) by object class category.

A separate budget justification should be included to explain fully and justify major items, as indicated below. The types of information to be included in the justification are indicated under each category. The budget justification should immediately follow the second page of the SF 424A.

Personnel—Line 6a. Enter the total costs of salaries and wages of applicant/grantee staff. Do not include the costs of consultants, which should be included on line 6h, "Other."

Justification: Identify the project director, if known. Specify by title or name the percentage of time allocated to the project, the individual annual salaries, and the cost to the project (both Federal and non-Federal) of the organization's staff who will be working on the project.

Fringe Benefits—Line 6b. Enter the total costs of fringe benefits, unless treated as part of an approved indirect cost rate.

Justification: Provide a break-down of amounts and percentages that comprise fringe benefit costs, such as health insurance, FICA, retirement insurance, etc.

Travel—6c. Enter total costs of out-of-town travel (travel requiring per diem) for staff of the project. Do not enter costs for consultant's travel or local transportation, which should be included on line 6h, "Other."

Justification: Include the name(s) of traveler(s), total number of trips, destinations, length of stay, transportation costs and subsistence allowances.

Equipment—Line 6d. Enter the total costs of all equipment to be acquired by the project. For State and local governments, including Federally recognized Indian Tribes, "equipment" is non-expendable, tangible, personal property having a useful life of more than one year and an acquisition cost of $5,000 or more per unit. For all other applicants, the threshold for equipment is $500 or more per unit. The higher threshold for State and local governments became effective October 1, 1988, through the implementation of 45 CFR part 92, "Uniform Administrative Requirements for Grants and Cooperative Agreements to State and local governments."

Justification: Equipment to be purchased with Federal funds must be justified. The equipment must be required to conduct the project, and the applicant organization or its subgrantees must not have the equipment or a reasonable facsimile available to the project. The justification also must contain plans for future use or disposal of the equipment after the project ends.

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

Justification: Specify general categories of supplies and their costs.

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

Justification: Attach a list of contractors, indicating the names of the organizations, the purposes of the contracts, and the estimated dollar amounts of the awards as part of the budget justification. Whenever the applicant/grantee intends to delegate part or all of the program to another agency, the applicant/grantee must complete this section (Section B, Budget Categories) for each delegate agency by agency title, along with the supporting information. The total cost of all such agencies will be part of the amount shown on Line 6f. Provide backup documentation identifying the name of contractor, purpose of contract, and major cost elements.

Construction—Line 6g. Not applicable. New construction is not allowable.

Other—Line 6h. Enter the total of all other costs. Where applicable, such costs may include, but are not limited to: Insurance; 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. Note that costs identified as "miscellaneous" and "honoraria" are not allowable.

Justification: Specify the costs included.

Total Direct Charges—Line 6i. Enter the total of Lines 6a through 6h.

Indirect Charges—6j. Enter the total amount of indirect charges (costs). If no indirect costs are requested, enter "none." Generally, this line should be used when the applicant (except local governments) has a current indirect cost rate agreement approved by the Department of Health and Human Services or another Federal agency.

Local and State governments should enter the amount of indirect costs determined in accordance with HHS requirements. When an indirect cost rate is requested, these costs are included in the indirect cost pool and should not be charged again as direct costs to the grant. In the case of training grants to other than State or local governments (as defined in title 45, Code of Federal Regulations, part 74), the Federal reimbursement of indirect costs will be limited to the lesser of the negotiated (or actual) indirect cost rate 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 alterations and renovations.

For training grant applications, the entry under line 6j should be the total indirect costs being charged to the project. The Federal share of indirect costs is calculated as shown above. The applicant's share is calculated as follows:

(a) Calculate total project indirect costs (a*) by applying the applicant's approved indirect cost rate to the total project (Federal and non-Federal) direct costs.

(b) Calculate the Federal share of indirect costs (b*) at 8 percent of the amount allowed for total project (Federal and non-Federal) direct costs exclusive of any equipment charges, rental of space, tuition and fees, post-doctoral training allowances, contractual items, and alterations and renovations.

(c) Subtract (b*) from (a*). The remainder is what the applicant can claim as part of its matching cost contribution.

Justification: Enclose a copy of the indirect cost rate agreement. Applicants subject to the limitation on the Federal reimbursement of indirect costs for training grants should specify this.

Total—Line 6k. Enter the total amounts of lines 6i and 6j.

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.

Justification: Describe the nature, source, and anticipated use of program income in the Program Narrative Statement.

Section C—Non-Federal Resources. This section summarizes the amounts of non-Federal resources that will be applied to the grant. Enter this information on line 12 entitled "Totals." In-kind contributions are defined in title

45 of the Code of Federal Regulations, Part 74.51, as "property or services which benefit a grant-supported project or program and which are contributed by non-Federal third parties without charge to the grantee, the subgrantee, or a cost-type contractor under the grant or subgrant."

Justification: Describe third party in-kind contributions, if included.

Section D—Forecasted Cash Needs. Not applicable.

Section E—Budget Estimate of Federal Funds Needed For Balance of the Project. Not applicable.

Totals—Line 20. Not applicable.

Section F—Other Budget Information.

Direct Charges—Line 21. Not applicable.

Indirect Charges—Line 22. Enter the type of indirect rate (provisional, predetermined, final or 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.

Remarks—Line 23. If the total project period exceeds 17 months, you must enter your proposed non-Federal share of the project budget for each of the remaining years of the project.

3. Project Summary Description

Clearly mark this separate page with the applicant name as shown in item 5 of the SF 424, and the title of the project as shown in item 11 of the SF 424. The summary description should not exceed 300 words. These 300 words become part of the computer database on each project.

Care should be taken to produce a summary description which accurately and concisely reflects the proposal. It should describe the objectives of the project, the approaches to be used and the outcomes expected. The description should also include a list of major products that will result from the proposed project, such as software packages, materials, management procedures, data collection instruments, training packages, or videos (please note that audiovisuals should be closed captioned). The project summary description, together with the information on the SF 424, will constitute the project "abstract." It is the major source of information about the proposed project and is usually the first part of the application that the reviewers read in evaluating the application.

4. Program Narrative Statement

The Program Narrative Statement is a very important part of an application. It should be clear, concise, and address the specific requirements mentioned under the priority area description in Part II. The narrative should also provide information concerning how the application meets the evaluation criteria using the following headings:

(a) Objectives and Need for the Project;

(b) Results and Benefits Expected;

(c) Approach; and

(d) Level of Effort.

The specific information to be included under each of these headings is described in Section C of Part III, Evaluation Criteria.

The narrative should be typed double-spaced on a single-side of an 8½" × 11" plain white paper, with 1" margins on all sides. All pages of the narrative (including charts, references/footnotes, tables, maps, exhibits, etc.) must be sequentially numbered, beginning with "Objectives and Need for the Project" as page number one. Applicants should not submit reproductions of larger size paper, reduced to meet the size requirement.

The length of the application, including the application forms and all attachments, should not exceed 60 pages. A page is a single side of an 8½" × 11" sheet of paper. Applicants are requested not to send pamphlets, brochures or other printed material along with their application as these pose photocopy difficulties. These materials, if submitted, will not be included in the review process if they exceed the 60-page limit. Each page of the application will be counted to determine the total length.

5. Organizational Capability Statement

The Organizational Capability Statement should consist of a brief (two to three pages) background description of how the applicant organization (or the unit within the organization that will have responsibility for the project) is organized, the types and quantity of services it provides, and/or the research and management capabilities it possesses. This description should cover capabilities not included in the Program Narrative Statement. It may include descriptions of any current or previous relevant experience, or describe the competence of the project team and its demonstrated ability to produce a final product that is readily comprehensible and usable. An organization chart showing the relationship of the project to the current organization should be included.

6. Part V—Assurances/Certifications

Applicants are required to file an SF 424B, Assurances—Non-Construction Programs, and the Certification Regarding Lobbying. Both must be signed and returned with the application. In addition, applicants must certify their compliance with: (1) Drug-Free Workplace Requirements; and (2) Debarment and Other Responsibilities. These certifications are self-explanatory. Copies of these assurances/certifications are reprinted at the end of this announcement and should be reproduced, as necessary. A duly authorized representative of the applicant organization must certify that the applicant is in compliance with these assurances/certifications. A signature on the SF 424 indicates compliance with the conditions set forth in the Drug Free Workplace Requirements, and Debarment and Other Responsibilities certifications located in Appendices and of this announcement.

D. Checklist for a Complete Application

Applications may be mailed to the Department of Health and Human Services, Administration for Children and Families, Division of Discretionary Grants, 370 L'Enfant Promenade, SW., 6th Floor OFM/DDG, Washington, DC 20447.

Hand delivered applications are accepted during the normal working hours of 8 a.m. to 4:30 p.m., Monday through Friday, on or prior to the established closing date at: Administration for Children and Families, Division of Discretionary Grants, 901 D Street, SW., 6th Floor (OCS 94–08), OFM/DDG, Washington, DC 20447.

The checklist below is for your use to ensure that your application package has been properly prepared.

—One original, signed and dated application, plus three copies. Applications for different priority areas are packaged separately;

—Application is from an organization which is eligible under the eligibility requirements defined in the priority area description (screening requirement);

—Application length does not exceed 60 pages, unless otherwise specified in the priority area description.

—A complete application consists of the following items in this order:

—Application for Federal Assistance (SF 424, REV 4–88);

—A completed SPOC certification with the date of SPOC contact entered in line 16, page 1 of the SF 424 if applicable.

—Budget Information—Non-Construction Programs (SF 424A, REV 4–88);

—Budget justification for Section B—Budget Categories;

—Table of Contents;
—Letter from the Internal Revenue Service to prove non-profit status, if necessary;
—Copy of the applicant's approved indirect cost rate agreement, if appropriate;
—Project summary description and listing of key words;
—Program Narrative Statement (See Part III, Section C);
—Organizational capability statement, including an organization chart;
—Any appendices/attachments;
—Assurances—Non-Construction Programs (Standard Form 424B, REV 4–88);
—Certification Regarding Lobbying; and
—Certification of Protection of Human Subjects, if necessary.

E. The Application Package

Each application package must include an original and three copies of the complete application. Each copy should be stapled securely (front and back if necessary) in the upper left-hand corner. All pages of the narrative (including charts, tables, maps, exhibits, etc.) must be sequentially numbered, beginning with page one. In order to facilitate handling, please do not use covers, binders or tabs. Do not include extraneous materials as attachments, such as agency promotion brochures, slides, tapes, film clips, minutes of meetings, survey instruments or articles of incorporation.

Applicant should include a self-addressed, stamped acknowledgment card. All applicants will be notified automatically about the receipt of their application. If acknowledgment of receipt of your application is not received within eight weeks after the deadline date, please notify ACF by telephone at (202) 401–9233.

Dated: June 10, 1994

Donald Sykes

Director; Office of Community Services.

BILLING CODE 4184-01-P

OMB Approval No. 0348-0043

APPLICATION FOR FEDERAL ASSISTANCE

2. DATE SUBMITTED		Applicant Identifier
3. DATE RECEIVED BY STATE		State Application Identifier
4. DATE RECEIVED BY FEDERAL AGENCY		Federal Identifier

1. TYPE OF SUBMISSION:

Application	*Preapplication*
☐ Construction	☐ Construction
☐ Non-Construction	☐ Non-Construction

5. APPLICANT INFORMATION

Legal Name:	Organizational Unit:
Address (*give city, county, state, and zip code*):	Name and telephone number of the person to be contacted on matters involving this application (*give area code*)

6. EMPLOYER IDENTIFICATION NUMBER (EIN): ☐☐ — ☐☐☐☐☐☐☐

7. TYPE OF APPLICANT: (*enter appropriate letter in box*) ☐

A. State
B. County
C. Municipal
D. Township
E. Interstate
F. Intermunicipal
G. Special District
H. Independent School Dist.
I. State Controlled Institution of Higher Learning
J. Private University
K. Indian Tribe
L. Individual
M. Profit Organization
N. Other (Specify) _____

8. TYPE OF APPLICATION:

☐ New ☐ Continuation ☐ Revision

If Revision, enter appropriate letter(s) in box(es): ☐ ☐

A. Increase Award B. Decrease Award C. Increase Duration
D. Decrease Duration Other (*specify*):

_____

9. NAME OF FEDERAL AGENCY:

10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER: ☐☐ - ☐☐☐

TITLE:

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:

12. AREAS AFFECTED BY PROJECT (*cities, counties, states, etc.*):

13. PROPOSED PROJECT:		14. CONGRESSIONAL DISTRICTS OF:	
Start Date	Ending Date	a. Applicant	b. Project

15. ESTIMATED FUNDING:		
a. Federal	$	.00
b. Applicant	$	.00
c. State	$	.00
d. Local	$	.00
e. Other	$	.00
f. Program Income	$	.00
g. TOTAL	$	.00

16. IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?

a. YES. THIS 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

17. IS THE APPLICANT DELINQUENT ON ANY FEDERAL DEBT?

☐ Yes If "Yes," attach an explanation. ☐ No

18. TO THE BEST OF MY KNOWLEDGE AND BELIEF, ALL DATA IN THIS APPLICATION/PREAPPLICATION 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 AWARDED

a. Typed Name of Authorized Representative	b. Title	c. Telephone number
d. Signature of Authorized Representative		e. Date Signed

Previous Editions Not Usable

Standard Form 424 (REV 4-88)
Prescribed by OMB Circular A-102

Authorized for Local Reproduction

BILLING CODE 4184-01-C

INSTRUCTIONS FOR THE SF 424

This is a standard form used by applicants as a required facesheet for preapplications and applications submitted for Federal assistance. It will be used by Federal agencies to obtain applicant certification that States which have established a review and comment procedure in response to Executive Order 12372 and have selected the program to be included in their process, have been given an opportunity to review the applicant's submission.

Item and Entry

1. Self-explanatory.
2. Date application submitted to Federal agency (or State if applicable) & applicant's control number (if applicable).
3. State use only (if applicable).
4. If this application is to continue or revise an existing award, enter present Federal identifier number. If for a new project, leave blank.
5. Legal name of applicant, name of primary organizational unit which will undertake the assistance activity, complete address of the applicant, and name and telephone number of the person to contact on matters related to this application.
6. Enter Employer Identification Number (EIN) as assigned by the Internal Revenue Service.
7. Enter the appropriate letter in the space provided.
8. Check appropriate box and enter appropriate letter(s) in the space(s) provided:
   —"New" means a new assistance award.
   —"Continuation" means an extension for an additional funding/budget period for a project with a projected completion date.
   —"Revision" means any change in the Federal Government's financial obligation or contingent liability from an existing obligation.
9. Name of Federal agency from which assistance is being requested with this application.
10. Use the Catalog of Federal Domestic Assistance number and title of the program under which assistance is requested.
11. Enter a brief descriptive title of the project. If more than one program is involved, you should append an explanation on a separate sheet. If appropriate (e.g., construction or real property projects), attach a map showing project location. For preapplications, use a separate sheet to provide a summary description of this project.
12. List only the largest political entities affected (e.g., State, counties, cities).
13. Self-explanatory.
14. List the applicant's Congressional District and any District(s) affected by the program or project.
15. Amount requested or to be contributed during the first funding/budget period by each contributor. Value of in-kind contributions should be included on appropriate lines as applicable. If the action will result in a dollar change to an existing award, indicate *only* the amount of the change. For decreases, enclose the amounts in parentheses. If both basic and supplemental amounts are included, show breakdown on an attached sheet. For multiple program funding, use totals and show breakdown using same categories as item 15.
16. Applicants should contact the State Single Point of Contact (SPOC) for Federal Executive Order 12372 to determine whether the application is subject to the State intergovernmental review process.
17. This question applies to the applicant organization, not the person who signs as the authorized representative. Categories of debt include delinquent audit disallowances, loans and taxes.
18. To be signed by the authorized representative of the applicant. A copy of the governing body's authorization for you to sign this application as official representative must be on file in the applicant's office. (Certain Federal agencies may require that this authorization be submitted as part of the application.)

BILLING CODE 4184-01-P

SECTION C - NON-FEDERAL RESOURCES

(a) Grant Program	(b) Applicant	(c) State	(d) Other Sources	(e) TOTALS
8.	$	$	$	$
9.				
10.				
11.				
12. TOTALS (sum of lines 8 and 11)	$	$	$	$

SECTION D - FORECASTED CASH NEEDS

	Total for 1st Year	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
13. Federal	$	$	$	$	$
14. NonFederal					
15. TOTAL (sum of lines 13 and 14)	$	$	$	$	$

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 (sum of lines 16 -19)	$	$	$	$

SECTION F - OTHER BUDGET INFORMATION

(Attach additional Sheets if Necessary)

21. Direct Charges:	22. Indirect Charges:
23. Remarks	

SF 424A (4-88) Page 2
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BUDGET INFORMATION — Non-Construction Programs

OMB Approval No 0348 0044

SECTION A – BUDGET SUMMARY

Grant Program Function or Activity (a)	Catalog of Federal Domestic Assistance Number (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 (5)
	(1)	(2)	(3)	(4)	
a. Personnel	$	$	$	$	$
b Fringe Benefits					
c. Travel					
d. Equipment					
e. Supplies					
f. Contractual					
g Construction					
h. Other					
i. Total Direct Charges (sum of 6a - 6h)					
j. Indirect Charges					
k. TOTALS (sum of 6i and 6j)	$	$	$	$	$
7 Program Income	$	$	$	$	$

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Standard Form 424A (4-88)

Instructions for the SF–424A

General Instructions

This form is designed so that application can be made for funds from one or more grant programs. In preparing the budget, adhere to any existing Federal grantor agency guidelines which prescribe how and whether budgeted amounts should be separately shown for different functions or activities within the program. For some programs, grantor agencies may require budgets to be separately shown by function or activity. For other programs, grantor agencies may require a breakdown by function or activity. Sections A, B, C, and D should include budget estimates for the whole project except when applying for assistance which requires Federal authorization in annual or other funding period increments. In the latter case, Sections A, B, C, and D should provide the budget for the first budget period (usually a year) and Section E should present the need for Federal assistance in the subsequent budget periods. All applications should contain a breakdown by the object class categories shown in Lines a–k of Section B.

Section A. Budget Summary

Lines 1–4, Columns (a) and (b)

For applications pertaining to a *single* Federal grant program (Federal Domestic Assistance Catalog number) and *not requiring* a functional or activity breakdown, enter on Line 1 under Column (a) the catalog program title and the catalog number in Column (b).

For applications pertaining to a *single* program *requiring* budget amounts by multiple functions or activities, enter the name of each activity or function on each line in Column (a), and enter the catalog number in Column (b). For applications pertaining to multiple programs where none of the programs require a breakdown by function or activity, enter the catalog program title on each line in *Column* (a) and the respective catalog number on each line in Column (b).

For applications pertaining to *multiple* programs where one or more programs *require* a breakdown by function or activity, prepare a separate sheet for each program requiring the breakdown. Additional sheets should be used when one form does not provide adequate space for all breakdown of data required. However, when more than one sheet is used, the first page should provide the summary totals by programs.

Lines 1–4, Columns (c) through (g.)

For new applications, leave Columns (c) and (d) blank. For each line entry in Columns (a) and (b), enter in Columns (e), (f), and (g) the appropriate amounts of funds needed to support the project for the first funding period (usually a year).

For continuing grant program applications, submit these forms before the end of each funding period as required by the grantor agency. Enter in Columns (c) and (d) the estimated amounts of funds which will remain unobligated at the end of the grant funding period only if the Federal grantor agency instructions provide for this. Otherwise, leave these columns blank. Enter in columns (e) and (f) the amounts of funds needed for the upcoming period. The amount(s) in Column (g) should be the sum of amounts in Columns (e) and (f).

For supplemental grants and changes to existing grants, do not use Columns (c) and (d). Enter in Column (e) the amount of the increase or decrease of Federal funds and enter in Column (f) the amount of the increase or decrease of non-Federal funds. In Column (g) enter the new total budgeted amount (Federal and non-Federal) which includes the total previous authorized budgeted amounts plus or minus, as appropriate, the amounts shown in Columns (e) and (f). The amount(s) in Column (g) should not equal the sum of amounts in Columns (e) and (f).

Line 5—Show the totals for all columns used.

Section B. Budget Categories

In the column headings (1) through (4), enter the titles of the same programs, functions, and activities shown on Lines 1–4, Column (a), Section A. When additional sheets are prepared for Section A, provide similar column headings on each sheet. For each program, function or activity, fill in the total requirements for funds (both Federal and non-Federal) by object class categories.

Lines 6a–i—Show the totals of Lines 6a to 6h in each column.

Line 6j—Show the amount of indirect cost.

Line 6k—Enter the total of amounts on Lines 6i and 6j. For all applications for new grants and continuation grants the total amount in column (5), Line 6k, should be the same as the total amount shown in Section A, Column (g), Line 5. For supplemental grants and changes to grants, the total amount of the increase or decrease as shown in Columns (1)–(4), Line 6k should be the same as the sum of the amounts in Section A, Columns (e) and (f) on Line 5.

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 under the program narrative statement the nature and source of income. The estimated amount of program income may be considered by the federal grantor agency in determining the total amount of the grant.

Section C. Non-Federal-Resources

Lines 8–11—Enter amounts of non-Federal resources that will be used on the grant. If in-kind contributions are included, provide a brief explanation on a separate sheet.

Column (a)—Enter the program titles identical to Column (a), Section A. A breakdown by function or activity is not necessary.

Column (b)—Enter the contribution to be made by the applicant.

Column (c)—Enter the amount of the State's cash and in-kind contribution if the applicant is not a State or State agency. Applicants which are a State or State agencies should leave this column blank.

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

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

Line 12—Enter the total for each of Columns (b)–(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 cash needed by quarter from the grantor agency during the first year.

Line 14—Enter the amount of cash from all other sources needed by quarter during the first year.

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

Section E. Budget Estimates of Federal Funds Needed for Balance of the Project

Line 16–19—Enter in Column (a) the same grant program titles shown in Column (a), Section A. A breakdown by function or activity is not necessary. For new applications and 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 funding periods (usually in years). This section need not be completed for revisions (amendments, changes, or supplements) to funds for the current year of existing grants.

If more than four lines are needed to list the program titles, submit additional schedules as necessary.

Line 20—Enter the total for each of the Columns (b)-(e). When additional schedules are prepared for this Section, annotate accordingly and show the overall totals on this line.

Section F. Other Budget Information

Line 21—Use this space to explain amounts for individual direct object-class cost categories that may appear to be out of the ordinary or to explain the details as required by the Federal grantor agency.

Line 22—Enter the type of indirect rate (provisional, predetermined, final or 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.

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

Assurances-Non-Construction Programs

Note: Certain of these assurances may not be applicable to your project or program. If you have questions, please contact the awarding agency. Further, certain Federal awarding agencies may require applicants to certify to additional assurances. If such is the case, you will be notified.

As the duly authorized representative of the applicant I certify that the applicant:

1. Has the legal authority to apply for Federal assistance, and the institutional, managerial and financial capability (including funds sufficient to pay the non-Federal share of project costs) to ensure proper planning, management and completion of the project described in this application.

2. Will give the awarding agency, the Comptroller General of the United States, and if appropriate, the State, through any authorized representative, access to and the right to examine all records, books, papers, or documents related to the award; and will establish a proper accounting system in accordance with generally accepted accounting standards or agency directives.

3. Will establish safeguards to prohibit employees from using their positions for a purpose that constitutes or presents the appearance of personal or organizational conflict of interest, or personal gain.

4. Will initiate and complete the work within the applicable time frame after receipt of approval of the awarding agency.

5. Will comply with the Intergovernmental Personnel Act of 1970 (42 U.S.C. §§ 4728–4763) relating to prescribed standards for merit systems for programs funded under one of the nineteen statutes or regulations specified in Appendix A of OPM's Standards for a Merit System of Personnel Administration (5 C.F.R. 900, Subpart F).

6. Will comply with all Federal statutes relating to nondiscrimination. These include but are not limited to: (a) title VI of the Civil Rights Act of 1964 (P.L. 88–352) which prohibits discrimination on the basis of race, color or national origin; (b) Title IX of the Education Amendments of 1972, as amended (20 U.S.C. §§ 1681–1683, and 1685–1686), which prohibits discrimination on the basis of sex; (c) Section 504 of the Rehabilitation Act of 1973, as amended (29 U.S.C. § 794), which prohibits discrimination on the basis of handicaps; (d) the Age Discrimination Act of 1975, as amended (42 U.S.C. §§ 6101–6107), which prohibits discrimination on the basis of age; (e) the Drug Abuse Office and Treatment Act of 1972 (P.L. 92–255), as amended, relating to nondiscrimination on the basis of drug abuse; (f) the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act of 1970 (P.L. 91–616), as amended, relating to nondiscrimination on the basis of alcohol abuse or alcoholism; (g) §§ 523 and 527 of the Public Health Service Act of 1912 (42 U.S.C. 290 dd-3 and 290 ee-3), as amended, relating to confidentiality of alcohol and drug abuse patient records; (h) Title VIII of the Civil Rights Act of 1968 (42 U.S.C. § 3601 et seq.), as amended, relating to non-discrimination in the sale, rental or financing of housing; (i) any other nondiscrimination provisions in the specific statute(s) under which application for Federal assistance is being made; and (j) the requirements of any other nondiscrimination statute(s) which may apply to the application.

7. Will comply, or has already complied, with the requirements of Titles II and III of the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 (P.L. 91–646) which provide for fair and equitable treatment of persons displaced or whose property is acquired as a result of Federal or federally assisted programs. These requirements apply to all interests in real property acquired for project purposes regardless of Federal participation in purchases.

8. Will comply with the provisions of the Hatch Act (5 U.S.C. §§ 1501–1508 and 7324–7328) which limit the political activities of employees whose principal employment activities are funded in whole or in part with Federal funds.

9. Will comply, as applicable, with the provisions of the Davis-Bacon Act (40 U.S.C. §§ 276a to 276a–7), the Copeland Act (40 U.S.C. § 276c and 18 U.S.C. §§ 874), and the Contract Work Hours and Safety Standards Act (40 U.S.C. §§ 327–333), regarding labor standards for federally assisted construction subagreements.

10. Will comply, if applicable, with flood insurance purchase requirements of Section 102(a) of the Flood Disaster Protection Act of 1973 (P.L. 93–234) which requires recipients in a special flood hazard area to participate in the program and to purchase flood insurance if the total cost of insurable construction and acquisition is $10,000 or more.

11. Will comply with environmental standards which may be prescribed pursuant to the following: (a) institution of environmental quality control measures under the National Environmental Policy Act of 1969 (P.L. 91–190) and Executive Order (EO) 11514; (b) notification of violating facilities pursuant to EO 11738; (c) protection of wetlands pursuant to EO 11990; (d) evaluation of flood hazards in floodplains in accordance with EO 11988; (e) assurance of project consistency with the approved State management program developed under the Coastal Zone Management Act of 1972 (16 U.S.C. §§ 1451 et seq.); (f) conformity of Federal actions to State (Clear Air) Implementation Plans under Section 176(c) of the Clear Air Act of 1955, as amended (42 U.S.C. § 7401 et seq.); (g) protection of underground sources of drinking water under the Safe Drinking Water Act of 1974, as amended, (P.L. 93–523); and (h) protection of endangered species under the Endangered Species Act of 1973, as amended, (P.L. 93–205).

12. Will comply with the Wild and Scenic Rivers Act of 1968 (16 U.S.C. §§ 1271 et seq.) related to protecting components or potential components of the national wild and scenic rivers system.

13. Will assist the awarding agency in assuring compliance with Section 106 of the National Historic Preservation Act of 1966, as amended (16 U.S.C. 470), EO 11593 (identification and protection of historic properties), and the Archaeological and Historic Preservation Act of 1974 (16 U.S.C. 469a–1 et seq.).

14. Will comply with P.L. 93–348 regarding the protection of human subjects involved in research, development, and related activities supported by this award of assistance.

15. Will comply with the Laboratory Animal Welfare Act of 1966 (P.L. 89–544, as amended, 7 U.S.C. 2131 et seq.) pertaining to the care, handling, and treatment of warm blooded animals held for research, teaching, or other activities supported by this award of assistance.

16. Will comply with the Lead-Based Paint Poisoning Prevention Act (42 U.S.C. §§ 4801 et seq.) which prohibits the use of lead based paint in construction or rehabilitation of residence structures.

17. Will cause to be performed the required financial and compliance audits in accordance with the Single Audit Act of 1984.

18. Will comply with all applicable requirements of all other Federal laws, executive orders, regulations and policies governing this program.

Signature of Authorized Certifying Official

Title

Applicant Organization

Date Submitted

Executive Order 12372—State Single Points of Contact

Arizona

Mrs. Janice Dunn, ATTN: Arizona State Clearinghouse, 3800 N. Central Avenue, 14th Floor, Phoenix, Arizona 85012, Telephone (602) 280–1315

Arkansas

Tracie L. Copeland, Manager, State Clearinghouse, Office of Intergovernmental Services, Department of Finance and Administration, P.O. Box 3278, Little Rock, Arkansas 72203, Telephone (501) 682–1074

California

Glenn Stober, Grants Coordinator, Office of Planning and Research, 1400 Tenth Street, Sacramento, California 95814, Telephone (916) 323–7480

Colorado

State Single Point of Contact, State Clearinghouse, Division of Local Government, 1313 Sherman Street, Room 520, Denver, Colorado 80203, Telephone (303) 866–2156

Delaware

Ms. Francine Booth, State Single Point of Contact, Executive Department, Thomas Collins Building, Dover, Delaware 19903, Telephone (302) 736–3326

District of Columbia

Rodney T. Hallman, State Single Point of Contact, Office of Grants Management and Development, 717 14th Street, N.W., Suite 500, Washington, D.C. 20005, Telephone (202) 727–6551

Florida

Florida State Clearinghouse, Intergovernmental Affairs Policy Unit, Executive Office of the Governor, Office of Planning and Budgeting, The Capitol, Tallahassee, Florida 32399–0001, Telephone (904) 488–8441

Georgia

Charles H. Badger, Administrator, Georgia State Clearinghouse, 254 Washington Street, S.W., Atlanta, Georgia 30334, Telephone (404) 656–3855

Illinois

Steve Klokkenga, State Single Point of Contact, Office of the Governor, 107 Stratton Building, Springfield, Illinois 62706, Telephone (217) 782–1671

Indiana

Jean S. Blackwell, Budget Director, State Budget Agency, 212 State House, Indianapolis, Indiana 46204, Telephone (317) 232–5610

Iowa

Steven R. McCann, Division of Community Progress, Iowa Department of Economic Development, 200 East Grand Avenue, Des Moines, Iowa 50309, Telephone (515) 281–3725

Kentucky

Ronald W. Cook, Office of the Governor, Department of Local Government, 1024 Capitol Center Drive, Frankfort, Kentucky 40601, Telephone (502) 564–2382

Maine

Ms. Joyce Benson, State Planning Office, State House Station #38, Augusta, Maine 04333, Telephone (207) 289–3261

Maryland

Ms. Mary Abrams, Chief, Maryland State Clearinghouse, Department of State Planning, 301 West Preston Street, Baltimore, Maryland 21201–2365, Telephone (301) 225–4490

Massachusetts

Karen Arone, State Clearinghouse, Executive Office of Communities and Development, 100 Cambridge Street, Room 1803, Boston, Massachusetts 02202, Telephone (617) 727–7001

Michigan

Richard S. Pastula, Director, Michigan Department of Commerce, Lansing, Michigan 48909, Telephone (517) 373–7356

Mississippi

Ms. Cathy Mallette, Clearinghouse Officer, Office of Federal Grant Management and Reporting, 301 West Pearl Street, Jackson, Mississippi 39203, Telephone (601) 960–2174

Missouri

Ms. Lois Pohl, Federal Assistance Clearinghouse, Office of Administration, P.O. Box 809, Room 430, Truman Building, Jefferson City, Missouri 65102, Telephone (314) 751–4834

Nevada

Department of Administration, State Clearinghouse, Capitol Complex, Carson City, Nevada 89710, Telephone (702) 687–4065, Attention: Ron Sparks, Clearinghouse Coordinator

New Hampshire

Mr. Jeffrey H. Taylor, Director, New Hampshire Office of State Planning, Attn: Intergovernmental Review, Process/James E. Bieber, 2½ Beacon Street, Concord, New Hampshire 03301 Telephone (603) 271–2155

New Jersey

Gregory W. Adkins, Acting Director, Division of Community Resources, N.J. Department of Community Affairs, Trenton, New Jersey 08625–0803, Telephone (609) 292–6613

Please direct correspondence and questions to: Andrew J. Jaskolka, State Review Process, Division of Community Resources, CN 814, Room 609, Trenton, New Jersey 08625–0803, Telephone (609) 292–9025

New Mexico

George Elliott, Deputy Director, State Budget Division, Room 190, Bataan Memorial Building, Santa Fee, New Mexico 87503, Telephone (505) 827–3640, FAX (505) 827–3006

New York

New York State Clearinghouse, Division of the Budget, State Capitol, Albany, New York 12224, Telephone (518) 474–1605

North Carolina

Mrs. Chrys Baggett, Director, Office of the Secretary of Admin., N.C. State Clearinghouse, 116 W. Jones Street, Raleigh, North Carolina 27603–8003, Telephone (919) 733–7232

North Dakota

N.D. Single Point of Contact, Office of Intergovernmental Assistance, Office of Management and Budget, 600 East Boulevard Avenue, Bismarck, North Dakota 58505–0170, Telephone (701) 224–2094

Ohio

Larry Weaver, State Single Point of Contact, State/Federal Funds Coordinator, State Clearinghouse, Office of Budget and Management, 30 East Broad Street, 34th Floor, Columbus, Ohio 43266–0411, Telephone (614) 466–0698

Rhode Island

Mr. Daniel W. Varin, Associate Director, Statewide Planning Program, Department of Administration, Division of Planning, 265 Melrose Street, Providence, Rhode Island 02907, Telephone (401) 277–2656

Please direct correspondence and questions to: Review Coordinator, Office of Strategic Planning

South Carolina

Omeagia Burgess, State Single Point of Contact, Grant Services, Office of the Governor, 1205 Pendleton Street, Room 477, Columbia, South Carolina 29201, Telephone (803) 734–0494

Tennessee

Mr. Charles Brown, State Single Point of Contact, State Planning Office, 500 Charlotte Avenue, 309 John Sevier Building, Nashville, Tennessee 37219, Telephone (615) 741–1676

Texas

Mr. Thomas Adams, Governor's Office of Budget and Planning, P.O. Box 12428, Austin, Texas 78711, Telephone (512) 463–1778

Utah

Utah State Clearinghouse, Office of Planning and Budget, ATTN: Carolyn Wright, Room 116 State Capitol, Salt Lake City, Utah 84114, Telephone (801) 538–1535

Vermont

Mr. Bernard D. Johnson, Assistant Director, Office of Policy Research & Coordination, Pavilion Office Building, 109 State Street, Montpelier, Vermont 05602, Telephone (802) 828–3326

West Virginia

Mr. Fred Cutlip, Director, Community Development Division, West Virginia Development Office, Building #6, Room 553, Charleston, West Virginia 25305, Telephone (304) 348–4010

Wisconsin

Mr. William C. Carey, Federal/State Relations, Wisconsin Department of Administration, 101 South Webster Street, P.O. Box 7864, Madison, Wisconsin 53707, Telephone (608) 226–0267

Wyoming

Sheryl Jeffries, State Single Point of Contact, Herschler Building, 4th Floor, East Wing, Cheyenne, Wyoming 82002, Telephone (307) 777–7574

Guam

Mr. Michael J. Reidy, Director, Bureau of Budget and Management Research, Office of the Governor, P.O. Box 2950, Agana, Guam 96910, Telephone (671) 472–2285

Northern Mariana Islands

State Single Point of Contact, Planning and Budget Office, Office of the Governor, Saipan, CM, Northern Mariana Islands 96950

Puerto Rico

Norma Burgos/Jose H. Caro, Chairman/Director, Puerto Rico Planning Board, Minillas Government Center, P.O. Box 41119, San Juan, Puerto Rico 00940–9985, Telephone (809) 727–4444

Virgin Islands

Jose L. George, Director, Office of Management and Budget, #41 Norregade Emancipation Garden Station, Second Floor, Saint Thomas, Virgin Islands 00802, Please direct correspondence to: Linda Clarke, Telephone (809) 774–0750

BILLING CODE 4184–01–P

U.S. Department of Health and Human Services

Certification Regarding Drug-Free Workplace Requirements

Grantees Other Than Individuals

By signing and/or submitting this application or grant agreement, the grantee is providing the certification set out below.

This certification is required by regulations implementing the Drug-Free Workplace Act of 1988, 45 CFR Part 76, Subpart F. The regulations, published in the May 25, 1990 **Federal Register**, require certification by grantees that they will maintain a drug-free workplace. The certification set out below is a material representation of fact upon which reliance will be placed when the Department of Health and Human Services (HHS) determines to award the grant. If it is later determined that the grantee knowingly rendered a false certification, or otherwise violates the requirements of the Drug-Free Workplace Act, HHS, in addition to any other remedies available to the Federal Government, may taken action authorized under the Drug-Free Workplace Act. False certification or violation of the certification shall be grounds for suspension of payments, suspension or termination of grants, or governmentwide suspension or debarment.

Workplaces under grants, for grantees other than individuals, need not be identified on the certification. If known, they may be identified in the grant application. If the grantee does not identify the workplaces at the time of application, or upon award, if there is no application, the grantee must keep the identity of the workplace(s) on file in its office and make the information available for Federal inspection. Failure to identify all known workplaces constitutes a violation of the grantee's drug-free workplace requirements.

Workplace identifications must include the actual address of buildings (or parts of buildings) or other sites where work under the grant takes place. Categorical descriptions may be used (e.g., all vehicles of a mass transit authority or State highway department while in operation, State employees in each local unemployment office, performers in concert halls or radio studios.)

If the workplace identified to HHS changes during the performance of the grant, the grantee shall inform the agency of the change(s), if it previously identified the workplaces in question (see above).

Definitions of terms in the Nonprocurement Suspension and Debarment common rule and Drug-Free Workplace common rule apply to this certification. Grantees' attention is called, in particular, to the following definitions from these rules:

"**Controlled substance**" means a controlled substance in Schedules I through V of the Controlled Substances Act (21 USC 812) and as further defined by regulation (21 CFR 1308.11 through 1308.15).

"**Conviction**" means a finding of guilt (including a plea of nolo contendere) or imposition of sentence, or both, by any judicial body charged with the responsibility to determine violations of the Federal or State criminal drug statutes;

"**Criminal drug statute**" means a Federal or non-Federal criminal statute involving the manufacture, distribution, dispensing, use, or possession of any controlled substance;

"**Employee**" means the employee of a grantee directly engaged in the performance of work under a grant, including: (i) All "direct charge" employees; (ii) all "indirect charge" employees unless their impact or involvement is insignificant to the performance of the grant; and, (iii) temporary personnel and consultants who are directly engaged in the performance of work under the grant and who are on the grantee's payroll. This definition does not include workers not on the payroll of the grantee (e.g., volunteers, even if used to meet a matching requirement; consultants or independent contractors not on the grantee's payroll; or employees of subrecipients or subcontractors in covered workplaces).

The grantee certifies that it will or will continue to provide a drug-free workplace by:

(a) Publishing a statement notifying employees that the unlawful manufacture, distribution, dispensing, possession or use of a controlled substance is prohibited in the grantee's workplace and specifying the actions that will be taken against employees for violation of such prohibition;

(b) Establishing an ongoing drug-free awareness program to inform employees about:

(1) The dangers of drug abuse in the workplace; (2) The grantee's policy of maintaining a drug-free workplace; (3) Any available drug counseling, rehabilitation, and employee assistance programs; and, (4) The penalties that may be imposed upon employees for drug abuse violations occurring in the workplace;

(c) Making it a requirement that each employee to be engaged in the performance of the grant be given a copy of the statement required by paragraph (a);

(d) Notifying the employee in the statement required by paragraph (a) that, as a condition of employment under the grant, the employee will:

(1) Abide by the terms of the statement; and, (2) Notify the employer in writing of his or her conviction for a violation of a criminal drug statute occurring in the workplace no later than five calendar days after such conviction;

(e) Notifying the agency in writing, within ten calendar days after receiving notice under subparagraph (d)(2) from an employee or otherwise receiving actual notice of such conviction. Employers of convicted employees must provide notice, including position title, to every grant officer or other designee on whose grant activity the convicted employee was working, unless the Federal agency has designated a central point for the receipt of such notices. Notice shall include the identification number(s) of each affected grant;

(f) Taking one of the following actions, within 30 calendar days of receiving notice under subparagraph (d)(2), with respect to any employee who is so convicted:

(1) Taking appropriate personnel action against such an employee, up to and including termination, consistent with the requirements of the Rehabilitation Act of 1973, as amended; or, (2) Requiring such employee to participate satisfactorily in a drug abuse assistance or rehabilitation program approved for such purposes by a Federal, State, or local health, law enforcement, or other appropriate agency;

(g) Making a good faith effort to continue to maintain a drug-free workplace through implementation of paragraphs (a), (b), (c), (d), (e) and (f).

The grantee may insert in the space provided below the site(s) for the performance of work done in connection with the specific grant (use attachments, if needed):

Place of Performance (Street address, City, County, State, ZIP Code)_____

Check ___ if there are workplaces on file that are not identified here.

Sections 76.630(c) and (d)(2) and 76.635(a)(1) and (b) provide that a Federal agency may designate a central receipt point for STATE-WIDE AND STATE AGENCY-WIDE certifications, and for notification of criminal drug convictions. For the Department of Health and Human Services, the central receipt point is: Division of Grants Management and Oversight, Office of Management and Acquisition, Department of Health and Human Services, Room 517-D, 200 Independence Avenue, S.W., Washington, D.C. 20201.

DGMO Form#2 Revised May 1990

BILLING CODE 4184-01-C

Certification Regarding Debarment, Suspension, and Other Responsibility Matters—Primary Covered Transactions

By signing and submitting this proposal, the applicant, defined as the primary participant in accordance with 45 CFR Part 76, certifies to the best of its knowledge and believe that it and its principals:

(a) Are not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from covered transactions by any Federal Department or agency;

(b) Have not within a 3-year period preceding this proposal been convicted of or had a civil judgment rendered against them for commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, State, or local) transaction or contract under a public transaction; violation of Federal or State antitrust statutes or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, or receiving stolen property;

(c) Are not presently indicted or otherwise criminally or civilly charged by a governmental entity (Federal, State or local) with commission of any of the offenses enumerated in paragraph (1)(b) of this certification; and

(d) Have not within a 3-year period preceding this application/proposal had one or more public transactions (Federal, State, or local) terminated for cause or default.

The inability of a person to provide the certification required above will not necessarily result in denial of participation in this covered transaction. If necessary, the prospective participant shall submit an explanation of why it cannot provide the certification. The certification or explanation will be considered in connection with the Department of Health and Human Services (HHS) determination whether to enter into this transaction. However, failure of the prospective primary participant to furnish a certification or an explanation shall disqualify such person from participation in this transaction.

The prospective primary participant agrees that by submitting this proposal, it will include the clause entitled "Certification Regarding Debarment, Suspension, Ineligibility, and Voluntary Exclusion—Lower Tier Covered Transaction. " provided below without modification in all lower tier covered transactions and in all solicitations for lower tier covered transactions.

Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion—Lower Tier Covered Transactions

(To Be Supplied to Lower Tier Participants)

By signing and submitting this lower tier proposal, the prospective lower tier participant, as defined in 45 CFR Part 76, certifies to the best of its knowledge and belief that it and its principals:

(a) are not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any Federal department or agency.

(b) where the prospective lower tier participant is unable to certify to any of the above, such prospective participant shall attach an explanation to this proposal.

The prospective lower tier participant further agrees by submitting this proposal that it will include this clause entitled "Certification Regarding Debarment, Suspension, Ineligibility, and Voluntary Exclusion—Lower Tier Covered Transactions. " without modification in all lower tier covered transactions and in all solicitations for lower tier covered transactions.

Certification Regarding Lobbying

Certification for Contracts, Grants, Loans, and Cooperative Agreements

The undersigned certifies, to the best of his or her knowledge and belief, that:

(1) No Federal appropriated funds have been paid or will be paid, by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal contract, the making or any Federal grant, the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement.

(2) If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal contract, grant, loan or cooperative agreement, the undersigned shall complete and submit Standard Form—LLL, "Disclosure Form to Report Lobbying," in accordance with its instructions.

(3) The undersigned shall require that the language of this certification be included in the award documents for all subawards at all tiers (including subcontracts, subgrants, and contracts under grants, loans, and cooperative agreements) and that all subrecipients shall certify and disclose accordingly.

This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by section 1352, title 31, U.S. Code. Any person who fails to file the required certification shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure.

State for Loan Guarantee and Loan Insurance

The undersigned states, to the best of his or her knowledge and belief, that:

If any funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this commitment providing for the United States to insure or guarantee a loan, the undersigned shall complete and submit Standard Form–LLL "Disclosure Form to Report Lobbying," in accordance with its instructions.

Submission of this statement is a prerequisite for making or entering into this transaction imposed by section 1352, title 31, U.S. Code. Any person who fails to file the required statement shall be subject to a civil penalty of not less then $10,000 and not more than $100,000 for each such failure.

Signature

Title

Organization

Date

BILLING CODE 4184–01–P

DISCLOSURE OF LOBBYING ACTIVITIES

Approved by OMB
0348-0046

Complete this form to disclose lobbying activities pursuant to 31 U.S.C. 1352
(See reverse for public burden disclosure.)

1. Type of Federal Action:	2. Status of Federal Action:	3. Report Type:
☐ a. contract b. grant c. cooperative agreement d. loan e. loan guarantee f. loan insurance	☐ a. bid/offer/application b. initial award c. post-award	☐ a. initial filing b. material change For Material Change Only: year _____ quarter _____ date of last report _____

4. Name and Address of Reporting Entity:	5. If Reporting Entity in No. 4 is Subawardee, Enter Name and Address of Prime:
☐ Prime ☐ Subawardee Tier _____, *if known:* Congressional District, *if known:*	Congressional District, *if known:*
6. Federal Department/Agency:	7. Federal Program Name/Description: CFDA Number, *if applicable:* _____
8. Federal Action Number, *if known:*	9. Award Amount, *if known:* $
10. a. Name and Address of Lobbying Entity *(if individual, last name, first name, MI):*	b. Individuals Performing Services *(including address if different from No. 10a)* *(last name, first name, MI):*

(attach Continuation Sheet(s) SF-LLL-A, if necessary)

11. Amount of Payment *(check all that apply):*	13. Type of Payment *(check all that apply):*
$ _____ ☐ actual ☐ planned	☐ a. retainer ☐ b. one-time fee ☐ c. commission ☐ d. contingent fee ☐ e. deferred ☐ f. other; specify: _____
12. Form of Payment *(check all that apply):* ☐ a. cash ☐ b. in-kind; specify: nature _____ value _____	

14. Brief Description of Services Performed or to be Performed and Date(s) of Service, including officer(s), employee(s), or Member(s) contacted, for Payment Indicated in Item 11:

(attach Continuation Sheet(s) SF-LLL-A, if necessary)

15. Continuation Sheet(s) SF-LLL-A attached: ☐ Yes ☐ No

16.	
Information requested through this form is authorized by title 31 U.S.C. section 1352. This disclosure of lobbying activities is a material representation of fact upon which reliance was placed by the tier above when this transaction was made or entered into. This disclosure is required pursuant to 31 U.S.C. 1352. This information will be reported to the Congress semi-annually and will be available for public inspection. Any person who fails to file the required disclosure shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure.	Signature: _____ Print Name: _____ Title: _____ Telephone No.: _____ Date: _____

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[FR Doc. 94–14759 Filed 6–16–94; 8:45 am]
BILLING CODE 4184–01–C

Federal Register

Friday
June 17, 1994

Part VII

Department of the Interior

Bureau of Indian Affairs

St. Regis Mohawk Tribal Alcohol Beverages Control Act; Notice

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

St. Regis Mohawk Tribal Alcohol Beverages Control Act

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: This Notice is published in accordance with authority delegated by the Secretary of the Interior to the Assistant Secretary—Indian Affairs by 209 DM8, and in accordance with the Act of August 15, 1953, 67 Stat. 586, 18 U.S.C. § 1161. I certify that the St. Regis Mohawk Tribal Alcohol Beverages Control Act was duly adopted by the St. Regis Mohawk Tribe on November 19, 1993. The Ordinance provides for the regulation, manufacture, distribution, possession, sale, and consumption of liquor on the St. Regis Mohawk Indian Reservation of the State of New York.

DATES: This Ordinance is effective as of June 17, 1994.

FOR FURTHER INFORMATION CONTACT: Chief, Branch of Judicial Services, Division of Tribal Government Services, 1849 C Street NW., MS 2611–MIB, Washington, DC 20240–4001; telephone (202) 208–4400.

SUPPLEMENTARY INFORMATION: The St. Regis Mohawk Tribal Alcohol Beverages Control Act is to read as follows:

St. Regis Mohawk Tribal Alcohol Beverages Control Act

This Ordinance shall be cited as the "St. Regis Mohawk Tribal Alcoholic Beverages Control Act" and, pursuant to the inherent sovereignty of the St. Regis Mohawk Indian Tribe of the State of New York, shall be deemed an exercise of the Tribe's powers for the purpose of protecting the welfare, health, peace, morals and safety of all people residing on the St. Regis Mohawk Indian Reservation of the State of New York.

All of the provisions of this Ordinance shall be liberally construed to accomplish the above declared purpose. It is the St. Regis Mohawk Tribe's declared intent in enacting this Ordinance to regulate and control all traffic in liquor on the St. Regis Mohawk Indian Reservation of the State of New York except to the extent allowed and permitted under the express terms of this Ordinance.

Section 1. Definitions

As used in this Ordinance, the following definitions shall apply unless the context clearly indicates otherwise:

1.1 *Alcohol* shall mean neutral spirits distilled at or above 190 proof, whether or not such product is subsequently reduced for non-industrial use.

1.2 *Alcoholic beverage* shall mean any liquid suitable for human consumption, which contains one-half of one percent or more of alcohol by volume.

1.3 *Barter* or *bartering* shall mean the trading for any commodity, act or consideration whether or not there is intrinsic value in the item traded.

1.4 *Beer* shall mean any malt beverage containing more than one-half of one percent of alcohol by volume.

1.5 *Distilled spirits* shall mean any alcoholic beverage that is not beer, wine, sparkling wine or alcohol.

1.6 *Enterprise of the Tribe* shall mean the St. Regis Mohawk Tribe, a member of the St. Regis Mohawk Tribe or his or her spouse, or a business entity or association owned and controlled by any of the foregoing, that is licensed by the Tribal Council and pays the appropriate fee set by the Tribal Council by Resolution at not less than Two Hundred ($200.00) Dollars and no more than Five Thousand ($5,000.00) Dollars annually.

1.7 *Liquor* shall mean all varieties of liquid, semisolid, or solid substance containing alcohol, whether brewed, fermented, formulated, or distilled, which is intended for human consumption.

1.8 *Minor* shall mean any person under twenty-one (21) years of age.

1.9 *Possession* or *possessing* shall mean having on one's person, vehicle or other property and includes constructive possession through control without regard to ownership.

1.10 *Purchase* shall mean the exchange, barter, traffic, receipt with or without consideration in any form.

1.11 *Sale* shall mean the exchange, barter, traffic, donation, with or without consideration, in addition to the selling, supplying or distribution by any means, by any person, to any person.

1.12 *Transport* shall mean the introduction of alcoholic beverage onto the St. Regis Mohawk Indian Reservation of the State of New York by any means of conveyance for the purpose of sale, or distribution, to any licensed dealer.

1.13 *Tribal Council* shall mean the duly elected governing body of the St. Regis Mohawk Indian Tribe of New York, a federally recognized Indian Tribe.

Section 2. Relation of Other Tribal Regulations

Any and all prior ordinances, resolutions, regulations or other form of control of the St. Regis Mohawk Tribe of the State of New York whether written or unwritten, which authorize, prohibit, or deal with the sale of alcohol are hereby repealed and have no further force and effect. No Tribal Ordinance or Regulation shall be applied in a manner inconsistent with the provisions of this ordinance.

Section 3. Prohibition

The introduction on the Reservation for resale, wholesale purchase, sale and dealing in liquor other than by the Tribe or an Enterprise of the Tribe is prohibited. Possession of liquor on the Reservation by any person not prohibited by Federal law shall be lawful so long as possession is in conformity with this Ordinance.

Section 4. Conformity With State Laws

Tribal standards for liquor transactions and possessions and consumption of liquor shall meet or exceed those required by the State of New York including but not limited to:

(a) *Hours of Sale: Wine, Beer and Mixed Beverages.* The Tribe or an Enterprise of the Tribe may sell or offer for sale wine, beer and mixed beverages at all times not specifically prohibited by this Section. The Tribe or an Enterprise of the Tribe may not sell or offer for sale wine and beer and mixed beverages on Sunday between the hours of 2 a.m. and 12 noon. On any other day, the Tribe or an Enterprise of the Tribe may not sell or offer for sale wine, beer, or mixed beverages between the hours of 2 a.m. and 8 a.m.

(b) *Minor.* A minor is *any* person who has not celebrated his or her twenty-first (21st) birthday.

(c) *Purchase of Alcohol by a Minor.* Purchase of an alcoholic beverage by a minor [is] prohibited.

(d) *Sales to Minor.* Sale of an alcoholic beverage to a minor by the Tribe or an Enterprise of the Tribe is prohibited.

(e) *Consumption of Alcohol by a Minor.* Consumption of an alcoholic beverage by a minor is prohibited.

(f) *Possession of Alcohol by a Minor.* Possession of an alcoholic beverage by a minor is prohibited unless such minor is in possession of the alcoholic beverage while in the course and scope of his employment and he is any employee of the Tribe or an Enterprise of the Tribe.

(g) *Purchase of Alcohol for a Minor; Furnishing Alcohol to a Minor.* A person commits a violation of this Ordinance if he knowingly purchases an alcoholic beverage for or knowingly gives or makes available an alcoholic beverage to a minor.

(h) *Misrepresentation of Age by a Minor.* A minor is in violation of this

Ordinance if he falsely states that he or she is 21 years of age or older or presents any document that indicates he/she is 21 years of age or older to a person engaged in selling or serving alcoholic beverages.

(i) *Employment of Minors.* The Tribe or an Enterprise of the Tribe shall not employ any person under 18 years of age to sell, prepare, serve, or otherwise handle liquor, or to assist in doing so. The Tribe or an Enterprise of the Tribe may, however, employ a person under 18 years of age to work in any capacity other than the actual selling, preparing, serving or handling of liquor.

Section 5. Prohibition of Sales During Emergencies or Dates and Times Established by the Tribal Council

The Tribal Council Head Chief, by authority of Tribal Council Resolution, may on an emergency basis and for a period of time not to exceed five (5) business days, by written order, act, directive or notice, prohibit the sale of liquor until such emergency order can be considered by the Tribal Council which may in its discretion, terminate or extend such order for any length of time it deems necessary, or may issue emergency rules, regulations directions or orders concerning the sale of liquor which will be valid during the stated emergency period. The Tribal Council may likewise issue orders prohibiting or limiting the sale of liquor for any period net to exceed seventy-two (72) consecutive hours.

Section 6. Sovereign Immunity Preserved

Nothing in this Ordinance is intended nor shall be construed as a waiver of the sovereign immunity of the St. Regis Mohawk Tribe of the State of New York. No officer, manager or employee of an enterprise of the Tribe shall be authorized nor shall attempt to waive the sovereign immunity of the Tribe.

Section 7. Penalty

Any person or entity purchasing, possessing, selling, bartering, or otherwise trafficking in liquor on the Reservation is in violation of this ordinance or any Rule or Regulation adopted pursuant to this ordinance and shall be subject to a fine or forfeiture, as applicable, of not more than Five Thousand Dollars ($5,000.00) and may be barred from admission to the Reservation through Due Process of law. In addition, persons or entities subject to the full jurisdiction of the Tribe may be subject to such other appropriate actions as the Tribal Council may determine. All contraband merchandise shall be confiscated by the Tribe and disposed of as directed by the Tribal Council.

Section 8. Severability

If any clause, part or section of this Ordinance shall be adjudged invalid, such judgement shall not affect or invalidate the remainder of the ordinance but shall be confined in its operation to the clause, part or section directly involved in controversy in which such judgement was rendered.

Section 9. Disclaimer

Nothing in this Ordinance shall be construed to authorize or require the criminal trial and punishment of non-Indians by the St. Regis Mohawk Tribe of the State of New York except to the extent allowed by an applicable present or future Act of Congress or any applicable laws.

Section 10. Regulations

The Tribal Council shall have the exclusive authority to adopt and enforce Rules and Regulations to implement the sale, transportation or introduction of liquor on the Reservation and to further the purposes of this ordinance. Such Rules and Regulations shall have the force of law upon promulgation by Resolution.

Section 11. Enforcement

This Ordinance shall be enforced by the Tribal Council, or any other Agency vested with such enforcement authority by resolution of the Tribal Council.

Section 12. Effective Date

This ordinance shall be effective upon the date that the Secretary of the Interior certifies this ordinance and it is published in the **Federal Register**.

Section 13. Duration

The duration of this Ordinance shall be perpetual.

Dated: June 8, 1994.

Ada E. Deer,

Assistant Secretary—Indian Affairs.

[FR Doc. 94–14752 Filed 6–16–94; 8:45 am]

BILLING CODE 4310–02–M

Federal Register

Friday
June 17, 1994

Part VIII

Department of the Interior

Bureau of Indian Affairs

Indian Gaming; Confederated Tribes of the Grand Ronde Community of Oregon; Notice

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Indian Gaming

ACTION: Notice of Approved Tribal-State Compact.

SUMMARY: Pursuant to 25 U.S.C. § 2710, of the Indian Gaming Regulatory Act of 1988 (Pub. L. 100–497), the Secretary of the Interior shall publish, in the **Federal Register**, notice of approved Tribal-State Compacts for the purpose of engaging in Class III (casino) gaming on Indian reservations. The Assistant Secretary-Indian Affairs, Department of the Interior, through her delegated authority, has approved the Gaming Compact Between the Confederated Tribes of the Grand Ronde Community of Oregon and the State of Oregon, which was executed on August 21, 1993.

DATES: This action is effective June 17, 1994.

FOR FURTHER INFORMATION CONTACT: Joe B. Walker, Acting Director, Indian Gaming Management Staff, Bureau of Indian Affairs, Washington, DC 20240, (202) 219–4068.

Dated: June 10, 1994.

John Tippeconnic,

Assistant Secretary—Indian Affairs.

[FR Doc. 94–14788 Filed 6–16–94; 8:45 am]

BILLING CODE 4310–02–M

federal register

Friday
June 17, 1994

Part IX

Department of Education

Training Personnel for the Education of Individuals With Disabilities Program Administered by the Office of Special Education Programs, Office of Education and Rehabilitative Services; Notice

DEPARTMENT OF EDUCATION

Training Personnel for the Education of Individuals With Disabilities Program Administered by the Office of Special Education Programs, Office of Special Education and Rehabilitative Services

AGENCY: Department of Education.

ACTION: Notice of Intent to Collect Data.

SUMMARY: The Assistant Secretary provides notice that the Department intends to revise the forms it requires grantees under Part D of the Individuals with Disabilities Education Act (IDEA) to use in submitting their Annual Performance Reports under Section 634 of Pub. L. 101–476, as amended. These forms are the Personnel Data Form and the Parent Data Form.

The Department is publishing this notice of intent to collect data to solicit public comment from State education agencies, institutions of higher education, parent organizations, professionals in the field of special education, individuals with disabilities, professional organizations and advocacy groups for persons with disabilities, researchers, other Federal agencies, and other appropriate parties regarding the utility and burden of collecting and reporting data in addition to that specified in IDEA. The new data would be (1) Outcomes and placement information from grantees training personnel to serve children with disabilities and their families; and (2) the names of organizations networked or consulted with by parent information and training center grantees.

DATES: Comments must be received on or before August 16, 1994.

ADDRESSES: All comments concerning this notice should be addressed to Norman D. Howe, U.S. Department of Education, 400 Maryland Avenue SW., room 3072, Switzer Building, Washington, DC 20202–2643.

FOR FURTHER INFORMATION CONTACT: Janice S. Ancarrow, U.S. Department of Education, Maryland Avenue SW., room 3515, Switzer Building, Washington, DC 20202–2643. Telephone: (202) 205–8274. Individuals who use a telecommunications device for the deaf (TDD) may call the TDD number at (202) 205–9999.

SUPPLEMENTARY INFORMATION:

Statutory Provisions and Legislative History

Part D of the Act (IDEA) provides support for programs to increase the quantity and improve the quality of personnel trained to provide early intervention, education, and related services to infants, toddlers, children, youth, and their families. The Division of Personnel Preparation (DPP) in the Office of Special Education Programs (OSEP), Office of Special Education and Rehabilitative Services (OSERS), administers this program.

As amended in 1990 through 1992, section 634(a) (1) and (2) of IDEA requires personnel training grantees funded under 631(a) to report the number of personnel enrolled under each grant by category of training and level of training; and the number of individuals trained receiving degrees and certification, by category and level of training. The law further requires that applicants for training grants must provide a description of detailed strategies to recruit and train members of minority groups and persons with disabilities, as well as to give them priority consideration for stipend support when selecting among qualified trainees. See section 631(a)(2)(B) and (3) of IDEA. Therefore, trainees' race or ethnicity, and their disability status were added to the Personnel Data Form, as well as the information required by Section 634.

Under section 631(e)(11), as amended in 1990 through 1992, grantees who are parent training and information centers must report detailed information on their clients served. OSEP developed a separate Parent Data Form to capture these data.

Both forms were provisionally approved for one year by the Office of Management and Budget (OMB) on November 12, 1992.

Proposed Data Elements

To assist the Department of Education in monitoring the efficacy of this training program in meeting the educational and related needs of infants, children, youth, and their families, and to examine how grantees are implementing statutory requirements, the Department intends to add further data elements to the Personnel Data Form, as well as to the Parent Data Form.

The planned revision of the Personnel Data Form would add a Part III, which would include individual counts for student trainee outcomes data on: (1) Completers (such as length of time to the degree) and (2) noncompleters (such as reasons for not completing); and aggregate counts for placement outcomes (such as type of employment and geographic location).

The revised Parent Data Form would include data on the names of organizations networked or consulted with under IDEA section 631(e)(11) (E) and (F).

Invitation To Comment

The Assistant Secretary is interested in receiving public comment on the utility and burden of obtaining from personnel training grantees various outcomes data, including placement data by aggregated counts or by individual trainee; and from parent training and information centers, the names of organizations they networked or consulted with.

The DPP data collection package previously approved by OMB, and all comments submitted in response to this notice will be available for public inspection, during and after the comment period, in Room 3072, Switzer Building, 330 "C" Street SW., Washington, DC, between the hours of 8:30 a.m. and 4 p.m., Monday through Friday of each week except Federal holidays.

To familiarize the public with the format of the proposed changes, copies of the draft proposed Part III of the Personnel Data Form (Form 1) and the draft revised Parent Form (Form 2) are available by calling (202) 205–9554.

Please note that the Department has not yet submitted the proposed revised forms to OMB for its formal review and approval. Public comments received under this Notice will be considered prior to finalizing the forms for submission to OMB.

Authority: 20 U.S.C. 1409(g).

Dated: June 13, 1994.

Judith E. Heumann,

Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. 94–14858 Filed 6–16–94; 8:45 am]

BILLING CODE 4000–01–U

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Federal Register

Vol. 59, No. 116

Friday, June 17, 1994

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LIST OF PUBLIC LAWS

Note: No public bills which have become law were received by the Office of the Federal Register for inclusion in today's **List of Public Laws.**

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